State Plan to Prevent and Treat Prescription Drug Abuse



Governor's Prescription Drug Abuse Prevention Council

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GOVERNOR'S PRESCRIPTION DRUG ABUSE PREVENTION COUNCIL

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The Council would like to thank both Governor Haley and Inspector General Patrick Maley. Without their leadership, this Plan would not exist. The Council believes that their support of this effort will have an impact on the lives of countless South Carolinians for many years to come. The members of the Council are thankful for the opportunity to participate in this important endeavor.

BACKGROUND

Pain is a significant public health problem. Chronic pain alone affects approximately 100 million U.S. adults. "Pain reduces quality of life, affects specific population groups disparately, costs society at least \$560-635 billion annually (an amount equal to about \$2,000 for everyone living in the United States), and can be appropriately addressed through population health-level interventions."¹ According to the American Academy of Pain Medicine, pain affects more Americans than diabetes, heart disease and cancer combined. The chart below depicts the number of chronic pain sufferers compared to other major health conditions.²

Condition	Number of Sufferers	Source
Chronic Pain	100 million Americans	Institute of Medicine of The National Academies
Diabetes	25.8 million Americans (diagnosed and estimated undiagnosed)	American Diabetes Association
Coronary Heart Disease (heart attack and chest pain) Stroke	16.3 million Americans 7.0 million Americans	American Heart Association
Cancer	11.9 million Americans	American Cancer Society

Drugs that were initially developed to treat chronic pain, which is often debilitating and devastating, are now too often misused. The statistics associated with prescription drug misuse and abuse are staggering.³ In fact, this abuse has led the national Centers for Disease Control and Prevention to classify prescription drug abuse as a national epidemic.⁴

National Statistics

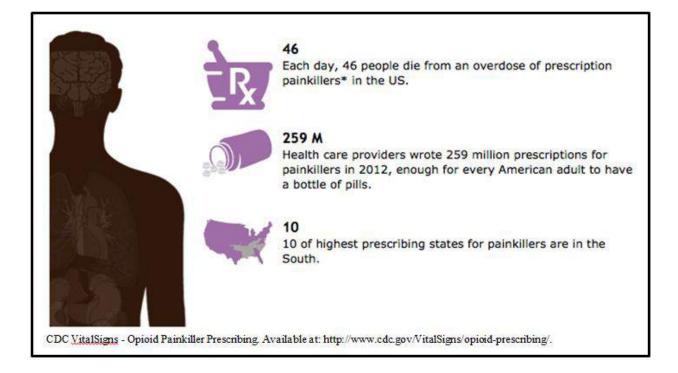
It is difficult to comprehend the number of Americans who have misused prescription drugs.⁵ In 2011, 52 million people in the United States, over the age of 12, had used prescription drugs non-medically in their lifetime, over six million of those in the past month.⁶ In 2010 alone, an estimated 2.4 million Americans used prescription drugs non-medically for the first time, on average approximately 6,600 new users a day.⁷

Unfortunately, prescription drug abuse has been increasing at an alarming rate for the past decade. Between 1991 and 2010, prescriptions for stimulants increased from 5 million to

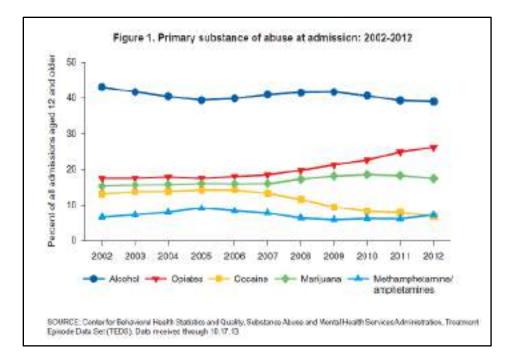
nearly 45 million and for opioid analgesics from 75.5 million to 209.5 million.⁸ And, sadly, based on the abuse and dependency statistics, this drug use does not appear to be limited to one occasion for many Americans. According to the National Survey on Drug Use and Health, 1.9 million people in the United States meet abuse or dependence criteria for prescription opioids alone.⁹

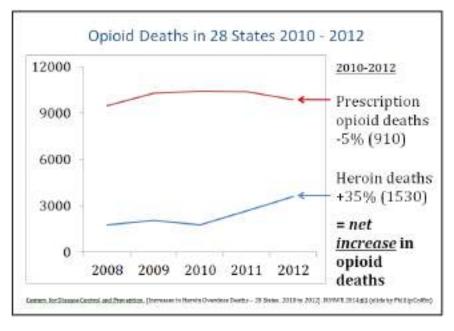
What are Opioids?							
 Heroin Codeine Demerol Morphine Darvocet Fentanyl Dilaudid 	 Hydrocodone Oxycodone Vicodin OxyContin Tylenol 3 Tylox Levorphanol 						
MethadoneOpium	PercocetPercodan						

Based on the prescribing patterns in the United States, however, this epidemic is not altogether surprising. Astonishingly, enough prescription painkillers were prescribed in the United States in 2010 to medicate every American adult every four hours for one month.¹⁰ In 2013, 207 million prescriptions were written for prescription opioid pain medications.¹¹ And, while the United States has only 5% of the world's population, its citizens consume 75% of the world's prescription drugs.¹²



This epidemic comes with real consequences, including tragic consequences for families and communities and increased costs to the healthcare and criminal justice systems. In 2012, drug overdose was the leading cause of injury death in the United States.¹³ Among people 25 to 64 years old, drug overdose deaths exceed those caused by motor vehicle accidents.¹⁴ And, as a corollary to the increased prescription drug abuse over the past decade, drug overdose deaths have increased by 117% from 1999 to 2012.¹⁵ In 2011, 1.4 million Americans visited an emergency department due to prescription drug use or abuse.¹⁶ A 2011 study estimated the total cost in the United States of nonmedical use of prescription opioids was \$53.4 billion, with \$42 billion attributable to lost productivity, \$8.2 billion to criminal justice costs, \$2.2 billion to drug abuse treatment, and \$944 million to medical complications.¹⁷





Perhaps the most troublesome component of this epidemic is the extent to which it affects two of our most vulnerable populations. Youth and older adults are at particular risk for prescription drug abuse.¹⁸ Abuse of prescription drugs is highest among young adults aged 18 to 25, with 5.9% reporting non-medical use in the past month.¹⁹ Among youth aged 12 to 17, 3% reported non-medical use in the past month.²⁰ And according to these youth, more than half of them were given these drugs by a friend or relative.²¹ Of all people misusing or abusing

prescription drugs, 70% report obtaining them from a friend or relative either for free, by purchase, or by stealing them.²² Essentially, home medicine cabinets become a repository of drugs when leftover prescription drugs are not properly discarded.

South Carolina

South Carolina is not immune from this epidemic. In 2011, South Carolina ranked 23rd highest per capita in both opioid painkiller prescriptions and overdose deaths;²³ however, many in South Carolina believe even this number is understated due to inconsistent and incomplete reporting of these deaths in previous years. Between July 1, 2013, and June 30, 2014, 354 adult deaths attributable to prescription poisoning occurred in our state. This total includes 281 deaths that were ruled accidental overdoses and 51 ruled suicides. The balance of those cases involved 6 underdetermined cause of death and 16 with other factors contributing to the cause of death. During this same period, one accidental prescription drug overdose involving a minor occurred. In addition to prescription overdose deaths, South Carolina has also seen an increase in the number of deaths attributable to heroin. From July 1, 2013, through June 30, 2014, 31 deaths involving heroin occurred in South Carolina. There have been more reported overdose deaths from prescribed opioids than heroin, cocaine and methamphetamine combined.²⁴

South Carolinians have created a significant demand upon resources for the treatment of opioid abuse, including inpatient admissions, emergency department visits, observation discharges, and outpatient visits to the South Carolina Department of Mental Health in acute care, long-term acute care and inpatient rehab facilities. Between July 1, 2011, and July 1, 2013, a total of 10,490 patients generated 12,947 visits relating to the treatment of opioid abuse.²⁵ According to the South Carolina Department of Alcohol and Other Drug Abuse Services (DAODAS), 687 patients were admitted to its programs alone with a primary diagnosis of opiate abuse or dependence in 2004. That number has consistently increased, rising to 2,011 patients admitted to DAODAS programs with a primary diagnosis of any opiate abuse or dependence in 2004. Similarly, 925 patients were admitted with a diagnosis of any opiate abuse or dependence in 2004. 2,968 patients with this diagnosis were admitted in 2013.



Opiates Trends in South Carolina Fiscal Years 2004 to 2013

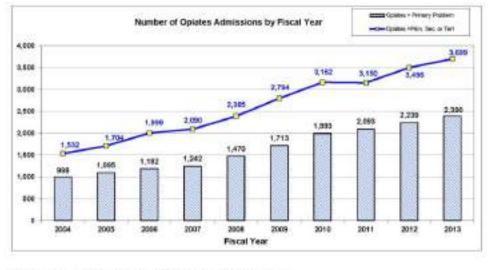
Opiate Admissions Primary"	-2934	2008	2008	2007	2008	3009	2018	2015	2012	2013
Any Oprate Admission Primary	004	1.008	1,182	1,242	1472	1.113	1.003	2.993	2.238	2,540
Heepin Admission Printery	165	124	. 562	291	338	380	307	.910	348	411

Opiate Admissions Primary, Secondary, Tertiary*

								2011		2013
Any Optidie Admission (P,8,7)	8.032	1.796	3.882	2,090	2385	27M	2,162	3.198	2.000	2,000
Any Hersis Admission (P.S.T)	534	445	4.08	4.45	413	959	457	40	459	- 634

Opiate Admission By Diagnosis

and a second second second second									2012	
Primary Opiate Abuse or Dependence									1394	
Any Optim Abuse or Dependence	105	1.045	5,286	1,210	1452	1.689	1,247	I.640	1,152	2,968



^{*} Opate advisaions include methadone, oxycontin and other goate RX admissions

These statistics regarding overdose deaths and treatment interventions are high, but are dwarfed when compared to the volume of pills actually prescribed and dispensed in our state. According to data collected by DHEC, from July 1, 2013, through June 30, 2014, **1,226,159** patients received **4,211,181** prescriptions for opioids. As a result of those prescriptions, **272,818,351** opioids were dispensed. **569,843** patients in South Carolina obtained **2,611,458** prescriptions for benzodiazepines during this same time frame, resulting in the dispensing of **157,508,374** benzodiazepines.²⁶ As shown in the chart below, South Carolina ranks in the highest quartile for painkiller prescriptions per person.

^{**} Opiate diagnoses include DSM IV categories of Opiate Abuse or Dependence

Quartile (Painkiller Prescriptions per 100 People)	States
52-71	HI, CA, NY, MN, NJ, AK, SD, VT, IL, WY, MA, CO
72-82.1	NH, CT, FL, IA, NM, TX, MD, ND, WI, WA, VA, NE, MT
82.2-95	AZ, ME, ID, DC, UT, PA, OR, RI, GA, DE, KS, NV, MO
96-143	NC, OH, SC, MI, IN, AR, LA, MS, OK, KY, WV, TN, AL

Some states have more painkiller prescriptions per person than others.

Data from IMS, National Prescription Audit (NPATM), 2012

Of the 24,082 South Carolina licensees with prescriptive authority, 20,101 have DHEC registrations authorizing the prescription of controlled substances in South Carolina. Only 21% of those prescribers who hold a DHEC registration are also registered with the Prescription Monitoring Program (PMP). Further, those who are registered with the PMP performed only 309,852 queries between July 1, 2013, and June 30, 2014.²⁷

Call to Action

While grim, there is hope that the Governor, the Legislature, the healthcare community, regulatory and enforcement agencies, the treatment community, and other stakeholders can work together to curb the tide of prescription drug abuse in our state. Responding to this epidemic will require comprehensive action, a long-term commitment, and coordinated efforts on the state and local level. Unquestionably, the healthcare community has one of the most vital roles in the fight.

Other states have paved the way, including New York, Florida, Tennessee, Utah, Kentucky, Maryland, and Ohio, having successfully implemented strategies in their states with positive outcomes. Following in their footsteps, South Carolina now must embark upon the journey to fight this epidemic in our state.

INTRODUCTION

In May 2013, South Carolina's Inspector General published a report, attached to at Appendix A, highlighting the fact that South Carolina lacked a statewide strategy to address prescription drug abuse for the many South Carolinians who struggle with this issue. In response, on March 14, 2014, Governor Haley signed Executive Order No. 2014-22, attached as Appendix B, establishing the Governor's Prescription Drug Abuse Prevention Council (Council). The Council is comprised of representatives from each agency with a regulatory, enforcement or treatment role in this issue, including the South Carolina Law Enforcement Division (SLED); South Carolina Department of Health and Environmental Control (DHEC); South Carolina Department of Labor, Licensing and Regulation (LLR); South Carolina Board of Dentistry; South Carolina Board of Medical Examiners; South Carolina Board of Nursing; South Carolina Board of Pharmacy; a South Carolina Solicitor's Office; South Carolina Department of Health and Human Services (DHHS); South Carolina Department of Alcohol and Other Drug Abuse Services (DAODAS); and a South Carolina coroner. The Council was charged with the following: 1) to analyze available data to determine the extent of prescription drug abuse in South Carolina; 2) to develop a comprehensive state plan (Plan) to proactively combat and prevent drug abuse in South Carolina; 3) to assist and encourage local communities to engage existing coalitions or to establish new coalitions to combat prescription drug abuse; and, finally 4) to continue to meet as a Council and at least annually report the progress of the Council's efforts. Significantly, the Council's efforts mark the first time in South Carolina's history that policy makers and stakeholders on a statewide level have assembled to begin the difficult task of addressing this issue.

To accomplish the objectives set forth in the Governor's Order, the Council met on numerous occasions, solicited input from a number of stakeholders and contacted numerous legislators to educate and garner support for its efforts. The Council also reviewed State Plans from at least six other states as well as relevant academic and evidence-based literature. Finally, several members of the Council traveled to Washington, D.C., to a work session entitled "Advancing Policy and Practice: A 50 State Working Meeting to Prevent Opioid-Related Overdose," sponsored by the United States Department of Health and Human Services. At this meeting, Council members were able to meet with representatives from federal agencies and other states that have successfully tackled this issue and spent several days planning the best approach to implement these strategies in our state.

Throughout this process, three things have become abundantly clear to the Council. One, chronic and acute pain are very real concerns for many South Carolinians, and any statewide plan must allow healthcare professionals to retain the professional judgment to prescribe controlled substances for treatment of these legitimate medical conditions. Two, the South Carolina Reporting and Identification Prescription Tracking System (SCRIPTS) (also known as the Prescription Monitoring Program or PMP) administered by DHEC is the state's most valuable resource in addressing this issue and is central to the prevention of prescription drug Three, an adequate surveillance system is vital to ensure that all prevention and abuse. intervention efforts are evidence based. It was discovered that many state and county agencies have data that is relevant to this issue, but the state's approach to collecting and mining this data has been fragmented and oftentimes inconsistent and/or incomplete. To gain a clearer understanding of the data that currently exists and to address gaps in data, the Council formed a Data Committee. The ongoing work of the committee will ensure that going forward South Carolina will more accurately measure the problem and hopefully the state's successes in reducing prescription drug abuse. The Council's Plan was written in light of these three considerations.

Ultimately, the Council's work culminated in this Plan. Specifically, the Plan designates eight key priority areas: (1) Prescribers; (2) South Carolina Prescription Monitoring Program; (3) Pharmacy; (4) Third-Party Payer; (5) Law Enforcement; (6) Treatment; (7) Education and Advocacy; and (8) Data and Analysis. The Plan contains over 50 recommendations, some of which propose legislative amendments. These priorities are consonant with the recommendations contained in the National Governor's Association, "Strategies for Reducing Prescription Abuse." The Council believes that these recommendations will provide clear, easy-to-understand guidance to prescribers; will unite regulatory, treatment and enforcement efforts; and ultimately, will reduce prescription drug abuse in our state.

This Plan simply marks the beginning of the Council's efforts. The Council will continue its work over the next months and years to oversee the implementation of the recommendations,

to measure the effectiveness of the state's efforts, and to make further recommendations based on measurable outcomes. The Council understands that several of these recommendations will have a fiscal impact that has yet to be analyzed, and those recommendations are denoted as such within the Plan. As the work of the Council progresses, the fiscal impact will be analyzed. Ideally, the benefits to the state in reduced healthcare and criminal justice costs and human suffering will outweigh the costs of implementation. It is the hope of the Council that its efforts, in conjunction with our many partners and stakeholders, will ultimately reduce the devastating emotional and economic effects suffered by so many South Carolinas as a result of prescription drug abuse.

PRIORITY AREA: PRESCRIBERS

Perhaps no other group in the state has a bigger role to play in combating prescription drug abuse than prescribers. The Council acknowledges that chronic and acute pain and other medical conditions are very real concerns for many South Carolinians. The Council strongly believes that healthcare professionals (i.e., licensed physicians, dentists, and physician assistants and advanced practice nurses with prescriptive authority working under the supervision of physicians and/or dentists) must retain the professional judgment to prescribe controlled substances for treatment of these legitimate medical conditions. However, the rate of prescribing, abuse and dependency, and deaths related to prescription drugs have dramatically increased over the past decade, with no end in sight. With only 21% of controlled substance prescribers enrolled in the SCRIPTS program, a powerful tool in ferreting out drug abuse and misuse, certainly more can be done. As gatekeepers of the prescription pad, and thus the supply of prescription drugs in our state, controlled substance prescribers must partner with the Council to combat this abuse.

I. Education and Advocacy

Healthcare professionals are trained to assist and heal their patients. This duty can present a dilemma for those professionals faced with treating a patient with a substance abuse disorder. Some prescribers may be simply naïve regarding certain patients' drug-seeking behavior, either due to lack of training on the issue, failure to use the tools available to them to detect this behavior, or lack of time to address the issue in today's competitive healthcare market. Further, because of the prescribers' desire to treat and heal, it may be difficult to tell their patients "no." Finally, many prescribers receive little formal education on this topic and may not be well versed in what to do when presented with a patient with a substance use disorder. And, given the state's low registration and utilization rates of SCRIPTS, healthcare professionals are either unaware of its existence or of the program's clinical benefits. The Council believes that most prescribers, once further educated, will be better equipped to more often utilize the tools at their disposal to identify patients who may be drug seekers, to more conservatively prescribe controlled substances, and to treat patients with addiction issues.

To that end, Act 244 was passed during the previous legislative session, mandating that all physicians complete as part of their annual continuing education requirement at least two hours related to approved procedures for prescribing and monitoring controlled substances listed in Schedules II, III, and IV of the schedules provided for in Sections 44-53-210, 44-53-230, 44-53-250, and 44-53-270. By statute, this education must be provided by: 1) a statewide organization recognized by the Accreditation Council for Continuing Medical Education; or 2) a statewide organization approved to provide continuing medical education by its national organization that is accredited by the Accreditation Council for Continuing Medical Education.

The South Carolina Board of Medical Examiners (Medical Board) has committed to meeting with stakeholders to discuss the implementation of this continuing education mandate for physicians.

<u>Recommendation:</u> The Council recommends that the Medical Board, the South Carolina Department of Health and Environmental Control, and other stakeholders work together to create a suggested list of topics for the education providers to include in the mandated training.

<u>Recommendation:</u> The Council recommends extending the education mandate contained in Act 244 to dentists, physician assistants, and advanced practice nurses with prescriptive authority.

While Act 244 mandated this education for physicians, it did not mandate education for the other types of prescribers in our state – dentists, physician assistants, and advanced practice nurses with prescriptive authority. For the same reasons that the education is beneficial for physicians, it would be beneficial to all controlled substance prescribers.

<u>Recommendation</u>: The Council recommends working with schools to increase course offerings related to this topic or make it a mandatory part of curriculum.

One study found that, on average, medical students receive only 12 hours of education related to pain and pain management.²⁸ In South Carolina, there are several schools that train prescribers, and the Council recommends partnering with the schools, outlined below, to increase course offerings.

- Medical Schools Medical University of South Carolina, University of South Carolina School of Medicine, University of South Carolina School of Medicine Greenville, Edward Via School of Osteopathic Medicine
- Dental Medical University of South Carolina College of Dental Medicine
- Physician Assistants Medical University of South Carolina
- Advance Practice Nurses Clemson University, University of South Carolina, Medical University of South Carolina, Francis Marion University

II. <u>Clinical Guidance</u>

It is critical that prescribers have clear clinical guidance that sets forth the appropriate treatment of pain to assist them in safely prescribing certain controlled substances. The Council acknowledges, however, that this clinical guidance should come from the South Carolina Boards of Medical Examiners, Dentistry, and Nursing (Boards) as the public bodies responsible for regulating prescribers in our state. Accordingly, the Council requested that the Board of Medical Examiners revise its Pain Management Guidelines, which were originally published in July of 2009, to offer clear guidance to prescribers on how to safeguard South Carolinians' access to pain care while combating drug misuse, abuse, diversion and addiction.

In order to facilitate input from the medical community at large, the Council formed a work group composed of physicians from various practice areas, licensed dentists and members of the treatment community. This work group offered valuable insight and recommendations for the Board of Medical Examiners' consideration in formulating appropriate revisions. Using the work product of this group, the Board of Medical Examiners has now issued Revised Pain Management Guidelines (Revised Guidelines) that are attached to the Plan as Appendix A. These Revised Guidelines were unanimously endorsed by both the Board of Dentistry and the Board of Nursing. The Council appreciates the hard and expedient work of the Boards to provide this important guidance to prescribers.

The Revised Guidelines are intended to alleviate prescriber uncertainty and to encourage patient-centered pain care. All prescribers should become knowledgeable about assessing patients' pain and effective methods for treatment of this pain, as well as statutory requirements for prescribing controlled substances. Prescribers must recognize that an individual's use of opioid analgesics for non-legitimate medical purposes poses a significant threat to the health and safety of the individual, as well as to the public. Further, prescribers must recognize that inappropriate prescribing of controlled substances may contribute to drug misuse and diversion by individuals who seek opioids for non-legitimate purposes. Accordingly, based on the Revised Guidelines the Council anticipates that all prescribers will incorporate safeguards into their practices to minimize the risk of misuse, abuse, and diversion of opioid analgesics and other controlled substances. The consensus of the Boards and the Council is that utilization of SCRIPTS, the state's prescription drug monitoring program, prior to prescribing opiates is the best safeguard against these risks and the best practice for prescribers.

The Council recommends the following related to the Revised Guidelines:

<u>Recommendation:</u> The Council strongly encourages all prescribers to be familiar with the Revised Pain Management Guidelines contained in Appendix A to this Plan and to conform their prescribing practice to these Revised Guidelines.

<u>Recommendation</u>: The Council recommends that prescribers be knowledgeable about all state and federal laws and regulations regarding controlled substances.

In order to dispense or administer controlled substances, the prescriber must be registered with the U.S. Drug Enforcement Administration (DEA), licensed by the state in which he or she practices, and compliant with applicable federal and state regulations. Prescribers are referred to the Practitioner's Manual of the DEA for specific rules and regulations governing the use of controlled substances; relevant provisions of the South Carolina Dental Practice Act, the South Carolina Medical Practice Act, and the South Carolina Nurse Practice Act; relevant regulations promulgated by the regulatory authorities governing these professions; and advisory opinions issued by the regulatory authorities governing these professions.

<u>Recommendation:</u> The Council recommends that registration and utilization of SCRIPTS be considered mandatory for prescribers to determine the appropriate controlled substance prescribing dosages, if any, to provide safe, adequate pain management and to protect the prescribers from inappropriate prescribing situations

<u>Recommendation</u>: The Council recommends that prescribers who prescribe chronic opioid therapy be familiar with treatment options for opioid addiction, including those available in licensed opioid treatment programs and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment, so as to make appropriate referrals when needed.

<u>Recommendation:</u> The Council recommends prescribers treating patients with controlled substances consider prescribing Naloxone when clinically indicated.

Patients prescribed more than 80 mg Morphine Equivalent Dose (MED) are at an increased risk of death from respiratory depression. The level of 80 mg MED should be considered an extreme, potentially unsafe therapeutic limit. Overdoses may occur at lower dosages. The 80 mg MED is not to be considered the upper limit of safe prescribing, but rather an alert limit to warn of possible increased risks of unsafe dosage levels, especially in narcotic naïve patients. Assessment of risk stratification for narcotic abuse and misuse should be performed at levels below 80 mg MED to be ensure appropriate clinical behavior. These patients require closer monitoring, and other respiratory depressants, such as alcohol and benzodiazepines, should be avoided. The Council and the Boards recognize that a prescription of Naloxone may be appropriate for patients in certain situations who are prescribed high-dose opioids or are more vulnerable to the risk of opioid overdose due to co-morbidities or other factors.

<u>Recommendation:</u> The Council strongly encourages the Boards of Medical Examiners, Dentistry, and Nursing to continue to update the Revised Pain Management Guidelines as lessons are learned and when data suggests that changes are needed.

III. State Agency Collaboration

In addition to the regulatory boards charged with the responsibility of regulating the prescribers licensed to practice in South Carolina, the DHEC Bureau of Drug Control (BDC) plays a significant role in the regulation of prescriptive behavior. The Council and the respective boards responsible for regulating prescribers jointly recommend the following collaboration

between the South Carolina Department of Labor, Licensing and Regulation (LLR), the Boards and the BDC:

Recommendation: SCRIPTS must be as user friendly as possible to facilitate easy use.

When possible, online registration capability may facilitate greater registration and utilization of the South Carolina Reporting and Identification Prescription Tracking System (SCRIPTS). To that end, DHEC may benefit from access to certain information in LLR's possession for the sole purpose of license and credential verification of prescribers. The Council and the Boards recommend that LLR and DHEC collaborate to identify and share the information necessary to expedite online SCRIPTS registration.

Recommendation: The BDC and Boards have a shared interest in correcting improper prescribing behaviors, through education when possible and enforcement when necessary. Upon establishment of criteria by the Board of Medical Examiners, which may include, but are not limited to, a MED threshold and prescription volume by prescriber, SCRIPTS shall generate reports by which outlier prescribers will be identified for further review by the BDC and, if necessary, referral to LLR for initiation of the complaint process.

Recommendation: Based on the Revised Guidelines, the Council recognizes that patients requiring more than 80 MED present an increased risk of death from respiratory depression. Accordingly, the Council recommends that, when capable, SCRIPTS offer an MED calculator that can generate an alert for each patient whose record is accessed and for which the MED exceeds 80 MED. The MED calculator and alert function will provide an additional tool for the prescriber to utilize when assessing a patient's prescriptive needs. This threshold is not a substitute for a prescriber's clinical judgment, but merely one factor for consideration in the prescribing process.

<u>Recommendation</u>: The BDC shall utilize the full analytical capabilities of SCRIPTS to identify prescribers engaged in questionable prescribing activities.

<u>Recommendation</u>: Information shared between LLR and DHEC may be used to assist the BDC in promptly identifying a prescriber's area of specialization, if applicable, when investigating a licensee's prescribing behavior.

Recommendation with Potential Fiscal Impact: The Council and the Boards support the compilation and distribution of report cards to all South Carolina licensed prescribers so that each prescriber can see how his or her prescribing patterns compare to other prescribers practicing in the same or similar clinical setting.

Such a report card will be private and communicated directly to the prescriber by DHEC. The purpose of the report card is solely to facilitate the prescriber's self-evaluation of his or her prescribing patterns. The report card will not be used for any regulatory purpose, including discipline by the respective licensing board should the prescriber become the subject of a disciplinary action. Although it is unclear whether the current SCRIPTS vendor can provide prescriber report cards, it is likely that this capability can be developed with the allocation of additional resources. The Council and the Boards respectfully recommend that DHEC, through SCRIPTS, work to develop this valuable tool that will prove useful for self-assessment purposes.

<u>Recommendation</u>: Prescribers engaged in prescribing conduct not rising to the level of criminal activity, but who may benefit from additional education or counseling regarding appropriate prescribing, shall be identified by the BDC and provided an educational intervention.

Once identified, the BDC inspector responsible for initiating contact with such a designated prescriber shall provide the prescriber a list of professional resources, to be identified by the Boards, that may counsel the prescriber in question about the prevailing prescribing practice standards in his or her respective profession. For example, if a dentist is identified by the BDC as a prescriber of concern, he or she will be provided a list of dentists approved by the Board of Dentistry who have volunteered to serve as mentoring resources. Communication with these volunteer mentors will be voluntary and will only occur at the prescriber's initiation. No educational intervention will prevent the BDC or the respective regulatory authorities from fully investigating and prosecuting improper or illegal prescribing patterns of a licensed prescriber.

<u>Recommendation</u>: Prescribers identified by the BDC engaged in conduct rising to the level of criminal activity, shall be subjected to the standard process of investigation by BDC, arrest, where appropriate, and referral to LLR for investigation of unprofessional conduct.

Recommendation: The Council recommends that the Boards identify licensees with expertise in ethical prescribing to serve as hearing officers or hearing panel members in any disciplinary cases arising from prescribing behavior. These designated individuals shall hear and review disciplinary matters and make recommendations to the applicable regulatory board for final action as set forth in each profession's Practice Act and regulations. These individuals shall not be the same licensees identified to serve as voluntary mentors.

PRIORITY AREA: SOUTH CAROLINA PRESCRIPTION MONITORING PROGRAM

The Bureau of Drug Control (BDC) at the Department of Health and Environmental Control (DHEC) administers South Carolina's prescription drug monitoring program. This centralized database, known as SCRIPTS (South Carolina Reporting and Identification Prescription Tracking System), allows authorized users access to data concerning the dispensing of controlled substances. It is intended to improve the state's ability to identify and stop diversion of prescription drugs in an efficient and cost-effective manner that will not impede the appropriate medical utilization of licit controlled substances where there is a valid prescriber-patient or pharmacist-patient relationship.

The SCRIPTS database includes all retail and outpatient hospital pharmacy dispensing of Schedules II, III, and IV controlled substances. It also includes dispensing activity of those controlled substances into the state of South Carolina by non-resident pharmacies. Dispensers that are exempt from reporting to SCRIPTS are: Veterans Affairs facilities, most long-term care and assisted-living facilities, methadone clinics, emergency departments dispensing less than a 48-hour supply of controlled substances, or veterinary offices dispensing less than a five-day supply.

SCRIPTS is accessible 24 hours a day, seven days a week. The SCRIPTS technology was upgraded in January 2014 to allow dispensers to report daily, rather than monthly. This transition to more frequent reporting enables prescribers to have access to more current information in SCRIPTS reports, as data is updated daily. A SCRIPTS report provides the Schedules II, III, and IV controlled substance prescriptions a patient has had filled in a specified period, as well as the prescriber and the dispenser of the prescriptions. The report should be used to supplement a patient evaluation, to confirm a patient's drug history, or to document compliance with a therapeutic regimen.

South Carolina currently exchanges prescription monitoring program data with 17 other states through the National Association of Boards of Pharmacy's Prescription Monitoring Program Interconnect hub. Although none of our border states are participating in interstate data sharing, we continue to have open communication with them to encourage them to join the hub for interstate sharing. All non-resident pharmacies that dispense controlled substances into our state were required to register with the BDC by October 31, 2014, or they may be subject to enforcement action.

In 2014, the South Carolina Legislature passed Act 244 to require dispensers to report daily to DHEC. The act extends access to authorized delegates, and requires at least two hours of continuing medical education on prescribing and monitoring controlled substances in Schedules II, III, and IV to be used toward the total number of continuing medical education requirements for physicians. The SCRIPTS database is scheduled to make the technological upgrades to allow the registration of authorized delegates by Spring 2015. Also, the SCRIPTS patient report will be enhanced to include a daily MED.

While technological upgrades to SCRIPTS and advancements in health policy have furthered the objectives of the prescription monitoring program, SCRIPTS remains underutilized by prescribers. The following recommendations are suggested to increase access to and utilization of the prescription monitoring program.

I. <u>Required Enrollment in SCRIPTS</u>

<u>Recommendation:</u> The Council recommends that prescriber registration and enrollment in SCRIPTS become required and recommends that each patient's prescription history is reviewed in certain circumstances prior to the prescription of controlled substances.

South Carolina should require: (1) universal prescriber enrollment in SCRIPTS; and (2) utilization of SCRIPTS to check patients' prescription-dispensing histories before prescribing controlled substances in certain circumstances. There should be careful consideration of exceptions to the mandatory utilization requirement for certain prescribers, such as oncologists who are treating patients at end of life. Under the current voluntary conditions, less than 25% of prescribers enroll in SCRIPTS and a smaller proportion of those enrolled actually utilize the program. The prescription monitoring program must be fully utilized by prescribers to most effectively combat prescription drug abuse and diversion.

As of June 2014, 22 states had legislation mandating that prescribers and in some cases dispensers use the prescription monitoring program in certain circumstances: Arizona, Colorado, Delaware, Indiana, Kentucky, Louisiana, Massachusetts, Minnesota, Mississippi, Nevada, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Rhode Island, Tennessee, Vermont, Virginia, Washington, and West Virginia.²⁹ Experiences in Kentucky, Tennessee, and New York, for example, indicate that statutory mandates rapidly increased enrollment and utilization of prescription monitoring programs, resulting in decreased doctor shopping and prescribing of certain controlled substances. Florida imposed other requirements with similar results.



http://www.cdc.gov/VitalSigns/opioid-prescribing/

II. <u>Analytics Tool</u>

Recommendation with Potential Fiscal Impact: The Council recommends that DHEC proceed to acquire analytic services and/or products to work with SCRIPTS data, expanding the capacity to develop predictive models and to detect anomalies in prescriber patterns and patient prescription behaviors. The Council further recommends that DHEC send letters notifying prescribers of suspicious behavior identified by the analytics.

SCRIPTS could be more effectively used as an analytic tool with advanced technological enhancements. Staff in the BDC currently complete the analysis of the prescription monitoring program data manually to identify patterns of suspicious behavior. Advanced technological enhancements to SCRIPTS would allow more efficient and thorough analysis of the prescription monitoring program data. By December 2014, DHEC will have advanced analytic, risk compliance, and fraud software. DHEC should use this capability to efficiently detect anomalies in prescribing patterns and patient behaviors by incorporating, among other information, the advisement of clinical professionals and widely accepted prescribing guidelines to determine predictive models and business rules to guide decision-making when contemplating enforcement action.

III. Data Sharing

Recommendation with Potential Fiscal Impact: The Council recommends that DHEC coordinate real-time hosting of data from other state agencies to include, but not be limited to, the South Carolina Department of Alcohol and Other Drug Abuse Services; South Carolina Department of Mental Health; South Carolina Department of Juvenile Justice; South Carolina Department of Social Services (DSS); South Carolina Department of Health and Human Services (DHHS); South Carolina Attorney General's Office; South Carolina Department of Corrections; South Carolina Probation, Parole, and Pardon Services; South Carolina Law Enforcement Division.

Addressing prescription drug abuse in the state is a coordinated effort between DHEC and other state agencies. As data sharing with other state agencies is currently limited to manual transmission, DHEC, the Attorney General's Office, DHHS and DSS have coordinated to create improved efficiencies and coordination of real-time data sharing between the agencies. Additional real-time data from other agencies should be included to maximize program integrity.

Recommendation with Potential Fiscal Impact: The Council recommends that DHEC and the Revenue and Fiscal Affairs Office collaborate and create capacity for information sharing between SCRIPTS and the South Carolina Health Information Exchange (SCHIEx).

The SCRIPTS database should be integrated with the SCHIEx web application to allow prescribers to log in to SCHIEx and access a patient's medical history while simultaneously viewing a patient's controlled substance prescription history, without having to log in to separate websites. As successfully achieved in Indiana, integrating data from the prescription monitoring program and the health information exchange would streamline workflow for prescribers and improve accessibility, as well as SCRIPTS utilization.

IV. Integration of SCRIPTS Reports in Electronic Health Records

Recommendation with Potential Fiscal Impact: The Council recommends that DHEC work with prescribers and healthcare providers to integrate SCRIPTS data into electronic health records, so that access to patients' controlled substance records does not interrupt prescriber workflow.

SCRIPTS staff have been working to identify opportunities to integrate SCRIPTS data directly into the clinical workflow of prescribers through electronic health records (EHRs). SCRIPTS was awarded a grant from the federal Substance Abuse and Mental Health Services Administration to financially assist in these efforts. Discussions are currently underway with prospective healthcare systems that are interested in participating in this endeavor. By integrating SCRIPTS data into EHRs, providers will be able to more easily and quickly access a patient's controlled substance record without interrupting their clinical workflow. This ease of use and time savings should greatly increase provider use of SCRIPTS reports in clinical decision making. This knowledge will allow them to make better prescribing and treatment decisions, decreasing prescription misuse and abuse.

V. <u>Interconnectivity Between States</u>

<u>Recommendation:</u> The Council recommends that Governor Haley request by letter the States of North Carolina and Georgia enroll in the National Association of Boards of Pharmacy's Prescription Monitoring Program Interconnect hub to afford enhanced regional monitoring.

Although a total of 18 states are currently enrolled in the Interconnect hub, neither of South Carolina's bordering states participate. This presents an obstacle to effective prescription drug monitoring, especially within the counties along South Carolina's border.

VI. Education and Advocacy

<u>Recommendation:</u> The Council recommends that the BDC continue and expand initiatives to coordinate education and awareness campaigns for SCRIPTS, to include outreach to more stakeholders such as provider associations, licensing boards, and investigative agencies.

The BDC has also launched an awareness campaign with active prescribers as identified by the SCRIPTS database, addressed with educational approaches through onsite visits and inspections, and recruited for enrollment in the prescription monitoring program. Staff members continue to make strides by collaborating with provider associations, licensing boards, and investigative agencies to provide educational presentations that explain the value and functions of accessing and utilizing SCRIPTS reports. It is recommended that BDC staff members continue and expand initiatives to coordinate education and awareness campaigns to include outreach to more stakeholders.

PRIORITY AREA: PHARMACY

I. <u>Take-Back Programs</u>

Recommendation with Potential Fiscal Impact: The Council recommends expanding prescription drug take-back programs across the state.

Take-back programs are an important part of any strategy to reduce supply and inappropriate access to prescription drugs. Because pharmacists constitute one of the most accessible healthcare professionals, coupled with the fact that they dispense medications, these professionals should be an integral part of any take-back program. The Secure and Responsible Drug Disposal Act of 2010 was passed in an effort to curtail prescription drug abuse by authorizing regulations that outline methods for ultimate users to dispose of their unused or unwanted pharmaceutical controlled substances. The U.S. Drug Enforcement Administration's Final Rule implementing the Secure and Responsible Drug Disposal Act took effect October 9, 2014, and now authorizes pharmacies and hospitals/clinics with on-site pharmacies to voluntarily maintain collection receptacles for unused prescription drugs. Because pharmacies are in the unique role of being readily accessible by the public, the Council recommends that these newly authorized venues volunteer to comply with federal regulations, and become certified collectors of unused and expired prescription drugs.

The Council recommends that successful programs that currently exist such as the ones listed in the Law Enforcement section be replicated in all counties within South Carolina. Coordination of law enforcement at the state, county, and local municipal level with pharmacies and healthcare facilities should be initiated and expanded. The South Carolina Sheriff's Association – in coordination with the professional pharmacy organization – should search for funding to advertise and facilitate expansion of these programs.

II. <u>Non-Resident Entities</u>

<u>Recommendation:</u> The Council recommends regulating non-resident entities dispensing controlled substances into the state.

Any licensed healthcare facility that is located in the state and dispenses controlled substances must register with the Department of Health and Environmental Control (DHEC)'s controlled substance division. This registration serves as an accountability mechanism for facilities within the state. For example, if a facility violates the controlled substance laws of South Carolina (including SCRIPTS reporting), the registration can be disciplined and even revoked. As of October 31, 2014, this registration now includes non-resident facilities dispensing controlled substances into the state.

III. Increase SCRIPTS Registrations

<u>Recommendation</u>: The Council recommends increasing the number of pharmacists registered to use SCRIPTS.

When looking at the successes of other state prescription drug abuse programs, it is evident that those state's prescription drug monitoring programs are the cornerstone. As shown in the Inspector General's report, pharmacists have been slow to register for this important tool. Educational programs by the professional organizations and in conjunction with DHEC should be conducted to allow for tutorials and Q&A sessions. As stated earlier, facilities located in the state that dispense controlled substances must register with DHEC. All pharmacists must seek initial licensure and renew that license with the Department of Labor, Licensing and Regulation (LLR) on an annual basis. LLR and the Board of Pharmacy should work with DHEC to allow registration with SCRIPTS at the time of initial licensure application or renewal. There should be a question about SCRIPTS registration on the license renewal and a link to the SCRIPTS registration site.

IV. <u>Electronic Submission of Controlled Substance Prescriptions</u>

<u>Recommendation:</u> The Council recommends that the professional boards and associations work with practitioners, pharmacies, and software vendors to encourage electronic transmission for all classes of controlled substance prescriptions.

Recently, the DEA and DHEC have amended their regulations to allow for electronic prescriptions for controlled substances. An electronically submitted prescription reduces the risk of diversion and prescription fraud. Many prescribers are now electronically submitting prescriptions for Schedule III, IV, and V drugs. The updated regulations, however, require prescribers, pharmacies and software vendors to have additional security measures in order to transmit prescriptions for Schedule II medications, and generally, in South Carolina, prescribers, pharmacies, and software vendors lack the requisite updates. Thus, almost universally in our state, Schedule II drugs are being prescribed on paper with the prescriber's original signature. The council recommends that the professional boards and associations work with practitioners, pharmacies and software vendors to encourage compliance with these updated regulations to facilitate electronic transmission of Schedule II drugs.

PRIORITY AREA: THIRD-PARTY PAYER

The prescription abuse and fraud-related costs to a medium-sized health insurer were estimated to be over \$42 million a year, and could exceed \$70 billion to all health insurers – private and public.³⁰ Thus, healthcare payers have an incentive and a unique opportunity to drive efforts to address opioid overuse and abuse in South Carolina. Payer policy can be used to influence prescriber requirements, behavior, and practice. Once prescribers contract to receive payment for services from a third-party payer, they necessarily agree to certain conditions that must be met for payment. While some of the recommendations by the Council require statutory changes, several of those changes can be accomplished, in part, though payer conditions. For commercial payers, the Council can only make suggestions to implement certain payer conditions. For Medicaid providers, however, the South Carolina Department of Health and Human Services (DHHS) can move forward with implementing certain payer conditions. In South Carolina, a large number of opiod prescribers are enrolled to receive Medicaid reimbursement.³¹

In addition, third-party payers can require beneficiaries to comply with certain conditions in order to qualify for coverage. Again, the Council can only make suggestions to commercial payers to implement certain conditions. DHHS can move forward now with implementing certain conditions of participation for over 1 million Medicaid beneficiaries.³²

Importantly, in considering the role of healthcare payers in addressing this issue, it must be noted that a key limitation of relying on payer policy is that it can be easily circumvented by not submitting claims for opioids to an insurance carrier. Thus, it is important to leverage payercentric strategies that can address opioid overuse without simply driving individuals to pay cash for opioid medications.

I. <u>Policy Adjustment</u>

<u>Recommendation:</u> The Council recommends that third-party payers adjust payer policies in accordance with the Revised Pain Management Guidelines outlined in the Prescriber section above and attached as Appendix A.

For instance, payers could require prescribers to check SCRIPTS in order to be reimbursed for a visit where certain controlled substances are prescribed. And, through the postpay audit process, payers could ensure that treatment goals and plans, informed consent documents, and proper medical charting are documented to establish the requisite medical necessity of treatment of certain chronic pain to justify reimbursement.

II. <u>Claims Analytics With Accompanying Intervention</u>

<u>Recommendation</u>: The Council recommends that third-party payers continue to adopt and revise interventions to address controlled substance misuse and abuse by beneficiaries, including participation in multi-agency data sharing with the Bureau of Drug Control Prescription Monitoring Program.

Third-party payers currently perform complex analytical evaluations of claims data to detect patterns that suggest misuse or abuse by beneficiaries. Once detected, payers employ various interventions to prevent further misuse or abuse. Two general types of interventions currently used are as follows:

- "Lock-In" Policy: Lock-in policies require that identified individuals get all medications from a single pharmacy provider. This allows for greater coordination and eliminates the ability to "pharmacy shop."
- Prescriber Information Programs: These efforts look to retrospectively inform prescribers of potential overuse behaviors exhibited by their patients.

Payers should continue to use opioid prescribing and dispensing data to identify aberrant behavior, develop means of predicting likely drug overuse, and ultimately adopt an assortment of additional policy interventions where appropriate. One such suggestion is to include referrals to substance abuse treatment services as part of lock-in policies.

III. Driving Evidence-Based Prescribing Through Utilization Management Techniques

<u>Recommendation:</u> The Council recommends that third-party payers adapt pharmacy benefits packages to encourage appropriate use of opioids.

The lack of generally accepted prescribing guidelines has resulted in a high degree of variation in the utilization management requirements of opioids, including dosage and day supply limits and prior authorization requirements.

Efforts by the Council and the Boards to foster the development of statewide guidelines for the use of opioids in non-malignant pain, such as the Revised Pain Management Guidelines, should be adopted by payers to design utilization parameters that are consistent with evidencebased medical practice. Additional guidance regarding the use of opioids in special populations (pregnant women, upon emergency room discharge, etc.) should also be developed by appropriate clinical organizations and adopted by healthcare payers to ensure appropriate utilization.

IV. Coverage of Screening and Treatment for Opioid Dependence or Addiction

Recommendation with Potential Fiscal Impact: The Council recommends healthcare payer coverage for screening and treatment for substance use disorders.

Coverage of screening for opioid abuse and treatment is inconsistent among healthcare payers. These inconsistencies are at least partially the result of the lack of generally accepted clinical guidance regarding the role of these services. Statewide guidance regarding the coverage of opioids abuse screening and treatment, using validated methods such as the Screening, Brief Intervention, and Referral to Treatment process, should be developed and implemented by payers, and these guidelines should form the basis for the coverage of these items by healthcare payers.

PRIORITY AREA: LAW ENFORCEMENT

I. <u>Take-Back Programs</u>

Recommendation with Potential Fiscal Impact: The Council recommends expanding law enforcement sponsorship of prescription drug take-back programs.

Presently, several law enforcement agencies throughout the state are involved in takeback programs but are in the minority. The following locations are permanent prescription drop off locations:

- Anderson County Sheriff's Office 305 Camson Road, Anderson
- Clover Police Department 112 Bethel Street, Clover
- Fort Mill Police Department 111 Academy Street, Fort Mill
- Greenville Law Enforcement Center 4 McGee Street, Greenville
- Greer Police Department 102 S. Main Street, Greer
- Horry County Police Department 2560 N. Main Street, Conway
- Lexington County Sheriff's Department 521 Gibson Road, Lexington
- Richland County Sheriff's Department 5623 Two Notch Road, Columbia
- Rock Hill Police Department 120 E. Black Street, Rock Hill
- Spartanburg County Sheriff's Office (*lobby*) 8045 Howard Street, Spartanburg
- Tega Cay Police Department 7705 Tega Cay Drive, Tega Cay
- Winthrop Campus Police Department 523 Myrtle Drive, Rock Hill
- York County Sheriff's Office 1675-2A York Highway, York
- York Police Department 12 N. Roosevelt Street, York³³

The South Carolina Law Enforcement Division (SLED) can work with sheriffs and police chiefs throughout the state, the South Carolina Sheriffs' Association, and the South Carolina Police Chiefs Association to encourage expanded take-back programs. Funding for these boxes could be secured through public safety grants that are applied for yearly through the South Carolina Department of Public Safety.

II. Awareness and Education

<u>Recommendation:</u> The Council recommends increasing awareness and education of law enforcement to identify potential misuse of prescription drugs.

Law enforcement in South Carolina has required annual in-service training along with federal and state education opportunities on a variety of subjects. An increase in prescription drug awareness through training can be facilitated by the South Carolina Criminal Justice Academy, along with the United States Drug Enforcement Administration's training department. Both of these agencies regularly tailor training to the needs of individual counties and states. The Council and SLED recommend a yearly increase in this type of training. That training would vary by audience, depending on whether the training was directed at uniformed line officers or drug investigators. Training for both groups is recommended.

Further, expanding or changing some of the curricula used by school resource officers to better deal with school-age children and teens should be a focus. This affected group has seen a continuous increase in exposure and use for the past 10 years.

III. Community-Based Prevention

<u>Recommendation:</u> The Council recommends increasing law enforcement participation in community-based prevention programs.

There are numerous community-based prevention programs that focus on opioid abuse. Most, if not all, include representation from law enforcement. Once the Council launches a statewide campaign in designated areas of the state to form individual groups or coalitions, law enforcement agencies could use personnel from their community action units to participate. Their participation would include providing statistical information on arrests for pharmaceuticalrelated crimes, prevention, and other ways to make the individuals aware of pharmaceutical drug abuse and how it negatively affects their communities.

IV. Expanded Investigation and Prosecution Efforts

Recommendation with Potential Fiscal Impact: The Council recommends continuing and expanding investigation and prosecution efforts specific to prescription drug diversion.

The main goal for the prosecution aspect is to educate prosecuting agencies and to raise awareness of the issues caused by prescription drug abuse. All state prosecuting agencies attend an annual Solicitor's Conference for required legal training and updates. The statewide prevention and education campaign should be presented at this conference. While local resource limitations may prevent assigning an assistant solicitor to exclusively prosecute prescription drug crimes, solicitors will be encouraged to designate one prosecutor to prosecute all of the prescription drug cases in the office/judicial circuit. Having designated prosecutors will allow the cases to be treated uniformly and in accordance with the Plan.

Training will be sought in conjunction with law enforcement to focus prosecution efforts on "prescription drug rings" rather than focusing on individuals. Ideally, prescription drug prosecutors will attend training with local law enforcement representatives. Grants can be sought both for training and for potential funding of a prosecutor position.

The South Carolina Prosecution Commission will be approached about coordinating the collection of statistical information regarding prescription drug prosecutions statewide. This will be accomplished by identifying the "codes" for all related or pertinent crimes.

V. <u>Define Statutory Amounts</u>

<u>Recommendation:</u> The Council recommends that law enforcement agencies and prosecutors work together to propose to the Legislature defined statutory amounts of opioids and other Schedule I through V controlled substances to qualify for the charges of Possession, Possession with the Intent to Distribute (PWID), and Trafficking.

Currently, there are no defined limits in statute regarding the charges of Possession, PWID, or Trafficking in Schedule I through V controlled substances. Setting limits or specifying the number of prohibited controlled substance dose units for each of these three charges would create uniformity with other drug charges in South Carolina that are set out by designated prohibited amounts (i.e., one gram or less, 10 grams to 28 grams, etc.). And, defining the necessary amounts of a PWID charge will create an inference rather than a per se violation in accordance with PWID charges for illicit drugs.

STATE	POSSESSION	PENALTY	MANUFACTURING / DISTRIBUTION	PENALTY
SC			Sch. I, II & III - 1g of Cocaine, 4 grains of opium, four grains of morphine, 2 grains of heroin (Section 44-53-370(d)(4)	1st. offense: 0-5 years; 2nd offense: 0-10 years; 3rd. offense: 5-20 years
			Sch.IV - No quantity established	1st. offense: 0-3 years; 2nd offense: 0-5 years; 3rd. offense: 0-5 years
			Sch.V - No quantity established	1st. offense: 0-1 years; 2nd offense: 0-2 years; 3rd. offense: 0-2 years
	Sch. I&II Narcotics - No quantity established	1st. offense: 0-2 years; 2nd offense: 0-5 years; 3rd. offense: 0-5 years		
	All non narcotic in Sch.I-V - No quantity established	1st. offense: 0-6 months; 2nd offense: 0-1 year		
NC			Distribution / Manufacturing of Sch. &II	Class H Felon
			Narcotics —No quantity established Distribution / Manufacturing of Sch.III, IV&V —No quantity established	Class I Felon
	Sch.I&II Narcotics - Less than 13	Class 1 Misd		
	Sch.II, II&IV - Option 1: more than 4 tablets, capsules, or other dosage units or equivalent quantity of Hydromorphone. Option 2: more than	Class I Felon		
	100 tablets Sch.V - No quantity established			
GA	Sch.I&II Narcotics - Less than 1g of a solid substance, less than 1ml of a	1-3 years		
	liquid substance Sch.I&II Narcotics - 1g-4g of solid substance, 1mI-4mI of liquid substance	1-8 years		
	Sch.I&II Narcotics - 4g-28g of solid substance, at least 4mI-28mI of liquid	1-15 years		
	substance		Distribution / Manufacturing of Sch.I&I Narcotics —No quantity established	1st offense: 5-30 years
				2nd offense: 10-40 years
	Poss. of Non Narcotic Sch. II less than 2q solid, less than 2ml liquid Poss. of Non Narcotic Sch. II 2q-4q	1-3 years 1-8 years		
	solid, 2ml-4ml liquid Poss. of Non Narcotic Sch. II 4g-28g	1-15 years		
	solid, 4ml-28ml liquid			
	Poss. of Non Narcotic Sch. II, 3rd or subsequent offense	Twice the length of the sentence applicable for to the particular crime		
	Sch.III, IV&V - No quantity established	1-3 years; 3rd or sub. offense: 1-5 years		
			Distribution / Manufacturing Sch.III, IV&V No quantity established	1-10 years
MS			Sch.I&II - Less than 2g or 10 dosage	0-8 years
			Sch.I&II - 2g-10g or 10-20 dosage units	3-20 years
			Sch.I&II - 10g-30g or 20-40 dosage units Sch.III&IV - Less than 2g or 10 dosage units	5-30 years 0-8 years
			Sch.III&IV - 2g-10g or 10-20 dosage units	0-8 years
			Sch.III&IV - 10g-30g or 20-40 dosage units	0-15 years
			Sch.V - Less than 2g or 10 dosage units	0-1 year
			Sch.V - 2g-10g or 10-20 dosage units Sch.V - 10g-30g or 20-40 dosage units	0-5 years 0-10 years
	Sch.I&II - Less than 0.1g or 2 dosage units	0-1 year	Sally - regroup of 20-10 doalge lines	o-ro years
	Sch.I&II - 0.1g-2g or 2-10 dosage units	0-3 years		
	Sch.l≪ - 2g-10g or 10-20 dosage units	0-8 years		
	Sch.I&II - 10g-30g or 20-40 dosage Sch.III, IV&V - Less than 50g or 100	3-20 years 0-1 year		
	dosage units Sch.III, IV&V - 50g-150g or 100-500 dosage units	1-4 years		
	Sch.III, IV&V - 150g-300g or 500-1000 dosage units	2-8 years		
	Sch.III, IV&V - 300g-500g or 1000-2500 dosage units	4-16 years		

STATE DRUG PENALTIES

PRIORITY AREA: TREATMENT

The basic tenets of these recommendations are based on evidence that availability and appropriate delivery of treatment services, including medication, can arrest the course of addiction to prescription opioids and other opiates, which is a substance use disorder (SUD).

Prescription opiate dependence is associated with dramatic costs to society, including lost productivity, social disorder, and increased healthcare utilization. Successful treatment leads to substantial improvements in a number of areas, including reduction of drug use, increased personal health and social function, and reduction in threats to public health and safety. As with other chronic disorders, continuing care and recovery support services are essential to maintaining improvements gained during SUD treatment. Despite this fact, addictions are often viewed as acute conditions; and as such, acute-care procedures, such as detoxification, are sometimes considered appropriate and definitive treatments. Access to a full continuum of care, including long-term continuing care options, is essential for an optimally functioning treatment system. Because of insurance restrictions and funding limitations, many patients receive only detoxification or acute stabilization, with no support for continuing care.

However, even when treatment is available and affordable, denial of problems associated with substance use is a core feature of addictions, and the stigma associated with addictions and addictions treatment can prevent people from seeking much-needed care.

Overcoming these barriers to treatment will depend on education and accurate information about the benefits and risks of treatment, and on directly addressing the stigma associated with methadone, buprenorphine, and other pharmacological interventions. Effective medication- assisted treatment does not cure SUDs, yet it is an extremely efficacious treatment for opioid addiction as a medical disorder when administered in conjunction with comprehensive services such as behavioral health counseling, case management, and treatment for co-occurring disorders. In turn, it reduces the incidence and severity of harm that occurs to the untreated individual, his or her family, and the community. Standards of treatment should be based upon clinical indications developed by the United States Substance Abuse and Mental Health Services Administration.

I. <u>Medication-Assisted Treatment</u>

Recommendation with Potential Fiscal Impact: The Council recommends expanding medication-assisted treatment (MAT) services for prescription opioid dependency and addiction, and integrating MAT and medication management services with recovery support services, and therapeutic interventions for substance use disorders, so that both are available to all individuals as conditions indicate.

Methadone is an opiate agonist that was originally developed for the treatment of opioid dependence in the mid-1960s. Methadone's dramatic efficacy in reducing heroin use, decreasing crime, and improving mortality rates made it a pro-social and lifesaving intervention for countless opioid-dependent persons. Methadone maintenance treatment (MMT) for opioid dependence in the United States is provided at clinics that are regulated by the Drug Enforcement Administration and the Center for Substance Abuse Treatment. Patients initially attend the clinic six or seven days per week (some clinics are routinely closed on Sundays) to receive a supervised dose of methadone, typically delivered in a flavored liquid form. While in the clinic, the patient may be asked to provide a urine sample for drug testing, have minor medical problems addressed, and/or attend an individual or group counseling session. MMT provides a context in which a number of pro-social activities and health issues can be addressed. Studies have clearly demonstrated that MMT can be highly effective, using outcomes of treatment retention and rates of illicit opioid use (e.g., as measured by urine testing). In addition, MMT is associated with decreases in criminal activity, decreases in illicit income, and decreases in non-opioid illicit drug use.

Buprenorphine is a mixed agonist-antagonist opioid that was approved in 2000 for the treatment of opiate dependence. A formulation of buprenorphine containing naloxone (initially marketed under the trade name Suboxone as a tablet, now available as a soluble film) is commonly used. Naloxone is an opioid antagonist that will precipitate opioid withdrawal if injected by a person who is physically dependent upon typical agonist opioids (e.g., heroin, oxycodone). The inclusion of naloxone in buprenorphine tablets and soluble film is a pharmacological strategy to decrease parenteral misuse of buprenorphine. While sublingual naloxone has poor bioavailability, injected naloxone has good bioavailability. As such, there is

no naloxone effect if the buprenorphine/naloxone is taken as indicated (sublingually), but if the combination is dissolved and injected by an opioid-dependent person, the person will experience precipitated opioid withdrawal. In contrast to methadone, a physician in an office-based setting in the United States can prescribe buprenorphine for the treatment of opioid dependence. In 2000, the Drug Addiction Treatment Act marked the beginning of a process designed to allow qualified physicians to prescribe approved narcotic drugs for the treatment of opioid dependence in office-based settings. There are a number of approved training programs in place to teach physicians about the use of buprenorphine. There is a limit to the number of patients a physician can concurrently treat with buprenorphine (30 in the first year, and then up to 100 in subsequent years after requesting this increase). This is the first time in modern medicine that physicians practicing in a variety of clinical settings, including office-based practice, are able to adequately treat opioid dependence with pharmacotherapy. Hopefully, this will greatly increase access to treatment for opioid-dependent individuals; however, the number of physicians in South Carolina who are qualified to prescribe buprenorphine is limited.

II. <u>Coordination of Treatment and Pain Management</u>

<u>Recommendation:</u> The Council recommends coordinating substance use disorder treatment services with co-occurring, clinically substantiated pain-management needs.

Opioids are an effective and appropriate intervention for pain, and are used in many cases of chronic pain management. The benefits of opioid therapy coexist with risks that patients may develop a dependency on the drug(s). Patients and prescribers are best served with full knowledge of these risks and mechanisms to eliminate or mitigate them. Extreme caution should be taken to ensure that those who truly need opioid therapy receive it without barriers. Monitoring and proper precautions should be taken with all people who are prescribed opioids. Elsewhere in this report, education programs and public awareness initiatives aim to address the significant lack of knowledge regarding risk of dependency and SUDs among prescribers and patients.

III. <u>Referral Protocols</u>

<u>Recommendation:</u> The Council recommends establishing a protocol for primary care practitioners to refer cases of prescription drug addiction to treatment, and establishing a protocol for treatment providers to refer and navigate individuals to primary care.

As the prescribing professionals encounter evidence of SUDs, they should have knowledge of and access to accredited alcohol and other drug treatment programs. Conversely, treatment programs should have or should develop a seamless referral process to primary care or other appropriate professional healthcare providers. This bilateral referral process should exist in every community in South Carolina. Furthermore, steps should be taken to expand access to treatment for SUDs and mental health concerns by building and expanding integrated health settings and medical homes. The Department of Alcohol and Other Drug Abuse Services should address existing barriers such as transportation, literacy, geography, income, and availability, and propose solutions that erode or eliminate the barriers to both behavioral health and primary health care. The use of telecommunications for services such as tele-medicine linkages and consults, and tele-recovery capacity using mobile devices, is an example of a solution that can overcome barriers.

IV. Family Involvement

<u>Recommendation</u>: The Council recommends providing family education and services, inclusive of substance use disorder treatment and recovery services.

Service to individuals in need of treatment is necessary but insufficient. Family education and services must be available when needed. Continuing service (aftercare or postdischarge service) is almost always helpful and necessary. Recovery-support services offered by specially trained peer support professionals should be offered to those in recovery.

V. <u>Community-Based Treatment</u>

<u>Recommendation with Potential Fiscal Impact:</u> The Council recommends expanding community-based services for substance use disorder treatment and recovery support.

Continuing treatment, such as post-discharge service, is almost always helpful and necessary for individuals recovering from SUDs. Treatment and recovery-support services offered by specially trained professionals should be readily available. All treatment programs, public and private, in South Carolina would benefit from expansion of peer-support training and financial support for recovery services beyond the minimum effective dose of inpatient or outpatient treatment.

Treatment services should also include screening for co-occurring disorders such as depression and anxiety. These conditions are linked very closely with current alcohol and other drug use and the subsequent primary withdrawal and secondary (post-withdrawal) period. Treating these conditions simultaneously results in positive outcomes for patients while conserving resources.

PRIORITY AREA: EDUCATION AND ADVOCACY

As with any public health epidemic, education will be a very important component in turning the tide of prescription drug abuse in our state. Many South Carolinians may be unaware of the astounding statistics associated with prescription drug abuse, both nationally and in our state. Two groups must be educated on the dangers of this epidemic and their role in preventing it: 1) present and future prescribers and dispensers of controlled substances; and 2) the general public.

In 2011, the Office of National Drug Control Policy published a national strategy that outlines specific tactics to reduce by 15% the non-medical use of prescription drugs among people 12 years of age and older, and included in those tactics is the education of patients, prescribers, and the general public.³⁴ In all of the successful state plans reviewed by the Council, education and advocacy proved to be a very important component. Utah developed a campaign titled "Use Only as Directed,"³⁵ and Kentucky embarked on a crusade to "unsell drugs" to the public, particularly their youth.³⁶ As a part of South Carolina's Plan, the Council recommends a similar campaign to educate the groups identified above.

The Council's Education and Advocacy recommendations for prescribers are listed in the Prescribers section above.

I. <u>Dispensers</u>

Recommendation: The Council recommends mandatory continuing education for pharmacists regarding SCRIPTS and general education on the problem itself. Further, the Council recommends reaching out to the pharmacy schools to increase course offerings related to the subject.

Pharmacists are partners in ensuring that all prescriptions filled for controlled substances are for legitimate medical purposes. In fact, pharmacists are the last line of defense prior to the controlled substance reaching the hands of the patient. Like prescribers, dispensers should utilize SCRIPTS to ensure that they are properly filling prescriptions. Similar to prescribers, dispensers have low utilization rates of this system, and do not receive much formal education regarding the system. The Council recommends partnering with the pharmacy schools in the state, Medical University of South Carolina, Presbyterian College, University of South Carolina School of Pharmacy, and South University to increase course offerings related to this topic.

II. <u>General Public</u>

Targeting healthcare professionals alone is not enough. Seventy percent of 12th-graders reported that they obtained prescription narcotics for nonmedical use from a friend or relative, not directly from a healthcare provider.³⁷ And, according to NIDA, public misperception about the safety of prescription drugs is one of the key factors driving the high prevalence of prescription drug abuse.³⁸ Given this, the Council must also focus its efforts on a public education campaign that warns about the dangers of prescription-drug misuse and easy access to them in the home.

Parents and educators might not realize that 1 in 12 high school seniors report nonmedical use of Vicodin, and 1 in 20 report abuse of OxyContin.³⁹ And more alarming, parents may be unaware of the statistic that 70% of these 12th-graders report obtaining these drugs from a friend or relative.⁴⁰

Further, many South Carolinians, adults and children alike, may be misled into believing that because a healthcare professional prescribes certain drugs, they are safer than illicit drugs. This is false. In fact, prescription drugs act directly or indirectly on the same brain systems affected by illicit drugs.⁴¹ And, although prescription drugs can be powerful allies, they also pose serious health risks related to their abuse.

Existing and future community coalitions will be a key component to any public education campaign. South Carolina currently has 11 Drug Free Communities Grant Program sites, which are funded by the federal Office of National Drug Control Policy and the Substance Abuse and Mental Health Services Administration. These coalitions have participated in the U.S. Drug Enforcement Administration's "take-back days" in the past and may also be working on other prevention strategies to address prescription drug abuse among young people. The 11 coalitions are:

- 1. York County All On Board Coalition
- 2. Coalition on Underage Drinking (Newberry)
- 3. The Project CARE Coalition (Richland School District Two)
- 4. The Berkeley County Prevention Board
- 5. Chesterfield County Coordinating Council
- 6. Richland One Community Coalition
- 7. Florence County Coalition for Alcohol and Other Drug Abuse Prevention
- 8. Steppin' It Up Coalition (Pickens)
- 9. Community Alcohol and Drug Impact Coalition (Spartanburg)
- 10. MCIAC Drug Free Marlboro Coalition
- **11.** Rise Above It (West Columbia)⁴²

Other coalitions may exist in communities that the Council is unaware of, and it will be important for the Council to work with the above coalitions, other existing coalitions, and assist communities in beginning new coalitions.

Recommendation with Potential Fiscal Impact: The Council recommends engaging a marketing firm or state or university employees to develop a marketing campaign and identify the target audience. The Council recommends that the campaign's message include, but not be limited to, the following three components:

- *dangers of prescription drug abuse;*
- proper disposal of prescription drugs, including available disposal sites; and
- use of SC 211 information helpline for opioid addiction.

<u>Recommendation:</u> Once the plan is developed, the Council recommends reaching out to the existing community coalitions, the South Carolina Department of Education, and professional associations to distribute marketing materials through schools, hospitals, physician and dental offices, and pharmacies. Further, the Council recommends reaching out to local communities without an existing coalition to assist them in building one.

PRIORITY AREA: DATA AND ANALYSIS

The Council formed a Data Committee, comprised of representatives from multiple state agencies, to identify how the State's management of data can assist with the design and measurement of success of a comprehensive prescription drug abuse prevention plan. The Data Committee reviewed the benchmarks established by the Council and assessed three factors for each of the nine policy tracks (i.e., Pharmacy, Prescription Drug Monitoring, Treatment, Law Enforcement, Third-Party Payers, Education and Advocacy, County/Community Initiatives, Unintended Consequences, and Prescribers). First, the Data Committee considered whether the proposed benchmarks are currently measured. If so, the Data Committee further inquired about how the data is currently collected and where it is stored. If not currently measured, the Data Committee identified potential gaps in either data currently collected or proposed for collection. Finally, the Data Committee identified action steps necessary to improve either the current or proposed statistics, including required legislative action. These are the benchmarks by which the Plan's impact will be measured.

The Data Committee's analysis is set forth in a spreadsheet as Appendix B.

I. Memorandum of Understanding on Information Sharing

<u>Recommendation</u>: The Council recommends that the Department of Health and Environmental Control (DHEC) and the Department of Health and Human Services (DHHS) work on a Memorandum of Understanding to facilitate information sharing between SCRIPTS and existing comprehensive databases.

SCRIPTS is a highly valuable, but underused, repository of raw data that may be analyzed for multiple purposes. However, SCRIPTS data is only one piece of the puzzle. South Carolina state agencies are utilizing other databases to collect data relevant to the prescription drug abuse epidemic.

For example, the South Carolina Health and Human Services Data Warehouse, created pursuant to S.C. Code Ann. 44-136-20, et. seq., collects data from over 17 different state

agencies. Segments of that data may relate to prescription drug use and abuse, mental health diagnoses, hospitalizations, and other treatment interventions and third-party payer information from the Medicaid and Public Employee Benefit Authority databases. Section 44-6-170 created the Data Oversight Council to make recommendations to the Joint Legislative Health Care Planning and Oversight Committee regarding the collection and release of healthcare-related data collected from healthcare providers or insurers. All the compiled data is stored by the newly formed Revenue and Fiscal Affairs (RFA) Office, formerly known as the Office of Research and Statistics.

The current challenge is that the data compiled in the databases supported by DHHS and housed by RFA is not linked to SCRIPTS. Accordingly, the Data Committee recommends that DHEC and DHHS work together to craft and execute a Memorandum of Understanding or other appropriate framework to facilitate the exchange of data stored in the respective databases while preserving the appropriate level of confidentiality and security.

II. Tracking Prescription Drug-Related Convictions

Recommendation with Potential Fiscal Impact: The Council recommends exploring with the South Carolina Court Administration and Solicitor's Association the possibility of creating a database for tracking all prescription drug-related convictions.

South Carolina currently has a system for tracking arrests, although even that does not currently segregate prescription drug offenses from illicit drug offenses or delineate which substances are involved. While there is a need to enhance the way South Carolina documents its arrests, there is an even greater need to develop a comprehensive database for capturing data regarding the prosecution of prescription drug-related offenses.

Solicitor's Offices around the state track the work conducted within each respective office. Each Solicitor's Office can track the arrest history, prosecutions, and specific criminal codes. However, there is no comprehensive database where the individual solicitors' information is compiled.

The Data Committee recommends exploration of the possibility of developing a comprehensive database for tracking prescription drug-related offenses so that the existing challenge can be properly identified and future progress measured.

III. Data From Adult Drug Courts

<u>Recommendation:</u> The Council recommends identifying counties with adult drug court and seeking information from those counties regarding currently collected data.

Adult drug courts are held in some, but not all, counties and may provide data regarding county-specific prescription drug issues. Data from the existing drug court programs can facilitate the identification and enrichment of alternatives to imprisonment for individuals who may need help more than incarceration. A further recommendation may include the development of a repository for the existing adult drug courts programs' data.

IV. Medication-Assisted Treatment

<u>Recommendation:</u> The Council recommends identifying medication-assisted treatment (MAT) options for individuals battling prescription drug addiction and tracking the use of MAT in South Carolina.

Other states have documented an increase in the number of prescriptions utilized in MAT programs, including but not limited to buprenorphine, naloxone, and methadone, as efforts to deter prescription drug abuse. There is anticipation that South Carolina will follow this trend. Accordingly, it will be useful to begin tracking this information to determine whether there is an increase in the utilization of MAT-related prescriptions. SCRIPTS can provide data regarding the number of prescriptions for these substances, excluding methadone from methadone clinics. However, that data will not provide a comprehensive analysis of the utilization of MAT programs.

Additional input is necessary from the treatment community regarding suggestions for appropriate metrics and data sources to accurately gauge how many South Carolinians pursue MAT options.

V. <u>Revision of ReLAES Database</u>

<u>Recommendation:</u> The Council recommends that the Department of Labor, Licensing and Regulation (LLR) revise its ReLAES database to designate disciplinary matters with a searchable identifier for prescription drug misuse/abuse/addiction cases.

ReLAES, LLR's internal database, does not currently specify the offenses for which licensees are disciplined relating to prescription drug issues. For example, if a physician is disciplined for diversion of a controlled substance or diagnosed with a prescription drug addiction, the system is not currently programmed to produce a report containing that information. ReLAES can be modified to add searchable fields for prescription drug-related actions.

VI. "Special Circumstances" Field for SLED

<u>Recommendation:</u> The Council recommends that the South Carolina Law Enforcement Division (SLED) add a "special circumstances" field to designate prescription drug matters.

South Carolina's Incident Reporting System is submitted to the Federal Bureau of Investigation (FBI) pursuant to FBI regulations. The information entered falls into general categories and currently does not specify offenses related to prescription drugs. SLED can customize the data entry to include a field called "special circumstances," whereby SLED can assign a one-letter code to represent prescription drug offenses. This would allow SLED to generate a report that accurately reflects the number and types of prescription drug cases investigated. A report is generated from the database and published annually. The addition of a "special circumstances" field for prescription drug cases will require training of all law enforcement agencies that enter data into the system. Local agencies may not utilize the field uniformly, so comprehensive training will be necessary to enhance the reliability of the data. The Data Committee recommends the designation of separate unique identifiers for opioids and benzodiazepines.

VII. Development of Comprehensive Database for Prescription Drug-Related Deaths

Recommendation with Potential Fiscal Impact: The Council recommends that coroners uniformly report causes and manner of death so that a comprehensive reporting system exists to track deaths associated with prescription drug abuse and/or overdose. To rectify this data error, the Council recommends that DHEC add a data field on the electronic death certificate that requires a coroner to specify the type of implicated drugs, prescription or illicit, in cases of overdose deaths.

<u>Recommendation:</u> Further, the Council recommends expanding training for coroners and medical examiners. In South Carolina, coroners must annually complete 16 hours of continuing education, most of which is offered by the South Carolina Coroner's Association. Currently, coroners are offered a course regarding best practices in identifying drug-related deaths. The Council recommends that DHEC work with the Coroner's Association to add a component to this course regarding the proper reporting of these deaths.

One important benchmark in establishing the baseline data and measuring the success of the Council's efforts going forward is the annual number of deaths attributable to prescription drug overdose/abuse (adult and youthful populations) in South Carolina. By statute, each of the 46 county coroners must report all suspected drug overdose deaths to DHEC. The Council has learned that this metric may not be consistently measured and reported throughout the state. In reporting, some coroners specify whether the implicated drug is a prescription or illicit drug, others do not, and others do so inconsistently. Thus, the number of prescription drug overdose deaths in South Carolina is likely understated. An existing database, Web Death, may be maximized to enhance greater uniform reporting. Additional training and allocation of resources may be necessary to assist with the push toward uniformity.

VIII. Inclusion of Additional Metrics

Recommendation: The Council recommends that additional metrics be added to the current benchmarks as the Plan is implemented and revised.

Additional benchmarks would include the following:

- the number of valid prescriptions held by a decedent at the time of death in cases where prescription drug use is a possible contributing factor to the death;
- the proportion of patients with <u>X</u> MED (to be determined by the Board of Medical Examiners) who have had at least one (1) SCRIPTS inquiry;
- the number or percentage of patients who are prescribed both opioids and benzodiazepines;
- the proportion of South Carolinians who have filled prescriptions for quantities in excess of <u>X</u>, to be determined by the Board of Medical Examiners; and
- the number of administrations of Naloxone by first responders.

PRESCRIPTION DRUG ABUSE PREVENTION COUNCIL RECOMMENDATION SUMMARY

PRIORITY AREA: PRESCRIBERS

<u>Recommendation:</u> The Council recommends that the Medical Board, the South Carolina Department of Health and Environmental Control, and other stakeholders work together to create a suggested list of topics for the education providers to include in the mandated training.

<u>Recommendation:</u> The Council recommends extending the education mandate contained in Act 244 to dentists, physician assistants, and advanced practice nurses with prescriptive authority.

<u>Recommendation</u>: The Council recommends working with schools to increase course offerings related to this topic or make it a mandatory part of the curriculum.

<u>Recommendation:</u> The Council strongly encourages all prescribers to be familiar with the Revised Pain Management Guidelines contained in Appendix A to this Plan and to conform their prescribing practice to these Revised Guidelines.

<u>Recommendation:</u> The Council recommends that prescribers be knowledgeable about all state and federal laws and regulations regarding controlled substances.

<u>Recommendation:</u> The Council recommends that registration and utilization of SCRIPTS be considered mandatory for prescribers to provide safe, adequate pain management.

<u>Recommendation</u>: The Council recommends that prescribers who prescribe chronic opioid therapy be familiar with treatment options for opioid addiction, including those available in licensed opioid treatment programs and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment, so as to make appropriate referrals when needed.

<u>Recommendation:</u> The Council recommends prescribers treating patients with controlled substances consider prescribing Naloxone when clinically indicated.

<u>Recommendation:</u> The Council strongly encourages the Boards of Medical Examiners, Dentistry, and Nursing to continue to update the Revised Pain Management Guidelines as lessons are learned and when data suggests that changes are needed.

Recommendation: SCRIPTS must be as user friendly as possible to facilitate easy use.

Recommendation: The Bureau of Drug Control (BDC) and Boards have a shared interest in correcting improper prescribing behaviors, through education when possible and enforcement when necessary. Upon establishment of criteria by the Board of Medical Examiners, which may include, but are not limited to, a daily MED threshold and prescription volume by prescriber, SCRIPTS shall generate reports by which outlier prescribers will be identified for further review by the BDC and, if necessary, referral to LLR for initiation of the complaint process.

<u>Recommendation</u>: Based on the Revised Guidelines, the Council recognizes that patients requiring more than 80 MED present an increased risk of death from respiratory depression. Accordingly, the Council recommends that, when capable, SCRIPTS offer an MED calculator that can generate an alert for each patient whose record is accessed and for which the MED exceeds 80 MED. The MED calculator and alert function will provide an additional tool for the prescriber to utilize when assessing a patient's prescriptive needs. This threshold is not a substitute for a prescriber's clinical judgment, but merely one factor for consideration in the prescribing process.

<u>Recommendation</u>: The BDC shall utilize the full analytical capabilities of SCRIPTS to identify prescribers engaged in questionable prescribing activities.

<u>Recommendation</u>: Information shared between LLR and DHEC may be used to assist the BDC in promptly identifying a prescriber's area of specialization, if applicable, when investigating a licensee's prescribing behavior.

Recommendation with Potential Fiscal Impact: The Council and the Boards support the compilation and distribution of report cards to all South Carolina licensed prescribers so that each prescriber can see how his or her prescribing patterns compare to other prescribers practicing in the same or similar clinical setting.

<u>Recommendation:</u> Prescribers engaged in conduct not rising to the level of criminal activity, but who may benefit from additional education or counseling regarding appropriate prescribing, shall be identified by the BDC and provided an educational intervention.

<u>Recommendation</u>: Prescribers identified by the BDC engaged in conduct rising to the level of criminal activity, shall be subjected to the standard process of investigation by the BDC, arrest, where appropriate, and referral to LLR for investigation of unprofessional conduct.

Recommendation: The Council recommends that the Boards identify licensees with expertise in ethical prescribing to serve as hearing officers or hearing panel members in any disciplinary cases arising from prescribing behavior. These designated individuals shall hear and review disciplinary matters and make recommendations to the applicable regulatory board for final action as set forth in each profession's Practice Act and regulations. These individuals shall not be the same licensees identified to serve as voluntary mentors.

PRIORITY AREA: THE SOUTH CAROLINA PRESCRIPTION MONITORING PROGRAM

<u>Recommendation:</u> The Council recommends that prescriber registration and enrollment in SCRIPTS become required and recommends that each patient's prescription history is reviewed in certain circumstances prior to the prescription of controlled substances.

Recommendation with Potential Fiscal Impact: The Council recommends that DHEC proceed to acquire analytic services and/or products to work with SCRIPTS data, expanding the capacity to develop predictive models and to detect anomalies in prescriber patterns and patient prescription behaviors. The Council further recommends that DHEC send letters notifying prescribers of suspicious behavior identified by the analytics.

Recommendation with Potential Fiscal Impact: The Council recommends that DHEC coordinate real-time hosting of data from other state agencies to include, but not be limited to, the South Carolina Department of Alcohol and Other Drug Abuse Services; South Carolina Department of Mental Health; South Carolina Department of Juvenile Justice; South Carolina Department of Social Services (DSS); South Carolina Department of Health and Human Services (DHHS); South Carolina Attorney General's Office; South Carolina Department of

Probation, Parole, and Pardon Services; South Carolina Department of Corrections; South Carolina Prosecution Commission; and the South Carolina Law Enforcement Division.

Recommendation with Potential Fiscal Impact: The Council recommends that DHEC and the Revenue and Fiscal Affairs Office collaborate and create capacity for information sharing between SCRIPTS and South Carolina Health Information Exchange (SCHIEx).

Recommendation with Potential Fiscal Impact: The Council recommends that DHEC work with prescribers and healthcare providers to integrate SCRIPTS data into electronic health records, so that access to patients' controlled substance records does not interrupt prescriber workflow.

<u>Recommendation:</u> The Council recommends that Governor Haley request by letter the States of North Carolina and Georgia enroll in the National Association of Boards of Pharmacy's Prescription Monitoring Program Interconnect hub to afford enhanced regional monitoring.

<u>Recommendation:</u> The Council recommends that the BDC continue and expand initiatives to coordinate education and awareness campaigns for SCRIPTS, to include outreach to more stakeholders such as provider associations, licensing boards, and investigative agencies.

PRIORITY AREA: PHARMACY

Recommendation with Potential Fiscal Impact: The Council recommends expanding prescription drug take-back programs across the state.

<u>Recommendation:</u> The Council recommends regulating non-resident entities dispensing controlled substances into the state.

<u>Recommendation:</u> The Council recommends increasing the number of pharmacists registered to use SCRIPTS.

<u>Recommendation:</u> The Council recommends that the professional boards and associations work with practitioners, pharmacies, and software vendors to encourage electronic transmission for all classes of controlled substance prescriptions.

PRIORITY AREA: THIRD-PARTY PAYERS

<u>Recommendation:</u> The Council recommends that third-party payers adjust payer policies in accordance with the Revised Pain Management Guidelines outlined in the Prescribers section above and attached as Appendix A.

<u>Recommendation:</u> The Council recommends that third-party payers continue to adopt and revise interventions to address controlled substance misuse and abuse by beneficiaries, including participation in multi-agency data sharing with the Bureau of Drug Control Prescription Monitoring Program.

<u>Recommendation</u>: The Council recommends that third-party payers adapt pharmacy benefits packages to encourage appropriate use of opioids.

Recommendation with Potential Fiscal Impact: The Council recommends healthcare payer coverage for screening and treatment for substance use disorders.

PRIORITY AREA: LAW ENFORCEMENT

Recommendation with Potential Fiscal Impact: The Council recommends expanding law enforcement sponsorship of prescription drug take-back programs.

<u>Recommendation:</u> The Council recommends increasing awareness and education of law enforcement to identify potential misuse of prescription drugs.

<u>Recommendation</u>: The Council recommends increasing law enforcement participation in community-based prevention programs.

Recommendation with Potential Fiscal Impact: The Council recommends continuing and expanding investigation and prosecution efforts specific to prescription drug diversion.

<u>Recommendation:</u> The Council recommends that law enforcement agencies and prosecutors work together to propose to the Legislature defined statutory amounts of opiods and other Schedule I through V controlled substances to qualify for the charges of Possession, Possession with the Intent to Distribute (PWID), and Trafficking.

PRIORITY AREA: TREATMENT

Recommendation with Potential Fiscal Impact: The Council recommends expanding medication-assisted treatment (MAT) services for prescription opioid dependency and addiction, and integrating MAT and medication management services with recovery support services, and therapeutic interventions for substance use disorders, so that both are available to all individuals as conditions indicate.

<u>Recommendation:</u> The Council recommends coordinating substance use disorder treatment services with co-occurring, clinically substantiated pain-management needs.

<u>Recommendation:</u> The Council recommends establishing a protocol for primary care practitioners to refer cases of prescription drug addiction to treatment, and establishing a protocol for treatment providers to refer and navigate individuals to primary care.

<u>Recommendation</u>: The Council recommends providing family education and services, inclusive of substance use disorder treatment and recovery services.

Recommendation with Potential Fiscal Impact: The Council recommends expanding community-based services for substance use disorder treatment and recovery support.

PRIORITY AREA: EDUCATION AND ADVOCACY

<u>Recommendation:</u> The Council recommends mandatory continuing education for pharmacists regarding SCRIPTS and general education on the problem itself. Further, the Council recommends reaching out to the pharmacy schools to increase course offerings related to the subject.

Recommendation with Potential Fiscal Impact: The Council recommends engaging a marketing firm or state or university employees to develop a marketing campaign and identify the target audience. The Council recommends that the campaign's message include, but not be limited to, the following three components:

- *dangers of prescription drug abuse;*
- proper disposal of prescription drugs, including available disposal sites; and
- *use of SC 211 information helpline for opioid addiction.*

<u>Recommendation:</u> Once the plan is developed, the Council recommends reaching out to the existing community coalitions, the South Carolina Department of Education, and professional associations to distribute marketing materials through schools, hospitals, physician and dental offices, and pharmacies. Further, the Council recommends reaching out to local communities without an existing coalition to assist them in building one.

PRIORITY AREA: DATA AND ANALYSIS

Recommendation: The Council recommends that the Department of Health and Environmental Control and the Department of Health and Human Services (DHHS) work on a Memorandum of Understanding to facilitate information sharing between SCRIPTS and existing comprehensive databases.

Recommendation with Potential Fiscal Impact: The Council recommends exploring with the South Carolina Court Administration and Solicitor's Association the possibility of creating a database for tracking all prescription drug-related convictions.

<u>Recommendation:</u> The Council recommends identifying counties with adult drug courts and seeking information from those counties regarding currently collected data.

<u>Recommendation:</u> The Council recommends identifying medication-assisted treatment (MAT) options for individuals battling prescription drug addiction and tracking the use of MAT in South Carolina.

<u>Recommendation:</u> The Council recommends that the Department of Labor, Licensing and Regulation (LLR) revise its ReLAES database to designate disciplinary matters with a searchable identifier for prescription drug misuse/abuse/addiction cases.

<u>Recommendation:</u> The Council recommends that the South Carolina Law Enforcement Division (SLED) add a "special circumstances" field to designate prescription drug matters.

Recommendation with Potential Fiscal Impact: The Council recommends that coroners uniformly report causes and manner of death so that a comprehensive reporting system exists to track deaths associated with prescription drug abuse and/or overdose. To rectify this data error, the Council recommends that DHEC add a data field on the electronic death certificate that requires a coroner to specify the type of implicated drugs, prescription or illicit, in cases of overdose deaths.

<u>Recommendation:</u> Further, the Council recommends expanding training for coroners and medical examiners. In South Carolina, coroners must annually complete 16 hours of continuing education, most of which is offered by the South Carolina Coroner's Association. Currently, coroners are offered a course regarding best practices in identifying drug-related deaths. The Council recommends that DHEC work with the Coroner's Association to add a component to this course regarding the proper reporting of these deaths.

<u>Recommendation:</u> The Council recommends that additional metrics be added to the current benchmarks as the Plan is implemented and revised.

SUMMARY OF RECOMMENDATIONS REQUIRING PROPOSED LEGISLATIVE CHANGES

Recommendation: The Council recommends extending the education mandate contained in Act 244 to dentists, physician assistants, and advanced practice nurses with prescriptive authority.

<u>Recommendation:</u> The Council recommends that prescriber registration and enrollment in SCRIPTS become required and recommends that each patient's prescription history is reviewed in certain circumstances prior to the prescription of controlled substances.

Recommendation with Potential Fiscal Impact: The Council recommends that DHEC proceed to acquire analytic services and/or products to work with SCRIPTS data, expanding the capacity to develop predictive models and to detect anomalies in prescriber patterns and patient prescription behaviors. The Council further recommends that DHEC send letters notifying prescribers of suspicious behavior identified by the analytics.

Recommendation: The Council recommends that law enforcement agencies and prosecutors work together to propose to the Legislature defined statutory amounts of opioids and other Schedule I through V controlled substances to qualify for the charges of Possession, Possession with the Intent to Distribute (PWID), and Trafficking.

<u>Recommendation:</u> The Council recommends mandatory continuing education for pharmacists regarding SCRIPTS and general education on the problem itself. Further, the Council recommends reaching out to the pharmacy schools to increase course offerings related to the subject.

<u>Recommendation</u>: A further recommendation by the Data Committee is that all public schools participate in surveys of nonmedical use of prescription and illicit drugs.

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ENDNOTES

¹ Institute of Medicine, "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research" (Washington, DC: National Academy of Sciences, 2011), p. 5. <u>http://www.nap.edu/openbook.php?record_id=13172</u>.

² The American Academy of Pain Medicine. *AAPM Facts and Figures on Pain*. http://www.painmed.org/patientcenter/facts_on_pain.aspx#incidence (accessed Nov. 25, 2014).

³ Prescription drug abuse is defined as the use of medication without a prescription, in a way other than prescribed, or for the experience or feelings elicited.

⁴ Centers for Disease Control. *Grand Rounds: Prescription Drug Overdose-a U.S. Epidemic.* Jan. 13, 2012; 61(01):10-13. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm?s_cid=mm6101a3_w.

⁵ Three classes of prescription drugs are the most commonly abused: opioids, usually prescribed to treat pain, such as Vicodin or Oxycontin; central nervous system depressants used to treat anxiety and sleep disorders, such as Valium or Xanax; and stimulants, most often prescribed to treat attention deficit hyperactivity disorder, such as Adderall or Ritalin.

⁶ National Institute on Drug Abuse. *Popping Pills: Prescription Drug Abuse in America*. Jan. 2014. http://www.drugabuse.gov/related-topics/trends-statistics/infographics/popping-pills-prescription-drug-abuse-in-america.

⁷ National Institute on Drug Abuse. *Prescription Drug Abuse: Trends in Prescription Drug Abuse.* Nov.2014. http://www.drugabuse.gov/publications/research-reports/prescription-drugs/trends-in-prescription-drug-abuse/how-many-people-abuse-prescription-drugs.

⁸ National Institute on Drug Abuse. *Topics in Brief, Prescription Drug Abuse*. Dec. 2011. http://www.drugabuse.gov/sites/default/files/prescription_1.pdf.

⁹ ibid.

¹⁰ Trust for America's Health. *Prescription Drug Abuse: Strategies to Stop the Epidemic*. Oct. 2013. http://healthyamericans.org/reports/drugabuse2013/TFAH2013RxDrugAbuseRpt12_no_embargo.pdf.

¹¹ National Institute on Drug Abuse. *Drug Facts: Prescription and Over-the Counter Medications*. Nov. 2014. http://www.drugabuse.gov/publications/drugfacts/prescription-over-counter-medications.

¹² National Institute on Drug Abuse. *Popping Pills: Prescription Drug Abuse in America*. Jan. 2014. http://www.drugabuse.gov/related-topics/trends-statistics/infographics/popping-pills-prescription-drug-abuse-in-america.

¹³ Centers for Disease Control and Prevention. *Prescription Drug Overdose in the United States: Fact Sheet*. Oct. 17, 2014. http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html.

¹⁴ ibid.

¹⁵ ibid.

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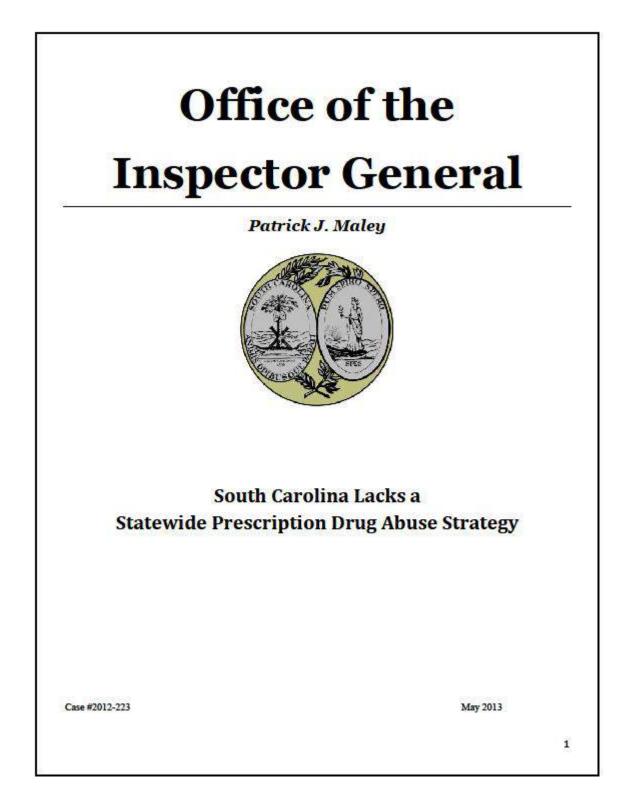
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APPENDIX A

OFFICE OF THE INSPECTOR GENERAL REPORT



I. <u>Executive Summary</u>

The National Center for Disease Control (CDC) classified prescription drug abuse as a National epidemic; South Carolina state authorities universally concur. Several supporting statistics include:

- In 2010, there were 22,134 overdose deaths from prescription drugs nationally, which were more than cocaine, heroin, and all other illegal drugs combined. The CDC reported prescription overdose deaths in 2010 climbed higher for the 11th year in a row.
- In two different studies, South Carolina ranked 10th (2008) and 23rd (2010) highest in opioid painkiller prescriptions per capita. In 2010, South Carolina ranked 23rd highest per capita in overdose deaths, with the most recent data, 2011, denoting 225 prescription overdose deaths.
- National prescription overdose deaths have tripled since 1990. This correlates with prescriptions
 for painkillers quadrupling since 1999, and more than 12 million Americans abusing prescription
 painkillers for non-medical reasons in 2010.
- The National economic impact-treatment, emergency room visits, rehab, and associated health
 problems--costs were calculated in three different studies at \$42, \$53, and \$72.5 billion annually.

The 225 annual prescription overdose deaths in South Carolina are just the tip of the iceberg. For every overdose death, there are hundreds of wrecked lives through addiction which are then multiplied by their impact on immediate families and friends, let alone the financial costs to society. Despite the aforementioned startling statistics, prescription painkillers are incredibly effective in medical treatments and life saving medications for many people, so it is critical to address this epidemic problem without impacting a physician's ability to prescribe to a patient in need.

The passion and commitment from each state agency "in the fight" against this epidemic was overwhelming. However, South Carolina does not have a prescription drug abuse strategy, current efforts are reactionary and fragmented. State authorities also do not have a rigorous, systematic understanding of South Carolina's painkiller problem. Based on ad hoc national data, South Carolina clearly has a significant problem that is likely worse than an average state, possibly as high as the 10th highest painkiller prescriptions per capita rate in the United States.

The state's Prescription Monitoring Program (PMP), a centralized electronic prescription data base, is the most critical tool to leverage efforts to impact this epidemic, yet the PMP is substantially underutilized. Likely its most important feature provides a prescribing physician their patient's prescription history to identify "doctor shoppers" who go to multiple doctors providing false information to obtain prescription drugs to abuse or resell "on the street" for large profits. This PMP data provides physicians intervention opportunities to help abusers and keeps excess prescription drugs off the street by denying "shoppers" for profit. Use of PMP is voluntary; only 22% of South Carolina physicians are registered and much fewer actually use it for prescription decisions.

This is a drug problem, but unlike the 15 billion dollars a year the United States spends for the war on illegal drugs like cocaine, heroin, and meth, the government actually controls the prescription drug

supply. The prescribing community, primarily physicians, has two gaps in its due diligence prescribing patterns driving this epidemic, which are inconsistent with the intent of the state's pain management medical standards. Unscrupulous "pill mill" doctors are motivated by money and a second category of high prescribing doctors can be described in a word—naïve. The reasons vary for this naïve group, but include physicians who lack education in dispensing opioids, "pleasers" to accommodate a patient's needs/demands, overly trusting, bullied by patients, or the speed of their practice undermines a thorough approach to dispensing opioid painkiller prescriptions. With today's desktop publishing capabilities, forged prescriptions seemed to be on the increase also contributing to this problem.

There has been no comprehensive federal approach to aggressively address this issue, which has left the states to piece together a fragmented response. States hardest hit have moved beyond speeches and filled this leadership vacuum by taking on the responsibility. These states, with a concentration of Midwest and Southern states (Florida, Georgia, Tennessee, Kentucky, Ohio, North Carolina, and West Virginia), literally surround South Carolina. Their strategies vary, but the common theme focuses on the physician. Many factors contributed to today's epidemic, but physicians need to lead us out using tools to match the increased risk of these addictive drugs. These states' general pattern is to clarify pain management protocols in a rigorous manner to squeeze out the ambiguity which allows pill mills and naïve physicians to comfortably, both intentionally and unintentionally, operate. Kentucky, which has the most aggressive laws, sums up its laws as not restricting physicians, but rather providing a standardized process to ensure "every time a physician makes a decision to prescribe an opioid to a chronic non-cancer pain patient, there is a thoughtful, deliberate decision between patient and the physician after considering the risks and benefits." In less than a year, these common sense protocols yielded the closure of 36 (81%) of the state's rogue pain clinics and a 14% reduction of commonly abused prescription drugs. Florida's new laws led to as high as a 20% decrease. The primary objective is to save lives and prevent wrecked families/communities, but there are also Medicaid and private insurers cost savings measured in the tens, if not hundreds, of millions of dollars.

Managing this issue, like nearly all complex problems, requires a proactive systems approach. This approach will require the state to establish clear prescribing painkiller protocols, notably mandatory use of PMP and specific safeguards for prescribing long term opiates to non-cancer chronic pain patients; physician training; regulators proactively use PMP to monitor unusual variations; provide PMP feedback to improve; audit/investigate prescribing outside of medical standards along with swift intervention; invest in drug treatment; and periodically analyze progress to modify strategy and improve.

There is no cookie cutter procedural list to address South Carolina's prescription drug abuse problem. The solution starts with a commitment that 1) there is a significant problem, 2) a proactive strategy focusing on the supply side--physician excess prescriptions, and to a lesser extent, prescription forgeries; and 3) integrate a team from responsible agencies to comprehensively work the problem with a marathon mentality and the creativity to fully exploit the variety of tools available and lessons learned from other states. As one doctor said, "we can solve this problem by doing the simple extra steps of education, using PMP, and closely monitor patients with long term opioid prescriptions." Currently, South Carolina does not have mechanisms to support robust pain management education, PMP use, nor proactively address physicians operating outside of pain management medical standards, often long-term treatment of non-cancer chronic pain patients. Given these drugs' pleasurable, addictive, and financially exploitable properties, this epidemic, left unchecked, has proven only to expand.

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II. Background

A. Objectives

This State Inspector General (IG) review was stimulated by the South Carolina Department of Health & Human Services (DHHS) based on the increasing Medicaid costs associated with prescription painkillers, particularly opioids, and a recent study identifying opioid's impact on Medicaid birth outcomes. This study, "Women of Childbearing Age and Opiates (September 2012)" determined 29%, on average, of women of child bearing age (18-34) on Medicaid received an opioid prescription in 2010-11. This data combined with the rising consensus in this country that prescription drug abuse is a national epidemic, resulted in three objectives:

- Determine the current status of prescription drug abuse in South Carolina;
- Assess the state's strategy to address prescription drug abuse; and
- Identify opportunities to improve.

B. National Epidemic Statistics

Nationally, the prescription drug abuse issue is being addressed in an ad hoc manner by individual states, but the pace has increased in the past several years with bold legislation in a number of states, with a concentration in the Midwest and South. Commonly abused prescription drugs include opioids, benzodiazepines, and amphetamines. However, most of the research tends to focus on opioids, also known as painkillers, due to its significant role in this issue. The Center for Disease Control classified prescription drug abuse as an epidemic; South Carolina state authorities universally concur. The supporting statistics are numerous and consistent, and below are several to illustrate this national epidemic:

- In 2010, there were 22,134 prescription drug overdose deaths in the United States, which were more than cocaine, heroin, and all other illegal drugs combined.
- A 2012 report depicted prescription painkillers as only second to marijuana for drug abuse.
- Prescription drug overdose deaths are currently the #1 cause of accidental death in 20 out of 50 states, surpassing motor vehicle accidents for the first time.
- A recently published (October 2012) robust research study concluded, based on examining 2008 data, South Carolina ranked the 10th highest painkiller prescriptions per capita rate in the United States, which was 33% higher than the national average. In 2010, another study South Carolina ranked 23rd highest per capita in opioid painkiller prescriptions.
- In 2010, South Carolina ranked 23rd highest per capita in overdose deaths, with the most recent data, 2011, denoting 225 prescription overdose deaths.

- National prescription overdose deaths have tripled since 1990. This correlates with
 prescriptions for painkillers quadrupling since 1999, and more than 12 million Americans
 used prescription painkillers for non-medical reasons in 2010.
- For every overdose death, there are 10 drug treatment admissions; 32 emergency room admissions; 130 people addicted; and 825 non-medical users.
- Emergency room treatments for opioids increased over 100% from 2004 (144,644) to 2008 (305,885).
- The Centers for Disease Control (CDC) estimates that enough opioids were sold in 2010 to give every American adult a 5mg Vicodin tablet every four hours for a month.
- The National economic medical impact—treatment, emergency room visits, rehab, and associated health problems—costs were calculated in three different studies at \$42, \$53, and \$72.5 billion annually.
- Prescription pain medications kill an estimated two people every hour and send 40 more to emergency rooms with life-threatening overdoses.

The prescription painkiller epidemic has sometimes been called the "silent epidemic." However, when the costs in human lives, wrecked lives, high morbidity, destroyed families, and economic costs are all lined up together, the epidemic becomes clear and even more tragic knowing the root cause is primarily drugs legally manufactured and sold to the public.

C. History of the Epidemic

The rise in the misuse and abuse of prescription drugs, opioids in particular, has been attributed to their increased availability over the last decade, a result of increased prescribing. Prescribers are primarily physicians, but also include those supervised by a physician, such as a nurse practitioner or physician assistant, and dentists. Increased prescribing in turn has been driven by more aggressive treatment of pain in response to patient advocacy groups and increased marketing of opioids by pharmaceutical companies. The advocacy groups and pharmaceutical companies, in retrospect, underestimated the downside risk of addiction which has led many to describe prescription drug abuse as the "largest man made epidemic in the United States." Because of their euphoric and addictive properties, these drugs also have a high street value. A routine 90 pill prescription of oxycondone (30 MG) costs \$122 retail, or even less through a \$25 insurance co-pay or \$3 Medicaid co-pay, which can then be converted to a \$2675 profit through street sales.

Despite the startling statistics on the misuse of prescription painkillers, these drugs are very effective in medical treatments and life saving medications for many people, so it is critical to address the problem without impacting a doctor's ability to prescribe to a patient in need. However, the grim statistics and a growing number of doctors paint the picture that the pendulum of these drugs' increasingly liberal use since the 1990s has swung too far. The medical community and the public are becoming increasingly

sensitive to the fact that prescription opioids come from the same narcotics family as heroin and can produce similar life altering addictions.

Americans have confidence in physicians' professional due diligence in practicing medicine. However, the data demonstrate there are definitely gaps in the profession's due diligence in prescribing painkillers. These gaps fall generally into two areas. First, a "pill mill" is the generic term for unscrupulous doctors motivated by money to prescribe controlled drugs. Even within this group, there are variations of players. From the most extreme, physicians are transported from out of state to operate a cash only, store front business several days a week to serve abusers and those motivated to divert drugs for profit, who literally stand in lines wrapped around the building. On the other end of the spectrum, physicians can slide down a slippery slope of medical ethics to increase their practice by serving this type of clientele and turn a blind eye towards the likely long term impact of their actions. Regardless of the degree of greed, this group would not be in compliance with the intent of medical due diligence standards set forth by the South Carolina Medical Board.

The second category is high prescribing doctors who are in a word--naïve. These physicians can lack education in dispensing opioids, "pleasers" to accommodate patient's needs/demands, overly trusting, bullied by patients, or the speed of their practice undermines a rigorous approach to opioid prescriptions. As a group, they appear to be well intended, but the result is excess drugs in the public domain contributing to this epidemic. Three doctors described this group:

- A Health Service Chief Medical Officer asserts, "as long as treating doctors remain naïve, but compliant, to the intimidating, manipulating, bullying behavior of drug-seeking, drug addicted pain patients, we will continue to see the many tragic faces of prescription drug abuse."
- According to Dr. Sanjay Gupta, "truth is, it is easier for a doctor to write a prescription than to
 explore other effective options to combat pain. And it is easier for patients to take those
 prescription pills than to search for alternatives themselves. Both those things must absolutely
 change."
- Part of the problem is that doctors do not have the time they need to properly assess patients for
 potential abuse. "You've got an awful lot of doctors prescribing not out of ill intents. They've
 got a limited amount of time, and pain patients require a lot of time," said Robert Walker,
 assistant professor of behavioral science at University of Kentucky's Center on Drug and Alcohol
 Research. "The easiest solution is the opioid."

The prescription drug abusers with addictions generally don't get started by corner drug dealers. Although there are many paths to addiction, a Federal Judge in Eastern Kentucky, likely the area of the country most impacted by this epidemic, describes the common path to addiction, "I sentence pill peddlers every month. They tell me the same story in nearly every case: Good person gets hurt, gets prescribed pain killers, gets addicted, loses job, and starts dealing to sustain his habit. A doctor prescribed it so it can't be bad for you." A medical expert similarly described the most common scenario for prescription drug abuse or death is when a middle-aged man goes to his doctor complaining of back pain; the doctor prescribes a painkiller; and the patient then later dies three years later from an overdose or by mixing the medication with alcohol. Unfortunately, this pattern may be changing as prescription drugs are becoming the drug of choice abused by teenagers to get recreationally high. With

the seemingly easy access adults have for these drugs, it provides the same access for our teenagers through the family's medicine cabinet.

The Journal of American Medical Association (JAMA) published two recent articles summarizing this epidemic and highlights physicians' role, "Curbing the Opioid Epidemic in the United States (August 2012)" and "Rethinking Opioid Prescribing to Protect Patient Safety and Public Health (November 2012)." Quotes from these articles include:

- "Health care professionals...have become the primary supplier of the drugs fueling this epidemic."
- "There is little evidence to suggest that physicians have curtailed their practice of prescription opioids in response to exponential increases in addiction and overdose deaths."
- "Although at its core the opioid epidemic may be iatrogenic (unintentional adverse effect by doctor's treatment), additional regulation may be needed to help ensure more informed and appropriate prescribing."
- "Efforts to prevent abuse and diversion to the illicit market should continue, but prescription
 practices also must change to reverse what has become a pervasive epidemic leading to widespread morbidity, mortality, and community strife."

Just recently, in February 2013, the CDC reported prescription overdose deaths climbed higher for the 11th year in a row. CDC reported, "the big picture is that this is a big problem that has gotten much worse quickly...the data show a need for more prescription drug monitoring at the state level, and more laws shutting down pill mills—doctor offices and pharmacies that overprescribe addictive medicines."

The prescription drug abuse epidemic is complex with many dynamic factors. However, the factor that has the greatest impact, either positively or negatively, is physicians' ability to limit the excess supply of these drugs being dispensed, intentionally or unintentionally, creating abusers/addiction or diverted to illegal drug markets with the same result. Many factors contributed to today's epidemic, but physicians need to lead us out using tools to match the increased risk of these addictive drugs.

III. National Trends Addressing Prescription Drug Abuse

A. Federal Government

In April 2011, the Office of National Drug Control Policy (ONDCP), White House, described prescription drug abuse as the Nation's fastest-growing drug problem, and the Nation must take "urgent action" to ensure the appropriate balance between the benefits these medications offer in improving lives and the risks they pose. This Prescription Drug Abuse Prevention Plan includes action in four major areas to reduce prescription drug abuse: education, prescription monitoring programs, proper disposal, and enforcement. The Congressional Caucus on Prescription Drug Abuse, led by Representatives Hal Rogers (Kentucky) and Nick Rahall (West Virginia), are active in raising awareness and supporting legislative action.

The ONDCP sums up the federal government's position, "no one agency, system, or profession is solely responsible for this undertaking. We must address this issue as partners in public health and public safety." As a result, there is no comprehensive federal approach to aggressively address this issue, leaving the states to piece together a fragmented response. States hardest hit with this problem have moved beyond the federal government's approach that no one entity is solely responsible. These states have taken on the responsibility. This ownership mentality to address the problem has led to state legislation with firm mandates and corresponding enforcement mechanisms to get results. Certainly, the legislation requires coordinated efforts by many entities within each state, but there is no doubt about who has exercised leadership and assumed responsibility—the state.

B. State Governments

Numerous research studies have identified the Appalachian region and Southern states as historically having the most significant prescription drug abuse and misuse problems. South Carolina is both. Those states aggressively attacking this epidemic with innovation and initiatives virtually surround South Carolina: Kentucky, Ohio, Tennessee, Georgia, Florida, North Carolina, and West Virginia. Their strategies vary, but have a common theme focusing on the physician. Many factors contributed to today's epidemic, but physicians need to lead us out. This is a drug problem, but unlike the 15 billion dollars a year the United States spends for the war on illegal drugs like cocaine, heroin, and meth, the government actually controls the drug supply. The debate in these proactive states highlights the fact that unlike the supply chain for illicit drugs, those who supply excess prescription drugs are largely legitimate businesses and professionals. The gatekeepers, generally physicians, are not fully managing this issue or the United States would not have more overdose deaths from prescription drugs than all illegal drugs combined.

Despite obstacles, states hit hardest by this epidemic are now moving beyond passive encouragement. These states are now mandating regulations to put clear standards in place to ensure physicians rigorously conduct their medical due diligence in prescribing opioids and other commonly abused drugs commensurate to the risks of these powerful narcotics. Kentucky, which has 1000 overdose prescription drug deaths a year, passed legislation to regulate physicians prescribing commonly abused drugs with the pragmatic goal of ensuring "every time a physician makes a decision to prescribe an opioid to a chronic non-cancer pain patient, there is a thoughtful, deliberate decision between patient and the physician after considering the risks and benefits." The regulations were common sense standards on pain clinics and physician prescription protocols which has yielded the closure of 36 (81%) of the state's 44 rogue pain clinics. In less than a year, prescriptions of commonly abused drugs have been reduced by 14%. Kentucky recently passed a second wave of legislation to fine tune its successful approach to incorporate feedback from the medical community. An initial major concern by the medical community was the impact of the mandatory use of PMP, but after nearly a year under the law, this concern has seemed to recede. Florida's recent legislation resulted in as high as a 20% decrease.

All around the country, this tension between balancing the benefits of these drugs with the significant potential for abuse and misuse seems to be hitting a tipping point where the public, as well as increasing voices within the medical community, are demanding action to address this prescription painkiller epidemic. States taking proactive measures implement their initiatives through legislation and new regulations. The general pattern is to clarify pain management standards in a rigorous manner to

squeeze out the ambiguity which allows pill mills and naïve physicians to comfortably, both intentionally and unintentionally, operate. Areas addressed in new legislation and regulation generally include all or part of the following:

- Mandatory use of a centralized electronic prescription data base (Prescription Monitoring Program) to review a patient's prescription history by physicians <u>prior</u> to dispensing painkillers, but allowing exceptions such as for hospice, cancer patients, hospitalization, and post-operative pain;
- Enhanced physician protocols and documentation, particularly safeguards for treating long term (greater than 3 months), chronic non-cancer pain patients with painkillers due to these patients' heightened risk for abuse and misuse;
- Establish a Pain Clinic category of medical practice based on specific criteria, and then set higher
 oversight standards commensurate with the increased risk in this category for abuse and misuse;
 standards include, but not limited to, a quality assurance program, practice required to accept
 insurance (i.e., can't be "cash only" typically used by egregious pill mills), education, and
 operated by a certified pain management specialist.
- Proactively use PMP to identify unusual prescription variances/patterns and use feedback techniques to identify potential drug diverters for physicians and pill mills for audit and referral to Medical Board;
- Systematic physician & community education; and
- Enforcement mechanisms to ensure compliance.

The early results from leading states, such as Kentucky and Florida, demonstrate success in closing a large number of rogue pain clinics and as high as a 20% drop in painkiller prescriptions. Rogue pain clinics rapidly disappear with common sense regulations and behaviors change with naïve physicians through increased information and enhanced protocols. A leading expert on drug abuse summed up these efforts, "nobody is trying to stop physicians from prescribing pain relievers as appropriate...if you prescribe them, just take the extra steps and we'll save kids' lives." These states are only setting clear expectations on physicians to "take the extra steps" to carry out their due diligence in an enhanced manner and safeguards commensurate with the risks associated with these powerful narcotics.

Getting Kentucky's and Florida's results do not happen overnight. It took these states many years to develop support for their plans. Hopefully, their positive results and lessons learned will shorten the timeline for other states following. For example, North Carolina has been working this issue for several years culminating with pending legislation to make PMP use mandatory, delegate PMP authority to physician's staffs, proactively use PMP to identify diverters and suspicious physician prescribing patterns, and launch a state-wide community based campaign in every county known as the "Chronic Pain Initiative" to educate and reduce overdose deaths.

C. Prescription Monitoring Program:

Currently, 49 states have legislatively approved Prescription Monitoring Programs (PMP), with 41 states having operational programs. State PMPs serve as a central repository for all Schedule II, III, and IV prescriptions filled by pharmacies. With the central electronic repository, PMPs serve as a flexible tool to address the factors contributing to the prescription drug epidemic: a "doctor shopper" goes from physician to physician with false information to deceptively obtain painkiller prescriptions to abuse or

sell for large profits; fraud/counterfeit prescriptions; and problematic physician prescribing. PMPs' information serves physicians, pharmacists, regulators, and law enforcement.

PMP has a reactive capability to check on a specific name. Likely its most important feature provides the prescribing physician their patient's prescription history to identify "doctor shoppers." This prevents dispensing drugs that are immediately resold on the streets for large profits. More importantly, from a quality of care and duty to care perspective, identifying "doctor shoppers" who are abusers provides an intervention opportunity. For all other patients, the PMP data provides an opportunity to identify potential drug interactions and organized data to facilitate the prescription decision. Like most all states, South Carolina's 2008 original PMP legislation did not require physician participation; participation was voluntary. Participation results have been generally disappointing with all states having less than 50% of physicians registered with an average in the mid-20%; registered physicians actually using PMP regularly are at much lower levels. Given the current epidemic, states have begun making PMP mandatory for physicians, such as Kentucky, Tennessee, New York, West Virginia, and Massachusetts, with an increasing number of states considering the same.

Others using PMP in a reactive mode include pharmacists, law enforcement, and Medical Boards. When a pharmacist suspects a counterfeit prescription, a PMP query by the pharmacist can depict information corroborating or refuting suspicions. When law enforcement suspects illegal activity by a "doctor shopper," a PMP query can depict prior activity to assist in evidence collection and fully develop the scope of the criminal activity. When the Medical Board suspects a physician prescribing painkillers outside of medical standards, a PMP query can depict patterns to guide the investigation.

In a September 2012 report from Brandeis University, a leading expert on PMPs, the report concluded PMPs need to shift from a reactive to a proactive strategy. "Being proactive is the key to success in the fight against prescription painkiller abuse," said John L. Eadie, Brandeis University. "State programs should analyze the data they collect," Peter Kreiner, principal investigator of the Brandeis' Center of Excellence, continued, "and reach out to prescribers, pharmacists, insurers, law enforcement agents and others who can prevent powerful narcotics from falling into the wrong hands. Where this is already taking place, it has proven to be very effective."

Examples of proactive strategies include:

- PMPs develop criteria to identify suspected "doctor shoppers," which are provided to treating
 physicians to alert them of this potential to assist in future patient prescribing decisions;
- PMPs develop criteria to identify unusual prescription patterns, then provide unsolicited letters to these doctors as feedback and reminder of pain management guidelines and the benefits of using PMP;
- PMPs develop criteria to identify potential "pill mills," such as unusual prescription patterns and the concentration of suspected "pill shoppers" as patients, which is then referred for further audit or review by the Medical Board;

- PMPs develop criteria to identify pharmacies with unusual prescription patterns and the concentration of suspected "pill shoppers," which is then referred to the Pharmacy Board for educational intervention or review; and
- Most importantly, have doctors use PMP, either voluntarily through education or mandatory through regulation, to review a patient's prescription history prior to dispensing painkillers.

The informational and analytic capabilities of PMP to understand the prescription epidemic, influence physicians and pharmacies behavior, provide feedback to increase capabilities and address weaknesses, and guide the limited resources of oversight and investigators is the key to making significant strides to fight this epidemic. Encouraged by the federal government, many states had the foresight to establish PMPs. States have the data to really "drive" solutions to this epidemic, but have been inhibited to overcome PMPs' original voluntary approach to have physicians participate and reactive nature to exploit information collected.

IV. Current Prescription Drug Problem in South Carolina

A. State Epidemic Statistics

State authorities do not have a rigorous, systematic understanding of South Carolina's painkiller problem. However, from ad hoc national data, South Carolina clearly has a significant problem that is likely worse than an average state. The most recently published (October 2012) robust research study (Appendix A) examined 2008 data and concluded South Carolina had the 10th highest painkiller prescriptions, by weight, per capita rate in the United States, which was 33% above the national average. A 2011 national survey of non-medical use of prescription drugs identified South Carolina (4.62% of population) as marginally above the national average (4.57%), with the high of 6.37% (Oregon) and the low of 3.62% (Iowa). In 2010, another study ranked South Carolina as the 23rd highest per capita in opioid painkiller prescriptions.

In 2010, South Carolina ranked 23rd highest per capita in overdose deaths, with the most recent data, 2011, denoting 225 prescription overdose deaths (Appendix B). The prescription overdose death data appears understated, as in most states not rigorously tracking this epidemic. For example, DHEC data had two prescription overdose deaths in York County, while the York County Coroner identified 34 drug overdose deaths, which statistically are caused by prescription drugs 60% (20 deaths) of the time. Given the above data, anecdotal data from state authorities, and South Carolina's proximity to the geographic epicenter of this crisis in the Appalachian Region and the South, South Carolina's prescription drug problem is at least above average, if not much higher.

B. View from the Front Line

To obtain data from the communities impacted, interviews were conducted in three rural counties (Pickens, Union, and Darlington) with a high combination of overdose deaths (Appendix B) or high opioid prescriptions per capita (Appendix A), as well as a metropolitan county, Greenville, with the highest number of overdose deaths (39) and a high opioid prescriptions per capita.

1. Pickens County

Pickens County has one of the highest per capita opioid Medicaid prescription rates in the state, and prescription drugs are the most significant criminal drug problem in the county. Several years ago, the coroner noted an unusually high number of prescription overdose deaths, possibly as high as 25. This coupled with unusual patterns of emergency room patient demands for prescription painkillers led to an ad hoc task force of medical professionals and law enforcement to address this issue. This group initially focused on educating emergency room doctors. This led to a 50% reduction in painkiller prescriptions in emergency rooms. These doctors used the PMP system, which was of great value in facilitating their medical decisions curbing excess painkiller prescriptions. Education has been expended to school nurses, medical practices, and public forums, often funded with personal funds of task force members.

The problem has gotten better, but it is still an epidemic. A source of frustration is a well known medical practice in Pickens County suspected of overprescribing to chronic abusers and shoppers, which has operated with impunity due to the perceived lack of administrative or criminal tools to address. With this gaping hole in curbing the supply of illegal prescriptions into the community, it can create a hopeless feeling.

The prescription painkiller issue surfaced 10 years ago and has progressively gotten worse. This has seemingly led to a sub-culture where there is an expectation of being prescribed powerful painkillers upon demand. This sub-culture leverages its knowledge that emergency room doctors are concerned with a negative patient satisfaction survey, because it impacts hospital Medicare reimbursements and performance ratings. Drug seekers can often successfully manipulate emergency room doctors in almost an extortionate manner to prescribe painkiller drugs. As a doctor described this phenomenon to the IG, nearly the entire room of 20 medical professionals nodded their heads in agreement. Another private practice doctor intimated a reputation of being conservative in prescribing painkillers can negatively impact a medical practice.

Other anecdotes provided include a gynecologist observing the first pregnant mother with an opioid addiction about 10 years ago, but now this is a common situation. A Department of Juvenile Justice worker reported systemic abuse of prescription drugs by teenagers. Even with this passionate and energetic task force of medical and law enforcement, the progress has been positive but there is still a prescription drug abuse crisis in their community.

2. Union County

Prescription drugs are the county's most significant criminal drug problem. In the traditional open air drug markets, availability of prescription pills has superseded in volume the traditional illegal drugs, such as crack, meth, and cocaine. The prescription drug supply is high because of easy access from three local county doctors operating family practices, not pain clinics. Two doctors appeared to be more blatant by attracting abusers and shoppers traveling from surrounding counties, while the third is a self-described "pleaser" who can't say no to hard luck stories from long time patients. An exacerbating problem is law enforcement's approach to interdict shoppers and illegal sales has negligible deterrence due to the lenient view of these crimes by the judicial system. A local narcotic investigator opined, "we need to stop this problem at the prescription pad."

3. Darlington County

The abuse of pharmaceutical drugs in Darlington County is substantial, so much so it led a county narcotics officer to state, "I've never seen as many pills in all the other counties I worked." The county is overrun with pharmaceutical diversion and it is at least on the same level as crack cocaine trafficking. Many trafficking outlets specialize in just the exclusive distribution of pharmaceuticals. Oxycodone, Hydrocodone, and Methadone are the drugs prevalent in the county's illicit drug trade imported largely from physician prescriptions written in adjacent Florence and Sumter Counties. Previously, the narcotics unit was required to submit pills to the State Lab for testing prior to a Grand Jury Appearance. The numbers of submissions were so great the Lab requested the Agency not submit evidence until it was determined the case would go to trial.

4. Greenville County

In 2011, Greenville County had the state's highest number of prescription drug overdose deaths (39). Prescription drugs are a significant problem due to the easy supply of the drugs. Narcotics officers identified at least seven physicians who are suspected of acting as pill mills where abusers and shoppers easily obtained drugs. Most of these physicians are "cash only" businesses, which is a traditional red flag indicator of a pill mill. One physician operates from his personal residence, with a living room serving as a waiting room and the records are kept in a bathroom. It was noted that prescription forgeries are prevalent and significantly contribute to the illegal supplies on the streets. There is no shortage of shoppers and street level traffickers of prescription pills, but the judicial system laws and outcomes have no deterrent effect to address the underlying problem. Prescription drug abuse increases every year.

The general pattern in all of these counties was the same: high availability of prescription painkillers "on the street"; social costs associated with addictions; and the county doctors systemically overprescribing were well known and unaddressed. Counties with lesser indicators in terms of overdose deaths and opioid prescriptions likely have fewer problems. Even in these counties, such as York County, a review of 200 emergency room files for overdose admissions noted 186 (93%) cases involved prescription pain pills, and only 14 (7%) were from only illegal drugs. Given prescription painkiller drugs' pleasurable, addictive, and financially exploitable properties, this epidemic, left unchecked, has proven only to expand.

C. Regulator & Enforcement Roles of State Agencies

There are five state agencies with regulatory and enforcement roles in the prescription drug abuse issue:

 Bureau of Drug Control (BDC), Department of Health & Environmental Control (DHEC): Conducts audits of pharmacies and criminal investigations of subjects diverting controlled pharmaceutical drugs. The BDC also operates the state's PMP, where pharmacies are required to enter every prescription into this system to then be queried, by physicians, regulators, and law enforcement.

- The Surveillance and Utilization Review (SUR) Unit, Department of Health & Human Services (DHHS): Conducts data analysis of Medicaid claims to identify aberrant or suspicious billing patterns by Medicaid providers; the results are forwarded to the Division of Program Integrity for audit and investigation to identify fraud, abuse, or improper payments. These audits/investigations can lead to fraud referrals to the Attorney General's Office, referrals to the appropriate medical boards, and other state or federal agencies; provider sanctions; and overpayment recovery.
- Medical Board and Pharmaceutical Board, Department of Licensing & Labor Regulation (LLR): Both boards license practitioners, set forth professional guidelines, and investigate/adjudicate complaints of unprofessional practices or conduct.
- Medicaid Fraud Control Unit (MFCU), Attorney General's Office (AG): Investigates and prosecutes Medicaid fraud.
- Department of Alcohol and Other Drug Abuse Services (DAODAS): Provides services to prevent or reduce negative consequences of substance use and addiction.

In addition to state agencies, the Drug Enforcement Agency (DEA), the Federal Bureau of Investigation (FBI), and United States Department of Health & Human Services have diversion enforcement authorities. State and local law enforcement conduct daily law enforcement actions arresting drug diverters, often "shoppers," who go to multiple doctors obtaining painkillers then reselling "on the street" making large profits.

D. Weaknesses in Current State Approach

The passion and commitment from each agency "in the fight" against this epidemic was noteworthy. DAODAS's successful drug treatments certainly impact the issue by saving lives and reducing demand, and the AG indirectly does the same through successful prosecutions of related fraud cases. However, the three agencies having the core responsibilities and capabilities to address this epidemic are DHEC, DHHS, and LLR.

DHEC arrests hundreds of doctor shoppers and health practitioners abusing or diverting, prescription forgers, and criminal networks trafficking in diverted prescription drugs, as well as maintains a presence in the pharmacy community to maintain tight inventory controls and provide education. DHHS's analytical capability to identify shoppers, abusers, and potential pill mills is cutting edge, and then recovers funds based on fraud or channeling individuals into programs to curb Medicaid costs. LLR-Medical Board investigates and adjudicates complaints.

Despite each agency's independent contribution, the sum of their collective efforts falls far short of an effective strategy to address the growing prescription painkiller epidemic. State efforts are reactive, generally geared at chasing after the symptoms of the problem, rather than address the root cause in a prevention effort. The root cause is excess prescription drugs resulting in addiction, rather than medical benefit, causing more deaths than all other illegal drugs combined. At the core, this is a supply problem. Other than the nominal loss in pharmacy thefts and increasingly more significant prescription forgeries,

this excess supply enters the public domain generally through a single gatekeeper—physicians. No state agency has a proactive posture on addressing pill mills or high prescribing, naïve physicians.

The state's most critical tool to leverage agencies' efforts with information and analysis, the PMP, is substantially underutilized, extremely limiting its effectiveness. Like most states, South Carolina's original PMP legislation conservatively placed limits on data use, inhibiting exploiting the data and limiting the database to a reactionary mode. Likely its most important feature is to provide the prescribing physician their patient's prescription history to identify "doctor shoppers." Use of PMP is voluntary, and only 22% of physicians are registered and much fewer actually use it for prescription decisions. Further, PMP, based on restrictive legislation, does not exploit proactive strategies to leverage information to focus efforts to address the problem. Examples of proactive strategies include notifying physicians of potential doctor shopping patients; providing high prescribing physicians feedback; identifying "hot spots" of high opioid prescriptions and overdose deaths to target resources; identifying potential pill mills for Medical Board review. South Carolina is sitting on the data to really "drive" solutions to this epidemic, but has been inhibited to overcome PMPs' original voluntary approach for physicians' participation and passive nature to fully exploit information collected.

DHEC, which is responsible for drug control, deploys all its personnel resources on pharmacy audits and the never ending pill shoppers and ad hoc trafficking networks. Audits maintain internal controls and arrests provide value through disruptions, particularly forgers, despite nominal criminal penalties, but neither activity addresses the underlying prescription drug excess supply emanating from rogue and naïve physicians. DHHS periodically identifies pill mills through audits, but its referrals have had problematic deterrent value and impact.

The LLR-Medical Board is by its nature complaint reactive. The Board caseload currently stands at 408 complaints handled by six investigators. During calendar years 2011-2012, 24 cases were opened with indications of systemic overprescribing opioids. Six cases have been investigated and closed, averaging six months to completion. Fifteen cases remain under investigation, averaging six months of investigative activity. Surprisingly, the Medical Board no longer initiates investigations on DHHS referrals based on their field audits because DHHS does not, due to privacy concerns, provide specific patient file names. There were three cases with physician sanctions, and all three had a crisis component involving the physician admitting a crime or a blatant overprescribing pattern connected to an overdose death.

The Medical Board's "Pain Management Guidelines (2009)" provides a systematic approach to pain management. What other states have concluded is the broad policy language in similar guidelines allows physicians broad discretion in their application, which in turn allows naïve and pill mill doctors to unintentionally flourish. South Carolina's policy states, "the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances." Many physicians in South Carolina rigorously apply this policy through the application of PMP and safeguards for long-term opioid prescribing, such as urine testing, dosing quantities, patient contracts, and mandatory office visits; many others physicians do not. Proactive states have increased the specificity of their pain management guidelines to add rigor, such as mandatory PMP and specified safeguards to ensure all physicians enhance their due diligence to match the increase

risk associated with prescribing these drugs. Applying a general policy, as compared to a specific policy, inherently makes it more difficult to subjectively discern conduct outside of the guidelines.

In total, South Carolina lacks a prescription drug abuse strategy and current efforts are reactionary and fragmented. There is no single entity charged with the responsibility to address the prescription drug problem. All the state agencies involved clearly recognized prescription drugs as an epidemic, but they did not have a rigorous, systematic understanding of South Carolina's painkiller problem through PMP data analysis, comparative analysis with national data, integrating narcotics units' intelligence, or monitoring prescription drug overdose deaths in the state. The six tactical components of the states proactively meeting this challenge (see page 10) are all absent in South Carolina.

Many involved in this prescription drug battle inaccurately believe law enforcement can address prescription pill mills. Certainly, Federal law enforcement does address pill mills. However, history has clearly demonstrated that these Federal efforts provide individual justice on occasion, but take too long and are too infrequent to have any deterrent impact on the problem. The reality is the excess prescription drug problem is generally not criminal, or at least not practically provable in most instances outside of the most egregious pill mills. The core issue falls back to physicians prescribing excessive painkillers, both intentionally and unintentionally, generally outside of medical standards, which is a state regulatory issue.

V. Developing a Statewide Strategy—A Systems Approach

By all measures, the current system of prescribing opioids has unacceptable outcomes. Despite the startling statistics, prescription painkillers are effective in medical treatments and life saving medications for many people, so it is critical to address the problem without impacting a doctor's ability to prescribe to a patient in need. Managing this issue, like nearly all complex problems, requires a systems approach. A systems approach to this problem on a large scale, such as Kentucky, has been successful. A systems approach on a smaller scale, such as the Kaiser Permanente Medical Group, was successful in reducing opioid prescriptions by 80% through education and an information management system to promote more rigorous analysis by its physicians prior to dispensing opioids. Even Pickens County Hospitals Emergency Rooms used a systems approach to consistently reduce opioid prescriptions by 50%. The key is to fuse education, information, and a supporting system so, like Kentucky's approach, "every time a physician makes a decision to prescribe an opioid to a chronic non-cancer pain patient, there is a thoughtful, deliberate decision between patient and the physician after considering the risks and benefits." Applying this approach to the state's prescription drug abuse problem can be organized in seven components, which are:

Step #1-Training: A significant number of doctors in the United States have no formal training in prescribing opioid medications. According to the President of the American Society of Interventional Pain Physicians, "I would never prescribe chemotherapy or heart medication to a patient, because I have no formal training in how to do so. But many doctors who haven't been properly trained are prescribing opioids." Many primary care doctors prescribe opioids in an effort to help their patients, and often don't realize the complexity of the issues. "When you prescribe opioids, you need to be a doctor, detective, parent and policeman all in one." Education would include drug-drug interactions, safe dosing, how to transition from one medication to another, how to monitor for signs of abuse, and how to use the state's PMP.

As an illustration of this issue, a study at the Albert Einstein College of Medicine and Montefiore Medical Center in New York examined 1,600 primary care patients prescribed long-term opioids and looked at how frequently they received three strategies for reducing the risk of misuse. The three risk-reduction strategies are urine tests, face-to-face office visits at least every six months and within a month of changing an opioid prescription, and limiting the number of early refills. Data showed that only 8% of the patients in the study had any urine drug testing, less than half had regular office visits, and nearly 25 percent received multiple early refills. The lead researcher Joanna Starrels commented, "this suggests that primary care physicians are not using these risk reduction strategies very frequently." Another study, "Long-Term Use of Opioids" (2012) conducted by the Workers Compensation Research Institute, determined there is a continued pattern of low compliance by the medical community with their own state medical guidelines for longer-term use of narcotics. This study examined 21 states' worker compensation programs, which also noted South Carolina being in the top five for claimants remaining on narcotics for more than six months (10%); twice the number as lower tiered states (5%).

Sten #2-Physicians Use PMP Prior to Prescribing Painkillers: Medical associations have universally opposed mandatory use of PMP. Their objections range from time away from patients; privacy concerns; chilling effect on physicians prescribing painkillers; administrative cost; a perception a small percentage of doctors cause the problem; and the potential for unintended consequences. These concerns are real! However, when balancing this epidemic against these concerns, states have successfully managed and mitigated physicians' concerns during the process of legislatively requiring physicians to use PMP in at least five states with many more contemplating the same.

Since PMP's inception in 2008, South Carolina physicians' use of PMP, like all states at that time, has been voluntary. As a result, 22% of physicians are registered, and of those registered, much less actually use the system. An analysis of 51 high prescribing physicians with suspicious prescribing patterns for 2012 determined 23 (45%) did not query PMP and 28 (55%) did. Interestingly, 9 of the 23 not querying PMP were actually registered but did not use the system. Of the 28 PMP users, the mean frequency was 350 queries/year (15 low; 9622 high) which was about 1.5 queries per business day. It is positive the high painkiller prescribing physicians use PMP much more than the average physician, but with 45% of this high prescribing group not using PMP when abusers and shoppers are inherently seeking these types of drugs, it raises a huge red flag in how PMP is underutilized. A hindrance in physicians using PMP is their inability, based on legislation, to delegate access to staff, thus requiring the physician to personally sign on to the system and make the query.

If PMP access is delegated to a staff member, which is critical to its full utilization, a report can be run in less time than it takes for a blood pressure test. The doctor will expend no clinical time yet have the single most important piece of information to make the proper prescribing decision prior to dispensing addictive and dangerous drugs to a patient. Putting aside the benefits of identifying and not prescribing to doctor shoppers for profit, having this data improves patient care for every patient. For an identified abuser, it provides unique intervention opportunity; and for the routine patient, it is a quality control for potential drug interactions with these powerful

narcotics. No one wants a physician to be law enforcement, but a physician should be expected to use easily available data to make better prescribing judgments in the best interest of their patient, as well as the significant byproduct of contributing to addressing the prescription painkiller epidemic.

For pill mill physicians, a PMP mandatory requirement has likely a catastrophic impact on its business model to hide behind the wide prescription discretion physicians currently have. When a pill mill physician is looking at a PMP report indicating the patient is an abuser or shopper based on a pattern of obtaining the same prescriptions concurrently with other physicians, the pill mill physician will certainly pause knowing a future audit can easily demonstrate a pattern of knowingly prescribing to abusers and shoppers. Mandatory PMP review prior to dispensing facilitates well intentioned physicians to make better prescription decisions, and inhibits pill mill physicians from freely operating safe from Medical Board review.

Change always brings hesitation, but research has shown physicians using PMP have a high satisfaction rate and the PMP data materially impacts their prescription decisions. States with upwards of 1000 overdose deaths a year finally mustered the leadership to set a new standard by mandating PMP and overcame natural resistance to change; how high does South Carolina's overdose deaths have to go to trigger this near zero cost, high return common sense measure? The state's single most important tool to fight this epidemic, PMP, resembles a fighter jet, both in capabilities and taxpayer expense, yet it is only being used for crop dusting.

<u>Step #3-Establish Internal Controls to Monitor & Address Variances</u>: Data suggests a small percentage of physicians are driving excessive prescriptions to the public. Numerous studies had similar results:

- 80% of the opioid prescription drugs are prescribed by 20% of the physicians;
- 30% of opioid prescribing doctors prescribe 88% of the prescriptions;
- In Los Angeles, 1/10 of 1% of physicians wrote prescriptions for 17% of overdose deaths;
- In New York City, 15% of the doctors prescribe 82% of the prescription painkillers; and
- In Massachusetts, 30% of the physicians prescribe 90% of the painkillers.

Internal control monitoring should not be used without a reason due to cost and human nature's desire for professional autonomy. However, when there is a problem, particularly involving public safety, the lack of internal controls to understand and address equates to abdicating responsibility. Monitoring will not be intrusive, and will impact very few doctors. Those impacted due to their inordinate variances in volume and/or unusual prescription patterns should understand the need to monitor and follow up, not necessarily criticize, given the high risks of pill mills, abuse, and diversion associated with this epidemic. Further, unless a physician operates a pill mill, the monitoring feedback only enhances the profession and patient care.

To help doctors, PMPs identify suspected doctor shoppers or abusers based on prescription patterns and frequencies. Proactive states then deploy "targeted" feedback to physicians with documented variances, often through letters known as "unsolicited letters." In Maine, 42% of the feedback resulted in physicians concluding the suspected patient was misusing or abusing painkillers. PMPs can also identify indicators of potential prescribing issues, which include an

unusual volume of suspected pill shoppers as patients, volume of prescriptions, and unusual combinations of prescriptions known as "cocktails." This data can be combined with other data to identify pill mills.

Private insurers already aggressively manage policy members through data mining and analysis, which can lead to requiring prescription painkillers pre-approval, limits on dosing quantities, and inquiries with physicians on medical necessity. On occasions, physicians will push back that the insurer is "not the doctor," but ultimately the physicians tend to understand because private insurer inquiries are based on obvious indicators of potential abuse or diversion.

Step #4-Conduct On-Site Audits for Persistent Patterns of Unusual Variances: If unusual variance patterns persist, it is not an evidence of wrongdoing, but it is a reason for further inquiry to understand. Additional data can be brought to bear by the volume of pill shoppers in the doctor's practice easily developed from PMP analysis and local narcotic units' evidence, which has largely been an untapped resource. Expensive audit resources are then cost effectively deployed to this analytically high risk group, along with PMP data on geographic hot spots for painkiller prescriptions and overdose deaths. Audit evidence of doctors performing outside of medical standards is referred for review, adjudication, and discipline.

Step #5-Discipline in the form of Medical Board Interventions: The Medical Board has the tools to bring intervention to doctors operating outside of medical standards. One South Carolina Medical Board case illustrates the complexity of the problem using current standards. A physician was investigated for overprescribing opioids to a patient. This physician haphazardly used PMP several times over a 10 month period and made some attempts to follow-up suspected abuse by the patient. The medical board expert concluded there were clues missed by the physician on the patient's abuse, but did not see any evidence of intent by the physician to knowingly overprescribe. Therefore, the expert concluded that the physician did nothing that fell outside of the Standard of Care guidelines. Most interesting, the expert went on to say, "as physicians, we always want to give patients the *benefit of the doubt* and I think we offen are too careless with our use of controlled substances for this reason. In a perfect world, we could spend all the time that we need with our patients to better diagnose and treat them. In this age of forced EHR (electronic health records) implementation, insurance demands, poor reimbursement and physician shortages, causing us to see more patients in the same time frame, it is easy to see how these mistakes could be made by any physician."

This case and expert's assessment vividly illustrates the core issue that today's "real world" prescribing practices have a pattern that is inconsistent with the increased risks of these drugs, as well as the difficulty in managing chronic pain care. Proactive states are just mandating the "extra steps" (specific education, PMP use, and safeguards for long-term prescribing) needed to enhance physician protocols to meet the increased risks of these powerful drugs. These common sense "extra steps" are not meant to restrict physicians, but rather support physicians in their due diligence for patient care commensurate with the risks involved, for both the patient and society.

Enhanced protocols prevent problems. Further, if problems occur, the mandatory use of PMP facilitates oversight due to a clear audit trail of a patient's circumstances known to the physician prior to prescribing. Enhancing the specificity on protocols for long term opioid prescribing also

creates a common sense mechanism to easily discern appropriate medical care from misconduct. Proactive state's clarity of expectations and the clarity to identify non-compliance both add up to deterrence of the inappropriate prescribing patterns underpinning this epidemic.

<u>Step #6-Invest in Treatment</u>: It has been a decade building this epidemic, and it may take a decade to unwind it. As the excess prescription painkiller supply is successfully reduced, a successful strategy must have treatment available as abusers' easy access is eliminated. Further, lack of access to opioid prescriptions has the predictable consequence of drug seekers turning to heroin absent treatment alternatives.

<u>Step #7-Periodic Review & Strategy Adjustments</u>: Given the dynamic nature, complexity, and long-term resolution of this epidemic, progress must be measured against the strategy to drive the inherent adjustments needed in any plan to continually improve.

Managing this issue, like nearly all complex problems, requires a proactive systems approach. There is no magic number of "steps," but rather there is the need for a detailed plan to execute a strategy. The added benefit of a successful strategy and execution is its deterrent effect. If South Carolina develops a reputation for diligent oversight, it will inhibit pill mills from starting up in the state, as well as the slippery slope of naïve, casual prescribing of these dangerous drugs.

Whatever new costs are incurred by state agencies, the financial benefits in terms of Medicaid and private sector costs reductions will be exponentially higher. In 2010, 15% of South Carolina Medicaid recipients (134,000 patients) obtained opioid prescriptions at a cost totaling \$24 million. The associated Medicaid office visits were difficult to estimate, but the average Medicaid physician costs of these 134,000 patients amounted to \$492 per patient. When adding the cost of private health insurers, the overall direct opioid costs are much higher inasmuch as only 25% of South Carolina's population is covered by Medicaid. As another example of sky-rocketing opioid health care costs, birth mothers' opioid use increased fivefold in the past ten years and drug dependent newborns have tripled totaling 13,500 babies (77% Medicaid insured) nationally per year. The average cost of immediate neonatal care was \$53,400 per incident.

In states like Kentucky (14%) and Florida (20%), the number of painkiller prescriptions reduced significantly in less than a year. Do the math and one can easily see how basic, low cost regulations of physician education, PMP use, and protocols for long term use of opioids by non-cancer chronic pain patients will lower health care costs significantly. Even with the benefits of health care savings, this is not predominately a cost driven issue; this is a public safety issue addressing an epidemic causing high deaths, morbidity, and family/community dysfunction. A small investment in state personnel resources at DHEC and LLR to drive this system will leverage and magnify the efforts of hundreds in local and state government, let alone facilitate physicians providing better medical care to their patients.

VI. <u>Conclusion</u>

Data from state authorities, medical community, medical literature, and front line narcotics officers describe the same prescription drug abuse problem in South Carolina as it is nationally—a significant, escalating epidemic. As Agency Heads and the political process consider a way forward, we need to reflect on the four counties' common problem of knowing the physicians in their counties highly

suspected of overprescribing, both intentionally and unintentionally, to abusers and doctor shoppers. This known group is strongly suspected of pumping addicting and dangerous drugs into the community, unabated. This known problem is not being transmitted to, nor proactively sought by, state regulatory authorities. Given these drugs pleasurable, addictive, and financially exploitable properties, this epidemic, left unchecked, has proven only to expand.

Neighboring states have blazed the early trail to address this problem by 1) proactively identifying and addressing pill mills; 2) proactively promoting education; 2) mandating use of PMP prior to dispensing to screen out abusers and shoppers; and 4) enhanced protocols for treating chronic non-cancer pain patients. These states have only codified fundamental expectations already contained in generally accepted pain management medical practices. Dr. Scott Fishman, author of "Responsible Opioid Prescribing", which is prominently displayed on the Federation of State Medical Board's website homepage, writes "most clinicians are grossly under-trained in pain assessment, pain management, and appropriate use of controlled substances." He goes on to say when screening a new patient, "always check a prescription drug-monitoring database." He manages long term opioid dispensing by "closely monitor utilizing urine toxicity screens and prescription drug monitoring systems." Dr. Fisher sums up the entire thrust of this report, "as the gatekeepers of prescription medications, clinicians are being enlisted to fight on two fronts: combating pain, while simultaneously defending against the misuse and addiction to opioid pain medications...the combination of potential therapeutic benefit and high risk associated with opioid analgesics leaves us no alternative but to become more committed and sophisticated risk managers." South Carolina needs to codify these common sense risk management tools into its laws and regulations to squeeze out any ambiguity which allows pill mills and naïve physicians to comfortably, both intentionally and unintentionally, operate.

This report is not intended to blame physicians for this epidemic. This epidemic has many fathers, but the state needs physicians to lead us out because they are uniquely positioned in this epidemic to have an immediate, lasting impact on the problem. There are other tools, such as demand reduction through patient and community education, drug disposal drop boxes, and law enforcement, which all play a role. However, the cornerstone to start turning the tide on this epidemic is to reduce the excess supply of prescription drugs causing addiction, rather than medical benefit, emanating from the physician prescription pad, both from unscrupulous pill mills and unwittingly from naïve physicians. If we don't get this cornerstone set right, the cancer will continue to grow while we all debate the other tools which are closer to the margin of the problem than its core. In the states where the pain of prescription drug abuse has become just too great, they have mustered the leadership to push forward with proactive, preventative strategies and successfully manage the concerns of those with opposing views. To address this issue in South Carolina, the state must do the same.

There is no single solution to address South Carolina's prescription drug abuse problem. The solution starts with a commitment that 1) there is a significant problem; 2) a proactive strategy focusing on addressing the supply side--physician excess prescriptions, and to a lesser extent, prescription forgeries; and 3) integrate a committed team from responsible agencies to comprehensively work the problem with the creativity to fully exploit the wide variety of tools available. This report focused on opioids due to their leading role in the prescription drug problem, but it is important to recognize solutions need to also incorporate other abused drugs, such as benzodiazepines and amphetamines. The solution phase will be a marathon and not a sprint. However, the time is to act is now. As every surrounding state aggressively addresses this problem within their borders, pill mills, shoppers, and drug seekers will flow

to states without proactive oversight and enforcement capabilities, which is where South Carolina is currently well positioned.

VII. <u>Findings & Recommendations</u>

Finding #1: The state does not have an integrated, rigorous understanding of the prescription painkiller drug abuse problem.

<u>Recommendation #1</u>: DHEC should develop protocols to periodically integrate data from PMP, DAODAS drug treatment, state and federal partners, overdose death records, state narcotic units, comparative data from other states and nationally, and other sources to understand the prescription drug abuse domain at the county level; this analysis will underpin strategy and execution plan development to address the problem.

Finding # 2: The state does not have a statewide strategy to address the prescription drug abuse problem.

<u>Recommendation #2a</u>: The Governor, through liaison with Agency commissions, the Budget Control Board, and in coordination with direct subordinate agencies, should lead the effort to fix responsibility, preferably with DHEC, to establish a statewide strategy and execution plan to address the prescription drug abuse problem.

Recommendation #2b: Medical Board, LLR, should:

- Seek legislative authority to require mandatory use of PMP for all physicians and providers prescribing painkillers. This can be incrementally implemented over a number of years with the highest prescribing physicians enrolled first, as well as some flexibility on the frequency of PMP after the initial prescription with a mandatory PMP requirement.
- Coordinate systematic prescription drug abuse training to all physicians who
 prescribe painkillers and other commonly abused prescription drugs.
- Explore developing a pain clinic classification for licensing medical practices, and apply enhanced oversight and requirements on these practices based on higher risks of abuse and misuse.
- Review its current pain management guidelines and considers enhanced specificity, either through regulation or legislation, to provide maximum clarity and expectations to the medical community, particularly specific safeguard protocols for long-term opioid prescriptions for chronic non-cancer pain patients.

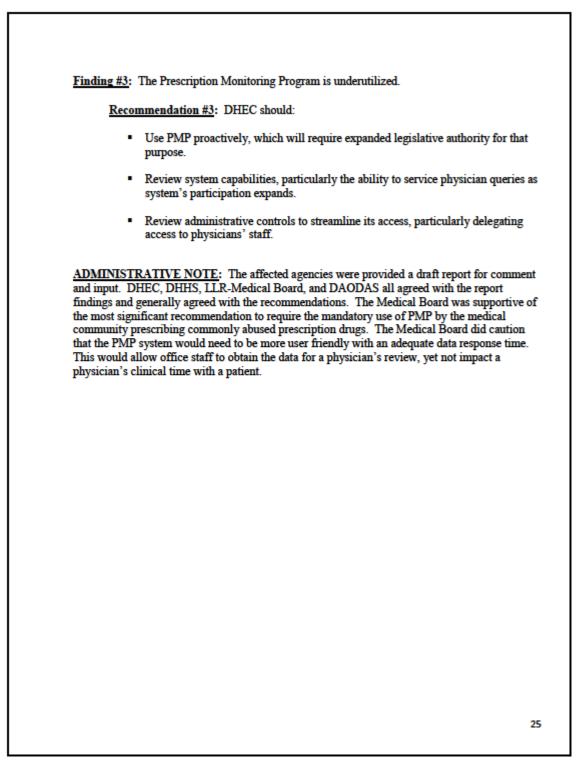
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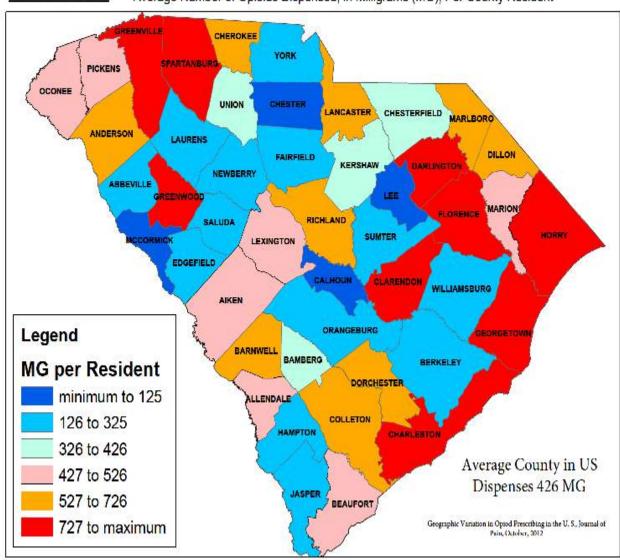
Recommendation #2c: DHEC should:

- Develop a protocol to identify high risk physicians operating with indicators of being a pill mill through data from, but not limited to, unusual physician drug prescription patterns through PMP, tasking to all narcotics units identifying medical practices exhibiting pill mill indicators, DEA, the medical community as a whole, and vendors with expertise in analyzing PMP data. Prioritize more indepth reviews and audits based on state's "hot spots" through PMP analysis of painkiller prescriptions and overdose deaths, then make appropriate referrals to Medical Board.
- Annually analyze all prescription drug related deaths through historical review of PMP to provide feedback to physician community and trends with specific physicians, as well as improve DHEC's data collection system to increase accuracy of coroners reporting prescription drug overdose deaths.
- Develop, in coordination with the Pharmacy Board, methodology to quantify the forged prescription problem to determining cost/benefit of considering a standard pre-numbered prescription form for statewide use.
- Take the lead in building relationships and a common information sharing framework with DHHS and private sector insurance companies to leverage all entities' efforts, most notably overcoming the excessive conservative legal interpretations undermining multiple entities combining efforts to meet the challenge of addressing a common problem of epidemic proportions.
- Maintain situational awareness of other states' proactive postures towards the prescription painkiller abuse to fully exploit lessons learned.

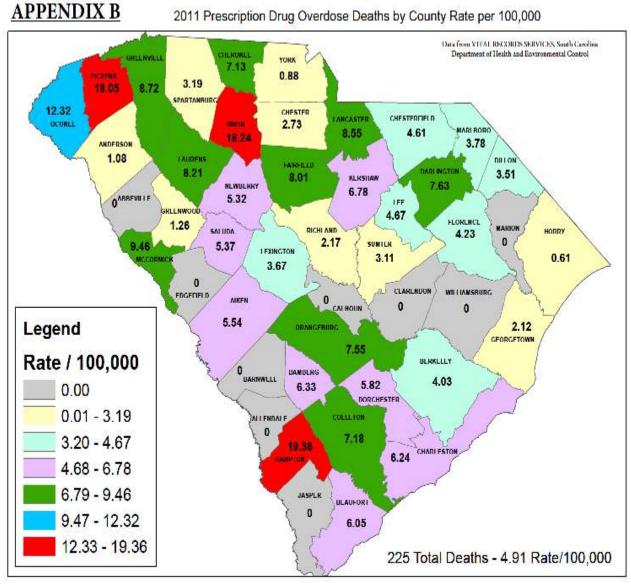
Recommendation #2d: DHHS should:

- Develop a protocol that allows, based on public safety concerns, its full audit reports of suspected physicians prescribing outside of medical standards to the Medical Board, LLR, rather than the current practice of limited disclosure due to legal disclosure concerns.
- Consider implementing regulations requiring Medicaid providers use PMP prior to prescribing painkillers.





APPENDIX A Average Number of Opioids Dispensed, in Milligrams (MG), Per County Resident

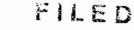


2011 Prescription Drug Overdose Deaths by County Rate per 100,000

APPENDIX B EXECUTIVE ORDER NO. 2014-22

State of South Carolina

Executive Repartment



MAR 14 2014

SECHETARY OF STATE 8



Office of the Governor

EXECUTIVE ORDER NO.

2014-22

WHEREAS, in November 2011, the National Center for Disease Control and Prevention classified prescription drug abuse as a national epidemic; and

WHEREAS, the South Carolina State Inspector General published a report in May of 2013 entitled. 'South Carolina Lacks a Statewide Drug Abuse Strategy," which illustrates that South Carolina is not immune from this epidemic, and in fact, South Carolina ranked 23rd highest per capita in both opioid painkiller prescriptions and in overdose deaths, with 225 prescription overdose deaths in 2011; and

WHEREAS, this epidemic has a significant financial and emotional impact on South Carolina families and a negative economic impact on the State, including rising healthcare costs for opioid use in pregnant women and drug-dependent infants and rising emergency room and rehabilitation costs, with an estimated 30 percent of South Carolina Medicaid recipients receiving an opioid prescription in 2010 at a cost of \$24 million; and

WHEREAS, the State Inspector General's report highlights five South Carolina state agencies with regulatory and enforcement roles in the prescription drug abuse issue and the lack of a comprehensive, proactive plan to combat the problem; and

WHEREAS. many state agencies have begun to address prescription drug abuse and are committed to protecting and improving the lives of South Carolinians,

NOW, THEREFORE, pursuant to the authority vested in me by the Constitution and Statutes of the State of South Carolina, I hereby establish the Governor's Prescription Drug Abuse Prevention Council (the "Council") to develop a comprehensive State Plan to combat and prevent prescription drug abuse. The Council shall be composed of ten members to include a representative from the South Carolina Law Enforcement Division: South Carolina Department of Health and Environmental Controt; South Carolina Department of Labo?, Licensing and Regulation: South Carolina Board of Dentistry; South Carolina Board of Medical Examiners. South Carolina Board of Executive Order 2014-22 Page 2

Nursing: South Carolina Board of Pharmacy; a representative from a South Carolina Solicitor's Office; South Carolina Department of Health and Human Services; and the South Carolina Department of Alcohol and Other Drug Abuse Services.

I hereby direct the Council as follows:

- The Council shall develop a comprehensive State Plan to proactively combat and prevent prescription drug abuse in South Carolina that incorporates all state and local agencies that have a regulatory, enforcement, or treatment role in this issue.
- The Council shall invite participation from legislators, professional associations, other state agencies, and other entities as necessary to enhance the development and implementation of a comprehensive State Plan.
- The Council shall integrate data from State and fede/all agencies, overdose death records, state narcotics units, and other sources as necessary to evaluate and identify the extent of prescription drug abuse in South Carolina.
- 4. The Council shall identify the extent of prescription drug abuse in South Carolina, shall track and report such data in the final State Plan, and shall continue to report such data at least annually to the Governor.
- 5. The Council shall assist and encourage local communities to engage existing community coalitions or to establish new coalitions at the local level, recognizing that prescription drug abuse is as much a local issue as a State issue.
- 6. The Council shall provide an Interim Report to the Governor and the State Inspector General on the status of the Council's work no later than May 30, 2014 The Council shall submit the final comprehensive State Plan to the Governor and the State Inspector General no later than October 1, 2014. The Council shall meet as frequently as necessary to meet the above deadlines.

This Order shall take effect immediately.



GREAT SEAL OF THE STATE OF SOUTH CAROLINA, THIS 14th DAY OF MARCH, 2014.

GIVEN UNDER MY HAND AND THE

KIR. HAL Governor

APPENDIX C

JOINT REVISED PAIN MANAGEMENT GUIDELINES APPROVED BY THE SOUTH CAROLINA BOARDS OF MEDICAL EXAMINERS, DENTISTRY AND NURSING

November 2014

The South Carolina Board of Medical Examiners (Medical Board) published Pain Management Guidelines (Guidelines) to assist physicians in safely prescribing controlled substances in July of 2009. Increasing opioid misuse and abuse, recent research and clinical studies now require the revision of those Guidelines to provide adequate information to ensure safe and appropriate treatment of pain. Additionally, the Medical Board recognizes that physicians, dentists, physician assistants, and advance practice registered nurses with prescriptive authority should all adhere to uniform prescriptive guidelines. Accordingly, the South Carolina Board of Dentistry (Dental Board) and South Carolina Board of Nursing (Nursing Board) have joined the Medical Board in approving these Joint Revised Pain Management Guidelines (Revised Guidelines).¹ These Revised Guidelines strongly consider the evidence that the health risks of high dose opioid use have increased, while the evidence for benefits remains controversial and insufficient. In the Revised Guidelines, the Dental Board, Medical Board and Nursing Board (the Boards), adopt language, in part, similar to that used by the North Carolina Medical Board in an effort to create a uniform policy along our common border.

These Revised Guidelines are designed to communicate to licensees that the Boards view pain management as an important area of patient care integral to the practice of medicine; that opioid analgesics may be necessary for the relief of certain pain conditions; and that prescribers will not be sanctioned solely for prescribing opioid analgesics of the dose prescribed for legitimate medical purposes. Further, the Revised Guidelines are intended to alleviate prescriber uncertainty and to encourage patient-centered care. These Revised Guidelines are intended to reinforce the exercise of sound clinical judgment while discouraging prescriptive behaviors that may lead to misuse or abuse of controlled substances, including opioids.

These Revised Guidelines serve to protect South Carolinians' access to pain care while combating prescription drug misuse, abuse, diversion and addiction. Prescribers must be held to a safe and best clinical practice. The Federal Controlled Substances Act defines a "lawful prescription" as one that is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The use of opioids for other than legitimate medical purposes poses a threat to the individual and to the public health, thus imposing on prescribers a

¹¹ The Board of Medical Examiners endorsed the Revised Guidelines on November 3, 2014. The Board of Dentistry endorsed the Revised Guidelines on November 13, 2014. The Board of Nursing endorsed the Revised Guidelines on November 20, 2014.

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responsibility to minimize potential for misuse, abuse and diversion of opioids and all other controlled substances.

Prescribers must recognize that inappropriate prescribing of controlled substances may contribute to drug misuse and diversion by individuals who seek opioids for other than legitimate medical purposes. Inappropriate treatment can result from a mistaken belief on the part of patients and their prescribers that complete eradication of pain is an attainable goal that can be achieved without disabling adverse effects. Accordingly, the Boards urge prescribers to incorporate safeguards into their practices to minimize the risks of misuse, abuse and diversion of opioid analgesics and other controlled substances. The consensus is that utilization of SCRIPTS prior to prescribing opiates is the best safeguard against these risks and the best practice for prescribers.

Preamble

The Boards recognize that principles of quality medical practice dictate that South Carolinians have access to appropriate and effective pain relief.

The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain, as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. These Revised Guidelines apply to the treatment of both acute and chronic pain with opioid analgesics, as well as clinical strategies to improve appropriate, safe prescribing of controlled substances and treatments. The use of opiates in end of life and palliative care may present unique benefits and risks not fully addressed herein. However, concepts presented will be relevant and generally applicable to the use of opiates for end of life and palliative care.

Persistent, intractable pain, like all chronic illnesses, is managed optimally with a biopsychosocial model and not with opio-centric practices of the past. A continuum of care in choosing possible opioid and nonopioid alternatives is preferred, depending on the clinical situation and prescriber discretion as to safe and appropriate treatment.

Below, the Boards issue guidance on the Treatment of Pain, including chronic and acute pain and pain in the emergency department; the Inappropriate Treatment of Pain; Actions Outside the Scope of Appropriate Pain Management; and other Special Considerations.

I. <u>GENERAL PRINCIPLES ON STANDARD OF CARE</u>

It will be considered the standard of care to assess and evaluate the current status of pain treatment prior to initiating new treatment or adjusting current treatment. The registration and utilization of SC PMP/SCRIPTS program (SCRIPTS), which provides both a current and historical survey of narcotic, sedative and controlled substance use, is considered mandatory for prescribers to provide safe, adequate pain treatment. Drug screening is strongly recommended, when indicated. Prescribers are responsible for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Boards regulating prescribers will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based upon documented, sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a practitioner-patient relationship must exist and the prescription should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state and federal law is required.

The Boards recognize that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancerous or noncancerous origins. The Boards will refer to current clinical practice guidelines and expert review in the investigation and review of cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and nonpharmacologic modalities according to the judgment of the prescriber.

Pain should be assessed and treated promptly. The selection of therapeutic modalities, including the quantity and frequency of medication doses, should be adjusted according to the nature of the pain, the patient's response to treatment, and the patient's risk level relative to the use of medications with abuse potential. Prescribers should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

II. GUIDELINES FOR THE TREATMENT OF PAIN

These Revised Guidelines are meant to help prescribers evaluate and manage pain appropriately, prescribe opiates responsibly, and prevent opioid diversion and abuse. Incorporation of these best practices will help prescribers mitigate some of the burden that pain and its attendant opiate use place on patients, prescribers, medical institutions and society. The Boards strongly recommend the following as a reference for behavior when using opiates to treat pain.

A. TREATMENT OF CHRONIC PAIN

Prescribers who treat patients with chronic pain are strongly encouraged to be knowledgeable about addiction, including behaviors that indicate addiction and circumstances under which it is appropriate to refer a patient for addiction evaluation and treatment. Essential elements of appropriate pain management include: evaluation of the patient, consideration of alternative treatments, development of a treatment plan and goals individualized to the patient's needs, informed consent and a treatment agreement, initiation of treatment on a trial basis, periodic review and possible drug testing, consideration of drug diversion, possible consultation and referrals, thoughtful discontinuation of treatment, and appropriate documentation of medical records.

Evaluation of the Patient

A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function and

history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

SCRIPTS utilization should be part of every patient's initial evaluation and subsequent monitoring program and is considered the standard of care. Failure to utilize SCRIPTS to assess risk of opiate/sedative prescribing may be considered misconduct by the responsible regulatory board, depending upon the clinical situation. Prescribers should register with SCRIPTS and become familiar with analyzing and using SCRIPTS data. Information from the SCRIPTS should be used to help confirm each patient's compliance with treatment plans and opiate medication agreements. Relevant information from the SCRIPTS should become part of the patient's medical record.

A toxicology screen, such as a urine drug screen, is a useful tool in the assessment of risks associated with prescribing higher dose opioids and should be utilized prior to prescribing opioids for treatment of chronic pain. It may reveal the use of controlled medications other than those prescribed, such as opioids or benzodiazepines, or the use of illicit drugs.

Evaluation and risk stratification assume even greater importance when dealing with a patient who is taking opioids prescribed by another prescriber. The prescriber's decision to prescribe opioid analgesics should reflect the totality of the information collected, the prescriber's own knowledge and comfort level in prescribing, and the resources available in the community for patient support.

Consideration of Alternative Treatments to Opioid Therapy

Consideration and utilization of a multimodal approach to patient care is essential. A prescriber treating a patient seeking care for pain should have knowledge of all available treatment options, including, but not limited to: physical therapy; non-opioid medications; injections; surgical options; cognitive and behavioral methods; rehabilitation approaches; and complementary treatments. These should be explored and documented as part of a routine evaluation. Early treatment with non-pharmacologic interventions including physical therapy, exercise, and cognitive behavioral techniques, should be employed whenever possible. First line pharmacotherapy should be the appropriate use of non-opioid analgesics, including over the counter medication, non-steroidal anti-inflammatory drugs, and acetaminophen. Other treatment modalities, including minor intervention such as anesthetic and steroid joint injections, cutaneous stimulation, topical anesthetics, and local therapies employing heat, massage, and manipulations, should be considered before using opiates.

If the prescriber determines that opioid therapy is the best course of treatment after review and/or utilization of alternative treatments, the prescriber should minimize the risks of respiratory depression, addiction, and diversion. When opioids are identified as the best treatment option for complex or high-risk patients, specialists in psychology, psychiatry, and addiction management should be consulted, if possible.

Development of a Treatment Plan and Goals

The decision to initiate opioid therapy for treatment of chronic pain should be the prescriber and patient's joint decision. This decision may extend to another person responsible for the patient's care (Caretaker). Once the joint decision to prescribe is made, a treatment plan and goals should be established as early as possible in the treatment process and revisited regularly. The prescriber should discuss the risks and benefits of the treatment plan, including any proposed use of opioid analgesics, with the patient and any Caretaker or other person(s) designated by the patient. If opioids are prescribed, the patient and any Caretaker should be counseled on safe ways to store and dispose of medications.

Appropriate goals of pain treatment include: reasonable attainable improvement in pain and activity; improvement in pain-associated problems such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications. Individualized goals for pain relief and improved physical, functional and psychosocial activity should be set to help guide the choice and response to treatment. The treatment plan should contain information supporting the selection of pharmacologic and non pharmacologic control of pain and achievement of specific physical, functional and psychosocial activity goals. The plan should document any further diagnostic evaluations, consultations or referrals, and/or additional therapies that have been considered, including any follow up plans. A prescriber may reduce risks of abuse, misuse, diversion, and/or unintentional overdose by incorporating a schedule for reassessment and re-evaluation in the treatment plan, as discussed in Periodic Review herein below.

Informed Consent and Treatment Agreement

Use of a written informed consent, memorializing the joint decision to prescribe, and a treatment agreement, memorializing the treatment plan and goals, is the standard of care. They may be combined into one document for convenience. Informed consent should always be considered for higher dose or ongoing acute or chronic pain opiate prescribing.

Informed consent documents typically address:

- The potential risks and anticipated benefits of chronic opioid therapy;
- Potential short and long term side effects of the medication, such as constipation and cognitive impairment;
- The likelihood that tolerance to and physical dependence on the medication will develop;
- The risk of drug interactions and over-sedation, including the increased risk of using opiates in disease and conditions such as obesity and sleep apnea;
- The risk of impaired motor skills affecting driving and other tasks;
- The risk of opioid misuse, dependence, addiction and overdose;
- The limited evidence of the benefit of long-term opioid therapy;

- The prescriber's policies and expectations, including the number and frequency of prescription refills, early refills, and replacement of lost or stolen medications; and
- Specific reasons for which drug therapy may be changed or discontinued, including violation of the policies and agreements spelled out in the treatment agreement.

Treatment agreements outline the joint responsibilities of the prescriber and the patient in the management of chronic pain and may be applicable in some cases of acute pain. Treatment agreements are indicated when opioid or other abusable medications are prescribed. Agreements typically discuss:

- The treatment goals for pain management, restoration of activities, and safety;
- The patient's responsibility for using medication safely, including not using more medication than prescribed, not using an opioid in combination with alcohol or other potentially dangerous substances, storing medications in a secure location, and safely disposing of unused medication;
- The patient's responsibility to obtain opioids from only one prescriber or practice and to fill prescriptions at an in-state pharmacy or one that participates in SCRIPTS reporting;
- The patient's agreement to submit to periodic drug testing of blood, urine, hair, saliva, or other body material;
- The prescriber's responsibility to be available or to have a covering prescriber be available to care for unforeseen problems and to prescribe scheduled refills; and
- The prescriber's responsibility to provide referrals to substance abuse counseling when abuse potential is present and for failed drug screens.

Initiating an Opioid Trial

Safer alternative treatments should be considered before initiating opioid therapy. When the decision to use an opiate has been made, it should be presented to the patient as a therapeutic trial to test for a defined period of time, usually no more than ninety (90) days, and with specified evaluation points. The prescriber should explain that progress will be carefully monitored for benefit and harm in terms of the effect of opioids on the patient's level of pain, physical function and psychosocial activities. Attention will be focused on adverse events and risks to safety. Prescribers should develop and implement appropriate safe practices for patients identified as at risk for misuse, abuse, diversion, and/or overdose. At risk patients should be candidates for abuse deterrent formulations of the prescribed opioid.

The lowest dose possible should be given to an opioid naive patient at the beginning of opioid therapy and titrated to effect while monitoring for complication. Opioid therapy should begin with a short acting drug and rotate to a long acting/extended release, if indicated. A decision to continue opioid therapy beyond the trial period should reflect a careful evaluation of benefits, adverse events, and potential risks.

Periodic Review

As stated previously, review of SCRIPTS data at the time of clinical exam and prescription writing of opiates is the standard of care. The prescriber should regularly review the patient's progress, including any new information about the etiology of the pain or the patient's overall health and level of activities. When possible, collateral information about the patient's response to opioid therapy, including the medication's affect on physical, functional, and psychosocial activities, as well as signs of adverse effects, such as sedation or other impairment, should be obtained from family members or other close contacts. The prescriber should regularly review SCRIPTS data. The patient should be seen more frequently while the treatment plan is being initiated and when the opioid dose is being adjusted. As the patient is stabilized in the treatment regimen, follow up visits may be scheduled less frequently.

Continuation, modification or termination of opioid therapy for pain should be contingent on the prescriber's evaluation of the patient's progress toward treatment goals and assessments of substantial risks or adverse events. A satisfactory response to treatment would be indicated by a reduced level of pain and improved physical, functional, and psychosocial activities. Use of measurement tools to assess the patient's level of pain, activity, and quality of life can be helpful in documenting therapeutic outcomes.

Risks associated with opioids increase with escalating doses. When a patient is prescribed 80 Morphine Equivalent Dose (MED) for longer than three continuous months, it is recommended that the prescriber: re-establish informed consent; review the patient's functional status, including daily activities, analgesia, aberrant behavior, and adverse effects, as it relates to progress toward treatment objectives established at the onset of opioid therapy; consult SCRIPTS to verify compliance; re-establish office visit intervals; review frequency of drug screens; and review and execute a new treatment agreement. Relevant information from SCRIPTS should become part of the patient's medical record.

The prescriber should avoid opiate dose escalation without adequate attention to risks or alternative treatments. The prescriber should be mindful that not all pain can be alleviated through the use of opioids. Clinicians should avoid over-reliance on opioids as the primary or only treatment modality, including using opioid dose escalation as the only response to a complaint of inadequate pain relief. The prescriber should be continuously attentive to the use of opiates in the presence of other comorbidities, such as mental illness, respiratory disorders and sleep apnea, and a pre-existing substance use disorder. The prescriber should dispel any mistaken expectation that complete eradication of pain is an attainable goal when a reasonable level of discomfort is the best clinical outcome a patient may achieve.

Prescribers should reconsider a referral to one or more other providers specializing in the treatment of the area, system or organ of the body perceived to be the source of the patient's pain. This may include consultation with a pain specialist if the prescriber is not a pain specialist.

Periodic Drug Testing

Periodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs. Drug testing is an important monitoring tool because self-reports of medication use and behavioral observations are not always reliable. Urine may be the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing. When testing is conducted as part of a pain treatment plan, forensic standards are generally not Sample collection may not need to be observed and chain-of-custody employed. protocols are not customarily followed. Initial testing may be done using class-specific immunoassay point-of-care or laboratory-based test. These tests do not typically identify a particular specific drug within a class. However, the tests are available as panels and immunoassays for specific drugs can be included. It is important that the clinician formulate these panels to include the specific medications being prescribed, and, if possible, the drugs commonly abused in the local community. If necessary, initial testing can be followed with more specific techniques, including gas chromatography/mass spectrometry (GC/MS) or other chromatographic tests. It is important to identify the specific drug, not just the class of the drug, when drug testing a pain patient.

Prescribers should be knowledgeable about the specific drug tests they order. They should be aware of the limitation, sensitivity and specificity of the tests they order and take care to order tests appropriately. When a drug test is ordered, it is important to specify that it include the opioid being prescribed. Because of the complexities involved in interpreting drug test results appropriately, it is advisable to confirm significant or unexpected results with the testing laboratory's toxicologist or a clinical pathologist.

Test results that suggest illicit or prescribed medication misuse should be discussed with the patient. Results of drug testing and subsequent discussion with the patient should be documented in the medical record.

If the patient's progress is unsatisfactory, the prescriber must decide whether to revise or augment the treatment plan, whether other treatment modalities should be added to or substituted for the opioid therapy, or whether a different approach, possibly involving a referral to a pain specialist or other health professional, should be employed.

Drug Diversion

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require an immediate response. Failure to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempt, arrest and incarceration or death. For this reason, prescribers who prescribe chronic opioid therapy should be knowledgeable about substance use disorders and be able to distinguish substance use disorder from physical dependence on opiates. Detection of opioid diversion is one of the most difficult duties a prescriber has. The combination of periodic, unscheduled and random pill counting and a concomitant UDS with a confirmation is an effective way to ascertain whether a patient is diverting. Warning signs that a patient may be seeking opioid medications for reasons other than legitimate pain relief include:

Suspicious history:

- Patient referred is already taking controlled substances, especially a combination of narcotics, muscle relaxants, and sedative/hypnotics;
- Soft diagnosis, perhaps based solely on chief complaint;
- Multiple doctors and pain physicians in the past;
- Patient travelled out of the way to come to your clinic;
- Solicitous behavior ("You're the best. I always wanted to come to you.");
- No past medical records are provided and patient states he is unable to obtain records from "referring doctor";
- Patient brings records that look old, tattered or suspicious in some other way; or
- Patient asks for a specific controlled substance (example: prefers Lortab \mathbb{R} over Norco).

Suspicious physical exam:

- No abnormal findings;
- Abnormal findings in exam room inconsistent with witnessed behavior (For example, the patient has normal gait from car to office door, but limps once inside door.);
- Exaggerative behaviors, pain is always a 10 on a scale of 1 to 10;
- Unimpressive imaging;
- Presence of injecting behavior (old or recent "track marks" or multiple healed or current abscesses) or marked nasal erythema from insufflation (snorting); or
- Patient smells like marijuana smoke.

Equivocal compliance:

- SCRIPTS shows multiple providers, multiple pharmacies, prescriptions for multiple types of medications, and prescriptions from out of area doctors, etc.
- UDS is refused or abnormal, for which patient offers multiple excuses, or detects any illegal substance;
- Inconsistent tests results over time;
- Patient seeks recurrent early refills for lost or stolen prescriptions or for increased opioid use without consultation with prescriber; or
- Patient has excuses for lost pills.

No or equivocal clinical improvement:

- Subjective improvement alone does not count;
- Lack of evidence of objective improvement in physical, functional and psychosocial activities; or
- Lack of evidence of decreasing use of opioid medications, decreasing visits to emergency rooms, etc.

What you should do when the clinician suspects misuse, abuse or addiction:

- Request picture I.D. or other I.D. and a Social Security Number. Photocopy these documents and include in the patient's record;
- Call a previous practitioner, pharmacist or hospital to confirm the patient's story;
- Confirm a telephone number, if provided by the patient;
- Confirm the current address at each visit;
- Investigate suspicions further by presenting and discussing specific concerns with the patient, re-checking SCRIPTS data, increasing the use of drug screens, and talking with family members;
- Write prescriptions for limited quantities until conflicts are resolved and it is safe to do so;
- Increase frequency of visits and drug screens; and
- Document all activities in support of mitigating potential misuse, abuse, or addiction.

Consultation and Referral

The treating prescriber should seek a consultation with or refer the patient to a pain, psychiatric, addiction, or other mental health specialist as needed. A patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment.

Prescribers who prescribe chronic opioid therapy should be familiar with treatment options for opioid addiction, including those available in licensed opioid treatment programs (OTPs) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment (OBOT), so as to make appropriate referrals when needed.

Discontinuing Opioid Therapy

The prescriber and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate. Opioids should be tapered or discontinued when a patient's pain is poorly controlled on appropriate doses of medication or if when opioid treatment produces no improvement in physical, functional, or psychosocial activity. Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, deteriorating physical, functional or psychosocial activities or significant aberrant medication use.

If opioid therapy is discontinued in the setting of appropriate use, but inadequate response, and the patient has become physically dependent, they should be provided with a safely structured tapering regimen. In the setting of abuse or addiction, when it is necessary to discontinue opioids quickly because of safety, withdrawal can be managed either by the prescriber or by referring the patient to an addiction specialist. The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate. The discontinuation of opioid therapy where continuation is not clinically indicated does not constitute patient abandonment.

Medical Records

Every prescriber who treats patients for pain must maintain accurate and complete medical records. The medical record should include the following:

- Copies of the signed consent and/or treatment agreement as appropriate for level of treatment;
- The patient's medical history;
- Results of the physical examination and all laboratory tests;
- Results of the risk assessment, including results of any screening instruments used;
- A description of the treatment provided, including all medications prescribed or administered (including date, type, dose, and quantity.);
- SCRIPTS data;
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others;
- Results of ongoing monitoring of patient progress in terms of pain management and physical, functional and psychosocial improvement;
- Notes on evaluation by and consultations with specialists;
- Any other information used to support the initiation, continuation, revision or termination of treatment and the steps taken in response to any aberrant medication use behaviors. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers;
- Authorization for release of medical information to other treatment providers; and
- All prescription orders for opioid analgesics and other controlled substances, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record. The name, telephone number, and address of the patient's pharmacy should also be recorded in an accessible manner so as to be readily available for review.

Good records demonstrate that a medically necessary service was provided to the patient. Even if the outcome is less than optimal, thorough records protect both the prescriber and the patient.

B. TREATMENT OF ACUTE PAIN

Acute pain was defined historically simply in terms of duration. It is now viewed as a complex, unpleasant experience with emotional and cognitive, as well as sensory, features that occur in response to tissue trauma. In contrast to chronic pain, relatively high levels of pathology usually accompany acute pain. Acute pain resolves with healing of the underlying injury. Acute pain is usually nociceptive, but may be neuropathic. Common sources of acute pain include trauma, surgery, labor, medical and dental procedures and acute disease states. Acute pain, by definition, does not last longer than six months and resolves when the underlying cause of pain has been treated or healed. An accurate assessment of acute pain should be performed when a patient presents with pain to the health care setting. A solid understanding of the patient and the etiology of the pain are essential for the development of an effective and appropriate short-term pain management plan.

Recommendations for Treatment of Acute Pain:

- Develop an office policy for opioid prescribing and have this clearly posted and available for patients;
- Perform a thorough history and physical at the onset;
- Utilize SCRIPTS data as part of every patient's initial evaluation prior to prescribing opiates. Failure to utilize SCRIPTS to assess risk of opiate/sedative prescribing may be considered misconduct by the responsible regulatory board, depending upon the clinical situation.
- Maintain accurate and complete medical records that include all of the components outlined above in the Chronic Pain section.
- Evaluate acute pain patients frequently for physical, functional and psychosocial improvement, with adjustment to treatment as needed. It is generally contraindicated to include refills on opioid prescriptions for acute pain;
- Educate your patients about pain and analgesia. Explain the underlying diagnosis causing the pain, the natural history of the condition, and how your patient can help the healing process;
- Exhaust non-opioid medications and collaborate with other professionals, including physical therapists and pain specialists, if possible. Consider nontraditional therapies such as acupuncture and massage therapy;
- Prescribe a complete pain management program when an opioid is used to treat acute pain: utilize NSAIDS, develop and recommend specific exercises, and utilize other modalities (e.g. heat, ice, massage, topical medications);
- Prescribe opioids intentionally. With the first opioid prescription, set patient responsibilities and the expectation that opioids will be discontinued when the pain problem has resolved or is not responding to what you are doing;
- Write the taper on the prescription (e.g., po every 6 hours for 3 days, po every hours for days, po every 24 hours for 3 days, stop);
- Do not prescribe long-acting or controlled-release opioids (e.g. long-acting oxycodone and oxymorphone, fentanyl patches, long-acting hydromorphone and morphine or methadone) for acute pain;
- Consider performing risk stratification, including urine drug monitoring, after accessing SCRIPTS at the onset of pain care;
- Clearly instruct patients to take opiates only as prescribed, not more frequently or in greater quantities. Educate your patients about the risks of taking opioid analgesics, including, but not limited to: overdose that can slow or stop their breathing and even lead to death; fracture from falls especially in patients over 60; drowsiness leading to injury, especially when driving or operating heavy or dangerous equipment; and tolerance and addiction. Educate your patients about acute pain – tell them it is likely that their acute pain will diminish and resolve,

and tell them that prolonged use of scheduled opioids may actually impair their ability to fully recover;

- Advise patients to avoid medications that are not part of their treatment plan because they may worsen the side effects and increase the risk of overdose from opiates;
- Prepare patients that it may be difficult to taper off opioids, particularly from higher dose regimens, even when they are eager to do so;
- Consider referrals and consultations with a pain specialist if the patient is not responding to your treatment plan. You may want to do this early in the course of treatment if the patient does not respond to standard first line medications and before you prescribe narcotics. Pain specialists may offer procedures or other interventions that will help your patient improve and avoid unnecessary opiate use; and
- Assure that patients are provided with easy to follow and graduated activity instructions that help them quickly improve their quality of life in physical, functional and social domains.

C. TREATMENT OF PAIN IN THE EMERGENCY DEPARTMENT

Emergency medical physicians practice in a unique clinical setting, whereby the urgency of the healthcare services available naturally render the practitioners prime targets for patients seeking prescriptions for opioids for non-medical reasons. In addition to the emergent nature of the patient encounters, these practitioners often must treat patients without the benefit of prior medical records, creating a higher probability of presentation with an incomplete or inaccurate medical history. These factors necessitate the identification of additional prescribing considerations:

- Emergency medical prescribers are reminded that patterns of prescription of opiate/sedative medications in quantities or frequencies excessive of what may be considered reasonable by prudent emergency physicians practicing in a similar circumstance may be considered misconduct by the responsible regulatory board;
- Emergency medical prescribers should maintain a high index of suspicion for potential diversion or abuse of their prescriptions, and should utilize SCRIPTS data and consult with a patient's primary opioid prescriber, as feasible, prior to prescribing opiate/sedative medications when there is a suspect clinical presentation or in the circumstance of chronic pain management. If a rare case should occur where such a prescription is indicated, only a quantity sufficient to prevent morbidity until the patient's primary provider can be seen should be provided;
- Emergency medical prescribers should not provide replacement prescriptions for controlled substances that were lost, destroyed or stolen;
- Emergency medical prescribers should not provide replacement doses of methadone for patient in a methadone treatment program;
- Long-acting or controlled-release opioids (such as OxyContin[®], fentanyl patches and methadone) should not be prescribed routinely by emergency department prescribers, and then only in a quantity sufficient to prevent morbitiy until the patient's primary provider can be seen;

- Emergency department prescribers should utilize SCRIPTS data prior to prescribing opioids. Failure to utilize SCRIPTS to assess risk of opiate/sedative prescribing may be considered misconduct by the responsible regulatory board, depending upon the clinical situation as documented in the patient's medical record;
- All prescribers who manage patients with chronic pain should be encouraged to send patient agreements to local emergency departments for reference, and work to develop appropriate plans for the evaluation and management of their patients in the emergency department in conjunction with emergency department prescribers;
- Prescriptions for opioid pain medication from emergency department providers for acute injuries, such as fractured bones, should not exceed a five day supply in most cases; and
- When appropriate, emergency department patients should be screened for substance abuse prior to receiving a prescription for opioids for acute pain management.

III. INAPPROPRIATE TREATMENT OF PAIN

The inappropriate treatment of pain includes nontreatment, under treatment, overtreatment and the continued use of ineffective treatments. Inappropriate pain treatment may result from a prescriber's lack of knowledge about pain management. Fear of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating prescriber's responsibility. Accordingly, the appropriate regulatory board will consider a departure from standards of practice to be the inappropriate treatment of pain and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

While acknowledging that undertreatment of pain exists in certain instances, it must be understood that chronic pain often is intractable, that the current state of medical knowledge and medical therapies, including opioid analgesics, does not provide for complete elimination of chronic pain in most cases, and that the existence of persistent and disabling pain does not in and of itself constitute evidence of undertreatment.

Circumstances that contribute to both the inadequate treatment of pain and the inappropriate prescribing of opioid may include: (1) prescriber's lack of knowledge as to prevailing best clinical practices; (2) inadequate research into the sources of and treatments for pain; (3) sometimes conflicting clinical guidelines for appropriate treatment of pain; (4) prescriber's concern that prescribing needed amounts of opioid analgesics will result in added scrutiny by regulatory authorities; (5) prescriber's misunderstanding of causes and manifestations of opioid dependence and addiction; (6) prescriber's fear of causing addiction or being deceived by a patient who seeks drugs for purpose of misuse; (7) prescriber's practice outside the bounds of professional conduct by prescribing opioid analgesics without a legitimate medical purpose; and (8) inadequate prescriber education about regulatory policies and processes. Inappropriate treatment also can result from a mistaken belief on the part of patients and their prescribers that complete eradication of pain is an attainable goal, and one that can be

achieved without disabling adverse effects. Additionally, treatment options may be limited based on availability and/or health plan policies on covered benefits or drug formularies.

IV. ACTIONS OUTSIDE THE SCOPE OF APPROPRIATE PAIN MANAGEMENT

The applicable regulatory boards will consider a departure from accepted best clinical practices for the management of pain, particularly chronic pain, to be improper, including, but not limited to the following:

- Inadequate attention to initial assessment to determine if opioids are clinically indicated and to determine the risks associated with their use in a particular individual with pain: There are significant risks associated with opioids; therefore, benefits must outweigh the risks.
- **Inadequate monitoring during the use of potentially abusable medications:** Opioids may be associated with addiction, drug abuse, aberrant behaviors, chemical coping and other dysfunctional behavioral problems. Some patients may benefit from opioid dose reductions or tapering or weaning off the opioid.
- **Inadequate attention to patient education and informed consent:** The decision to begin opioid therapy for chronic pain should be a shared decision of the prescriber and patient after a discussion of the risks and a clear understanding that the clinical basis for the use of these medications for chronic pain is limited, that some pain may worsen with opioids, and that taking opioids with other substances or certain conditions (i.e. sleep apnea, mental illness, pre-existing substance use disorder) may increase risk.
- Unjustified dose escalation without adequate attention to risks or alternative treatments: Risks associated with opioids increase with escalating doses as well as in the presence of other comorbidities (i.e., mental illness, respiratory disorders, pre-existing substance use disorder and sleep apnea) and with concurrent use with respiratory depressants, such as benzodiazepines or alcohol.
- Excessive reliance on opioids, particularly high dose opioids for chronic pain management: Prescribers should be prepared for risk management with opioids in advance of prescribing and should use opioid therapy for chronic noncancerous pain only when safer and reasonable effective options have failed. The prescriber should maintain the lowest opioid dosage possible and continue only if clear and objective outcomes are being met.
- Not making use of available tools for risk mitigations: SCRIPTS should be utilized prior to prescribing opioids and for ongoing monitoring.

The appropriate regulatory board will judge the validity of the prescriber's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administered. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

The appropriate evaluation and management of a patient's pain, including the prescription of opiate medications, is the treating prescriber's responsibility. Prescribers should not fear disciplinary action from the respective regulatory board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice, when current best clinical practices are met. In fact, the regulatory body will consider the failure to prescribe controlled substances responsibly to be a departure from the standards of practice and will investigate such allegations, utilizing current clinical practice guidelines and expert review in determining whether or not standard of care have been met.

Allegations of inappropriate pain management will be evaluated on a case by case basis. The regulatory board may not necessarily take disciplinary action against a prescriber for deviating from these guidelines when contemporaneous medical records document reasonable cause for deviation. The prescriber's conduct will be evaluated by the outcome of pain treatment, recognizing that some type of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient function and/or quality of life.

V. <u>SPECIAL CONSIDERATIONS</u>

Compliance with Controlled Substances Laws and Regulations

In order to dispense or administer controlled substances, the prescriber must be registered with the DEA, licensed by the state in which he or she practices, and in compliance with applicable federal and state regulations. Prescribers are referred to the *Physician's Manual of the US.S Drug Enforcement Administration* for specific rules and regulations governing the use of controlled substances; relevant provisions of the South Carolina Dental Practice Act, the South Carolina Medical Practice Act, and the South Carolina Nurse Practice Act; relevant regulations promulgated by the regulatory authorities governing these professions; and advisory opinions issued by the regulatory authorities governing these professions.

Naloxone

Patients prescribed more than 80 mg MED are at an increased risk of death from respiratory depression. These patients require closer monitoring and other respiratory depressants, such as alcohol and benzodiazepines, should be avoided. The Board recognizes that a prescription of Naloxone may be appropriate in certain situations involving patients who are prescribed high dose opioids or are more vulnerable to the risk of opioid overdose due to comorbidities or other factors. Whether Naloxone is medically necessary for a particular patient is within the discretion of the patient's primary opioid prescriber.

Pregnancy

When treating females of childbearing age, prescribers must consider pregnancy or the risk of pregnancy and provide appropriate counseling before prescribing opioids. Female patients of childbearing age should be counseled regarding the risks of opioid use during pregnancy, the effect of chronic opioid therapy on the neonate (neonatal abstinence syndrome) and the consideration for a high risk obstetrical consult prior to attempting conception.

Telemedicine

Chronic pain shall not be treated by the use of controlled substances through telemedicine.

DEFINITIONS

Abuse: A term with a wide array of definitions depending on the context. The American Psychiatric Association defines drug abuse as "a maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by one or more behaviors." The DSM-V replaces the term "abuse" with "misuse." In addition, **Substance abuse (SA)** can mean the use of any substance(s) for non-therapeutic purposes, or use of medication for purposes other than those for which it is prescribed. The medical diagnosis of **SA** is defined by any one of the following four criteria during a 12-month period: (1) failure to fulfill major obligations at work, school, or home; (2) recurrent use in situations in which it is physically hazardous; (3) recurrent substance-related legal problems; (4) continued use despite persistent social or interpersonal problems. Substance abuse can lead to substance dependence.

Acute pain: The normal, predicted physiological response to a noxious chemical, thermal, or mechanical stimulus and typically is associated with invasive procedures, trauma, and disease. Acute pain is generally time-limited. Duration of acute pain generally coincides with the time frame of normal healing, and serves to protect and injured body segment.

Addiction: A primary, chronic, neurobiological disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. Addiction is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic pain: The state in which pain persists beyond the usual course of an acute disease or healing of an injury or that may or may not be associated with an acute or chronic pathological process that causes continuous or intermittent pain over months or years.

Dependence or Physical dependence: A state of adaptation that is manifested by drug classspecific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction. The medical diagnosis of **Substance Dependence (SD)** is defined by any three of the following seven criteria during a 12-month period: (1) tolerance; (2)withdrawal; (3) substance often taken in large amounts or over longer period than intended; (4) persistent desire or unsuccessful efforts to cut down or control use; (5) great deal of time spent in activities necessary to obtain, use, or recover from the substance; (6) important social, occupational, or recreational activities given up or reduced; (7) continued use despite knowledge of having persistent or recurrent physical or psychological problem likely to have been caused or exacerbated by the substance.

Diversion: The use of prescriptions drugs for recreational consumption, i.e. diverting them from their original medical purpose. The Federal Controlled Substances Act (CSA) establishes a closed system of distribution for drugs classified as controlled substances. Records must be kept from the time a drug is manufactured to the time is it dispensed. Any pharmaceutical which escapes the closed system is said to have been "diverted" and is illegal. Those people who "diverted" the drug are in violation of the law. Conversely, drug diversion may also refer to

legal programs which educate, rehabilitate, and "divert" first-time drug offenders from jail and their original destructive life course.

Misuse or **non-medical use:** Incorporates all uses of a prescription medication other than those that are directed by a prescriber and used by a patient within the law and requirements of good medical practice.

Opioid abuse/dependence: Repeated use of a drug while producing problems in three or more areas over a 12-month period. Areas include tolerance, withdrawal, overdose, and use despite impending consequences. The most commonly abused opioid is oxycodone from diverted prescriptions. Others include, but are not limited to, hydrocodone, morphine, meperidine, fentanyl, methadone, buprenorphine, butorphanol, tramadol and pentazocine.

Pain: An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. Pain is a complex experience embracing physical mental, social and behavioral processes, compromising the life of many individuals.

Prescriber: A health care practitioner licensed by the State of South Carolina and authorized to prescribe medications, including physicians, physician assistants, dentists and advanced practice nurses with prescriptive authority.

Pseudoaddiction: The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug seeking behaviors that are commonly seen with addiction. The relief seeking behaviors of pseudoaddiction resolve upon institution of effective analgesic therapy. Addiction and pseudoaddiction can both occur in the same person.

Tolerance: A physiological state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect. Or, a reduced effect is observed with a constant dose over time. Tolerance may, or may not, be evident during opioid treatment and does not equate with addiction. Tolerance can occur to an opioid's analgesic effects and to its unwanted side effects, i.e., sedation and nausea. Physiologically, when using a drug like alcohol, nicotine, some prescription medications, or opioids, changes take place in the brain. Over time, these changes reduce natural dopamine production and reduce the brain's ability to respond to dopamine. An addict will perceive this relative lack of dopamine in the brain as increased tolerance and he/she will often counter it with increased drug use.

Trial period: The period of time when medication or other treatment efficacy is tested to determine whether treatment goals can be met. If goals cannot be met, the trial is discontinued and an alternate treatment may be considered.

Withdrawal: If drug use is stopped abruptly, a withdrawal syndrome can occur where adaptive body responds, originally present to counter and detoxify the drug, become unopposed and often produce a painful experience for the drug user. Withdrawal is the cardinal sign of physical dependence on a drug.

APPENDIX D

DATA COMMITTEE ANALYSIS

Policy Track	<u>Measurement</u>	<u>Is this</u> <u>currently</u> <u>measured?</u>	Does a database currently contain this info? If yes, which?	If currently <u>measured,</u> <u>baseline</u> <u>measurement</u>	What are gaps in existing data?	If not measured how can we measure?	What additional information is necessary for an accurate measurement?	Action Steps to Improve Statistic	Responsible Party	Legislative Action Required?
I. Pharmacy	1. Number of In-state Pharmacies in Compliance with Daily Reporting Requirement	Yes	РМР	# of pharmacies registered - 85% of 1,147 in-state pharmacies registered w/ BDC October 2014	Getting reports and time to drill down; ≥1,100 pharmacies reporting	N/A	ARCOS report from DEA (Automation of Reports & Consolidated Orders System)	ARCOS report	DHEC	No
	2. Number of pharmacists enrolled in PMP	Yes	РМР	# of pharmacists enrolled – 2,326 September 30, 2014	N/A	N/A	N/A	N/A	DHEC	No
	3. Annual # of queries in PMP by RPhs	Yes – can be tracked via report	РМР	304,647 Time frame: July 1, 2013 – June 30, 2014	N/A	N/A	N/A	N/A	DHEC	No
	4. Annual # of queries in PMP by practitioners	Yes – can be tracked via report	РМР	309,852 Time frame: July 1, 2013 – June 30, 2014	N/A	N/A	N/A	N/A	DHEC	No

Policy Track	<u>Measurement</u>	Is this currently measured?	Does a database currently contain this info? If yes, which?	If currently measured, baseline measurement	What are gaps in existing data?	If not measured how can we measure?	What additional information is necessary for an accurate measurement?	Action Steps to Improve Statistic	Responsible Party	Legislative Action Required?
II. Prescription Drug Monitoring	1. # of opioids* prescribed annually, by county See attached	Yes	PMP	Time frame: July 1, 2013 – June 30, 2014	N/A	N/A	N/A	N/A	DHEC	No
	2. # of benzodiaze- pines* prescribed annually, by county See attached	Yes	PMP	Time frame: July 1, 2013 – June 30, 2014	N/A	N/A	N/A	N/A	DHEC	N/A
	3. # of deaths (annually) attributable to prescription drug overdose/ abuse (adult and youthful populations)	Currently captured, but not uniformly or with same category reported	WebDeath	N/A	Absence of uniformity in reporting	N/A	Perhaps a simple form like the SLED form used in mass fatalities	Additional resources needed: People, Software & Training	S.C. Coroners	Perhaps, for allocation of resources

Policy <u>Track</u>	<u>Measurement</u>	<u>Is this</u> <u>currently</u> <u>measured?</u>	Does a database currently contain this info? If yes, which?	If currently <u>measured,</u> <u>baseline</u> <u>measurement</u>	What are gaps in existing data?	If not measured how can we measure?	What additional information is necessary for an accurate measurement?	Action Steps to Improve Statistic	Responsible Party	Legislative Action Required?
	4. # of "frequent flyer" letters sent to prescribers by DHEC, by county	No. DHEC concluded this is beyond the current scope of authority.	N/A	N/A	N/A	N/A	N/A	N/A	DHEC, if authorized	Yes
	5. # of prescribers referred to LLR by DHEC for potential improper prescribing patters (Data Committee suggests tracking this by all sources, not just DHEC.)	No. LLR doesn't currently track the source of complaints.	Yes, RELAES	N/A	N/A	Need to reformat data entry in RELAES to capture this data	Complaint source	Review RELAES to determine whether this can be extracted; adopt new data entry process	LLR	No

Policy Track	<u>Measurement</u>	<u>Is this</u> <u>currently</u> <u>measured?</u>	Does a database currently contain this info? If yes, which?	If currently measured, baseline measurement	<u>What are</u> gaps in existing data?	If not measured how can we measure?	What additional information is necessary for an accurate measurement?	Action Steps to Improve Statistic	Responsible Party	Legislative Action Required?
	6. # of patients flagged by DHEC as potential "doctor shoppers" or drug abusers, by county	No one has officially defined parameters for "doctor shopper," but PMP can run a report once parameters are set.	PMP contains this information, but needs parameters to run report.	N/A	Reporting criteria	Establish reporting criteria	Reporting criteria	Establish reporting criteria	DHEC	Νο
	7. # of pharmacists referred to LLR by DHEC for potential dispensing abuse, by county	No, see above re: prescribers	See above	N/A	See above	See above	See above	Review RELAES to determine whether this can be extracted; adopt new data entry process	LLR	No

Policy <u>Track</u>	<u>Measurement</u>	<u>Is this</u> <u>currently</u> <u>measured?</u>	Does a database currently contain this info? If yes, which?	If currently <u>measured,</u> <u>baseline</u> <u>measurement</u>	<u>What are</u> gaps in existing data?	If not measured how can we measure?	What additional information is necessary for an accurate measurement?	Action Steps to Improve Statistic	Responsible Party	Legislative Action Required?
III. Treatment	1. # of SC citizens treated annually for prescription drug abuse/ addiction (in- patient and OP; adult and youthful populations). Data Committee suggests breaking this down into public and private treatment centers.	Yes, for public facilities	DAODAS and DMH have information about public facilities; RFA has info from hospitals for public and private.	N/A	*Billing data is available for Medicaid and State Insurance Plan, but lacks uniform coding; *Billing data is built around a business coding system, not treatment *Possible midpoint is DAODAS data; *Private providers/ private ambulatory treatment coding system; *granularity of coding for illicit vs. Rx drugs	Establish reporting criteria with caveat for gaps		Review private and public treatment system to identify possible repository for needed information; identify strategy for uniformity	RFA (with data from DMH, DAODAS, HHS, Voc Rehab, SC State Insurance Plan) WCC? Private Sources	Possibly

Policy <u>Track</u>	Measurement	Is this currently measured?	Does a database currently contain this info? If yes, which?	If currently measured, baseline measurement	What are gaps in existing data?	If not measured how can we measure?	What additional information is necessary for an accurate measurement?	Action Steps to Improve Statistic	Responsible Party	Legislative Action Required?
	2. # of hospitalizations, either ED or inpatient admissions, annually, relating to prescription drug abuse/ addiction. Data Committee suggests "public facility" restriction.	Yes, RFA from Uniform Billing Data	RFA – Uniform Billing Data	N/A	May not be specific as to Rx or illicit	Need PDAP's restriction to public facilities so that we can utilize RFA data	Perhaps EMS records regarding destination, but those records do not reflect disposition.	Review RFA data; Identify possible improvement (billing vs. treatment data); Review EMS	RFA/ DHEC	No
	3. # of treatment facilities available, by county	Yes	DHEC	# of centers	Unregistered facilities		All "mom & pop" operations		DHEC	No

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IV. Law Enforcement	1. # of arrests (annually) attributable to prescription drugs (DUI, diversion, possession, PWID, theft, etc.)	Yes	SLED, through SCIBRS, which replaced UCR	Currently, "other drugs" is global category, so no baseline exists for specific Rx drugs.	Need to add "special circumstances" designation to be directed by PDAP; need separate code for opiates and benzo		Designation by drug	Revise SCIBRS to add special circumstances designations	SLED	No

Policy <u>Track</u>	<u>Measurement</u>	Is this currently measured?	Does a database currently contain this info? If yes, which?	If currently <u>measured,</u> <u>baseline</u> <u>measurement</u>	What are gaps in existing data?	If not measured how can we measure?	What additional information is necessary for an accurate measurement?	Action Steps to Improve Statistic	Responsible Party	Legislative Action Required?
	2. # of convictions of obtaining by fraud (annually) attributable to prescription drug crimes	NEED INFO FROM SOLICITORS/ NCIC	Each Solicitor's Office tracks dispositions, but there is no central repository or uniformity.	N/A	There is no central repository with uniform reporting standards.	A centralized repository can facilitate this, which may require action by Court Administra- tion.	Centralized repository	Solicitors Association can work toward uniform reporting system.	Solicitors Associa- tion	Perhaps, for allocation of resources

Policy <u>Track</u>	Measurement	Is this currently measured?	Does a database currently contain this info? If yes, which?	If currently <u>measured,</u> <u>baseline</u> <u>measurement</u>	<u>What are</u> g <u>aps in</u> <u>existing</u> data?	If not measured how can we measure?	What additional information is necessary for an accurate measurement?	Action Steps to Improve Statistic	Responsible Party	Legislative Action Required?
	3. # of convictions of trafficking (annually) attributable to prescription drug crimes *Frank indicates that PWID may be better metric since there are few trafficking convictions of Rx.	NEED INFO FROM SOLICITORS/ NCIC	Each Solicitor's Office tracks dispositions, but there is no central repository or uniformity.	N/A	There is no central repository with uniform reporting standards.	A centralized repository can facilitate this, which may require action by Court Administra- tion.	Centralized repository	Solicitors Association can work toward uniform reporting system.	Solicitors Associa- tion	Solicitors Associa- tion
	4. # of prescription drugs seized by law enforcement (by lb.)	Not uniformly; SLED gleans information from incident reports, which are not uniformly executed.	No common repository; DEA tracks take-back days	Frank to follow up with DEA contacts	N/A	Lack of uniform reporting	Uniform reporting by all law enforcement agencies	Funding (fed'l grant?) SLED can initiate action with locals	SLED	Yes

Policy Track	Measurement	<u>ls this</u> <u>currently</u> <u>measured?</u>	Does a database currently contain this info? If yes, which?	If currently measured, baseline measurement	What are gaps in existing data?	If not measured how can we measure?	What additional information is necessary for an accurate measurement?	Action Steps to Improve Statistic	Responsible Party	Legislative Action Required?
	5. # of take- back programs, by county	NO. This can be done manually by going to each county.	N/A	N/A	N/A	N/A	Would have to be done manually by county; need a uniform tracking system	Funding/ training	SLED could be repository	No
V. Third- Party Payers	1. Costs to government- provided benefit programs arising from prescription drug abuse/ addiction (hospitalization, treatment, fraud, etc.)	Yes – Data must be sorted by HHS for submission to RFA.	Yes	HHS can provide.	N/A	N/A	N/A	Sorting/ reporting mechanism	HHS/RFA	No
	2. Costs to third-party payers arising from prescription drug abuse/ addiction (hospitalization, treatment, fraud, etc.)	PEBA is only data set currently available; need help from private sector	Yes, but we don't have access to non-PEBA	N/A	Non-PEBA data	Need non- PEBA data	Need non- PEBA data	Need non- PEBA data	RFA for PEBA; need coopera- tion for non- PEBA	

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	3. # of negative Press Gainey scores attributable to limited access to prescription drug abuse	Unknown at this time								
VI. Education of the Public, Patients, and Providers	1. Number/ Percentage of SC youth who admit inappropriate use of prescription drugs, by County (may be a % of measured population)	Yes, by surveys conducted in alternating years by DOE and DAODAS	Yes, DAODAS and DOE	Not established	Survey participation is not mandatory, so results are limited.		Mandatory participation by all schools	Legislative change to mandate survey participa- tion	DOE and DAODAS	Yes

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	2. Percentage of licensed prescribers with controlled substance registration enrolled in PMP	Yes – A report can be generated with the number of registered prescribers.	PMP has the number of registered prescribers; LLR has number of prescribers - 24,082 Total (2,907 Dentists in state and OOS; 17,924 MDs & D.O.s; 267 P.A.s (C2- 5); 486 P.A.s (C3- 5); 687 APRNs with PA; 1,811 Vets In State & OOS	21% Total # of unduplicated registered prescribers with BDC to include: Dentists, MD, DO, PA-C, APRNs, Vets, OD, DPM = 20,101	N/A	N/A	N/A	N/A	DHEC/ LLR	No

Policy <u>Track</u>	Measurement	Is this currently measured?	Does a database currently contain this info? If yes, which?	If currently <u>measured,</u> <u>baseline</u> <u>measurement</u>	What are gaps in existing data?	If not measured how can we measure?	What additional information is necessary for an accurate measurement?	Action Steps to Improve Statistic	Responsible Party	Legislative Action Required?
	3. # of prescribers enrolled to access PMP	Yes	РМР	4,201 as of September 30, 2014	N/A	N/A	N/A	N/A	DHEC	No
	4. # of patients accessed by the prescribers via PMP	Not at this time	РМР	Not at this time	N/A	N/A	N/A	N/A	DHEC	No
	5. # of patients counseled (or referred for rehabilitation) by prescribers as a result of PMP review	No		N/A	See note				DHEC	Possibly
	6. # of prescription drugs collected at take back events (by lb.)	No. See discussion above re: DEA Take- Back programs.								

Policy	Measurement	<u>Is this</u>	Does a	If currently	What are	<u>lf not</u>	<u>What</u>	Action Steps	<u>Responsible</u>	Legislative
<u>Track</u>		<u>currently</u> <u>measured?</u>	database currently contain this info? If yes, which?	<u>measured,</u> <u>baseline</u> <u>measurement</u>	g <u>aps in</u> <u>existing</u> <u>data?</u>	<u>measured</u> <u>how can we</u> <u>measure?</u>	additional information is necessary for an accurate measurement?	<u>to Improve</u> <u>Statistic</u>	<u>Party</u>	Action Required?
	7. # of Prescribers attending Prescription Drug Abuse Continuing Education	Yes and No	LLR currently tracks CME hours, but information is simply scanned in and not currently pulled into a database.	N/A	ReLAES does not currently track specific CME requirements.	This can be measured by linking revised renewal and initial applications containing CME certification with ReLAES.	Certification from prescribers re: CME compliance.	Modify ReLAES and applications to capture this information.	LLR	No
	8. # of Prescribers Disciplined for Prescription Drug Abuse Prescribing Issues	No	LLR has the disciplinary orders, but ReLAES does not currently categorize offenses with this specificity.	N/A	ReLAES does not currently categorize offenses with this specificity.	ReLAES and the order processing system can be revised to track offenses this way.	N/A	Modify ReLAES to capture this information.	LLR	No

<u>Policy</u> <u>Track</u>	<u>Measurement</u>	<u>Is this</u> <u>currently</u> <u>measured?</u>	Does a database currently contain this info? If yes, which?	If currently <u>measured,</u> <u>baseline</u> <u>measurement</u>	<u>What are</u> gaps in existing data?	If not measured how can we measure?	What additional information is necessary for an accurate measurement?	Action Steps to Improve Statistic	Responsible Party	Legislative Action Required?
	9. # of Prescribers Disciplined for Drug Diversion Issues	No	LLR has the disciplinary orders, but ReLAES does not currently categorize offenses with this specificity.	N/A	ReLAES does not currently categorize offenses with this specificity.	ReLAES and the order processing system can be revised to track offenses this way.	N/A	Modify ReLAES to capture this information.	LLR	No
VII. County/ Community Initiatives	1. # of Counties/ Communities with Initiative to Curb Prescription Drug Abuse	*Need information from Michelle Nienhius at DAODAS								
	2. # of Hospitals with Initiative to Curb Prescription Drug Abuse, by County	*Need to obtain information from SCHA								

<u>Policy</u> <u>Track</u>	<u>Measurement</u>	<u>Is this</u> <u>currently</u> <u>measured?</u>	Does a database currently contain this info? If yes, which?	If currently <u>measured,</u> <u>baseline</u> <u>measurement</u>	<u>What are</u> gaps in existing data?	<u>If not</u> <u>measured</u> <u>how can we</u> <u>measure?</u>	What additional information is necessary for an accurate measurement?	Action Steps to Improve Statistic	Responsible Party	Legislative Action Required?
VIII. Unintended Consequen- ces	1. # of deaths related to heroin overdose	Yes, but not uniformly	WebDeath, as secondary condition on Cause of Death designation	N/A	Not all deaths are identified as heroin related; Lack of uniform reporting		Increased education and training for all coroners/ medical examiners	Increased education and training for all coroners/ medical examiners	Coroners and Individual Counties	Possibly, for alloca- tion of resources
IX. Prescriber	#of Patients with > 80 MED			52,967 between July 1, 2013, and September 30, 2014						

*Opioid and benzodiazepine were substituted for the more general word "narcotics" per PDAP Council and Data Committee.

OPIATE AND BENZO TOTALS BY COUNTY

TOTALS for	Opiates fron	n 07/01/13 t	o 06/30/14	TOTALS for	Benzo from	07/01/13 to	06/30/14
COUNTY	Recipient Count	Rx Count	Qty Dispensed	COUNTY	Recipient Count	Rx Count	Qty Dispensed
Abbeville	6,503	23,837	1,564,764	Abbeville	2,951	15,086	891,015
Aiken	39,798	128,343	7,910,699	Aiken	21,693	94,247	5,505,505
Allendale	2,874	7,670	461,323	Allendale	782	2,759	148,909
Anderson	52,659	196,383	13,502,000	Anderson	27,025	134,574	8,657,904
Bamberg	3,639	11,800	676,402	Bamberg	1,530	6,528	392,544
Barnwell	6,659	21,286	1,398,602	Barnwell	2,973	12,969	790,237
Beaufort	36,067	101,112	5,064,396	Beaufort	19,700	65,077	3,295,102
Berkeley	49,831	171,251	10,521,904	Berkeley	20,573	87,976	5,013,172
Calhoun	3,308	10,256	603,652	Calhoun	1,212	5,837	344,944
Charleston	86,857	261,507	15,675,050	Charleston	44,271	186,772	10,282,188
Cherokee	15,770	72,141	5,746,006	Cherokee	7,504	41,172	2,836,422
Chester	10,736	38,622	2,452,112	Chester	4,272	21,935	1,383,437
Chesterfield	12,774	52,960	3,682,830	Chesterfield	6,090	32,108	1,853,917
Clarendon	9,021	31,872	2,146,402	Clarendon	3,123	15,123	974,524
Colleton	12,631	47,769	3,328,543	Colleton	5,092	22,947	1,424,466
Darlington	22,668	101,323	8,019,375	Darlington	10,576	57,761	3,705,005
Dillon	9,490	37,209	2,640,401	Dillon	3,239	15,530	916,172
Dorchester	38,079	125,789	7,431,890	Dorchester	16,734	72,564	4,000,275
Edgefield	5,594	16,646	947,392	Edgefield	2,609	11,620	654,390
Fairfield	6,065	22,079	1,435,833	Fairfield	2,215	10,983	697,094
Florence	40,760	153,478	10,730,121	Florence	17,129	81,857	4,943,585
Georgetown	17,340	68,709	4,849,624	Georgetown	7,796	34,864	2,049,160
Greenville	115,927	385,825	25,545,039	Greenville	54,689	251,963	15,575,267
Greenwood	19,840	67,185	3,947,973	Greenwood	8,291	38,063	2,201,502
Hampton	6,032	19,881	1,098,015	Hampton	1,890	8,079	448,048
Horry	81,426	298,858	21,293,212	Horry	42,371	185,140	10,878,675
Jasper	6,123	16,910	843,484	Jasper	2,251	7,736	407,964
Kershaw	16,803	59,185	3,566,440	Kershaw	8,188	40,466	2,404,662
Lancaster	19,900	65,703	4,008,425	Lancaster	9,020	40,867	2,558,170
Laurens	20,524	81,404	5,688,014	Laurens	9,230	47,919	3,193,671
Lee	4,251	14,480	996,511	Lee	1,490	6,800	399,511
Lexington	73,711	244,344	13,441,412	Lexington	36,076	174,749	10,325,218
Marion	8,151	34,150	2,568,577	Marion	3,610	18,356	1,157,789
Marlboro	6,835	29,164	2,183,361	Marlboro	2,510	12,919	739,889
McCormick	1,947	5,882	345,087	McCormick	745	2,912	170,901
Newberry	11,182	36,924	2,048,353	Newberry	4,242	19,228	1,131,651
Oconee	22,891	94,024	7,237,019	Oconee	11,603	57,590	3,903,916

S.C. State Plan to Prevent and Treat Prescription Drug Abuse - December 2014

	oplates non			-						
COUNTY	Recipient Count	Rx Count	Qty Dispensed		COUNTY	Recipient Count	Rx Count	Qty Dispensed		
Orangeburg	22,421	70,348	4,432,503		Orangeburg	8,171	38,034	2,251,432		
Pickens	33,098	125,075	8,534,608		Pickens	16,440	80,935	5,281,049		
Richland	79,992	220,365	12,234,250		Richland	34,274	145,348	8,418,643		
Saluda	4,427	12,962	642,886		Saluda	1,695	7,756	449,075		
Spartanburg	83,069	325,102	23,243,560		Spartanburg	42,888	217,030	14,080,537		
Sumter	23,994	70,711	4,395,821		Sumter	8,051	35,771	2,100,320		
Union	8,300	37,829	2,883,837		Union	3,992	22,876	1,584,314		
Williamsburg	9,184	31,560	2,044,885		Williamsburg	2,838	13,475	811,382		
York	57,008	161,268	8,805,760		York	26,199	107,157	6,274,824		
TOTAL	1,226,159	4,211,181	272,818,351		TOTAL	569,843	2,611,458	157,508,374		

TOTALS for Opiates from 07/01/13 to 06/30/14

TOTALS for Benzo from 07/01/13 to 06/30/14

APPENDIX E ADDITIONAL RESOURCES

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