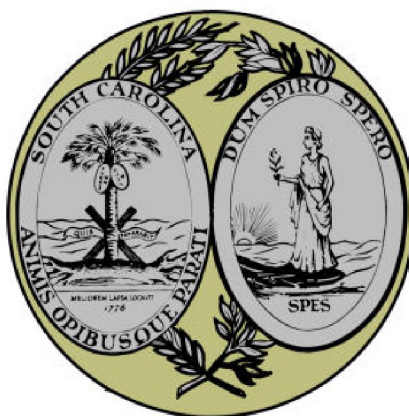


Office of the Inspector General

Patrick J. Maley



South Carolina Lacks a Statewide Prescription Drug Abuse Strategy

I. Executive Summary

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.

Table of Contents

| | <u>Page</u> |
|--|-------------|
| I. Executive Summary | 2 |
| II. Background | 5 |
| A. Objectives | 5 |
| B. National Prescription Drug Epidemic Statistics | 5 |
| C. History of the Prescription Drug Epidemic | 6 |
| III. National Trends Addressing Prescription Drug Abuse | 8 |
| A. Federal Government | 8 |
| B. State Governments | 9 |
| C. Prescription Monitoring Programs | 10 |
| IV. Current Prescription Drug Problem in South Carolina | 12 |
| A. State Prescription Drug Statistics | 12 |
| B. View from the Front Line | 12 |
| 1. Pickens County | 13 |
| 2. Union County | 13 |
| 3. Darlington County | 14 |
| 4. Greenville County | 14 |
| C. Regulator & Enforcement Roles of State Agencies | 14 |
| D. Weaknesses in Current State Approach | 15 |
| V. Developing a Statewide Strategy—A Systems Approach | 17 |
| VI. Conclusion | 21 |
| VII. Findings & Recommendations | 23 |
| <u>Finding #1:</u> The state does not have an integrated, rigorous understanding of the prescription drug abuse problem ... | 23 |
| <u>Finding # 2:</u> The state does not have a statewide strategy to address the prescription drug abuse problem | 23 |
| <u>Finding #3:</u> The Prescription Monitoring Program is underutilized ... | 25 |

Appendix A: 2008 Opioids Dispensed by County in South Carolina

Appendix B: 2011 Prescription Drug Overdose Deaths by County in South Carolina

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 **prior** 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 over-prescribing 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 pharmacies with unusual patterns for educational opportunities by the Pharmacy Board; and 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%).

Step #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.

Step #3-Establish Internal Controls to Monitor & Address Variances: 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 often 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.

Step #6-Invest in Treatment: 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.

Step #7-Periodic Review & Strategy Adjustments: 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. Conclusion

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. Findings & Recommendations

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

Recommendation #1: 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.

Recommendation #2a: 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.

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 in-depth 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.

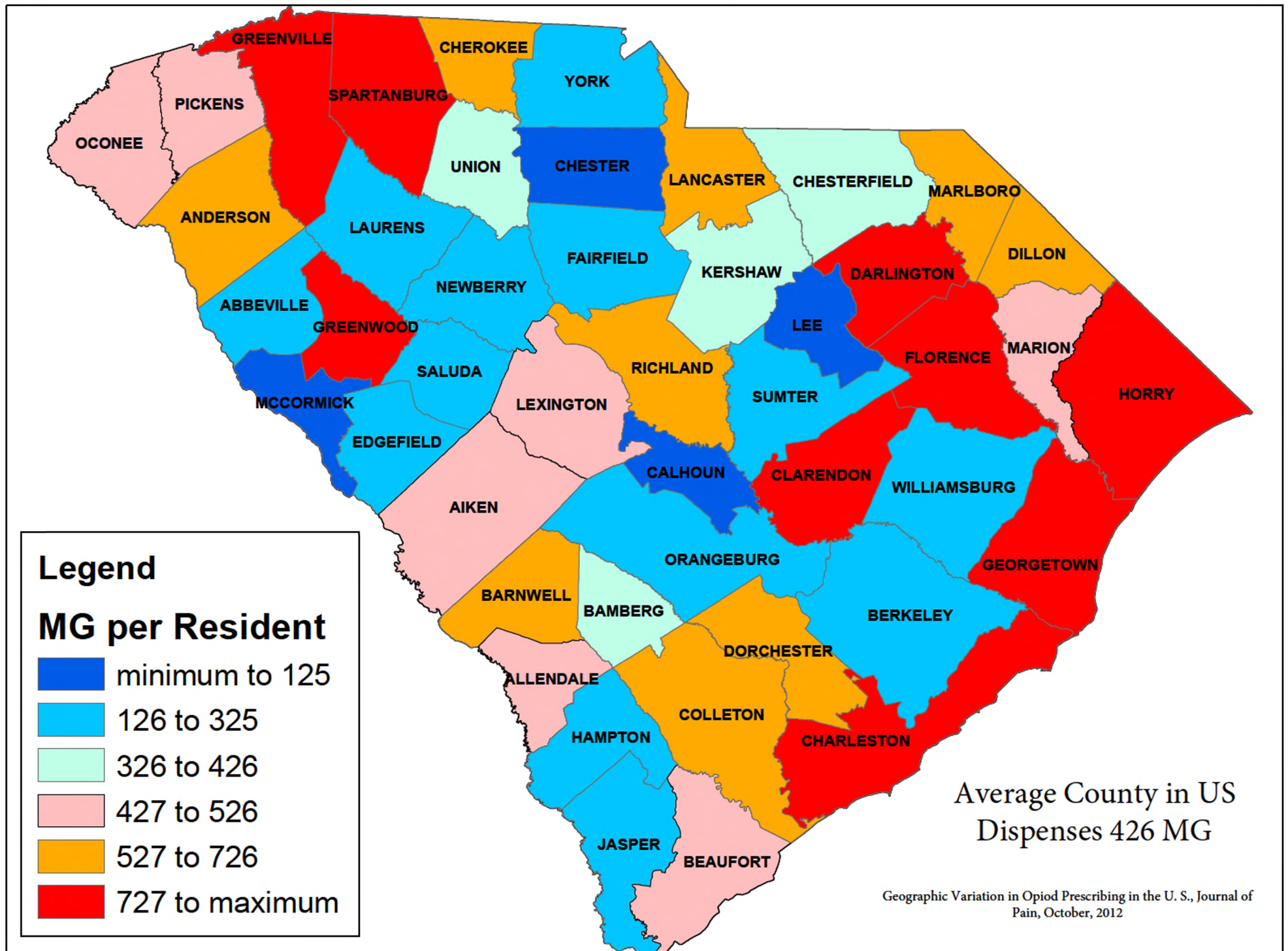
Finding #3: The Prescription Monitoring Program is underutilized.

Recommendation #3: DHEC should:

- Use PMP proactively, which will require expanded legislative authority for that purpose.
- Review system capabilities, particularly the ability to service physician queries as system's participation expands.
- Review administrative controls to streamline its access, particularly delegating access to physicians' staff.

ADMINISTRATIVE NOTE: The affected agencies were provided a draft report for comment and input. DHEC, DHHS, LLR-Medical Board, and DAODAS all agreed with the report findings and generally agreed with the recommendations. The Medical Board was supportive of the most significant recommendation to require the mandatory use of PMP by the medical community prescribing commonly abused prescription drugs. The Medical Board did caution that the PMP system would need to be more user friendly with an adequate data response time. This would allow office staff to obtain the data for a physician's review, yet not impact a physician's clinical time with a patient.

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



APPENDIX B

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

Data from VITAL RECORDS SERVICES, South Carolina
Department of Health and Environmental Control

