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The Perception of Emergency Department Physicians Regarding Economic and Regulatory

Factors Impacting Management of Drug Seeking Patients

by

Sharon S. Kelley

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy Department of Environmental and Occupational Health College of Public Health University of South Florida

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> Date of Approval: November 22, 2013

Keywords: opioids, PDMP, economic, regulatory, ED physicians Copyright © 2013, Sharon S. Kelley

DEDICATION

This is dedicated to my Dad and Mom. You're the best parents I could have ever asked for and your love, support and sacrifice has made this possible.

To my family "cheerleaders" - Debi, Liz, Ruby, Darlene and Monika - thanks for your love and encouragement through these years.

To Russ, Jim and John, thanks for always driving me to "finish strong."

And, to my Lord and Savior, Jesus Christ, who has provided me with all these blessings and so very much more.

ACKNOWLEDGMENTS

Thank you to Dr. Raymond Harbison, my chief adviser who has not only guided me through the academic process but has demonstrated a passion for quality and integrity in his field that will continually serve as a standard for which I will strive.

Thank you to my dissertation committee and chairperson: Dr. Jim Hillman, Dr. Giffe Johnson, Dr. Steve Morris and Dr. Jay Wolfson.

Thank you to my review committee: William Alt, BSN, RN, Robin Choe, ARNP, Mark Jones, BS, PMD, Robert Philpot, PhD, PA, Jennifer Sweeney, MSN, RN, CEN, and Ken Webster, PhD.

Thank you to following for their support in distributing the survey: Dr. Michael Lozano, President - Florida College of Emergency Physicians (FCEP) and Dr. John Rodgers, President – Georgia College of Emergency Physicians; Dr. Paul Perry, Dr. Brian James, Dr. Stephen Mitchell, Dr. David Wilcher, Dr. Eb Karkevandian, Brian Baker, MPH, PA, Jim Milhollen, BSN, RN, Linda Pallo, RN, and the emergency medicine research and residency groups from University of Florida, Tampa General Hospital and Orlando Regional Medical Center.

Thank you to the many ED physicians who were willing to give us their time for participating in our survey and for continuing to meet the present challenges of providing quality care to your patients.

TABLE OF CONTENTS

List of Figures	iii
Abstract	iv
Chapter One: Introduction	1
Background	1
Statement of the Problem	1
Purpose of the Study	2
Research Questions	2
Hypotheses	4
Significance of the Study	5
Limitations	5
Delimitations	6
Terms	6
Chapter Two: Literature Review	8
Historical Perspective	
Pharmacologic Culture	
Pain as the "Fifth Vital Sign"	
Declaration of an Epidemic	
The Impact of Regulatory Actions	
Joint Commission	13
Litigation and Case Law	13
Boards of Medicine	15
Emergency Medical Treatment & Labor Act (EMTALA)	17
Controlled Substance Prescribing Guidelines and Protocols	
Legislation for Deterrence of Prescription Opioid Abuse	25
The Changing Economic and Healthcare Climates	25
Paradigm Shift to Patient Satisfaction Based Reimbursement	25
Electronic Medical Records (EMR)	30
Economic Impact of Oxycodone	30
Impact of the "Great Recession" on ED Patient Volume	
Reduction of Resources	33
Hospital Administration	
The Management of Patients Exhibiting Drug Seeking Behavior	
Training in Management of Prescription Opioid Abuse	36
Identification of Prescription Opioid Abuse	
Opioid Prescribing Practices	40
Summary	41

Chapter Three: Methodology	
Design	
Sample	
Instrument.	42
Procedure	
Data Analysis	
Chapter Four: Results	45
Sample Demographics	
Management Practices	
Training	
Opioid Abuse Identification	
Opioid Prescribing Practices	
Regulatory and Legal Actions	
Economic Impact	
Chapter Five: Discussion	
Introduction	
Purpose of the Study	
Demographics of Sample	
Methodology	
The Management of Patients Exhibiting Drug Seeking Behavior	
Training	
Opioid Abuse Identification	
Opioid Prescribing Practices	
Regulatory Factors Influencing ED Physician Practices	
The Changing Economic and Healthcare Climates	
Conclusions	
Recommendations	
Summary	
References	
Appendix A: Survey Questions	115
Appendix B: Survey Consent Form	
Appendix C: Study Invitation	
Appendix D: IRB Approval - Initial	
Appendix E: IRB Approval – Amendment	

LIST OF FIGURES

Figure 1:	Age of Participants	54
Figure 2:	Years of Experience in ED	55
Figure 3:	Characteristics of Drug Seeking Behavior	56
Figure 4:	Commonly Requested Drugs of Abuse	57
Figure 5:	Training on Prescription Opioid Abuse	58
Figure 6:	Physician Recommendation for CME on Opioid Abuse	59
Figure 7:	Utilization of Opioid Abuse Identification Methods	60
Figure 8:	Drug Screen Availability for Opioids	61
Figure 9:	Correlation between Drug Testing and Availability	62
Figure 10:	Database Inquiries Indicating Potential "Doctor Shopping"	63
Figure 11:	Factors Discouraging Utilization of PDMP	64
Figure 12:	Factors Influencing Utilization of PDMP	65
Figure 13:	Opioid Prescribing Practices	66
Figure 14:	Drug Screens Prior to Prescribing Opioids	67
Figure 15:	Factors Influencing Non-Utilization of Drug Screens	
	Prior to Prescribing Opioids	68
Figure 16:	Laboratory Findings in Patients Exhibiting Drug Seeking Behavior	69
Figure 17:	Administrative Position on Utilization of PDMP	70
Figure 18:	Cultural Expectations of Pharmacologic Agents	71
Figure 19:	Physician Course of Action When "Doctor Shopping" Indicated	72
Figure 20:	Perceived Pressures to Prescribe Opioids	73

Figure 21:	Administrative Criticism for Failure to Prescribe Opioids	74
Figure 22:	Administrative Opioid Prescribing Protocols	75
Figure 23:	Physician Impact from Administrative Opioid Prescribing Protocols	76
Figure 24:	Emphasis on Patient Satisfaction Scores	77
Figure 25:	Changes in ED Patient Volume - 2011 to Present	78
Figure 26:	Factors Influencing ED Patient Volume	79
Figure 27:	Financial Trends Noted with Patients Exhibiting Drug Seeking Behavior	80

ABSTRACT

Physicians in the emergency department (ED) are facing a number of unique challenges in the currently changing healthcare and economic climates. Dramatic increases in ED patient volumes have been noted nationwide with visits related to prescription opioid abuse and misuse alone having increased by 111% between 2004 and 2008.

Ironically, several challenges ED physicians are facing arise from regulatory and economic initiatives which were originally designed for the protection of patients. Regulatory requirements to address pain as the fifth vital sign, along with entities utilizing patient satisfaction based reimbursement, have inadvertently created an environment conducive to exploitation by the prescription opioid abuser.

A literature review revealed an informational gap with regard to the impact economic and regulatory factors exert on the management of patients, exhibiting drug seeking behavior, by ED physicians. The lack of available information is the basis for this original research. A descriptive, cross-sectional, non-experimental study was conducted over a two month period (October – November, 2013) to elicit opinions of ED physicians regarding the management of opioid seeking patients. Respondents were asked to include opinions on factors perceived to impact treatment of this patient population.

Of the ED physicians surveyed, 71% reported a perceived pressure to prescribe opioids to avoid administrative and regulatory criticism and 98% perceive patient satisfaction scores as being too highly emphasized by reimbursement entities as a means of evaluating healthcare

viii

quality. Rising patient volumes and changes in the healthcare climate were also cited as factors impacting management practices when treating patients exhibiting drug seeking behavior.

Emergency department physicians have a unique role in providing unrestricted access of care for the public. This role, in conjunction with the aforementioned concerns, has served to create an environment conducive to the potentiation of prescription opioid misuse and abuse.

CHAPTER ONE: INTRODUCTION

Background of the Problem

Ongoing changes in both healthcare and economic climates, have contributed to a significant increase in ED patient visits including those exhibiting drug seeking behavior. ¹ According to the Centers for Disease Control and Prevention (CDC), between 2004 and 2008, ED visits, related to the abuse of prescribed opioids, increased by 111% with a concurrent rise in visits for benzodiazepines increasing by 89%.² On July 1, 2011 Florida State Surgeon General Frank Farmer, MD declared Florida to be in a public health emergency. Dr. Farmer stated an average of seven deaths occurred daily in Florida due to prescription drug overdose specifically prescription opioids and other controlled substances.³ In November of this same year, a press release was issued by the director of the CDC, Dr. Thomas Frieden, stating "Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined."⁴

Statement of the Problem

Several regulatory and economic initiatives, designed for the protection of patients and delivery of quality medical care, are now being identified by ED physicians as key challenges in the management of patients exhibiting drug seeking behavior. Other challenges such as increased patient volumes and time constraints, subsequent to integration of electronic medical records (EMR),⁵ are perceived by ED physicians as decreasing patient interaction as well as the ability⁶ to employ prescription opioid abuse identification tools.

The use of patient satisfaction scores, and strategies to reduce overall visit times by reimbursing agencies, serve as additional challenges for ED physicians. Patients exhibiting drug seeking behavior are often demanding in their requests for drugs, abusive to staff and provide inaccurate information due to the nature of their dependency and addiction. This creates an ethical dilemma for the ED physician of acquiescing to the patient's demands for the protection of staff and other patients.

Purpose of the Study

This purpose of the study was to elicit the opinions of practicing ED physicians in an effort to determine if economic changes and regulatory factors were perceived as impacting their management of patients exhibiting drug seeking behavior. The lack of available information, as evidenced in a literature search of peer-reviewed works, is the basis for this original research. Subsequent to analysis, the data will be used to identify and evaluate factors which may have a negative impact on treatment of patients exhibiting drug seeking drug seeking behavior by ED physicians.

Research Questions

Research questions were based upon personal interviews and Medline / internet searches for peer reviewed articles on this topic. The following research questions were formulated:

- Do ED physicians report they are pressured to prescribe opioids because of economic influences?
- 2. What economic influences do physicians cite as exerting a pressure on them to prescribe opioids?
- 3. What do ED physicians prefer regarding administrative opioid prescribing protocols?

- 4. Do ED physicians refrain from utilizing prescription opioid abuse detection methodologies such as Physician Drug Monitoring Programs (PDMP) or drug screening due to economic factors?
- 5. What rationale do ED physicians use with regard to their decision to cite "opioid overdose" on the patient's record?
- 6. Do ED physicians receive formal training on recognition and management of prescription opioid abuse?
- 7. Is there a difference in physician opinions, from those who work for for-profit versus not-for- profit organizations, with regard to economic pressures to prescribe opioids in order to maintain patient satisfaction scores?
- 8. Do ED physicians report that training on recognition and management of prescription opioid abuse should be part of their training / continuing education?
- 9. Do ED physicians report that their volume of patients manifesting "drug seeking" behavior has increased in recent years?
- 10. What do ED physicians report with respect to changes in the volume of patients manifesting "drug seeking" behavior that are supported by government insurance such as Medicare / Medicaid?
- 11. What do ED physicians report about the clarity and appropriateness of regulatory guidelines / statutes regarding pain management for ED patients manifesting "drug seeking" behavior?
- 12. What recommendations do ED physicians have for deterring prescription opioid / controlled substance abuse through actions of the ED?

- 13. What do ED physicians report with respect to socioeconomic factors impacting the volume of patients being seen in the ED manifesting "drug seeking" behavior?
- 14. Do ED physicians have concerns regarding patient complaints to the Board of Medicine, for under-treatment of pain, should they decline to prescribe opioids?
- 15. Are data regarding morbidity / mortality from prescription opioid abuse patients seen in the ED influenced by economic factors?

Hypotheses

Based upon results from the research questions, and subsequent to a literature search of peer-reviewed articles, the following hypotheses were formulated:

- Emergency department physicians report that they are pressured to prescribe opioids due to economic concerns arising from administrative and regulatory entities.
- 2. Emergency department physicians will prefer to have administrative / regulatory opioid prescribing protocols for the purpose of protecting them from disciplinary actions.
- 3. There will not be a statistically significant difference between ED physicians working in for-profit versus nonprofit hospitals with regard to their perceptions of economic pressures from administration to prescribe opioids.
- 4. Emergency department physicians will cite their failure to use prescription opioid abuse identification methodologies is often related to economic factors.
- 5. The majority of ED physicians in a convenience sample have not received formal training, through either continuing medical education (CME) or medical school/post-graduate curricula, on recognition and management of prescription opioid abuse in the last three years.

- Emergency department physicians will report they are treating an increased volume of ED patients manifesting "drug seeking" behavior due to economic and regulatory factors.
- 7. There will not be a statistically significant difference between ED physicians working in for-profit versus nonprofit hospitals with regard to economic factors (e.g. administrative, reimbursement, regulatory) regarding use of prescription opioid abuse identification methodologies.
- 8. Emergency department physicians will report a significant rise in patient volume, including those with "drug seeking" behavior, over the last two years.

Significance of the Study

This original research is being initiated to obtain the opinions of ED physicians regarding economic and regulatory factors impacting management of patients exhibiting drug seeking behavior. Once identified, this information could be utilized by medical associations, healthcare organizations, regulatory bodies, and public health officials in the development of continuing medical education for physicians, curricula for medical schools and residency programs, administrative protocols and legislation instrumental to the deterrence of prescription opioid abuse.

Limitations of the Study

This study employed a survey instrument to assess ED physicians opinions regarding management practices when treating patients with "drug seeking" behavior. While self-reporting may represent limited accuracy, overall trends and correlations may be helpful in future educational endeavors. Other potential limitations include:

1. Sampling was limited to ED physicians in Florida and Georgia potentially limiting the ability to "generalize" the population and thereby potentiating internal validity errors.

- 2. The number of participants responding was voluntary therefore non-controlled.
- 3. The instrument being utilized could be completed online or by written documents, therefore the potential for errors could not be controlled by the researcher.
- 4. The potential for bias could not be controlled.
- 5. As this research is non-experimental, there is no control for extraneous variables.
- 6. As a token of appreciation, survey participants were given an opportunity to view an approved continuing education presentation, which awarded them 6.5 hours of Category I continuing medical education (CME) credit, thereby potentially influencing participation response.

Delimitations of the Study

- 1. External validity was not limited as random selection was used.
- 2. Sample was diverse including a wide arrange of ages, corporate status of employers and experience levels.

Terms

- 1. "Drug Seeking" Behavior poorly defined but generally includes patients requesting narcotic opioids for pain management who commonly request specific opioids by name; are often abusive and demanding to staff; cite lost / stolen prescriptions, have obtained narcotic opioids from multiple prescribers in less than prescribed time frames; clinical presentation not consistent with reported level of pain, drug screens inconsistent with history, arrive in ED after normal business hours for private physicians, et al.
- 2. Opioids a group of synthetic analgesics having morphine-like effects and bind to opioid receptors such as μ (mu), κ (kappa) and δ (delta.)

- Prescription Drug Monitoring Program (PDMP) a state run database which collects dispensing information on controlled substances.
- 4. "Doctor Shopping"- seeking care from multiple providers, often simultaneously, without the knowledge of the primary or subsequent providers. This scenario is often identified in persons suffering from a dependency or addiction to an identified medical therapy.

CHAPTER TWO: LITERATURE REVIEW

The literature is robust with articles on the rise of prescription opioid abuse and public health initiatives for deterring this national epidemic. This research will seek to gain insight as to how changing regulatory and healthcare climates are impacting ED physicians when confronted with treating this special patient population.

Historical Perspective

This section will provide a historical perspective on economic and regulatory events associated with the prescription opioid abuse epidemic and how they relate to the ED physician.

Pharmacologic Culture. Americans live in a culture which views pharmaceuticals as a solution for multiple aspects of life. The United States is one of the few countries, the other being New Zealand, where it is legal to conduct "direct-to-consumer" marketing of pharmaceuticals⁷ using media such as television and internet sites to advertise various prescription drugs. ^{8,9} In the United States, the number of prescription drugs dispensed in 2011 was 4.02 billion compared with 3.99 billion in 2010. The total sales of prescription drugs increased from 308.6 billion in 2010 to \$319.9 billion in 2011¹⁰. The proclivity of Americans for pharmaceuticals may result in negative sequelae such as tolerance and potential dependency.

Several studies reflect the hypotheses that ED physicians perceive a pressure to prescribe drugs, such as antibiotics, to meet patient expectations and maintain patient satisfaction.^{10,11} The concerns for overprescribing of antibiotics was recently addressed by a CDC report which cited that antibiotic resistance is responsible for an additional \$20 billion in healthcare costs annually.

Also noted in the report was the fact that 50% of the antibiotics prescribed are unnecessary or inappropriately prescribed.¹² In many ways this parallels the current prescription opioid abuse epidemic. In both public healthcare crises, overuse of antibiotics and overuse of opioid analgesics, pharmaceutical agents are being sought from ED physicians. Prescribing, without appropriate need, has led to tremendous costs for healthcare as well as increased morbidity and mortality.¹³

The current CDC research on abuse of antibiotics may serve as an opportunity to discover more about the abuse of prescription opioids. Eliciting the prescribing perceptions of ED physicians could lead to the development of education constructed to serve the concerns of both healthcare crises.

Pain as the "Fifth Vital Sign." In medicine, the evaluation of "vital signs" is considered to be a standard of care upon which further evaluation and / or testing may be predicated. Vital signs include heart rate, blood pressure, respiratory rate and temperature.¹⁴ On November 11, 1996, Dr. James Campbell, president of the American Pain Society (APS), stated that physicians should assess pain with the same "zeal" as that of obtaining vital signs:

Vital Signs are taken seriously. If pain were assessed with the same zeal as other vital signs are, it would have a much better chance of being treated properly. We need to train doctors and nurses to treat pain as a vital sign. Quality care means that pain is measured and treated.¹⁵

Dr. Campbell based this on the APS's position that pain is undertreated. This condition, referred to as oligoanalgesia, was cited by Dr. Campbell as being based on a lack of communication between patient and physician.¹⁶ His presentation reinforced the society's 1995 initiative which introduced the concept of evaluating pain as the "fifth vital sign."^{15,17} The word "sign" in this

context is being used in a colloquial fashion. Webster's Medical Dictionary defines a sign as "objective evidence of disease as observed and interpreted by the physician." A symptom is defined as "subjective evidence of disease or physical disturbance observed by the patient."¹⁸ Therefore pain is not objective, but rather a subjective description expressed by the patient.

In the years immediately following Dr. Campbell's recommendation, pain was still deemed as being undertreated. Resnick, et al. postulated a number of reasons as to why this might be occurring.¹⁹ These reasons could easily apply to ED physicians as well as those in other disciplines. One of the reasons offered was that pain doesn't conform to the normal scientific approach. When treating other illnesses and injuries the evidence is often objective rather than subjective.

Also cited by Resnick et al. is that the etiology of pain is "often poorly understood" and therefore pain simply becomes a symptom and not considered as a disease. Emergency department physicians are not in a position to monitor chronic pain and may well not have had specialized training in pain management. The last reason they addressed is that pain is often not an easily resolved problem. This would be applicable for ED physicians as they are not in a position to provide full resolution for patients with long term, chronic pain.

Pain is one of the most common complaints (42%) heard from patients presenting to the ED.²⁰ Yet, without a means of accurately quantifying the patient's level of pain, ED physicians will have to make the determination as to whether they perceive the patient to be a reliable source of information. Patients who suffer with drug dependency or addiction issues are frequently desperate and may go to extremes, including criminal behavior in the case of addiction, to obtain a prescription for desired drugs. By definition, addiction is manifested by an intense drive to obtain their desired drug to the point of ignoring normal behavioral restraints.

"Doctor shoppers" and patients exhibiting drug seeking behavior commonly misrepresent their level of pain, frequency of medication usage, and illegal obtaining of the drug.²¹

For the ED physician, the literature contains a good deal of information regarding pain management and the initiation of the "fifth vital sign." While research supports the utilization of this as a tool, there is also research present which deems this tool to be less than successful. . Mularski et al. reported that no change was reported in pain when analyzing responses before and after the pain initiative.²² The quality of pain care was unchanged between visits before and after the pain initiative based upon subjective provider assessment, charted orders to assess pain, change in analgesic modalities, initiation of a new analgesic modality, treatment of co-existing pain or follow up for referral. Their findings indicated that even though a pain scale was reported initially, care was not received, later pain scale reports were not included in the written record, additional assessments were unnoted and no new therapeutic options were evidenced. They acknowledged that increased awareness to utilize the scale could be beneficial but the observed results were still a lack of adequate pain management.

A significant concern for ED physicians remains the subjective nature of self-assessed pain reporting especially when considering the presence of potential dependency and addiction issues. Without being able to quantify pain, and the incorporation of the "fifth vital sign" into accreditation requirements, ED physicians are influenced to treat the presence of pain as expressed by the patient. Inadvertently, the "fifth vital sign" may have become a significant factor in America's prescription drug abuse epidemic. ²³

Declaration of an Epidemic. Between 1999 and 2010, the sale of prescription opioids quadrupled. In 2010, the non-medical use of opioids in the US, in populations of \geq 12 years, was approximated at 4.8%. The cost to US healthcare is estimated at approximately \$72.5 billion

annually. According to the CDC, "There were enough opioids prescribed in 2010 to 'medicate every American adult with a standard pain treatment dose of 5 mg of hydrocodone taken every 4 hours for a month.²⁴ In 2007, approximately 100 persons died each day in the US due to a drug overdose. This represented a rate of approximately three times that in 1991. Since 1999, prescription drugs have shown a greater increase in deaths than illicit drugs such as heroin and cocaine.

Between 2004 and 2008, ED visits in the US, related to the abuse of prescribed opioids, increased by 111% with a concurrent rise (89%) in benzodiazepine visits.² In 2009, 1.2 million ED visits, representing a 98.4% increase since 2004, were the result of an abuse or misuse of prescription drugs.

The term "misuse" is identified with a patient who is taking a prescription medication for a purpose other than that for which it was originally intended. This would also include the individual taking a prescription drug not prescribed to them personally. Misuse can also be characterized as utilizing a drug at a dose and / or manner not prescribed in order for example, to receive an amplified effect. The term "abuse" would refer to an individual taking the drug for the sole purpose of the psychological effect or "high" which they might receive after ingestion.

Among the most noted of prescription drugs involved were opioid analgesics such as oxycodone (Oxycontin), hydrocodone with acetaminophen (Vicodin), hydromorphone (Dilaudid), oxycodone with acetaminophen (Percocet), methadone, and fentanyl (Duragesic).

On July 1, 2011 Florida State Surgeon General Frank Farmer, MD declared Florida to be in a public health emergency. Dr. Farmer stated an average of seven deaths occurred daily in Florida due to prescription drug overdose specifically prescription opioids and other controlled substances.²⁵ In November 2011, a press release was issued by the director of the CDC, Dr.

Thomas Frieden, stating "Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined."²⁶

The Impact of Regulatory Actions

Joint Commission. The Joint Commission on the Accreditation of Healthcare Organizations (Joint Commission, formerly referred to as JCAHO) was founded in 1951 by a number of professional organizations including the American Hospital Association, American Medical Association, American College of Physicians and the American College of Surgeons.²⁷ Their mission is to improve healthcare for the public through accreditation and monitoring of US hospitals. The organization awards accreditation to hospitals based upon safety and quality assurance recommendations and demonstrated adherence to these standards. Accreditation is voluntary, however, accreditation is of paramount importance to any hospital that receives reimbursement from Medicare and Medicaid programs, the organization must meet the standards established by the Joint Commission.

On January 1, 2001, the Joint Commission, formally included pain management standards into their accreditation guidelines²⁸ and initiated a campaign, "Pain: The Fifth Vital Sign", into their hospital inspections.²⁹ A review of responses suggest that when this occurred, namely management of pain would now be considered as a metric which could affect accreditation scores and ultimately reimbursement, physicians have become "more liberal" in their opioid prescription practices and thereby increasing the potential prevalence of addiction.³⁰

Litigation and Case Law. Subsequent to what is now perceived as an epidemic with regard to prescription opioid abuse, a number of legal challenges have occurred with respect to what is perceived as the over- and under treatment of pain by physicians.

In 2001, what was considered to be a landmark case was heard in the Superior Court of California. In *Bergman v. Chin*³¹, the presiding judge found Dr. Chin guilty of "elder abuse and reckless negligence" citing inadequate pain management. What was significant was the fact that the Medical Board of California had already reviewed the case but stated that, although their consultant agreed that pain management provided by Dr. Chin was inadequate, they did not find sufficient evidence to warrant a disciplinary action. The jury found in favor of the plaintiff's family and awarded them \$1.5 million in damages which was subsequently reduced to \$375,000 but the case drew national attention as a first of its kind.

Civil litigation cases have been documented for both over- and under-prescribing. The literature reveals both peer-reviewed articles, and physician websites including social media "blogs", which are robust with physician concerns of potential litigation for prescribing, or failing to prescribe adequate analgesia. The following is a patient quote derived from the literature: "I know I'm addicted to (opioids), and it's the doctors' fault because they prescribed them. But I'll sue them if they leave me in pain."³²

In December of 2007, *Coombes v Florio* was decided by the Massachusetts Supreme Judicial court. The decision "significantly expanded" the scope of what was traditionally expected by physicians with regard to the duty toward their patients. The Massachusetts Supreme Judicial Court allowed one of the state's lower courts to preside over a case involving a motor vehicle accident in which a child was injured and subsequently died. The driver was found to be under the care of a physician and had been prescribed medications for a multiple of medical etiologies. It was determined that the driver had lost consciousness behind the wheel subsequently resulting in the accident. The victim's family pursued litigation against the physician overseeing care of the driver citing that the driver had not been given adequate

education regarding the potential dangers of driving while under the influence of the stated medications.³³ The drugs included two drugs with potential central nervous system depression specifically Oxycodone and Paxil. In *Coombes v. Florio*, 450 Mass. 182 (2007), the Court, though divided, maintained that it is the ultimate duty of the physician to provide adequate education on the risks of pertinent medication both for the sake of the patient and those foreseeably at risk by actions of the patient.

A review of LexisNexis revealed no specific cases or case law that has been established subsequent to an ED physician being named in litigation for over- or under-prescribing practices. Attempts were also made by reviewing the Federation of Boards of Medicine's website to determine if any ED physicians had been reviewed by the various Boards for improper prescribing but no evidence was found.

Any potential disciplinary action by the BOM could have a negative financial impact on ED physicians both personally and professionally³⁴ and therefore have a possible impact on prescribing practices.

Boards of Medicine. The Board of Medicine (BOM) plays a significant role for all physicians in that their position is to educate, license, monitor, rehabilitate and discipline physicians within their jurisdiction. Therefore ED physicians must consider their actions in the treatment of patients as complaints are a realistic possibility. A literature search, query of LexisNexis and internet searches have failed to reveal any specific actions taken against ED physicians with regard to over / under prescribing of opioids. However, the literature did reveal a rising number of non-ED physician cases being presented to state Boards with complaints of inadequate treatment of pain as the basis.

Emergency department physicians should be aware of specific Board requirements within their states of practice. The California Medical Board, for example, had to review current laws on prescribing to patients with known addictions, which may be discovered by utilizing the state's PDMP, for the protection of physicians.³⁵ Under section 2241 of the California Business and Professions Code and section 11156 of the California Health and Safety Code, it was deemed as unprofessional for physicians to prescribe to an "addict." Due to changes in standard of care, prescribers are now offered provisions which would allow exclusion to that rule.

The Federation of State Boards of Medicine (FSBOM) cites insufficient training of physicians in the current guidelines for appropriate pain management, including knowledge of medical standards and clinical guidelines drawn from evidence based research, as contributing to the prevalence of under treatment of pain. This would be a legitimate concern as research supports an inadequate amount of training, if any, being provided as part of medical school curricula or in post-graduate training.^{36,37}

The FSBOM also recognizes that physicians are concerned that prescribing of opioids, and other controlled substances, could bring about scrutiny by regulatory agencies such as the Drug Enforcement Agency (DEA), local Department of Health (DOH) and law enforcement agencies. Other factors include a lack of knowledge regarding drug dependency and addiction syndromes, as well as regulatory policies as they pertain to the physician's specific state.³⁸

To assist physicians in their prescribing practices and address some of the aforementioned concerns, the FSBOM developed the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain.* This publication was formally adopted in April of 1998 and subsequently distributed to not only the individual state medical boards, but also to other medical professional organizations and regulator boards, both federal and state regulatory

agencies, pharmaceutical houses, various advocacy groups, physicians and allied health providers. Though not written for ED physicians specifically, this model represents a standardization that could supplant an ED physician's knowledge as well.

Emergency Medical Treatment & Labor Act (EMTALA). ED physicians are greatly impacted by EMTALA with regard to patients seeking medical care and demonstrating drug seeking behavior. Unlike their private practice counterparts, ED physicians cannot elect, or reject, patients to be seen as part of their practice. As part of the Consolidated Omnibus Reconciliation Act (COBRA), Congress passed the Emergency Medical Treatment and Active Labor Act (EMTALA) in 1986. The law was originated to insure access to emergency medical treatment and prevent uninsured patients from being transferred from private to public facilities due to their inability to afford care. "Patient dumping" was conducted without consideration of the patient's condition or stability to tolerate the transfer. It is considered to be one of the country's most comprehensive laws for assuring nondiscriminatory access to emergency departments. Enforcement of EMTALA regulations is overseen by the Centers for Medicare and Medicaid Services (CMS). Even though its initial language focused primarily on emergency medicine, EMTALA applies to patient care throughout the hospital and its departments.³⁹

There are three distinct legal duties imposed by EMTALA yet they only apply to facilities participating in Medicare. However, that encompasses approximately 98% of all US hospitals therefore this law has significant impact. The first law mandates that hospitals perform a medical screening examination on all patients presenting to the ED and requesting care to determine if an emergency medical condition is present. Second, if a condition is present, the ED staff must either stabilize the condition or, if not possible, must transfer to a facility with

appropriate capabilities to manage the patient's condition. Third, hospitals known for specialized care capabilities are required to accept transfers in need of those services.

Unlike their private practice counterparts, ED physicians cannot elect, or reject, patients to be seen as part of their practice including those exhibiting drug seeking behavior. One of the strategies being used by ED's to help deter prescription opioid abuse is the posting of signs advising patients of limitations on the prescribing of controlled substances including opioids. For example, signs are posted in the Denver Health ED advising patients that the hospital will no longer fill prescriptions for long acting opioid prescriptions and will limit prescriptions for short term courses of opioids as well.⁴⁰

However, when the South Carolina Medical Association attempted to utilize this strategy, they received a correspondence from a representative of CMS advising that this could be construed as a violation of EMTALA. The following is an excerpt from this communication to the South Carolina Medical Association. The pdf file of this correspondence is posted on the Emergency Physicians Monthly, open source website:

Accordingly, the language regarding 'Prescribing Pain Medication in the Emergency Department' which you have provided, and any similar language which the hospital might choose to post in patient waiting rooms or treatment rooms might be considered to be coercive or intimidating to patients who present to the ED with painful medical conditions, thereby violating both the language and the intent of the EMTALA statute and regulations.⁴¹

This type of regulatory communication would be of direct concern to ED physicians and their respective hospitals. As mentioned, CMS oversees the enforcement of EMTALA legislation therefore any hospital accepting Medicare patients would be adversely affected if CMS deemed

that a violation of EMTALA had occurred through the posting of these types of communiques in the ED.

Controlled Substance Prescribing Guidelines and Protocols. On a federal level, concerns regarding lack of clear ED management guidelines were addressed in the White House paper. The Office of National Drug Control Policy (ONDCP) stated it will coordinate with the American College of Emergency Physicians (ACEP) in order to "develop evidence-based clinical guidelines that establish best practices for opioid prescribing in the Emergency Department."⁴²

The Food and Drug Administration (FDA) initiated a strategic initiative known as Risk Evaluation and Mitigation Strategy (REMS) in April of 2011. REMS is being used as a means of educating physicians on the risks versus benefits associated with drug products. The FDA required REMS to be provided for those prescribing extended-release and long-acting (ER/LA) opioid analgesics.⁴³

On a state level, ED physicians must be aware of specific guidelines and requirements regarding the prescribing of opioids and controlled substances. Above what is required to obtain the DEA license, some states are now requiring CME on prescription opioid abuse, registration with the state's PDMP and / or querying the PDMP prior to the prescribing of opioids or other controlled substances.⁴⁴ As an example, in 2001, the Medical Board of California began requiring physicians to participate in a one-day pain management course.⁴⁵

State guidelines, such as those originated in Washington⁴⁶, address significant topics of importance to ED practitioners treating the patient exhibiting drug seeking behavior. The Washington guidelines reiterate the impact that ED's have with regard to opioid prescribing. As cited in their guidelines: "The emergency department (ED) is the largest ambulatory source for

opioid analgesics with 39% of all opioids prescribed, administered, or continued coming from emergency departments."⁴⁷ First, it is reiterated that the guidelines were originated to assist ED physicians in their opioid prescribing practices. The guidelines also emphasize that "preserving the vital role of the ED" is of paramount importance in treating patients needing emergency medical care. Some of the specific points within their guidelines include:

- 1. The ED is not the appropriate site to manage chronic pain. Their guidelines cite repetitive treatment as being "counter-therapeutic" to the patient receiving the most advantageous care. Further stated was the need for pain therapy only in the acute exacerbation of pain with objective findings.
- 2. The use of intravenous and intramuscular opioids in the ED is discouraged. Parenteral opioids only afford short term duration and provide a potential for euphoria. Oral opioids have a more gradual release and therefore longer cessation of pain. Oral opioids would have a more gradual release and therefore longer cessation of pain.
- 3. Lost or stolen prescriptions will not be filled due to the association with opioid abuse and misuse. Additionally, this could violate a contract with the patient's pain management specialist.
- 4. Opioids will not be administered as a means of replacing methadone doses. Due to the long half-life, methadone patients are not at risk for developing withdrawal.
- 5. As oxycodone and methadone are prevalent in unintentional drug overdoses, they will not be prescribed from the ED. Long acting opioids require monitoring that is unavailable in the ED therefore will not be given.
- 6. Physicians within the ED were encouraged to utilize an internal monitoring program with which they could share information regarding the patient and their history. The point

was stressed that sharing of information between medical providers who have both administered care for the patient is not a violation of the Health Insurance Portability and Accountability Act (HIPAA).

- 7. A working relationship should be established with local pain management physicians specifically in the forwarding of patient "pain" agreements. Having a copy of this directive will assist ED physicians with decisions regarding higher complexities of care.
- 8. The ED will require that the patient present a government issued, photo identification card prior to obtaining a script for any opioid. The stipulation to present the ID will also be printed on the actual computer generated prescription thereby requiring the patient themselves to fill the prescription. Exceptions were noted within the body of the Washington guidelines.
- 9. Their guidelines encouraged taking a photograph of patients should they not be able to present a photo ID. The photo is attached to the medical record and the writers of the guidelines deemed this to be a potential abuse deterrent.
- 10. Emergency department care coordinators are assigned to assist patients in establishing a relationship with a primary care doctor thus negating the need for return visits due to chronic pain.
- Emergency department care coordinators will maintain a list of primary care clinics for distribution to patients which frequent the ED.
- 12. Use of brief screenings, brief intervention, referral and treatment is included as part of the guidelines. This strategy has shown to be effective for the Washington participants citing reductions in days of drug use from 41% 54%.
- 13. Administration of Demerol is discouraged due to the possibility of seizure activity.

- 14. Urine drug testing is encouraged but with the caveat that training in the interpretation of drug screen results is highly suggested. Drug screening is also suggested for the purpose of identifying patients using illicit drugs and / or not taking medications reportedly prescribed to them. These scenarios would be sufficient for refusal to prescribe opioids.
- 15. Prescribe a limited supply of short acting opioids. For objective findings such as what would be found in trauma patients, no more than a 30 day supply is recommended. This discourages delay in seeking appropriate evaluation and follow-up.
- 16. Screenings should take place during obtaining of history to determine present or past history of abuse. For chronic pain, non-opioid analgesics should be offered. For acute pain in the presence of abuse, opioids would be given cautiously for these patients and subsequent to counsel on deleterious effects from the opioids and addiction.
- 17. EMTALA requires a medical screening but the guidelines specify that if an emergency medical condition is not found, there is no obligation on the physician's part to treat a patient's pain in the ED.

Subsequent to the review of these guidelines, there are several points of interest that could merit further discussion. The Washington guidelines serve to meet many of the recommendations found in the literature specific to treatment of patients exhibiting drug seeking behavior by ED physicians:

- 1. Recommendations for limited supplies of short acting opioids.
- 2. Screening for abuse.
- Strategy of brief screening followed by brief intervention as recommended by ONDCP method.⁴⁸
- 4. Limiting parenteral opioid administration.

- 5. Appropriate photo identification required.
- Laboratory screening for illicit drugs and absence of prescribed drugs is encouraged as support for refusal to prescribe.
- 7. Lost / stolen prescriptions are not replaced, nor are methadone doses.
- 8. The reference to EMTALA regarding "severe pain" as not being an "emergency medical condition" could be subject to scrutiny. In reviewing the aforementioned CMS correspondence to the South Carolina Medical Association, the verbiage is stated:"(e)(1) The term "emergency medical condition" means- (A) a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) etc. (emphasis added).⁴⁹ ED physicians electing to exercise the option not to treat a patient's pain due to the lack of emergency medical condition may be influenced by Joint Commission requirements to provide adequate pain relief.

The Washington guidelines serve to remind ED physicians in other states to be aware of their state requirements for prescribing and dispensing. For example, the state of Washington does not require patients to display a photo identification for obtaining opioids but the home state of the ED physician might make this stipulation.

Emergency department physicians should be concerned regarding state laws but also municipal requirements. Physicians must be aware of various statutes such as those requiring them to register with the PDMP, receive CME on prescription opioid abuse and or perform a query of the PDMP prior to prescribing.⁴⁹

A number of states and individual facilities throughout the United States, such as the ten public hospitals in New York City, have enacted administrative opioid prescribing protocols for ED's. This action serves to deter availability of prescription opioids which may lead to potential

abuse.^{50,51} Proponents suggest that opioid prescribing protocols would serve as a protection for physicians supporting their decision to prescribe or refuse to prescribe opioids / controlled substances to patients exhibiting drug seeking behavior. Opponents such as Dr. Alex Rosenau, president of the American College of Emergency Physicians (ACEP), have concerns of "legislative" medicine and its potential to hinder the professional judgment of ED physicians.⁵² Dr. Rosenau cited data which stated that ED physicians, "write fewer than 5% of immediate-release opioids prescriptions and an even smaller proportion of extended or long acting opioid prescriptions. Yet, guidelines for emergency physicians have garnered the most attention." ⁵³ In reviewing the data source however, this statistic was gained from a source utilizing a projected study which was based on insurance claims. A common characteristic of patients exhibiting drug seeking behavior is that their method of payment is often cash or through a government assistance program such as Medicare or Medicaid therefore the statistic cited may be questionable and need further verification.

This is supported by Paulozzi et al who stated that it can be difficult to obtain data regarding the extent to which prescriptions are originating from ED's. However, in 2009, ED physicians placed third in opioid prescriptions for two age groups and fourth in a separate age group. It was estimated in their study that 12% of the total prescriptions written for those age groups were initiated by ED physicians.⁵⁴

Legislation for Deterrence of Prescription Opioid Abuse. In June of 2011, the state of Florida enacted legislation known as the "Anti-Pill Mill" bill (HB 7095). This legislation provides a comprehensive strategy to deter the prescription opioid abuse epidemic through enhanced administrative penalties and criminal laws targeting physicians and pain clinics engaging in trafficking of prescription opioids. The bill also establishes prescribing guidelines,

invokes pain management physician registration with the DOH and prohibits dispensing of controlled substances. The bill also addresses oversight of distribution points and lessens the time allowed to enter data into the PDMP. ⁵⁵ As the amount of available opioids are diminished by the closure of local "pill mills", ED physicians must be prepared for increased volumes of patients exhibiting drug seeking behavior . Also, law enforcement agencies are reporting rises in heroin abuse subsequent to steps taken to reduce the number of pill mills and overprescribing practitioners. ⁵⁶

The Changing Economic and Healthcare Climates

Paradigm Shift to Patient Satisfaction Based Reimbursement. In 2002, CMS partnered with the Agency for Healthcare Research and Quality (AHRQ) to develop a patient survey to address specific areas of quality improvement.⁵⁷ The survey is referred to as Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) and, in May 2005, the survey received an endorsement from the National Quality Forum (NQF), which represents a large number of health related providers and service organizations. The survey was formally approved in December 2005 and implemented in October 2006.

The Deficit Reduction Act of 2005 created additional incentives to implement HCAHPS as, commencing in July 2007, hospitals receiving funds as part of the Inpatient Prospective Payment System (IPPS) must provide HCAHPS data to receive payment and avoid penalties. Per the Patient Protection and Affordable Care Act of 2010, the provision of HCAHPS data is a parameter utilized to calculate incentive payments as part of the Hospital Value-Based Purchasing program. As an example, CMS can withhold 30% of the hospital's incentive monies should patient scores be unsatisfactory."⁵⁸ In October 2012, CMS was to begin reducing the "base operating diagnosis-related group" (DRG) payments to hospitals, by 1%. The monies represented by this percentage were to be used to create what is estimated as an \$850 million incentive fund. ⁵⁹ Monies would be distributed based upon performance of certain quality measures such as patient responses to the HCAHPS survey. The amount actually distributed to the hospitals varies and is based on performance measures. Amounts are expected to increase and the possibility exists that other reimbursing agencies from the private sector will likely follow suit. Value-based purchasing is a requirement of the new Patient Protection and Affordable Care Act which was part of the healthcare reform legislation in 2010.

A number of vendors are authorized to distribute the HCAHPS survey including Press Ganey Associates. Up until the development of the HCAHPS survey, Press Ganey had been conducting patient satisfaction surveys for approximately 40% of the hospitals in the US. Though utilizing its own patient satisfaction based instrument in the past, it will now be serving as a vendor for the HCAHPS survey.

The purpose of the HCAHPS survey is to allow patients to rate their inpatient experience and perceived level of care. As HCAHPS will be the instrument of choice by CMS, all results will be located on a public domain and visible by internet at www.hospitalcompare.hhs.gov. Data from the site can be used for a number of quality improvement activities including evaluation of hospitals, enhancement of patient decision making, and to serve as an incentive for hospitals to deliver what patients report as high quality care.⁶⁰

The appropriateness of patient surveys as a means of assessing the quality of medical care offered by a physician is a highly controversial topic. The following are excerpts taken from the literature and physician based websites regarding this subject:

- "Doctors who refuse to prescribe opioids to certain patients out of concern about abuse are likely to get a poor rating from those patients."³²
- 2. "By creating a monetary incentive to increase patient satisfaction, the government is not only increasing its expenses but promoting a metric that significantly increases death rates," says William P. Sullivan, an emergency room doctor in Spring Valley, Ill.61
- 3. "Ask most emergency physicians and they will tell you that satisfaction surveys pressure physicians to overprescribe multiple medications, including antibiotics and opiates."⁶²
- 4. "These drugs are highly addictive, even in short-term use. These drugs have been associated with death, even in therapeutic dosing. These drugs, when accidentally ingested by children, are fatal. As doctors, we must stop fearing patient-satisfaction surveys and talk honestly to our patients about pain. It may take an extra few minutes, but it will save lives." ⁶³
- 5. "Some doctors say the many pressures they face create other incentives to quickly prescribe remedies for patients complaining of severe pain. For example, doctors are often rated by their hospitals with patient-satisfaction surveys for how they treat pain. "You can be faulted for not treating a patient's pain it's considered the 'fifth vital sign.⁶⁴

As noted by ED physicians, there are strong concerns regarding the inclusion of patient satisfaction scores as part of the reimbursement processes. Concerns have been expressed in the past regarding the accuracy of survey instruments such as those utilized by Press Ganey. The following is an excerpt from an article that ran in Forbes magazine in January 2013. The article was an investigative piece on the value of patient satisfaction scores and physician response. According to the article, these are the words of an ED doctor:

The doctor there responded by administering Dilaudid, a powerful intramuscular narcotic typically reserved for cancer-related pain. Why, his nurse queried, was he killing a flea with a sledgehammer? Afraid of malpractice? No, the doc replied, Press Ganey. 'My scores last month were low.⁶¹

According to Dr. Brenda Sirovich,

Our health care system already suffers from a 'more is always better' fallacy. Practicing physicians have learned–from reimbursement systems, the medical liability environment and clinical performance scorekeepers–that they will be rewarded for excess and penalized if they risk not doing enough. An overreliance on patient surveys, she says, only inflames the problem of overtreatment. ⁶¹

CMS has engaged researchers to identifying any potential bias in the HCAHPS survey and is reportedly considering the use of conversion factors to normalize the data where biases have been identified.

Emergency department physicians question the validity of utilizing patient satisfaction scores as a means of for evaluating medical care and ultimately administrative decisions. The bias aside, the question arising in the literature is whether they should be utilized as a metric for the quality of care delivered. Among the concerns are whether patients have the capacity and knowledge base to best evaluate their actual level of delivered medical care. Also, should a patient make a recommendation that is based on a medical procedure, could the hospital ethically or administratively be in a position to make changes based upon patient recommendations. In addition to the concerns regarding bias, does the survey instrument allow for variables with the capability of skewing the data. Also, ED physicians treat patients with substance abuse issues

who would not be satisfied should the ED physician refuse to prescribe a drug of potential abuse such as an opioid. There are other considerations such as patients with mental illness or without the physical capabilities to respond to the surveys. ⁶⁵

According to Dr. Joshua Fenton, higher patient satisfaction scores are associated with increased mortality, higher inpatient use, as well as increased healthcare and prescription drug expenditures.⁶⁶

Customer satisfaction is not a new concept. Corporate and service based industries rely on client satisfaction surveys however, consumers for those industries are in a better position to judge the quality of their experience. Emergency Physician Monthly posted survey results which revealed that 16% of their respondents stated that low satisfaction scores had threatened their employment. Twenty seven percent cited that their income was linked to patient satisfaction scores.⁶⁷

Recent research has determined inaccuracies in the methodology utilized by Press Ganey's measurement and reporting. Sullivan and DeLucia report that the firm uses comparative data based upon small sample sizes thereby creating a large margin of error. They also found that the firm often provides comparative data about hospital departments and individual physicians based on a smaller sample size that may create an unacceptably large margin of error. ⁶⁷ A possible bias can also be identified with ED patients and their wait times. Scores might be much lower for that population as opposed to the ED patient that's admitted, who received the highest level of care, but does not receive the survey.

Another metric now considered by CMS is that of "door to discharge" times.^{68,69} Emergency department volumes continue to rise and overcrowding has been the topic of numerous studies and litigation. Emergency department physicians must be attentive to this

aspect of care due to potential loss of reimbursement but also due to the potential revenue lost from patients leaving prior to being seen.^{70,71}

Electronic Medical Records. A federal investment of \$30 billion was established for the purpose of moving hospitals toward implementation of electronic medical records (EMR). The use of EMR is now a federal mandate but exacts a toll on ED physicians with regard to time spent with patients. According to a report published in May 2013, ED physicians spend less time with patients than they do entering data into the EMR. The report cited inefficiency in data entry processes and noted that improvement would permit greater time with patient, improve efficiency and increase hospital revenue.^{72,73}

Economic Impact from Oxycodone. Of the prescription opioids most commonly abused and drawing the most attention by ED physicians was the drug OxyContin. The following highlights a number of the economic and clinical factors impacting ED physicians:⁷⁴

- The drug was approved by the FDA in 1995 which coincided with the APS initiative of the "fifth vital sign."
- 2. The active ingredient in OxyContin tablets is oxycodone which is also mixed with acetaminophen and sold as Percocet. These are among the most commonly reported drugs of abuse seen in the ED.
- 3. Although the label warns users against this practice, ED's manage patients who have insufflated the drug.
- 4. OxyContin sales escalated rapid in 1996. In 2001 and 2002, sales exceed \$1 billion.
- 5. Reports of abuse and diversion began in 2000 appearing first in rural areas.
- 6. One report noted ED visits rising as early as 1999.

Impact of the "Great Recession" on ED Patient Volume. Ongoing changes in both healthcare and economic climates, have contributed to a significant increase in ED patient visits including those exhibiting drug seeking behavior. ¹ The impact of a recession is most often felt by disadvantaged groups such as those with lower incomes. An additional sequelae from recessional times is the risk of increased mental health issues. The World Health Organization stresses that "social capital and welfare protection" are critical to healthy lifestyles. Therefore the financial stress to those already unemployed, with higher debt, poorly educated and in poverty will be at risk for increased needs to seek out medical care.⁷⁵

In 2010, the Journal of the American Medical Association (JAMA) released a report, based on ED visit rates from 1997 – 2007, which revealed an increase being twice that of the US population growth rate.⁷⁶ Patients receiving Medicaid represented a higher percentage of that increase. A possible explanation would be that patients on Medicaid are experiencing greater difficulties in establishing a relationship with a primary care physician.^{77,78}

Subsequent to the JAMA study, ACEP conducted a survey among their ED physicians regarding their perspectives on increased ED volumes and the results were released in April 2011. The report indicated that > 80% of responding ED physicians noted that patient volumes were increasing and of those, > 90% felt increases should continue to be expected.⁷⁹ In 2009, ED visits increased to 136 million, from 124 million in 2008, representing an approximate 10% increase which is the greatest single year increase on record.

The "Great Recession" of 2008 coincided with the time of these studies and, though affecting healthcare costs, one of the most serious sequelae was the loss of employment ultimately leading to a loss in employer paid private insurance. Of the 136 million ED visits in

2009, the number of uninsured patients had risen from 15.4% to 19% and the percentage of privately insured patients had dropped from 41.9% to 39%.¹

With state budgets having to overcome a \$160 billion deficit, and federal government stimulus funds will only offset \$60 billion this year, growing pressures are being exerted to reduce funding for Medicaid.⁸⁰

Due to Medicaid's poor reimbursement, private physicians may limit the number of Medicaid patients in their practice or refuse to participate as a provider altogether.⁸¹ This excerpt from a pain management physician's internet site:

And I don't accept Medicaid or Medicare as payment for treatment. I feel guilty for admitting that, but I don't think I could stay in practice if I accepted what these government programs pay for treatment. When I first opened my own office in 2010, I saw a handful of these patients for free, since trying to file and going through the necessary red tape isn't worth the pittance these programs pay for an office visit.⁸²

This serves to increase the overall Medicaid patient volume in the ED but also may be a factor in the increased volume of these patients who are exhibiting drug seeking behavior. According to the CDC, Medicaid recipients are prescribed opioids at twice the rate of non-Medicaid recipients⁸³ and are six times more like to overdose on these analgesics. A study conducted in Washington State study reported that 45% of the fatalities from prescription opioid overdose were Medicaid recipients.^{84,85}

The sequelae of increased ED patient volumes, is decreased resources to the patient specifically time spent with the ED physician.¹ Dr. Anna Lembke, a psychiatrist from Stanford University writes,

Time spent with each individual patient is medicine's least valued commodity from a financial reimbursement perspective. That's especially true in emergency department settings, where physicians are often evaluated on the numbers of patients seen, rather than the amount of time they spend with each one... Currently, it is faster and pays better to diagnose pain and prescribe an opioid than to diagnose and treat addiction. Busy emergency physicians who would like to refer patients with addiction for appropriate treatment have few resources to call on.³²

Reduction of Resources. According to a 2010 report, the number of ED's in the United States has decreased to 3925 in 2007 from 4114 in 1997. Due to EMTALA, ED physicians work under a federal mandate to provide care for all individuals seeking emergency medical care, regardless of their financial status. However, the result is the ED physicians represent the least compensated of all disciplines with approximately half of the services provided not receiving proper compensation.⁸⁶ According to CMS, less than 3% of the \$2.1 trillion spent on healthcare will go to emergency medicine providers caring for 120 million annually. Decreased reimbursement and growing lack of compensation are resulting in the closures of emergency departments nationwide ultimately threatening public health as a whole.

The ACEP released a report in 2011 regarding a survey conducted among their members. Approximately half of those responding stated that the fear of litigation was considered to be the largest obstacle to decreasing ED costs. Dr. Sandra Schneider, president of ACEP at the time of the survey, was quoted as saying:

Emergency medicine provides lifesaving and critical care to millions of patients each year and yet only represents 2 percent of the nation's health care expenditures.

Emergency departments need more resources, not fewer, and medical liability reform would help reduce overall costs by reducing the need for defensive medicine. ⁸⁶

Hospital Administration. Emergency department physicians have an ethical obligation to advocate for the safety and overall health of their patients yet may feel pressure from hospital administrations with regard to daily practices including the prescribing of opioids. ^{5,32} The role of ED physicians is unique in that unlike the private practitioner, who may elect the patients to be seen in their practice, they serve under a federal mandate to provide services to all patients. The ED patient population is often among the most "vulnerable", may be physically and/or mentally disabled, may be uninsured, and may present as suffering from a catastrophic illness or trauma related injury. The need to advocate for the best interest of the patient may place the ED physician in a precarious position with hospital administrative staff. ⁸⁷

Emergency department physicians should have the privilege of due process rights if they are going to be in a position to advocate for their patients. Due process should insure ED physicians that they will not lose staff privileges without the benefit of a fair hearing.⁸⁸

A 1998 survey of ED physicians revealed that many of the respondents had been threatened by hospital administrations subsequent to questioning staff regarding quality assurance concerns and / or financial issues.⁸⁹ The timing of the survey coincided with the initiation of pain as the "fifth vital sign" and the beginning of significant rises in ED patient volumes.⁷⁶

Depending on the hospital, admissions may generate more revenue than the ED visit in and by itself thereby potentially placing on the ED physician to acquiesce the administration's desire for greater admissions. According to an article in the New York Times,

two ED physicians, employed by an ED management group, were interviewed and related that "hospital administrators created targets for how many patients they should admit."⁹⁰ The rationale was that more admissions generated greater revenue for the hospital.⁹¹ One of the ED physicians related receiving telephone calls questioning why he had not admitted an elderly patient when the hospitalization could easily have been explained. "The pressure to admit was so high" and subsequently the ED physician left the hospital. A second ED physician approached administration with concerns that the nurse to patient ratios were too high and causing an unsafe environment. In this case, an executive from the ED management group warned him to "back off." He was later fired, along with his wife who worked at the same hospital. Both the physician and his wife are pursuing a legal course of action.

A great number of ED physicians are employed by management groups rather than being individually paid by the hospital itself. These groups, referred to as a contract management groups (CMG) are primarily for-profit corporations which may relate in additional stress being perceived by the ED physicians with regard to finances and generation of revenue. CMG's often report to shareholders as opposed to the ED physician whose obligation is to the patient.

A nationwide survey completed in 2012⁸⁸ questioned ED physicians regarding their concerns regarding this topic. As indicated in the 1998 survey, due process and the ability to voice concerns without fear of repercussion were still of concern to the ED physician. Additional concerns were that of charging issues such as admissions and utilization of specific tests. Although still perceived as a pressure to admit, there were also opinions offered to the opposite specifically a pressure to discharge. With recent healthcare changes, a readmission within 30 days can be viewed as a quality measure violation and therefore denial of

reimbursement. Specific references were made as to pressures of admission or discharge when dealing with Medicaid patients.

CMG's rely on establishing and maintaining a good rapport with hospital administration in order to insure continuance of contracts.⁹² Less than half of the ED physicians reported that they would feel comfortable approaching administration with concerns.

Management of Patients Exhibiting Drug Seeking Behavior

Training in Management of Prescription Opioid Abuse. When reviewing the public health response to past epidemics, training and education has been viewed as an integral component to deterrence. As an example, in response to the Human Immunodeficiency Virus (HIV) epidemic, the Florida Omnibus Acquired Immunodeficiency Syndrome (AIDS) Act of 1988 was passed and includes the requirement that all healthcare professionals enroll in an HIV education course.⁹³ This education includes the identification of "high risk" populations, patient signs and symptoms associated with the virus, identification methodologies, including the use of previous medical records, and appropriateness of pharmacologic therapy and referral.

Though prescription opioid abuse has been declared an "epidemic", surveys of health care professionals and medical schools reveal significant gaps in education and training on pain management, substance abuse, and safe prescribing practices.⁹⁴ According to the 2013 White House Policy on Drug Control, healthcare prescribers and dispensers receive "little training" on the recognition and appropriate prescribing of opioids.⁹⁵ A 2000 survey of medical school residency programs revealed that only 56% required education in substance abuse disorders.⁹⁶ In 2008, follow up surveys showed "some progress" in the medical school, residency and post-residency education but no standardization has taken place among these areas.⁹⁷

In an article reported by Time Magazine, two ED physicians spoke on the topic of prescription opioid abuse as it relates to emergency medicine. The following describes their training with regard to prescribing of opioids:

Next, medical students and trainees were instructed that patients could never become dependent on narcotics if prescribed for legitimate pain. (We both remember being taught this myth.) Last, opioid pain medications like oxycodone (the active ingredient in Percocet) and hydrocodone (the active ingredient in Vicodin and Lortabs) were framed as safer alternatives to nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen, naproxen and Vioxx that could trigger peptic ulcers or cardiac conditions.⁹⁸

Inherently, all opioids have the potential for abuse and gaps in education, such as listed above, may facilitate improper prescribing of opioids and potential for abuse. In the 2011 White House Policy, issued by the ONDCP, titled "Epidemic: Responding To America's Prescription Drug Abuse Crisis",⁹⁹ the following recommendations have been made with regard to future education on prescription opioid abuse:

- Amend a Federal law which would require practitioners with DEA licenses to receive CME on "responsible opioid prescribing practices." Included in the training would be special topics on assessment and addressing the signs of prescription opioid abuse.
- 2. Drug manufacturers would be required to participate in REMS training which provides education initiatives for training prescribers on appropriate use of opioid analgesics.
- 3. Federal agencies will provide CME for their prescribers and allied healthcare providers.
- 4. Establish working relationships with medical schools and other healthcare schools to develop curricula and CME that would include instruction on recognition and management of patients exhibiting drug seeking behavior. In addition, these educational

entities could be used for community education and dissemination of educational materials.

Identification of Prescription Opioid Abuse. Several tools are available to ED physicians for the identification of prescription opioid abuse including drug testing, PDMP's and targeted history screening.^{100,101,102} The Current Opioid Misuse Measure (COMM) was initiated to assist clinicians in identifying potential prescription opioid abuse. The COMM utilizes self-reporting of present risk for "aberrant medication-related behavior" among patients being treated for chronic pain. The COMM varies from other tools in that it was not designed to identify the specific characteristics that many recognize as possibly leading to abuse but rather assists in the identification of patients who may be currently misusing opioids.

The two most common used media by ED physicians for performing drug screening are urine or blood. These tests are relatively inexpensive however the traditional Substance Abuse and Mental Health Services Administration (SAMHSA)¹⁰³ test, which includes screening for marijuana, cocaine, amphetamines, PCP and opiates, may not include synthetic opioids. Pilot studies indicated that a significant percentage of the ED physicians' hospitals did not screen for the synthetic opioids thereby requiring the samples to be sent to the hospital laboratory or an outside facility. The latter option is not practical logistically unless the patient was being admitted. The former option was perceived by ED physicians as possible but did contribute to time delays and increased cost to the patient.

In the 2011 Prescription Drug Abuse Prevention Plan, the use of PDMP's was recommended ¹⁰⁴ by the Office of National Drug Control Policy (ONDCP).¹⁰⁵ PDMP's are "substantially underutilized" in our efforts to reduce the prescription opioid abuse epidemic.¹⁰⁶ Key factors for failure to use this resource include non-standardization of information collected

by individual state PDMPs, concerns regarding safety of data storage and accessibility, the methodology for examining the data, variance in reports generated and a lack of consistency with regard to the availability of the data.

Emergency department physicians have cited that failure to utilize prescription opioid abuse identification tools such as laboratory drug screening and PDMP database queries is often attributed to economic factors and possible civil liability.^{107,108} Budgetary limitations, staff allocation and increased patient volumes decrease the time available for ED physicians to query the PDMP or await backlogged laboratory results. Any factors that would increase "door to discharge" time serve to decrease patient satisfaction thereby initiating a potential conflict with administration due to possible reimbursement ramifications. The ED physician must weigh these factors against the benefit of "establishing patterns of abuse" and whether treatment would be altered in any way based upon this information.

The fear of litigation is a concern as legal cases are well documented for instances where physicians failed to prescribe adequate pain medication¹⁰⁹ as well as prescribing without counsel on adverse effects.³³

Reasons cited in the pilot studies by this researcher include simple lack of knowledge as to how to access the database and administrative details viewed as cumbersome (e.g. frequent switching of passwords, mandatory tutorial).

Opioid Prescribing Practices. "Emergency department physicians have access to a number of sources who have published, or made public, evidence-based recommendations with regard to responsible opioid prescribing practices.^{5,46} The ONDCP as well as numerous states have published recommendations for opioid prescribing to chronic and acute pain patients. A duty to act is emphasized in the ethical treatment of pain while respecting the potential that

opioid analgesics possess with regard to possible dependency and addiction issues.¹⁶ When matched with identification tools such as utilization of PDMP's and laboratory testing, in addition to administrative protocols for management and referral, prescribing practices served as the foundation for prescription opioid protocols. The consensus among sources focused on the following:

- 1. Consideration of short-acting, as opposed to long-acting opioid analgesics for treatment of pain.
- 2. Consider lowered doses depending upon body weight and other clinical indicators.
- 3. Limit the supply. Some prescribing guidelines adhere to no more than 72 hours.
- 4. Screen for possible abuse utilizing EMR and targeted histories.
- 5. Query the state PMDP.
- 6. Utilize non-opioid and / or non-pharmacologic therapies.
- Avoid prescribing opioid to patients already prescribed long acting opioids and / benzodiazepines to prevent potential drug interaction and CNS depression.
- 8. Verify with treating physician the validity of claims that prescription is lost / stolen. If replacement is deemed warranted, a limited supply is advisable.
- 9. Provide information regarding the risk of impairment, overdose and potential long term effects of dependency and addiction.

Physicians stress taking the time to discuss the medications with the patient. Two excerpts from the literature are listed below:

1. "Time spent with each individual patient is medicine's least valued commodity from a financial reimbursement perspective. That's especially true in emergency department settings, where physicians are often evaluated on the numbers of patients seen, rather

than the amount of time they spend with each one... Currently, it is faster and pays better to diagnose pain and prescribe an opioid than to diagnose and treat addiction. Busy emergency physicians who would like to refer patients with addiction for appropriate treatment have few resources to call on.³²

2. "These drugs are highly addictive, even in short-term use. These drugs have been associated with death, even in therapeutic dosing. These drugs, when accidentally ingested by children, are fatal." As doctors, we must stop fearing patient-satisfaction surveys and talk honestly to our patients about pain. It may take an extra few minutes, but it will save lives."⁹⁸

Summary

Subsequent to a literature search of peer reviewed articles, periodicals and physician based media sites, it was confirmed that a significant information gap exists with regard to the perceptions of ED physicians and the economic and regulatory factors impacting their management of patients exhibiting drug seeking behavior.

As a further result, the content of survey questions has been validated and hypotheses formed for the pursuit of future research.

CHAPTER THREE: METHODOLOGY

Design

The research design selected for this study was a descriptive, cross-sectional, epidemiological model utilizing a survey tool to assess the current opinions of ED physicians with regard to the impact of economic and regulatory factors on their management of patients who are exhibiting "drug seeking" behavior. This study design was not constructed for the purpose of determining causation but to determine trends and commonalities observed through the participant's personal experience and training.

Sample

A convenience sample of ED physicians was asked to complete the online survey instrument. A power analysis revealed the need for at least one hundred (100) ED physicians to participate. The inclusion criteria specified that participants could be any physician serving in the capacity of an ED physician within the United States. Exclusion criteria specified that participation could not occur if you were not a physician serving in the capacity of an ED physician within the United States.

Instrument

This study utilized a survey tool which was developed and used in a pilot survey (February 2012). The questions were revised and tested for content validity by a group of experts in emergency medicine and education. The survey includes a maximum number of thirty nine (39) multiple choice questions with an optional essay question at the conclusion allowing

for the physician to provide additional comments. Screening questions within the survey reinforced inclusion criteria.

To decrease study limitations, all applicable survey questions included a provision at the end of the question which provided an option for the participant to provide an opinion not included in the multiple choice options for that particular question. Provision was also made at the conclusion of the survey for participants to add comments not addressed by survey questions. The same survey questions will be utilized as the basis of focus group sessions and personal interviews for those electing to participate through this option. The survey questions have received IRB approval through the University of South Florida (IRB #9509).

Procedure

A research study invitation was distributed to various medical/professional organizations, as well as individual clinicians, utilizing both publicly obtained, and personally known, email/physical addresses. Invitations were sent based upon the inclusion criteria and responses included in this study were collected over a two-month period. Any participants electing to participate through focus groups or personal interviews were provided with the same questions as those taking the online survey and their responses were merged with those entered through the online survey tool.

Data were downloaded from the online survey tool website in an Excel spreadsheet format. No identifying information was obtained and data was maintained in password protected computers throughout the research project.

Data Analysis

The data were analyzed using SPSS analytical software. Demographics of interest included age, length of time practicing as an ED physician, board certification status, venue and

description of practice. For specified hypotheses, the sample was divided into physicians working nonprofit versus for-profit hospitals.

To evaluate trends and overall responses, descriptive statistics (e.g. averages, standard deviations, frequencies and confidence intervals) were used in conjunction with all survey questions.

To establish relationships and possible correlations of the sample and sub-samples (i.e. physicians employed by for-profit versus nonprofit organizations). Independent t-tests were utilized. A critical alpha level of .05 was used as a means to reject, or fail to reject, the specified hypotheses.

For questions using a Likert type scale, Spearmen's correlation was utilized to measure associations between the ranked variables. A range of -1 to +1 was used to determine strength of correlation and the actual value would be subjected to significance testing to determine probability of chance.

CHAPTER FOUR – RESULTS

Sample Demographics

The sample for this study is comprised of 141 currently practicing ED physicians, MD's and DO's, from 31 – 70 years of age as depicted in Figure 1: Age of Participants. There is a wide range among the participants in years of ED experience with 40% having started in 1995 or before to 9% with less than 2 years of experience (Figure 2) The majority of the participants (88%) were boarded in emergency medicine, but other boards were listed as well including internal medicine, pulmonology, family medicine and pediatrics. The participants see adult, pediatric, or a combination of these patients and are fairly well distributed between for-profit and nonprofit hospitals.

Management Practices

Training. As a means of eliciting information regarding the physicians' recognition and management of patients exhibiting drug seeking behavior, the participant were presented with two questions. The first asked them to describe characteristics of drug seeking behavior based upon their clinical experience.(Figure 3) The second asked them to specify the drugs most commonly requested by patients exhibiting drug seeking behavior (Figure 4). While nearly half (47%) of the participants have received Continuing Medical Education (CME) in the last 3 years on recognition and management of prescription opioid abuse, nearly a quarter (22%) have had no training at all on this topic (Figure 5). When asked if ED physicians "should receive some type of specialized CME to assist them with recognition and management of prescription opioid abuse", 84% of the participants responded affirmatively (Figure 6). Hypothesis five stated 'Less

than 50% of ED physicians have received formal training through either continuing medical education or medical school/post-graduate curricula, on recognition and management of prescription opioid abuse.' This hypothesis is not supported as 57.1% of the participants had received training on this topic.

Opioid Abuse Identification. The participants were asked to rate their use of opioid abuse identification methods. Five specific methods were presented to the participants: physical examination, history, use of EHR, drug screening and query of the state prescription drug monitoring program (PDMP) database. Survey questions were designed using a four column Likert type scale. Options included "always", "frequently", "occasionally", and "never." Few respondents (9%) "always" utilized drug screens as part of their identification methods for potential opioid abuse. Of the remaining participants, 22% used it frequently, 46% used it occasionally and 23% never utilized this method (Figure 7). Only 25% of the respondents cited that their ED had the ability to screen for synthetic opioids. Twenty-nine percent (29%) stated that testing for synthetic opioids required submission to the hospital laboratory and 33% reported that screening for synthetic opioids had to be sent to an outside laboratory (Figure 8).

The following correlations were observed with regard to use of opioid identification methodologies. A low, positive correlation exists between the use of drug screens with the ability to perform screens for synthetic opioids in the ED (as opposed to sending samples to the hospital or outside laboratories). (r = 0.393, P, 0.001) (Figure 9). A low, negative correlation exists between the physician's willingness to use drug screens and their knowledge of using the PDMP (r = -0.186, P=0.031). A low, positive correlation was found between the physician performing a physical exam as a means of determining opioid abuse and the physician who avoids using the PDMP for fear of decreased patient satisfaction if the PDMP shows a positive

result for doctor shopping. (r = 0.179, P=0.039). Additionally, a low, negative correlation exists between the physician performing a physical examination to detect opioid abuse and the physician's knowledge of accessing the PDMP. (r = -0.174, P=0.045).

Regarding participant utilization of the PDMP, 18% always used this method as a means of identifying potential opioid abuse, 33% used it frequently, 26% occasionally and 23% never used this method. Of those querying the PDMP, 68% reported that the database had identified patients as "doctor shopping." As a note, 23% of the participants indicated that they are not registered with the database and as such, could be among those stating they never used the PDMP for identification (Figure 10). Respondents agreed that certain factors would discourage them from using the PDMP including being "too busy" (74%), query process is too time consuming (76%), and the risk of patient satisfaction scores being negatively affected should opioids be refused due to database findings (41%). Civil liability was only a concern among (14%) of the participants. Lack of awareness on how to access the database was cited by 36% of the participants, respondents were unaware of how to access the database (Figure 11). The participants were also asked to comment on factors which might encourage them to use the PDMP. Ninety-two percent indicated that signs of drug seeking behavior would encourage use, 80% felt that a PDMP query indicating "doctor shopping" would support their refusal to prescribe opioids and the next highest response was a history of past drug abuse (72%). Additional lesser cited reasons are listed. (Figure 12).

Opioid Prescribing Practices. When asked about the participant's opioid prescribing practices, the obtaining of the patient's history, a physical examination and review of past medical records were reported as always being conducted. Only 12% of the participants always used drug screens and the PDMP respectively prior to prescribing opioids. The highest

percentage (60%) of opinions, with regard to utilizing drug screens prior to prescribing, was noted as falling under the "occasionally" column (Figure 13). This was confirmed by a standalone second survey question which asked the participants if drug screens were conducted prior to prescribing opioids. Forty-nine percent of the participants responded that they would "occasionally" conduct the drug screens prior to prescribing opioids (Figure 14).

When asked what would discourage the respondent from performing a drug screen prior to prescribing opioids, 87% cited the wait time for laboratory reports would delay discharge (Figure 15). "Door to discharge" times are strong considerations to ED physicians due to economic factors such as administrative expectations to meet higher patient volumes and reimbursement entities such as Centers for Medicare &Medicaid Services (CMS) using this as a financial metric. Additional reasons cited by the participants as discouraging use included the perception that cost outweighs benefit (77%) and that treatment is not affected by laboratory results (77%). Returning back to the data provided by the participants, which related that more than half of the drug screens would have to be submitted to either the hospital laboratory or an outside laboratory, this could influence the reluctance to utilize drug screening more frequently.

When drug screens are conducted, the participants were asked to provide their opinions as to any trends which have been observed when reviewing the laboratory results from specimens belonging to patients exhibiting drug seeking behavior. The most common finding was the presence of illicit drugs. Sixty percent of the participants found this to be frequently reported. Drugs not prescribed to the patient was noted by 53% of the respondents (Figure 16).

When asked about hospital administration's position regarding use of the PDMP prior to prescribing opioids and/or other controlled substances, 54% of the respondents indicated that their hospital administration supported use of the PDMP prior to prescribe opioids, 2% stated

that use of the PDMP was discouraged and approximately 56% of the responses reflected either a "neutral" or "unknown" position from their respective hospital administrations (Figure 17).

It was hypothesized that there would not be a significant difference between the opinions of ED physicians working in for-profit hospitals, versus nonprofit hospitals, with regard to their perceptions of economic pressures from administration to prescribe opioids. Independent t-test results demonstrated this as no p-value results of less than 0.05.

		Levene's Test fo Varianc				
		F	Sig.	t	df	Sig. (2-tailed)
Joint Commission surveys negatively affected w/regard to pain mgmt	Equal variances assumed	2.150	.145	.484	126	.630
	Equal variances not assumed			.490	124.875	.625
Have you, or one of your colleagues, been criticized by administration for refusal to prescribe opioids?	Equal variances assumed	5.224	.024	-1.198	133	.233
	Equal variances not assumed			-1.203	130.022	.231
What is your administration's position regarding your use of the Rx monitoring database (PDMP) prior to prescribing opioids / controlled substances?	Equal variances assumed	1.853	.176	1.145	129	.254
	Equal variances not assumed			1.151	122.968	.252

Regulatory and Legal Actions

Physicians were asked to respond to the following statement: "Patients in our culture view drugs as a solution therefore you risk a patient complaint if you don't provide a script on discharge." Ninety percent (90%) of the physicians agreed with the statement and 50% of those indicated that they strongly agreed (Figure 18). The participants were asked to rate the significance of their concerns should they query the PDMP and be presented with a response indicating evidence that the patient queried was "doctor shopping." Specifically this question

addresses perception of statutory, regulatory, civil and administrative guidelines as to the course of action subsequent to receiving the query response. Eighty-six percent of respondents indicated a concern that hospitals do not provide physicians with a course of action, 82% were concerned that the Board of Medicine has not provided clarity on a course of action, 73% indicated a concern that statutes were not clear as a course of action, 60% were concerned that notifying law enforcement would result in a HIPAA violation, and 41% are concerned regarding civil liability for failure to report (Figure 19).

Participants were asked to rate their concerns regarding perceived "pressure to prescribe opioids, even in the presence of 'drug seeking' behavior," in order to avoid regulatory, civil and administrative scenarios. (Figure 20) Forty-six percent agreed that potential Board of Medicine complaints regarding adequate pain management would constitute a pressure to prescribe; 26% felt a pressure to prescribe due to potential civil liability (e.g. withdrawal, over/under prescribing); 72% felt pressured to prescribe in order to avoid administrative complaints from patients stating their pain was inadequately treated; 57% felt pressured to prescribe opioids due to potential negative impact on Joint Commission surveys; and 46% felt the pressure to prescribe to avoid decreased patient satisfaction scores and their direct relevance to reimbursement. Twenty-three percent of the participants stated that they were unconcerned regarding the aforementioned scenarios. When asked if the participant, or one of their colleagues, had been criticized by administration for failure to prescribe opioids, 40% answered affirmatively (Figure 21).

To determine the prevalence of administrative opioid / controlled substance prescribing protocols, the participants were asked about their hospital's position on this subject. Seventy-one percent indicated their hospital does not have an administrative protocol for opioid /

controlled substance prescribing by ED physicians, 23% reported that a protocol exists but physician use is voluntary, and 8% reported that ED physicians have a mandatory protocol (Figure 22). When asked about the components of the protocol, the most prominent (72%) response by participants was the requirement to prescribe a limited supply of opioids. Drug screening and use of the PDMP were not components.

The participants were asked to rate their attitudes toward a number of statements regarding the development of an administrative prescribing protocol for opioids and controlled substances. Respondents indicated that perceptions regarding administrative opioid / controlled substance prescribing protocols vary. Forty-two percent were opposed and 58% were in favor of a protocol. The participants were then provided with two statements regarding the possible impact on physicians should this protocol be established. The first statement asked the participants to rate their feelings as to whether this protocol would protect them from disciplinary actions. Sixty-eight percent responded affirmatively. They were also provided with a second statement which asked if they perceived that such a protocol would limit the professional judgment of the physician. Seventy-one percent responded affirmatively (Figure 23). A number of respondents indicated affirmative responses to both questions. The statistical inference is such that if the first statement is desirable, the second might not be desired. Percentages did not vary greatly indicating preferences for both statements.

A significant number of ED physicians reported they are treating an increased volume of ED patients manifesting 'drug seeking' behavior due to economic and regulatory factors . This is supported after an independent t-test showed that a statistically significant number of ED physicians feel that 'less private physicians accepting Medicare/Medicaid' had an impact on rising patient volumes (t= -3.068, P=0.003). A statistically significant number of ED physicians

attributed rising volumes to patient awareness that ED's are obligated to take them as patients.

(t= -2.329, P=0.021).

		Levene's Test for Equality of Variances				
		F	Sig.	t	df	Sig. (2-tailed)
Less private physicians accepting	Equal variances assumed	.566	.453	-3.049	123	.003
Medicare/Medicaid	Equal variances not assumed			-2.884	73.376	.005
Patients know that ED's can not refuse	Equal variances assumed	.924	.338	-2.631	129	.010
to treat them	Equal variances not assumed			-2.374	66.631	.020

Economic Impact

With many reimbursing and regulatory agencies utilizing patient satisfaction scores as a metric, physicians were asked if they felt patient satisfaction scores were too highly emphasized as a means of assessing good patient care. Responses indicated that 98% of the participants agreed with this statement and 78% of those responses indicated "strongly agree." (Figure 24). The participants were asked to indicate their impression of trends in ED patient volumes in the last two years. Ninety-one percent reported a perceived rise in overall volume. When asked if there was also a trend in volume of patients exhibiting drug seeking behavior in that same time period, 72% of the respondents indicated that they perceive the volume of patients exhibiting drug seeking has also increased (Figure 25).

Within the last two years, legislation was enacted to reduce the number of "pill mills" in numerous states. The participants were asked, subsequent to their impression that drug seeking behavior had increased, if there were any associations which they felt might have contributed to this increase. Eighty three percent noted that the pill mill legislation, and subsequent decreases in available opioids, may have contributed. Ninety percent agreed that patients feel they will not be turned away. Eighty percent (80%) of the participants attributed some influence to economic changes in that less private physicians are participating in Medicaid. From a regulatory standpoint, 70% of the participants indicated greater numbers of physicians are refusing to prescribe opioids in general (Figure 26). With regard to Medicaid, the participants were requested to rank any trends in methods of payment noted when treating patients exhibiting drug seeking behavior. Respondents perceived that the number of Medicaid patients exhibiting drug seeking behavior is rising. Thirty six percent of the participants perceive that Medicaid patients had increased and 43% indicated that private pay / cash payments have risen in that same two-year time period (Figure 27).

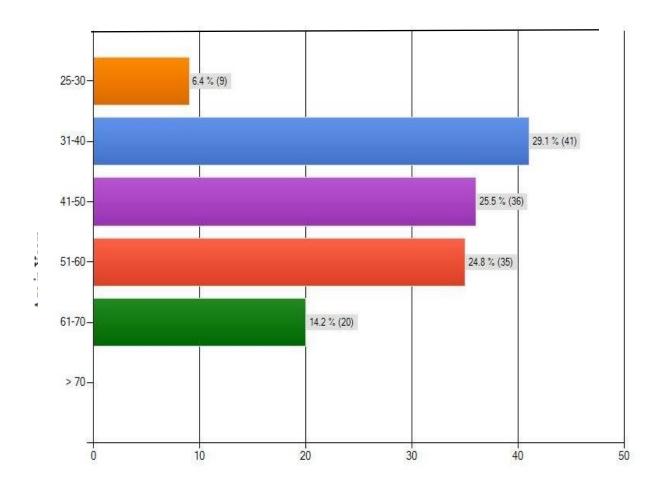


Figure 1: Age of Participants

Years of Experience in ED

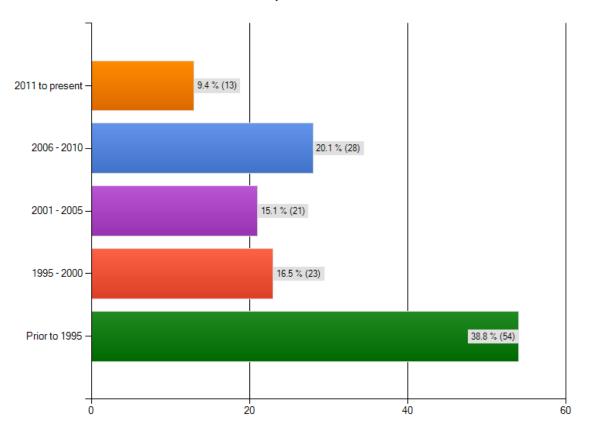


Figure 2: Years of Experience in ED- "When did you begin taking shifts in an ED"

Characteristics of Drug Seeking Behavior

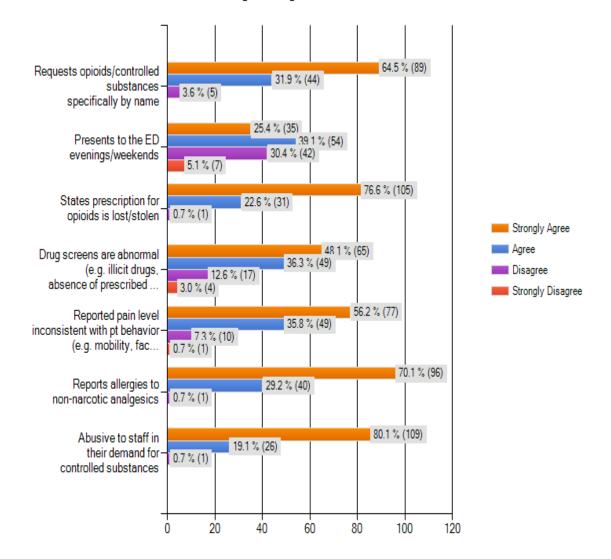
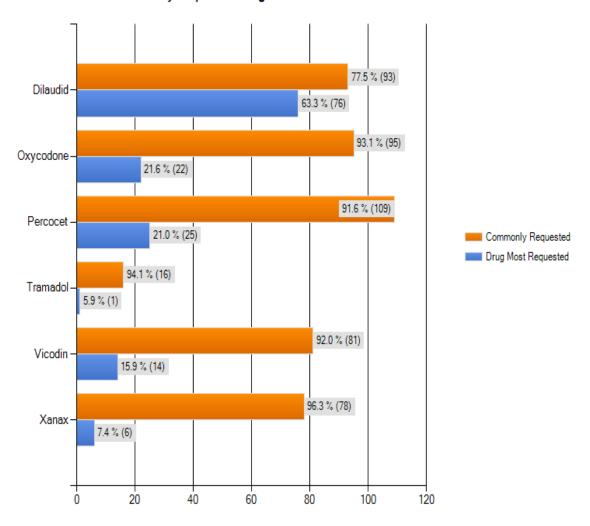


Figure 3: Characteristics of Drug Seeking Behavior



Commonly Requested Drugs of Abuse

Figure 4: Commonly Requested Drugs of Abuse

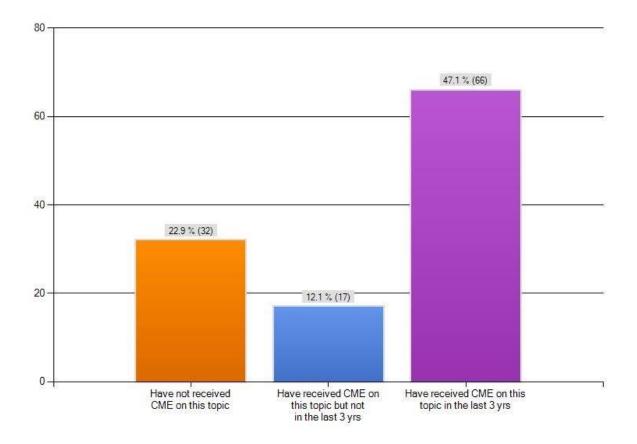


Figure 5: Training on Prescription Opioid Abuse

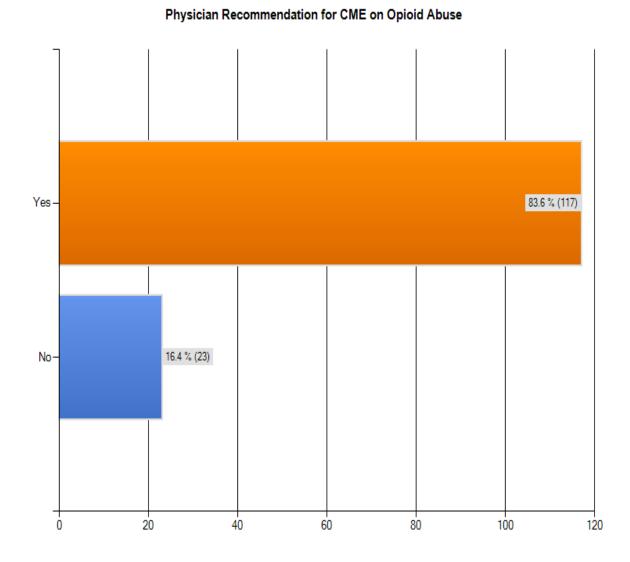


Figure 6: Physician Recommendation for CME on Opioid Abuse- physicians "Should physicians receive some type of specialized CME to assist them with recognition and management of prescription opioid abuse ?"

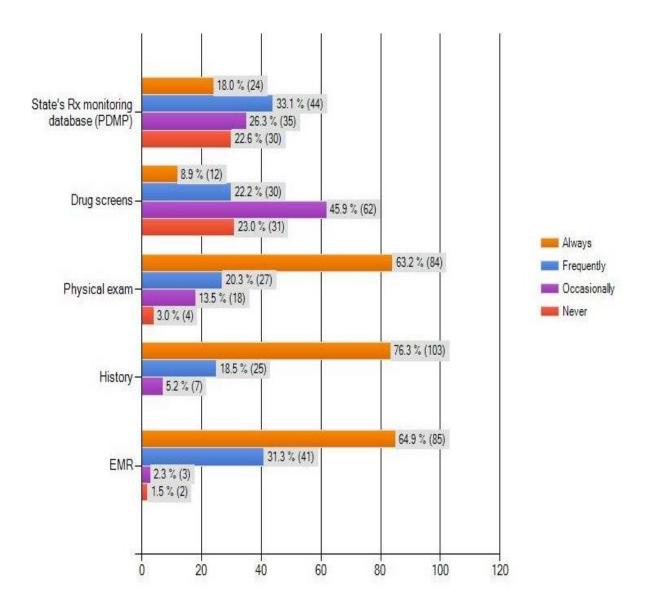
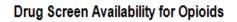


Figure 7: Utilization of Opioid Abuse Identification Methods



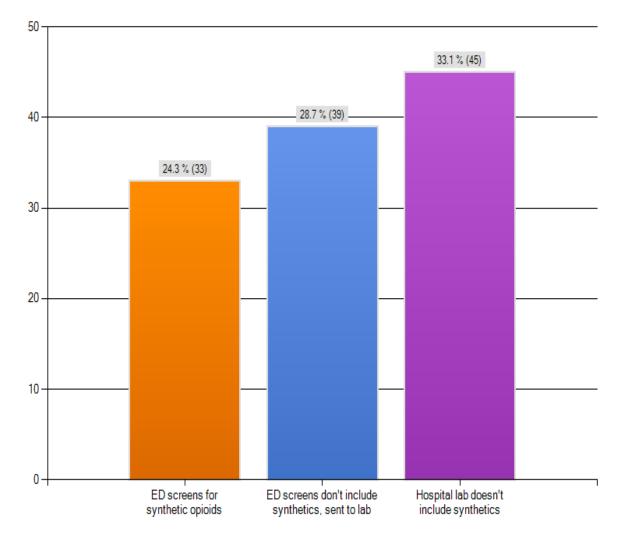


Figure 8: Drug Screen Availablilty for Opioids

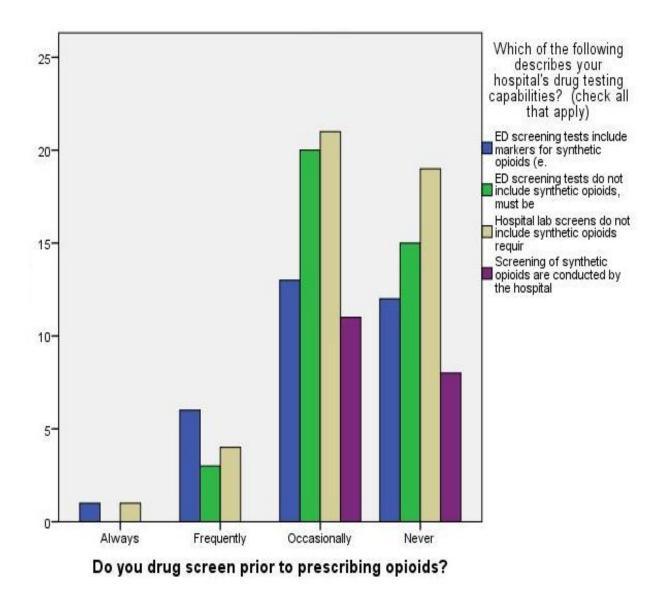


Figure 9: Correlation between Drug Testing and Availability

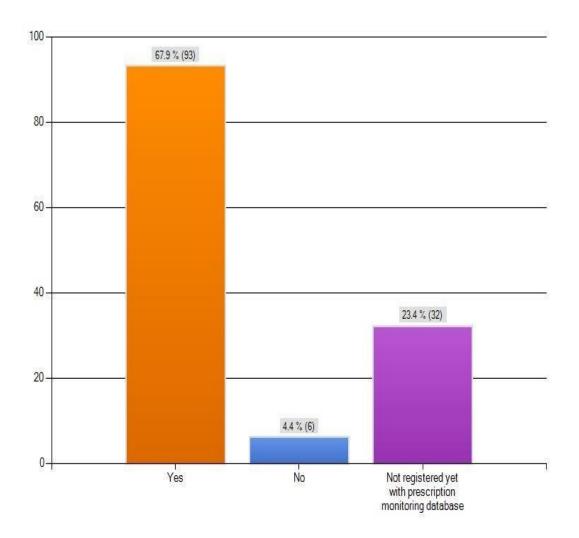


Figure 10: Database Queries Indicating Potential "Doctor Shopping"

Factors Discouraging Utilization of PDMP

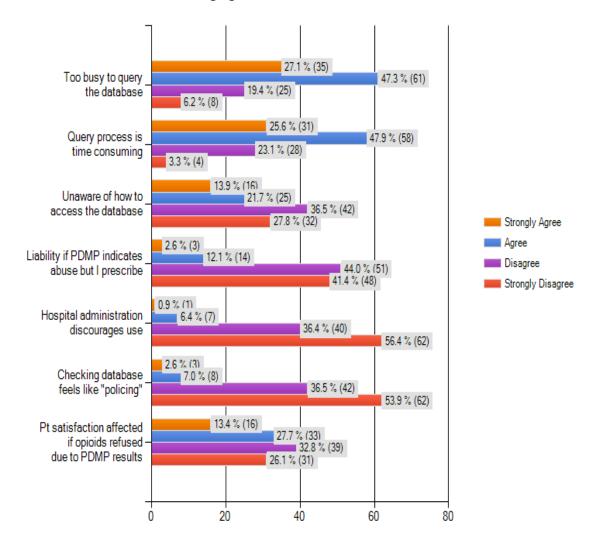


Figure 11: Factors Discouraging Utilization of PDMP

Factors Influencing Utilization of PDMP

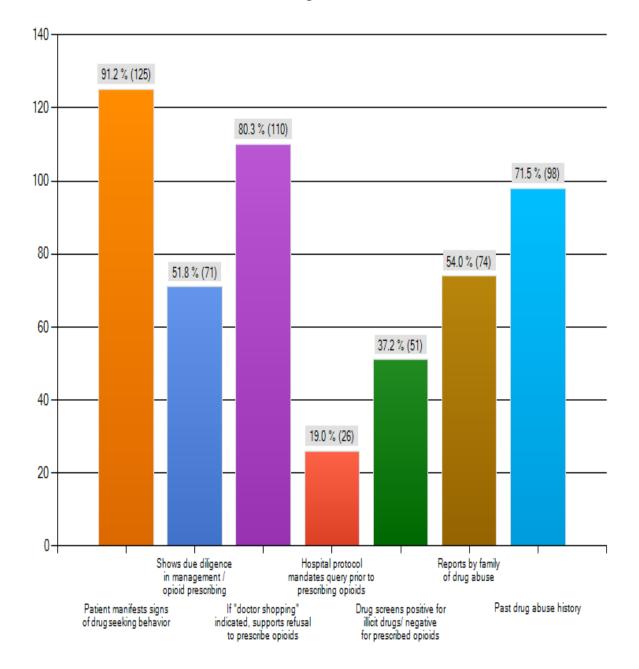


Figure 12: Factors Influencing Utilization of PDMP

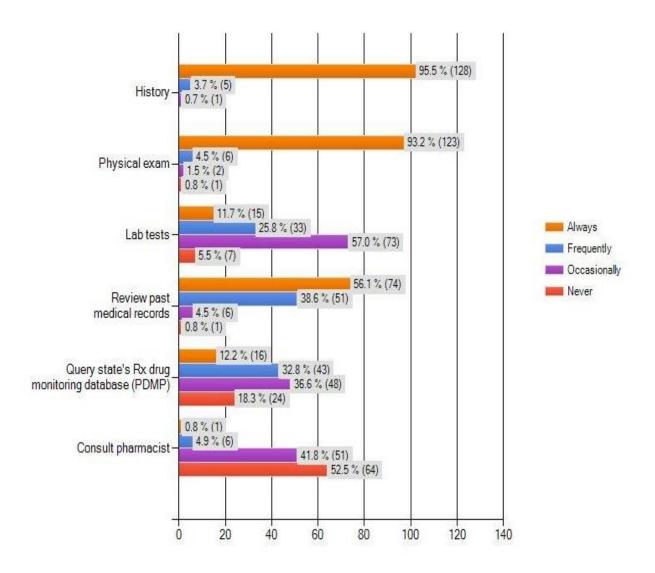


Figure 13: Opioid Prescribing Practices- Evaluation and assessment performed to guide decision to prescribe an opioid as part of the treatment course.

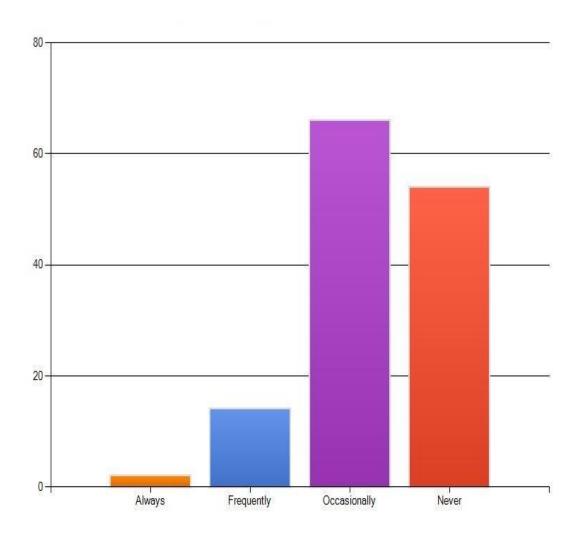


Figure 14: Drug Screens Prior to Prescribing Opioids

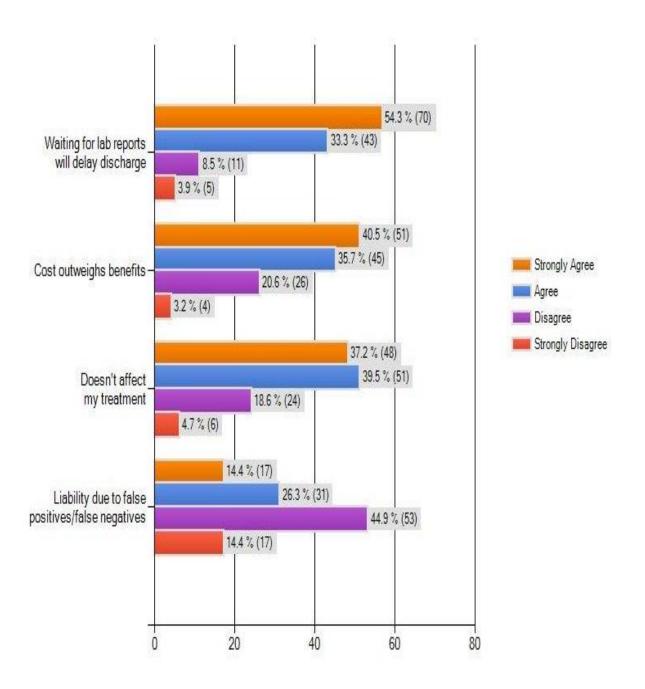


Figure 15: Factors Influencing Non-Utilization of Drug Screens Prior to Prescribing Opioids

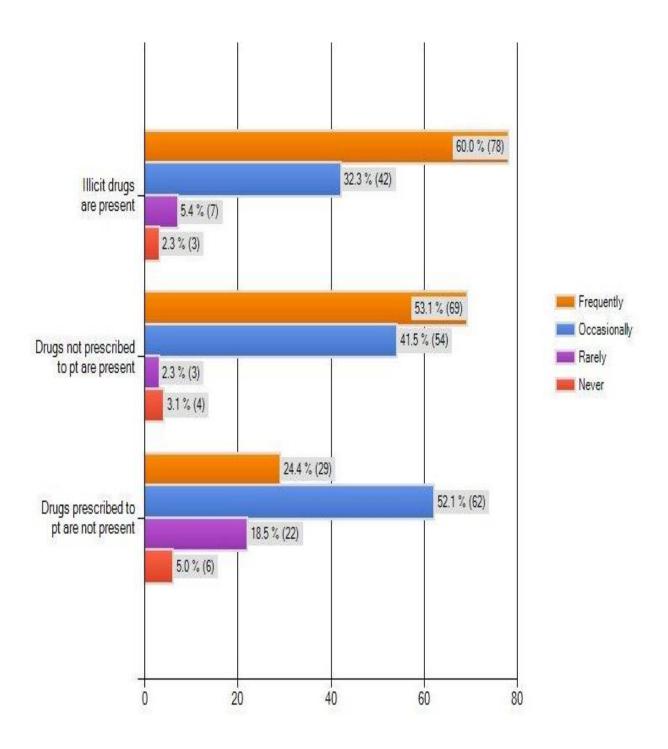


Figure 16: Laboratory Findings in Patients Exhibiting Drug Seeking Behavior

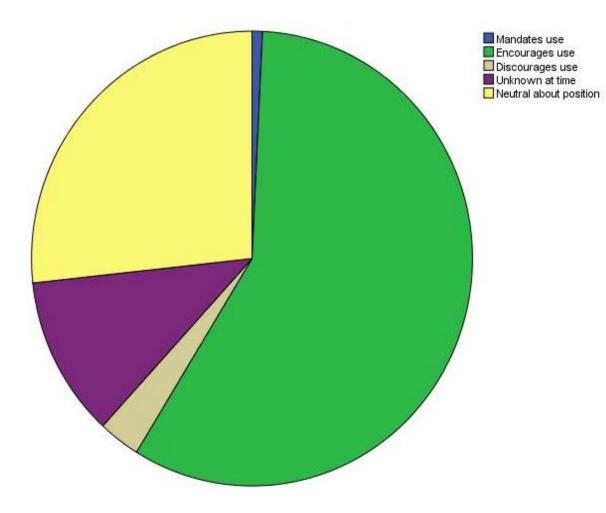


Figure 17: Administrative Position on Utilization of PDMP

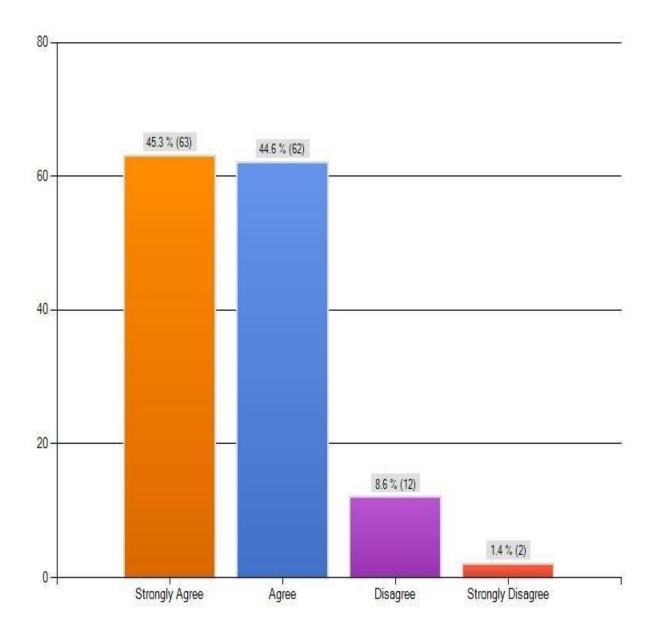


Figure 18: Cultural Expectations of Pharmacological Agents- "Patients in our culture view drugs as a solution therefore you risk a patient complaint if you don't provide a script on discharge."

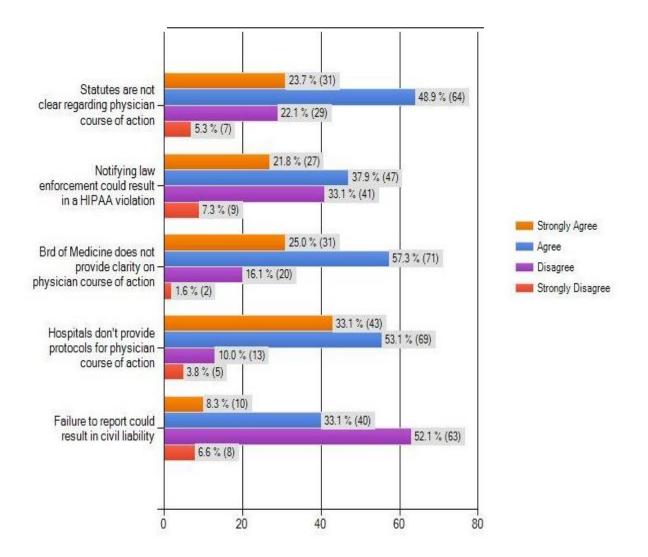


Figure 19: Physician Course of Action When "Doctor Shopping" Indicated

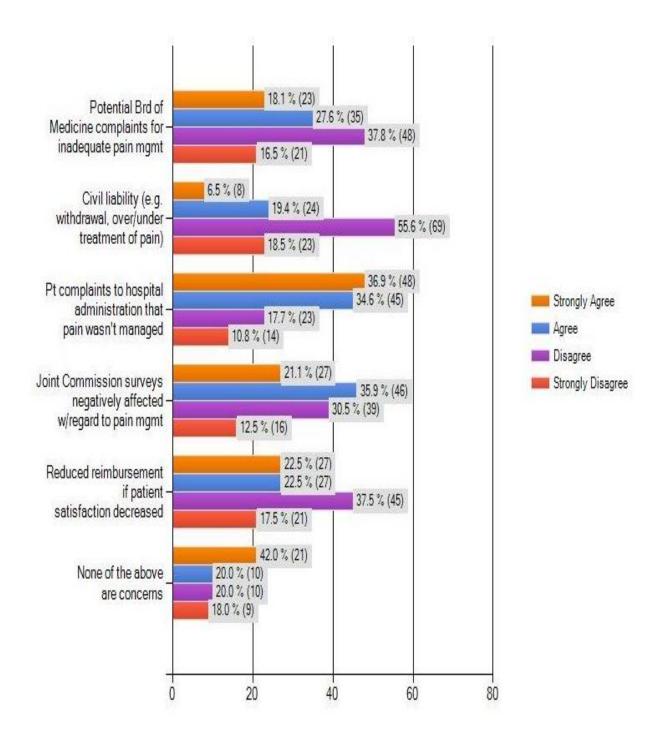


Figure 20: Perceived Pressures to Prescribe Opioids

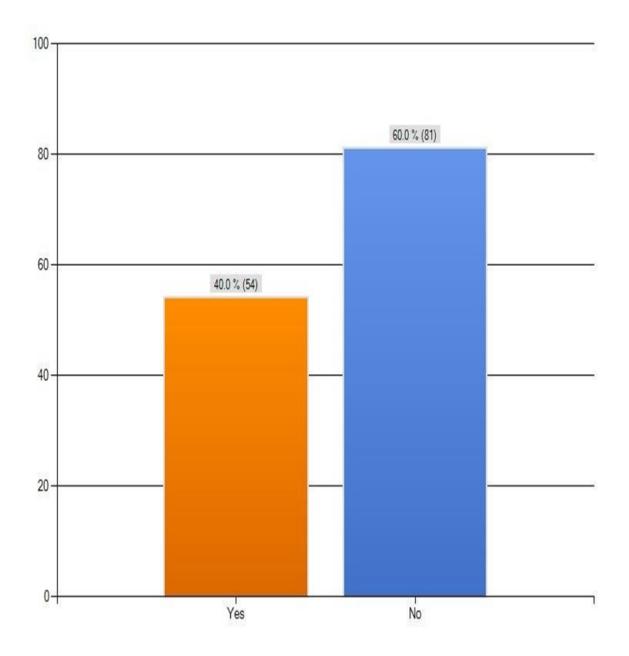


Figure 21: Administrative Criticism for Failure to Prescribe Opioids- "Have you, or one of your colleagues, been criticized by administration for failure to prescribe opioids?"

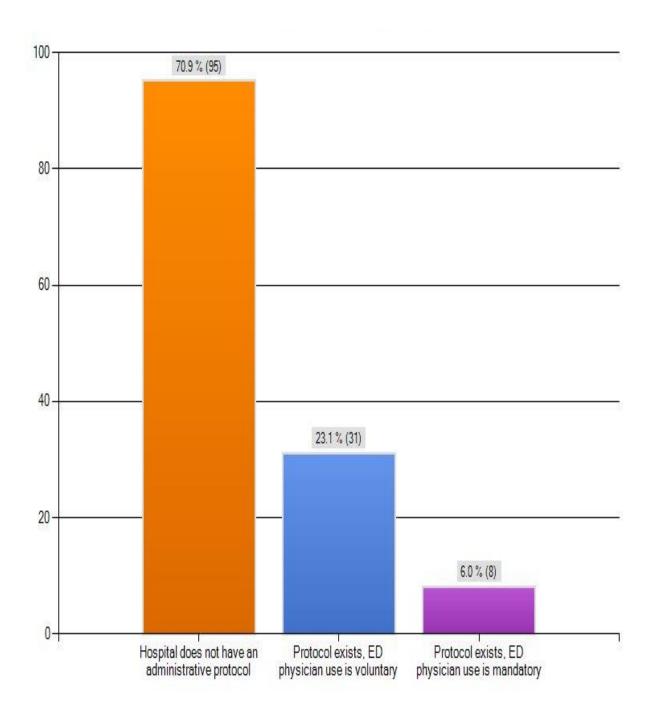


Figure 22: Administrative Opioid Prescribing Protocols

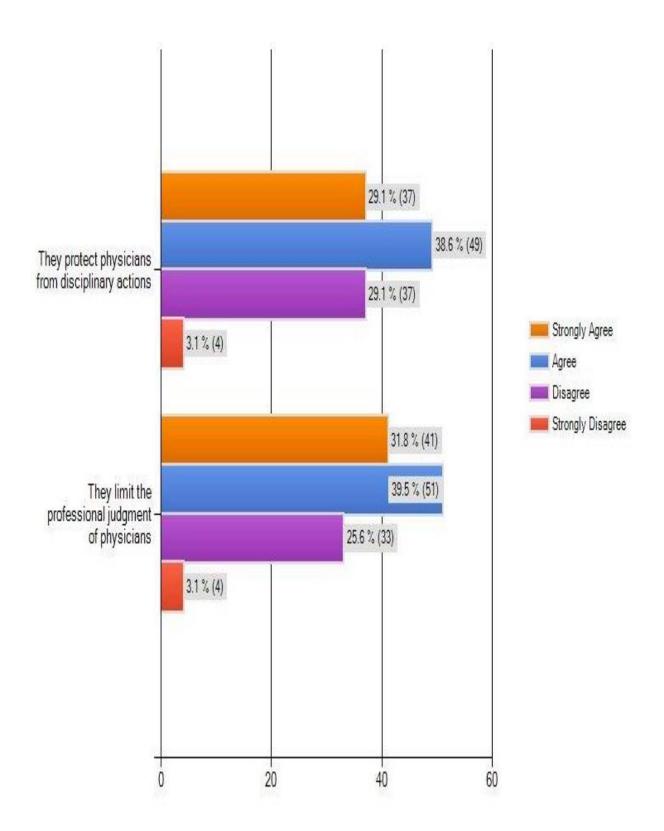


Figure 23: Physician Impact from Administrative Opioid Prescribing Protocols

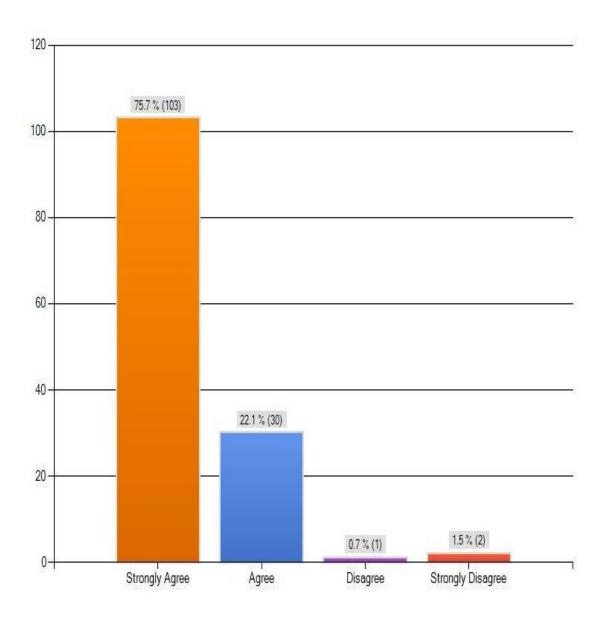


Figure 24: Emphasis on Patient Satisfaction Scores

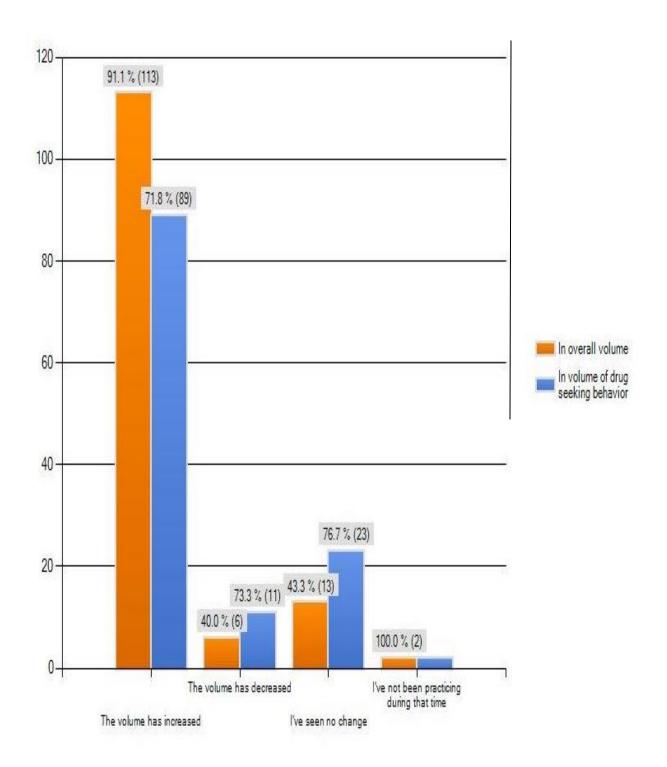


Figure 25: Changes in ED Patient Volume- 2011 to Present

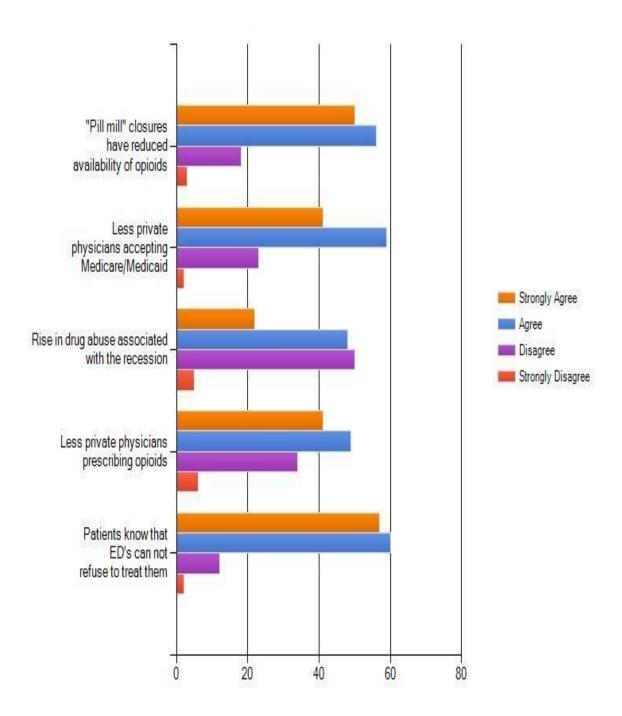


Figure 26: Factors Influencing ED Patient Volume

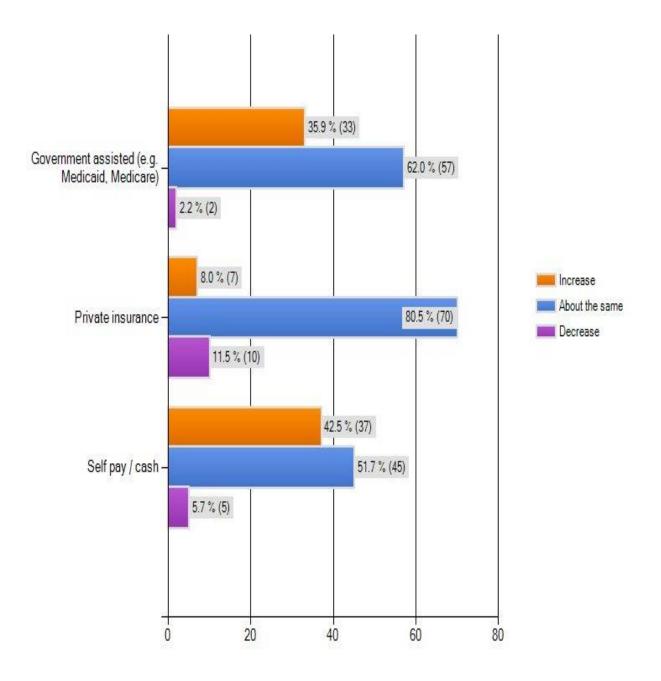


Figure 27: Financial Trends in Patients Exhibiting Drug Seeking Behavior

CHAPTER FIVE – DISCUSSION

This chapter will provide a summary and discussion of the research findings and provide recommendations as to potential future research.

Purpose of the Study

This purpose of the study was to elicit the opinions of practicing ED physicians in an effort to determine if economic changes and regulatory factors were perceived as impacting management of patients exhibiting drug seeking behavior. The lack of available information, as evidenced in a literature search of peer-reviewed works, is the basis for this original research. Subsequent to analysis, the data will be used to identify and evaluate factors which may have a negative impact on treatment of patients exhibiting drug seeking drug seeking behavior by ED physicians.

Demographics of Sample

The sample for this study was comprised of 141 currently practicing ED physicians. There was a wide range of ages and years of experience among the sample. This was deemed to be of importance to the research as an area of interest was whether newer physicians had received training on prescription opioid abuse while either in medical school or in their residencies. The majority of the participants (88%) are boarded in emergency medicine but other specialty boards were listed as well. There was a good distribution of participants with regard to their ED practice. Among the participants were physicians seeing adult patients only, pediatrics patients only, or a combination thereof. Also of interest was whether perceptions would differ between physicians working for nonprofit versus for-profit facilities both of which were represented.

Methodology

This study utilized a survey tool which was developed and used in a pilot survey (February 2012). The questions were revised and tested for content validity by a group of experts in emergency medicine and education. The current survey questions were distributed and tested for content validity. The survey includes a maximum number of thirty nine (39) multiple choice questions with an optional essay question at the conclusion allowing for the physician to provide additional comments. Screening questions within the survey reinforced inclusion criteria.

To decrease study limitations, all applicable survey questions included a provision at the end of the question which provided an option for the participants to provide an opinion not included in the multiple choice options for that particular question. Provision was also made at the conclusion of the survey for participants to add comments not addressed by survey questions The same survey questions were utilized for those preferring to participate by personal interview as opposed to the online option.

Management of Patients Exhibiting Drug Seeking Behavior

Training. Physicians in the ED are facing a number of unique challenges in the currently changing healthcare and economic climates. Dramatic increases in ED patient volumes have been noted nationwide with visits related to prescription opioid abuse and misuse alone having increased by 111% between 2004 and 2008. Participants were asked to describe their level of CME training with regard to recognition and management of prescription opioid abuse. Less than half had received formal CME on this topic. Initiatives by the ONDCP are encouraging

medical schools and residency programs to incorporate recognition and management of prescription opioid abuse into current curricula. From a public health standpoint, training is even more highly emphasized in the presence of an epidemic. Education on HIV became mandatory subsequent to the declaration of the AIDS epidemic and conversation continues by the ONDCP as to mandatory education for providers possessing a DEA license who would be in a position to prescribe opioid analgesics. When asked if the participants felt ED physicians should have some type of specialized CME to assist in recognition and management of prescription opioid abuse a vast majority (84%) responded affirmatively. However, what is evidenced through this study is that ED physicians would most benefit from education specifically to emergency medicine. Unlike the private practitioner, ED physicians do not elect which patients will enter into their practice. They must provide unrestricted access to all persons seeking emergency medical care as part of the EMTALA legislation. Management and care for a patient in the ED will differ greatly from the comprehensive care offered by non-ED practitioners.

Opioid Abuse Identification. When the ED physicians were asked to provide characteristics which they felt typified the patient exhibiting drug seeking behavior, a number of observations were made. Pain was inconsistent with the patient's behavior was highly mentioned. Patients reporting their pain to be a "10" on a 1 - 10 scale but manifest no grimacing, painful expressions, lack of mobility or change in heart and respiratory rates, will cause suspicion to many ED physicians in this current time.¹¹⁰ This observation could lead back to training. Understanding specific nuances as in vital signs not consistent with pain levels and recognition of objective findings consistent with drug abuse is paramount to best practice management of patients exhibiting drug seeking behavior in the ED.

Additional observations submitted by the participants as being consistent with drug seeking behavior included abusiveness to staff in their demand for controlled substances. This actually received the highest percentage of responses. This obviously is of considerable concern to ED physicians as they not only have the welfare of the patient as a responsibility but also that of the other patients and staff. It is not uncommon for those exhibiting drug seeking behavior to become verbally or even physically abusive to staff when threatened with the potential of not receiving their requested drug prescription. ED physicians will often feel pressured prescribe a limited amount of opioids and escalate discharge.⁶⁴ Another characteristic associated with this behavior is the actual demand for specific drugs and reported allergies to non-narcotic analgesics. These are significant signs of drug seeking behavior as per our participants. Dilaudid (hydromorphone) was noted as being the most requested drug with Oxycontin (oxycodone), Percocet (oxycodone with acetaminophen), and Vicodin (hydromorphone with acetaminophen) as commonly requested. Other findings which ED physicians noted to be suspicious were patients arriving at the ED on nights and weekends, patients who state their prescription for narcotics is "lost" or "stolen", patients relating their allergic to non-opioid analgesics, and abnormal drug screens specifically the presence of illicit drugs, absence of drugs stated as prescribed during the history, or presence of a drug not prescribed. The collection of responses as to what typifies drug seeking behavior is supported in the literature as being consistent with other research findings.

Participants were asked to identify what tools they would utilize to identify potential prescription opioid abuse. Performing a history, physical examination and often, review of EMR, were the most predominant responses. Drug screening and utilization of the PDMP are notably

good sources of identifying potential prescription opioid abuse however neither were predominantly utilized by survey participants.

When asked what discouraged participants from utilizing drug screening an interesting observation was made. Only 24% of the hospitals represented by participants in this study have the capability of detecting synthetic opioids (e.g. Dilaudid, Oxycontin, Percocet, Vicodin et al) in the ED drug screens. Therefore 76% must be sent out to the hospital laboratory or, in 33% of the cases, sent to an outside facility for testing. The latter would not be a logistical option unless the patient is being admitted. When asked what observations had been made in reviewing drug screens from patients exhibiting drug seeking behavior, 60% of the participants frequently found illicit drugs, 54% cited drugs not prescribed to patients as being present, and 24% specified drugs prescribed to patient as not being present. This information, in the hands of an ED physician contemplating whether to prescribe an opioid analgesic, could quite possibly impact prescribing practices.

Another tool available to the ED physician is the PDMP. When reviewing the states represented by participants, it was noted that a functioning PDMP is present in each state. Historically, PDMP's have been reported to be underutilized.¹⁰⁴ This research attempted to discover the factors which would encourage, or discourage, the ED physician specifically in their utilization decision. The first observation was that approximately one fourth of the participants were not registered with the PDMP. However, of those who are registered and have queried the database, approximately 70% reported having received confirmation of activity supportive of "doctor shopping." This information, as in abnormal laboratory screens, would have bearing on prescribing practices with regard to opioid analgesics. With regard to factors discouraging participant usage, the highest concerns noted were both related to time. The first factor listed

indicated that participants were too busy to check the database and the second being the query process is time consuming. Also listed among the concerns was the potential for patient satisfaction scores being negatively affected if opioids were refused subsequent to PDMP findings. Civil liability was not recognized as being of concern to participants. When asked what encourages participants to utilize the PDMP, patient exhibiting drug seeking behavior was the most dominant factor with the second being that a PDMP report indicating "doctor shopping" would support the ED physician's refusal to prescribe opioids. Other factors listed by participants were past history of drug abuse, reports of abuse by family and shows due diligence in opioid prescribing.

A Spearman correlation was applied regarding use of opioid abuse identification methodologies. Low correlations, both positive and negative respectively, were specific to use of drug screens and availability (r = 0.393, P, 0.001), and use of drug screens and physician knowledge of how to access the PDMP (r = -0.186, P=0.031). These results would seem to indicate that there is a small correlation between willingness to drug screens and whether the screen is available in the ED. Also observed is the negative correlation between drug screens and physician knowledge of how to access the PDMP. Additional correlations included low correlations, negative and positive respectively, specific to performance of physical examination and avoidance of PDMP utilization, due to fear of decreased patient satisfaction should PDMP results indicate "doctor shopping." (r = 0.179, P=0.039) This could suggest that the more a physician is willing to perform a physical examination, the less they are willing to utilize the PDMP and risk a patient complaint if opioids are refused based upon the PDMP results. This could coincide with the last correlation specifically the performance of physical examination to detect opioid abuse as opposed to the physician unaware of how to access the PDMP. (r = -0.174,

P=0.045) Relative frequencies, as discussed in this chapter's opioid abuse identification section, indicate that economic factors play a role in the decision of physicians to utilize prescription opioid abuse identification methodologies.

A t-test indicated no statistical significance between the profit and nonprofit groups when asked about the physician's administration's position regarding use of the PDMP for opioid abuse identification purposes. (t = 1.145, P = .254)

Opioid Prescribing Practices. Participants were specifically asked to comment on their opioid prescribing practices. History, physical examination and review of EMR received the highest percentage of responses as "always" being used. This is consistent with the pattern observed when participants were asked about the tools utilized to identify prescription opioid abuse. Also consistent was "occasional" utilization of drug screens but a change was noted with regard to the PDMP. Less participants utilized the PDMP prior to prescribing than as a means of identification. As in the case of why practitioners are not using the PDMP, time factors were listed as the most significant deterrent. Almost 90% of the participants cited that waiting for laboratory reports delayed discharge. Two factors received responses of 80% by participants specifically that cost outweighs the benefit and the treatment is unaffected by laboratory results.

When asked to describe their management of non-malignant pain, patients were requesting narcotic analgesics, the responses most often provided were to offer a limited supply of short acting opioids or non-narcotic analgesics. There was a strong aversion to providing long acting opioids. These responses are again consistent with the literature as to current responsible prescribing guidelines.

When asked if participants felt pressured to prescribe opioids evening to patients exhibiting drug seeking behavior, we found no statistical difference between physicians working in for-profit hospitals versus nonprofit hospitals. Specific questions included "Have you, or one of your colleagues, been criticized for refusal to prescribe opioids? (t = -1.198, P = .233), "Do you feel a pressure to prescribe opioids, even in the presence of "drug seeking" behavior, to avoid patient complaints to hospital administration?" (t = 237, P = .813), and "Do you feel a pressure to prescribe opioids, even in the presence of "drug seeking" behavior, to avoid negative impact on Joint Commission surveys?" (t = -1.198, P = .233) Seventy two percent (72%) of the participants feel a pressure to prescribe opioids, even when the patient is exhibiting drug seeking behavior in order to avoid administrative complaints while 57% feel this same pressure with regard to the potential negative effect that refusal to prescribe could have on Joint Commission accreditation surveys.

Regulatory Factors Impacting ED Physician Practices

In 1995, when the APS initiated the campaign to view pain as the "fifth vital sign", the management of pain became of much greater importance. The VA introduced a pain scale and results were to be entered into the EMR to raise awareness of changes or satisfaction with pain management. Of great note was when the Joint Commission adopted the idea of pain being viewed as the "fifth vital sign." At that point, hospital administrations had the expectation that ED physicians would insure adequate pain management or risk decreased scores on accreditation surveys. Joint Commission accreditation is crucial to hospitals as not only is it deemed as the body overseeing accreditation but reimbursement is directly linked to reimbursement from agencies such as CMS.

Submitting to patient's requests for medication is not a new dilemma for ED physicians. For example, the literature is robust with articles addressing the overprescribing of antibiotics. Recently the CDC issued a press release speaking to the current and future dangers now represented due to antibiotic resistant strains. Participants were asked to respond to the following statement: "Patients in our culture view drugs as a solution therefore you risk a patient complaint if you don't provide a script on discharge." Ninety percent (90%) of the participants agreed with 45% strongly agreeing.

Regulatory concerns for over- and under-prescribing are well documented in the literature. In reviewing case law on this topic, there were no judgments found against an ED physician in these types of cases. This may support why survey questions regarding civil liability concerns were not of significance to participants. However, in a landmark Massachusetts case, a physician was found to be at fault in a civil litigation where the patient lost consciousness and was involved in a fatal car accident where a child died. The physician had prescribed an opioid analgesic and the case was decided for the plaintiff based upon a lack of warnings being offered to the patient.³³ This could certainly be a subject for ED physician CME in opioid abuse.

When asked if participants perceived a pressure to prescribe opioids, to avoid a potential Board of Medicine complaint for failure to adequately treat pain, 46% cited concerns. Of greater concern (82%) was a perceived lack of clarity from the Board with regard to the ED physician's course of action should "doctor shopping" be identified. In a landmark California case, *Bergman* v *Chin*,³¹ the court adjudicated on behalf of a victim's family in a case of inadequate pain management. What was significant was that the Board had already reviewed the case and exerted no disciplinary action. The participants have indicated that they may be less concerned

about actions by the Board, but cite the need for recommendations by the Board. Seventy three percent (73%) stated that there are concerns due to lack of clarity in state statues regarding the physician's course of action when confronted with evidence of "doctor shopping." Other regulatory concerns were demonstrated in that 60% of the participants were concerned that reporting database confirmed cases where "doctor shopping" was indicated, could result in a HIPAA violation.

The Changing Economic and Healthcare Climates

In 2002, CMS initiated what was to become the patient satisfaction survey known as HCAHPS.⁵⁷ Patient satisfaction surveys had been administered for many years by vendors such as Press Ganey however, the Deficit Reduction Act of 2005 created financial incentives to implement HCAHPS which thrust patient satisfaction survey results to a heightened level. Per the Patient Protection and Affordable Care Act of 2010, the provision of HCAHPS data is a metric utilized to calculate incentive payments as part of the Hospital Value-Based Purchasing program.⁵⁸ This represents a paradigm shift from fee-for-service reimbursement. As an example, CMS can withhold 30% of the hospital's incentive monies should patient scores be unsatisfactory." This, as in accreditation by Joint Commission are obviously of extreme importance to hospitals and therefore a burden now borne by ED physicians as well.

As the Great Recession of 2008 occurred, patient volumes have increased significantly. ACEP and other entities cite a great percentage represented in the overall increased volume are patients receiving Medicaid.⁷⁹ When asked, 91% of the participants indicated that they have seen a rise in patient volume over the last two years and 72% have noted a rise in patients exhibiting drug seeking behavior. When queried regarding financial trends, of those participants aware of the patient's method of payment, only 2% had noticed a decrease in government

supplied insurance patients exhibiting drug seeking behavior. The only decrease noted was that of private insurance which may coincide with the unemployment and loss of private insurance induced by the recession.

When asked regarding their opinions as to why patient volumes have increased 84% attributed this to reduced availability of opioids subsequent to "pill mill" closures. Other reasons included that less private physicians were accepting Medicare/Medicaid (79%) and less private physicians willing to write prescriptions for opioids (68%). An independent t-test showed that a statistically significant number of ED physicians feel that 'less private physicians accepting Medicare/Medicaid' had an impact on rising patient volumes (t= -3.068, P=0.003). A statistically significant number of ED physicians also attributed rising volumes to patient awareness that ED's are obligated to take them as patients. (t= -2.329, P=0.021).

With increased volumes comes the need to see increased numbers of patients in lesser periods of time. CMS, in addition to patient satisfaction surveys, is now using "door to discharge" metrics as a quality assurance measure and can therefore withhold incentive monies should the times exceed those determined. Participants were asked to give their opinions as to the usefulness of patient satisfaction scores as a means of measuring the quality of healthcare. Ninety eight percent (98%) cited that these surveys are too highly emphasized with 78% of that number "strongly" agreeing. Physicians cited feeling a pressure to prescribe opioids, even in the presence of drug seeking behavior in order avoid administrative complaints (72%) and due to concerns about a negative effect on Joint Commission surveys (61%). Of significance is that 40% of the participants had either been criticized, or one of their colleagues been criticized, for refusal to prescribe opioids. The participants in this survey indicated that they feel a need for

administration opioids prescribing protocols. Eight six percent (86%) felt there was no clarity as to their course of action when treating a patient confirmed by the PDMP as a "doctor shopper." A little over half of the participants cited that their hospital does support the use of the PDMP however three fourths of the hospitals represented by participants do not have an active administrative protocol in place. The majority of participants expressed their preference for the initiation of a protocol with approximately 70% stating they felt this would protect them from potential disciplinary action. However, an almost equal number felt that the protocols could potentially limit the professional judgment of the ED physician.

Conclusions

The hypothesis is listed with the respective research questions listed below. A short narrative regarding the survey questions, and inferences drawn from the research, will follow as will the decision as to accept or reject the hypothesis.

Hypotheses #1ED physicians feel pressured to prescribe opioids due to economicconcerns arising from administrative and regulatory entities.

- Do ED physicians feel pressured to prescribe opioids subsequent to economic influences?
- 2. What economic influences do physicians cite as exerting a pressure on them to prescribe opioids?
- 11. Do ED physicians perceive that regulatory guidelines / statutes are clear as to appropriate pain management for ED patients exhibiting drug seeking behavior?
- 14. Do ED physicians have concerns regarding patient complaints to the Board of Medicine, for under-treatment of pain, should they decline to prescribe opioids?

This hypothesis was tested with survey question #29 using relative frequencies. Participant responses suggest ED physicians perceive a pressure to prescribe opioids due to economic concerns arising from Board of Medicine disciplinary actions (46%), civil liability (26%), administrative complaints (72%) and Joint Commission surveys being negatively affected by a refusal to prescribe (57%) and risk of reduced reimbursement (46%). Therefore Hypothesis #1 is supported.

Hypothesis #2. ED physicians will prefer to have administrative / regulatory opioid prescribing protocols for the purpose of protecting them from disciplinary actions.

3. What are the perceptions of ED physicians with regard to administrative opioid prescribing protocols?

This hypothesis was tested with survey questions 36 and 37 using relative frequencies. Participant responses indicated that 58% preferred to have an administrative / regulatory opioid prescribing protocol. Therefore Hypothesis #2 is supported.

Hypothesis #3. There will not be a statistically significant difference between ED physicians working in for-profit versus nonprofit hospitals with regard to their perceptions of economic pressures from administration to prescribe opioids.

- Do ED physicians feel pressured to prescribe opioids subsequent to economic influences?
- 2. What economic influences do physicians cite as exerting a pressure on them to prescribe opioids?
- 3. What are the feelings of ED physicians with regard to administrative opioid prescribing protocols?

- 7. Is there a difference in physician opinions, from those who work for for-profit versus nonprofit organizations, with regard to economic pressures to prescribe opioids in order to maintain patient satisfaction scores?
- 14. Do ED physicians have concerns regarding patient complaints to the Board of Medicine, for under-treatment of pain, should they decline to prescribe opioids?

This hypothesis was tested with questions #17, 29 and 30. A t-test was utilized to compare the profit versus nonprofit sub-samples. However, the p values were not greater than 0.05 indicating no statistical significance between the two groups. Specific questions included "Have you, or one of your colleagues, been criticized for refusal to prescribe opioids? (t = -1.198, P = .233), "Do you feel a pressure to prescribe opioids, even in the presence of "drug seeking" behavior, to avoid patient complaints to hospital administration?" (t = 237, P = .813), and "Do you feel a pressure to prescribe opioids, even in the presence of "drug seeking" behavior, to avoid patient complaints to hospital administration?" (t = 237, P = .813), and "Do you feel a pressure to prescribe opioids, even in the presence of "drug seeking" behavior, to avoid negative impact on Joint Commission surveys?" (t = -1.198, P = .233) Therefore Hypothesis #3 is supported.

Hypothesis #4. Emergency department physicians will cite their failure to use prescription opioid abuse identification methodologies is often related to economic factors.

- 4. Do ED physicians refrain from utilizing prescription opioid abuse detection methodologies, such as the Prescription Drug Monitoring Program (PDMP) and drug screening, due to economic factors?
- 5. What rationale do ED physicians use with regard to their decision to cite "opioid overdose" on the patient's record?

This hypothesis was tested using survey questions 15, 17 and 20. A Spearman correlation was applied regarding use of opioid abuse identification methodologies. Low correlations, both

positive and negative respectively, specific to use of drug screens and availability (r = 0.393, P, 0.001), use of drug screens and physician knowledge of how to access the PDMP (r = -0.186, P=0.031). Other correlations included low correlations, negative and positive respectively, specific to performance of physical examination and avoidance of PDMP utilization, due to fear of decreased patient satisfaction should PDMP results indicate "doctor shopping" (r = 0.179, P=0.039) and performance of physical examination to detect opioid abuse and physician knowledge of how to access database. (r = -0.174, P=0.045) Relative frequencies, as discussed in this chapter's opioid abuse identification section, indicate that economic factors play a role in the decision of physicians to utilize prescription opioid abuse identification methodologies. Therefore Hypothesis #4 is supported.

Hypothesis #5. Less than 50% of emergency department physicians have received formal training, through either continuing medical education (CME) or medical school/post-graduate curricula, on recognition and management of prescription opioid abuse.

- 6. Do ED physicians receive formal training on recognition and management of prescription opioid abuse?
- 8. Do ED physicians feel that training on recognition and management of prescription opioid abuse should be part of their training / continuing education?

Survey questions 6 and 7 were used to test this hypothesis. Frequencies were used to determine the percentage of ED physicians have received formal training in management of prescription opioid abuse. Forty seven percent (47%) indicated that they had received CME training in the last three years. An additional 12% had received training on the topic but more than 3 years ago. Therefore Hypothesis #5 is not supported.

Hypothesis #6. ED physicians will report they are treating an increased volume of ED

patients exhibiting drug seeking behavior due to economic and regulatory factors.

- 12. What recommendations do ED physicians have for deterring prescription opioid / controlled substance abuse through actions of the ED?
- 15. Is data regarding morbidity / mortality from prescription opioid abuse patients seen in the ED influenced by economic factors?

		F	Sig.	t	df	Sig. (2-tailed)
Less private physicians accepting Medicare/Medicaid	Equal variances assumed	.566	.453	-3.049	123	.003
	Equal variances not assumed			-2.884	73.376	.005
Patients know that ED's can not refuse to treat them	Equal variances assumed	.924	.338	-2.631	129	.010
	Equal variances not assumed			-2.374	66.631	.020

Levene's Test for Equality of Variances

Survey questions 26 and 27 were used to test this hypothesis. An independent t-test showed that a statistically significant number of ED physicians feel that 'less private physicians accepting Medicare/Medicaid' had an impact on rising patient volumes (t= -3.068, P=0.003). A statistically significant number of ED physicians attributed rising volumes to patient awareness that ED's are obligated to take them as patients. (t= -2.329, P=0.021). Therefore Hypothesis #6 is supported.

Hypothesis #7. There will not be a statistically significant difference between ED physicians working in for-profit versus nonprofit hospitals with regard to economic factors (e.g. administrative, reimbursement, regulatory) regarding use of prescription opioid abuse identification methodologies. Survey questions 15, 17 and 20 were utilized. A t-test indicated

no statistical significance between the profit and nonprofit groups when asked about the physician's administration's position regarding use of the PDMP for opioid abuse identification purposes. (t = 1.145, P = .254) Therefore Hypothesis #7 is supported.

Hypothesis #8. ED physicians will report a rise in patient volume, including those with drug seeking behavior, over the last two years.

- 9. Do ED physicians feel that their volume of patients exhibiting drug seeking behavior has increased in recent years?
- 10. Do ED physicians perceive that there has been an increased volume of patients exhibiting drug seeking behavior that are supported by government insurance such as Medicare / Medicaid?
- 13. Do ED physicians perceive that socioeconomic factors are impacting the volume of patients being seen in the ED exhibiting drug seeking behavior?

Survey questions 26 and 27 were used to test this hypothesis. Relative frequencies were obtained. Ninety one percent (91%) of the participants reported a rise in patient volumes in general and 72% with regard to patients exhibiting drug seeking behavior. Therefore Hypothesis #8 is supported.

Recommendations

Standardized, ED physician originated opioid prescribing guidelines. Approximately 40% of the physicians in this study have either been criticized, or know of a colleague who has been criticized for failure to prescribe opioids. Concomitantly, the results demonstrate that a predominance of physicians would prefer to have administrative and/or regulatory guidelines for opioid prescribing to avoid disciplinary action. Standardization of opioid prescribing guidelines should be formulated utilizing ED physicians to design the protocol. Protocols should occur on a

national level as this is not only a national problem but it would allow for physicians exiting medical schools and residency programs to continue practicing in a manner consistent with their training regardless of their new state of practice.

Modification of Patient Satisfaction Surveys. Survey procedures should be reviewed. Based upon the literature review and research data, there is a potential for both internal as well as external validity errors. Though components of the survey would be helpful for administrative purposes, it should not be used as a definitive tool for the evaluation of good medical care. ED physicians must have the freedom to provide the patient with the highest level of care, based upon their training. In light of the current prescription opioid abuse epidemic, refusal to prescribe may well result in a negative patient satisfaction score yet have a positive healthcare contribution.

Reduction of Patient Volume by Incorporation of Primary Care. Utilization of "door to discharge" times as a quality measure needs to be evaluated. A coordinated effort to supply primary care or urgent care facilities would detract from the escalating ED patient volumes and restore safe physician to patient number ratios. By segmenting the lesser acuity patients, a more rapid standard for door-to-discharge would be realistic. As termed by one of the respondents in the study, emergency medicine is evolving into "assembly line" medicine and lowering of the quality of delivered patient care. Utilization of "patient satisfaction" scores must be accomplished with the knowledge that the nature of addiction and drug dependency often correlates with non-reliable information. Refusal by an ED physician to prescribe a pharmacologic agent of potential harm may cause the patient to initiate a patient complaint but demonstrates good medical care which is the supposed intent of the tool.

Specialized Training in Management of Prescription Opioid Abuse. Participant responses clearly indicated the need for specialized training in prescription opioid abuse. Emergency department physicians share a high exposure to confronting this abuse due to the nature of emergency medicine and EMTALA. The research and literature review are robust with educational endeavors for physicians at large as well as pain management specialists. However, ED physicians face a unique set of challenges and education should be specialized to their discipline. Continuing medical education should be mandatory while our country is still in an epidemic. Rather than request additional CME, the hours could be incorporated into current CME requirements.

Opioid Abuse Identification Methodologies. The research results and literature review demonstrate poor utilization of an epidemiological tool. By integrating newer programs that can interface with EMR and streamline the query process, hopefully there will be greater utilization. Additionally, point of care lab testing, with the capability of screening for synthetic opioids, could streamline this additional epidemiologic tool.

Summary

This original research was initiated to obtain the opinions of ED physicians regarding economic and regulatory factors impacting management of patients exhibiting drug seeking behavior. This information can be utilized by medical associations, healthcare organizations, regulatory bodies, and public health officials in the development of continuing medical education for physicians, curricula for medical schools and residency programs, administrative protocols and legislation instrumental to the deterrence of prescription opioid abuse.

99

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Appendix A

Survey Instrument

Opinions of Emergency Department Physicians Regarding Prescription Drug Abuse

Informed Consent:

Please understand that by proceeding with the online survey you are indicating that you have read the description of the study and agree to participant.

Research Study Information:

USF IRB Study #9509 Version 2 (edited May 7, 2013) University of South Florida College of Public Health Principal Investigator: Ray Harbison, PhD Study Coordinator: Sharon Kelley, MS Contact information: sharon.kelley@aieme.com 813.240.9835 USF Institutional Review Board (IRB): 813.974.5638.

Purpose of Study:

The University of South Florida College of Public Health is engaged in a research study seeking to obtain the views of clinicians regarding management strategies including prescription monitoring programs (PMP's) when dealing with patients receiving controlled substances.

The survey is completely voluntary and participants can withdraw at any stage of the questionnaire by simply leaving the survey website. Participants will remain anonymous and an online survey tool will be utilized for security as well as convenience. Should a participant wish to contribute additional comments, contact information is provided in this advertisement as well as on the survey website which will direct the participants. At no place throughout the survey will personal information be requested thereby maintaining anonymity.

Eligibility Criteria:

The survey is open to clinicians, within the United States, who manage/have the potential of managing subjects receiving prescribed controlled substances. The survey is being distributed through medical/professional organizations with an anticipated 50,000 clinicians receiving word regarding the survey.

Study Procedures:

Completion of the survey should take approximately ten (10) minutes. By participating in this survey, you are consenting to allow your anonymous answers to be utilized in a statistical analysis for the purpose of evaluating the factors affecting medical professionals in their decision as to utilization of specific management strategies for opioid patients.

Compensation:

There is no compensation for your participation however, in appreciation for your time in completing the survey, we are offering participants a password which may be utilized to view "Prescribing in an Epidemic©", a 6.5 hour Category 1 CME/CEU course for physicians and nurses respectively, at no charge. This generic password will include the link to a separate, non-USF website thereby protecting the anonymity of your survey answers.

Risk / Benefit to Participants:

There are no foreseeable risks/discomforts to participants as the survey tool provides anonymity. Should a participant wish to contact the study team, they are provided contact information both on this advertisement as well as the survey website. No identifying information will be obtained through the website so as to maintain anonymity to the survey responses.

Educational development, as well as noted concerns being provided to public health officials, regulatory and legislative personnel, may result in long term benefit to the medical community as a whole. While there are no direct benefits to subjects participating in the survey, those who complete same will be afforded the opportunity of viewing an online course on prescription drug abuse which has been approved for 6.5 hours of continuing medical education credit. The information regarding the CME will be provided in the advertisements and on the informed consent page of the survey. A link to a separate site will be provided to participants as well as a generic password to be used on the site hosting the CME video This will insure that there will be no linking of participants, who wish to take advantage of the CME opportunity, with their respective responses on the separate survey site.

USF - Emergency Department Physicians

All responses are anonymous

- "Drug seeking" behavior in this survey refers to behavior associated with prescription opioid / controlled substance abuse

- "PDMP" refers to your state's prescription drug monitoring program (PDMP) database which provides information on your patient's past opioid / controlled substance prescriptions.

- Prescribing of opioids, as being examined in this survey, would be for non-trauma, non-malignant pain patients.

Thank you for assisting with our survey.

*1. What is your age?

- C 25-30
- O 31-40
- O 41-50
- C 51-60
- C 61-70
- C > 70

*2. Which of the following best describes your professional status? (check all that apply)

	MD			
	DO			
	Medical Student			
	Resident			
	Fellow			
Othe	Other (please specify)			

3. Are you board certified in any of the following: (check all that apply)



4. When did you begin taking shifts in the ED?



5. Which describes your ED shift status?

0	Full time
С	Part time
О	Locum tenens
О	PRN
C	Consulting hospitalist

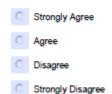
6. In which state do you predominantly practice?

Stater

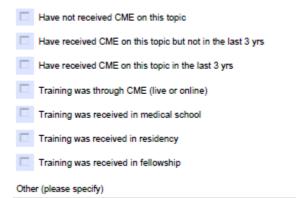
7. Please list your primary site of practice?

	For Profit Corp	Non-Profit Corp	Military / VA
ED (adult & pedi)	C	C	C
ED (adult only)	C	C	C
ED (pedi only)	С	С	С
Urgent Care (adult & pedi)	C	C	C
Urgent Care (adult only)	С	С	C
Urgent Care (pedi only)	C	C	C

8. Please comment on the following: "Patients in our culture view drugs as a solution therefore you risk a patient complaint if you don't provide a script on discharge."



9. Please describe your training on recognition and management of prescription opioid abuse? (check all that apply)



10. Do you feel that ED physicians should receive some type of specialized CME to assist them with recognition and management of prescription opioid abuse?



*11. Do you consider any of the following to be characteristic of patients manifesting "drug seeking" behavior? (check all that apply)

	Strongly Agree	Agree	Disagree	Strongly Disagree
Requests opioids/controlled substances specifically by name	С	С	С	С
Presents to the ED evenings/weekends	0	C	C	C
States prescription for opioids is lost/stolen	C	С	C	С
Drug screens are abnormal (e.g. illicit drugs, absence of prescribed drugs)	C	C	С	С
Reported pain level inconsistent with pt behavior (e.g. mobility, facial expression)	С	C	С	С
Reports allergies to non- narcotic analgesics	C	C	C	C
Abusive to staff in their demand for controlled substances	С	С	С	С
Other (please specify)				

12. If patients manifesting "drug seeking" behavior commonly request a specific drug(s), please indicate if the drug(s) is listed below. If applicable, please use the 2nd column to indicate which drug is most commonly requested.

	Commonly Requested	Drug Most Requested
Dilaudid		
Oxycodone		
Percocet		
Tramadol		
Vicodin		
Xanax		
Other (please specify)		

13. Do you utilize any of the following to identify potential prescription opioid abuse? (check all that apply)

	Always	Frequently	Occasionally	Never
State's Rx monitoring database (PDMP)	C	С	0	0
Drug screens	C	C	0	C
Physical exam	С	C	C	C
History	C	0	0	0
EMR	С	C	C	C
Other (please specify)				

14. Have any of your queries to the Rx monitoring database (PDMP) come back indicating that your patient was "doctor shopping"?

0	Yes
О	No
0	Not registered yet with prescription monitoring database
О	Registered with the prescription monitoring database, but haven't used it

15. Do any of the following discourage your use of the state's Rx monitoring database (PDMP)? (check all that apply)

	Strongly Agree	Agree	Disagree	Strongly Disagree
Too busy to query the database	C	C	C	С
Query process is time consuming	C	0	C	C
Unaware of how to access the database	0	0	C	C
Liability if PDMP indicates abuse but I prescribe	0	0	C	0
Hospital administration discourages use	0	0	С	C
Checking database feels like "policing"	0	0	C	0
Pt satisfaction affected if opioids refused due to PDMP results	С	C	C	C
Other (please specify)				

16. What would encourage you to utilize the **R**x monitoring database? (check all that apply)

	Patient manifests signs of drug seeking behavior
	Shows due diligence in management / opioid prescribing
	If "doctor shopping" indicated, supports refusal to prescribe opioids
	Hospital protocol mandates query prior to prescribing opioids
	Drug screens positive for illicit drugs/ negative for prescribed opioids
	Reports by family of drug abuse
	Past drug abuse history
Othe	r (please specify)

17. What is your administration's position regarding your use of the Rx monitoring database (PDMP) prior to prescribing opioids / controlled substances?

0	Mandates use
0	Encourages use
0	Discourages use
0	Does not permit use
Othe	r (please specify)

18. Would any of the following be concerns if "doctor shopping" is indicated by your Rx database query? (check all that apply)

	Strongly Agree	Agree	Disagree	Strongly Disagree
Statutes are not clear regarding physician course of action	C	C	С	С
Notifying law enforcement could result in a HIPAA violation	C	C	С	C
Brd of Medicine does not provide clarity on physician course of action	C	C	С	С
Hospitals don't provide protocols for physician course of action	C	С	С	C
Failure to report could result in civil liability	C	С	C	C
Other (please specify)				

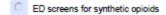
19. Do you drug screen prior to prescribing opioids?

С	Always
0	Frequently
0	Occasionally
0	Never
Othe	r (please specify)

20. What would discourage you from drug screening prior to prescribing opioids? (check all that apply)

	Strongly Agree	Agree	Disagree	Strongly Disagree
Waiting for lab reports will delay discharge	C	С	0	С
Cost outweighs benefits	0	C	0	C
Doesn't affect my treatment	C	С	C	С
Liability due to false positives/false negatives	C	C	0	C
Other (please specify)				

21. Which of the following describes your hospital's drug testing capabilities? (check all that apply)



- C ED screens don't include synthetics, sent to lab
- C Hospital lab doesn't include synthetics
- C Screening of synthetic opioids are conducted by the hospital lab

Other (please specify)

22. Are any of the following characteristic of drug screens from patients manifesting "drug seeking" behavior? (check all that apply)

	Frequently	Occasionally	Rarely	Never	
Illicit drugs are present	C	C	C	C	
Drugs not prescribed to pt are present	C	C	C	0	
Drugs prescribed to pt are not present	C	С	C	0	
Other (please specify)					

*23. When managing an opioid overdose patient, will you indicate "overdose" as part of the diagnoses?



24. If you do not always list this as a diagnosis, please indicate if any of the following are concerns leading to your decision. (check all that apply)

	Strongly Agree	Agree	Disagree	Strongly Disagree
Civil liability	C	С	C	C
Not a medical diagnosis	0	0	C	C
Risk of administrative complaint	С	C	C	0
Negative impact on reimbursement	C	C	C	0
ED doesn't track prescription opioid adverse events	С	С	C	C
Other (please specify)				

25. Are any of the following used to track the prevalence of Rx opioid abuse seen in your ED? (check all that apply)

	Always	Frequently	Occasionally	Never
Opioid overdose is specified as part of the diagnosis	C	С	C	С
Lab reports reflect presence of non-prescribed opioids	C	C	C	C
Opioid deaths are sent to the medical examiner	С	C	С	С
Patient admission of Rx opioid abuse	C	C	C	C
Other (please specify)				

26. In the last 2 years, have you noted a change in the volume of ED patients?

	In overall volume	In volume of drug seeking behavior
The volume has increased		
The volume has decreased		
I've seen no change		
I've not been practicing during that time		

27. Do you consider any of the following to influence the volume of ED patients with "drug seeking" behavior? (check all that apply)

	Strongly Agree	Agree	Disagree	Strongly Disagree
"Pill mill" closures have reduced availability of opioids	С	C	С	С
Less private physicians accepting Medicare/Medicaid	C	C	C	C
Rise in drug abuse associated with the recession	C	C	С	С
Less private physicians prescribing opioids	C	C	0	0
Patients know that ED's can not refuse to treat them	C	С	0	C
Other (please specify)				

28. If you are aware of the patient's method of payment, have you noted any trends in those patients manifesting "drug seeking" behavior?

	Increase	About the same	Decrease
Government assisted (e.g. Medicaid, Medicare)	C	C	С
Private insurance	C	C	C
Self pay / cash	С	C	C

*29. Do you feel a pressure to prescribe opioids, even in the presence of "drug seeking" behavior, to avoid any of the following: (check all that apply)

	Strongly Agree	Agree	Disagree	Strongly Disagree
Potential Brd of Medicine complaints for inadequate pain mgmt	C	C	С	C
Civil liability (e.g. withdrawal, over/under treatment of pain)	C	C	С	С
Pt complaints to hospital administration that pain wasn't managed	C	С	С	С
Joint Commission surveys negatively affected w/regard to pain mgmt	C	C	С	C
Reduced reimbursement if patient satisfaction decreased	C	С	С	C
None of the above are concerns	C	C	C	C
Other (please specify)				

30. Have you, or one of your colleagues, been criticized by administration for refusal to prescribe opioids?

C Yes

*31. Please comment on the following statement: "Patient satisfaction scores are too highly emphasized as a means of assessing good patient care."

0	Strongly Agree
0	Agree
0	Disagree
0	Strongly Disagree
Othe	r (please specify)

32. Are any of the following part of your opioid prescribing practices? (check all that apply)

	Always	Frequently	Occasionally	Never
History	С	C	C	C
Physical exam	C	C	C	C
Lab tests	С	С	С	С
Review past medical records	C	C	C	C
Query state's Rx drug monitoring database (PDMP)	C	С	C	С
Consult pharmacist	C	C	C	0
Other (please specify)				

33. Are any of the following included in your management of patients manifesting "drug seeking" behavior? (check all that apply)

	Always	Frequently	Occasionally	Never
Prescribe limited supply of short-acting opioids	С	C	C	C
Prescribe limited supply of long-acting opioids	C	C	C	C
Prescribe limited supply of non-narcotic analgesics	С	C	С	C
Recommend over the counter analgesics	C	C	C	C
None of the above	C	C	С	C
Other (please specify)				

34. Describe your administrative protocols for prescribing opioids / controlled substances in the ED?:

- C Hospital does not have an administrative protocol
- C Protocol exists, ED physician use is voluntary
- C Protocol exists, ED physician use is mandatory

35. Are any of the following components of that protocol?

	Opioids can only be prescribed in a limited supply
	Only non-narcotic analgesics can be prescribed
	Pharmacy must be consulted if available
	Patients must be referred to pain management physician
	State's Rx monitoring database (PDMP) must be queried prior to opioid prescribing

Drug screening must be performed to detect signs of abuse



36. Would you prefer to have an administrative prescribing protocol for opioids / controlled substances?



37. Please comment on the following statements regarding administrative protocols for prescribing opioids / controlled substances? (check all that apply)



38. Optional question: Please provide your opinions, advice, suggestions for management of patients manifesting "drug seeking" behavior in the ED. Thank you for your assistance with our survey.



Thank you for completing this survey.

In appreciation for your time, the Associates in Emergency Medical Education (AIEME) has offered to provide an online CME/CEU seminar package for you entitled: "Prescribing in an Epidemic®." By viewing this and completing a short quiz you can receive, at no charge, 6.5 hours of CME Category 1 for physicians and 6.5 hours of CEU credits for nurses.

If you are interested in this offer please copy and paste the following link into your browser to be transferred to AIEME:

https://www.aieme.com/component/dtregister/?eventId=1138&task=event_register&type=reg_individual

Coupon code: SurveyCredit100

This link will take you to the Associates in Emergency Medical Education (AIEME) website. The AIEME site is not linked in any way to the survey site thereby assuring your survey responses will remain anonymous. AIEME is not affiliated with the University of South Florida.

Thank you again,

USF Study Team

Appendix B

Survey Consent Form

Verbal Consent for Interviews IRB #9509 Version 1 – February 19, 2013 Informed Consent:

Thank you for your interest in participating in our research study. Prior to participation, please be advised of the following:

a) The purpose of the study is to obtain the opinions/views of medical professionals managing patients on opioid/scheduled drug therapies with regard to management strategies including the use of prescription monitoring programs. Opinions will be obtained through an interview.

b) There are no foreseeable risks, discomforts, or direct benefits of the research to participants. All responses will remain anonymous and no identifiable information will be collected by researchers.

c) Data collected will be maintained by researchers on password protected computer systems and will not be available for public review

d) There is no compensation for participation however a 6.5 hour CME video may be viewed on a separate website as a means of appreciation for participants' time in completing the survey. No foreseeable costs will be encountered by participants. This study is complete voluntary.

e) Participants may withdraw from the interview at any time and no questions are mandatory for response

f) I have been informed that I may contact the program coordinator or the IRB office at the University of South Florida should I have questions regarding this study. Their contact information is:

1) Sharon Kelley, Study Coordinator, sharon.kelley@aieme.com 813.240.9835

2) USF Institutional Review Board (IRB): 813.974.5638.

Waiver of Informed Consent:

This study provides subjects anonymity with regard to their responses thus presenting less than minimal risk to the subjects. No identifiable data will be collected through the survey. By agreeing to this interview you understand that you are participating in research.

I consent to participation in this study.

Appendix C

Survey Invitation

Invitation to Participate in Research Study:

Economic & Regulatory Factors Impacting Management of "Drug Seeking" Patients by ED Physicians

Internet Survey: https://www.research.net/s/EDphys Personal Interview: 813.240.9835

Purpose & Procedures of the Research Study:

To obtain the opinions of medical clinicians regarding the potential impact of economic and regulatory factors in their management of patients manifesting "drug seeking" behavior.

Time Needed / Pertinent Details:

This online survey will require approximately ten (10) minutes to complete, all responses are anonymous and participants may withdraw at any time.

Eligibility Criteria

Clinicians within the US who manage, or have the potential of managing patients on opioid/scheduled drug therapy.

Compensation:

In appreciation, participants will be given the opportunity to view, at no charge, an online prescription drug abuse seminar and receive 6.5 hours of CE credit.

This study is being conducted by the University of South Florida, IRB # 9509. Should you have any questions, please contact Study Coordinator, Sharon Kelley, at 813.240.9385 or sharon.kelley@aieme.com with questions.

Appendix D

DIVISION OF RESEARCH INTEGRITY AND COMPLIANCE

Institutional Review Boards, FWA No. 00001669 12901 Brace B. Downs Blvd. MDC035 • Tampa, FL 336124799

(813) 974-5638 · FAX (813) 97+5618

IRB Approval – Initial



January 17, 2013

Raymond Harbison, Ph.D. Environmental and Occupational Health 13201 Bruce B Downs Blvd. Tampa, FL 33612

RE: Exempt Certification for IRB#: Pro00009509

Title: Opinions of Medical Professionals Regarding Management Strategies, including utilization of Prescription Monitoring Programs (PMPs), for Patients on Opioid Therapy.

Dear Dr. Harbison:

On 1/17/2013 the Institutional Review Board (IRB) determined that your research meets USF requirements and Federal Exemption criteria as outlined in the federal regulations at 45CFR46.101(b):

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

As the principal investigator for this study, it is your responsibility to ensure that this research is conducted as outlined in your application and consistent with the ethical principles outlined in the Belmont Report and with USF IRB policies and procedures. Please note that changes to this protocol may disqualify it from exempt status. Please note that you are responsible for notifying the IRB prior to implementing any changes to the currently approved protocol.

The Institutional Review Board will maintain your exemption application for a period of five years from the date of this letter or for three years after a Final Progress Report is received, whichever is longer. If you wish to continue this protocol beyond five years, you will need to submit a new application. When your study is completed, either prior to, or at the end of the five-year period, you must submit a Final Report to close this study.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call \$13-974-5638.

Sincerely,

Kristen Salomon, Ph.D., Vice Chairperson USF Institutional Review Board

Appendix E

IRB Approval – Amendment



RESEARCH INTEGRITY AND COMPLIANCE Institutional Review Boards, FWA No. 00001669 12901 Bruce B. Downs Blvd., MDC035 • Tampa, FL 33612.4799 (813) 9745638 • EAX(813)9747091

10/17/2013

Raymond Harbison, PhD University of South Florida Environmental and Occupational Health 13201 Bruce B. Downs Blvd. Tampa, FL 33612-3805

RE: Expedited Approval for Amendment

IRB#: Ame3_Pro00009509

Title: Opinions of Medical Professionals Regarding Management Strategies, including utilization of Prescription Monitoring Programs (PMPs), for Patients on Opioid Therapy.

Dear Dr. Harbison:

On 10/17/2013, the Institutional Review Board (IRB) reviewed and APPROVED your Amendment. The submitted request has been approved for the following:

1) Revised survey - Survey ED Physicians 10-13.

2) Change in key personnel: removal of Catherine Jackson.

3) Revised advertising/recruitment materials - Research study invitation - ED.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

John Schinka, Ph.D., Chairperson USF Institutional Review Board