

October 14, 2019

To whom it may concern:

I am a former police detective, former State of Ohio Medical Board Investigator, former Director of Compliance for Cincinnati Pain Physicians, CME trainer, healthcare regulatory expert witness, and healthcare regulatory consultant. (See attached CV) As a healthcare regulatory consultant, I only assist clients that demonstrate a lack of criminal intent.

On September 12, 2019, I conducted an extensive independent review and audit of Dr. Margolin's pain management practice located at 5245 E. Main St. in Columbus, OH. Dr. Margolin is one only a few pain physicians in Ohio that is double specialty boarded in pain. Dr. Margolin has dedicated his life and education to learning the newest and most advanced methods to treat his pain patients in a medically sound, regulatory compliant, and patient focused manner.

The practice review and audit included a review of medical records for regulatory compliance and standards of care, general practice and patient observations, staff observations with patient interactions, policy and procedure reviews, and State of Ohio Pain Management License practice compliance inspection.

I can testify to the high level of compliance demonstrated by Dr. Margolin's medical practice in regards to the State of Ohio Pain Clinic (PMC) license requirements, Ohio's Revised and Administrative Codes, and exceeding minimum standards of care (The standard in which all pain practices should be operated).

Dr. Margolin not only complies with all state requirements and standards of care, Dr. Margolin had already implemented several of the recommendations listed in HHS Pain Management Best Practices Inter-Agency Task Force Final Report. Examples of compliance- Page 17- Clinical Best Practices lays the ground work for quality and complaint patient care. Patients must be thoroughly evaluated including the medical and probable biopsychosocial factors contributing to a pain condition. Dr. Margolin utilizes EMG and NCV studies to determine the medical factors contributing to their pain condition. Clinical best practices goes on to emphasize the importance of screening for Substance Use Disorder and in the second paragraph states "Finally, quality care must be adequately reimbursed." Dr. Margolin screens all patients for substance use disorder because not only is it recommended and required by best practices and state law, it is the safer for the patient, their family, and the community. Page 30- 2.2.1 Overdose Prevention Education and Overdose Risk. Dr. Margolin educates his patients on the dangers of opioids

not only in person, but also in their opiate agreement, and other patient forms every patient visit as part of their assessment. Dr. Margolin offers Naloxone prescriptions to his patients as well. Pages 39-40 sections 2.5.1 and 2.5.2 go only to further list and justify SUD screening and psychological evaluation and treatment. Dr. Margolin has long practiced these recommendations even before the expert report was completed. These examples only highlight a few ways that Dr. Margolin's policies and procedures were above compliant from the start. The report actually models Dr. Margolin's current pain practice and compliments his compliance.

I would like to mentioned the State of Ohio Pain Clinic (PMC) license requirement to document organic pathology prior to prescribing opioid medications. Dr. Margolin fulfills this requirements by obtaining records, imaging reports and performing electro diagnostic studies (EMG and NCV) that provide immediate objective results that document organic pathology.

Dr. Margolin made compliance with the state and national guidelines a high priority. Dr. Margolin contacted AANEM and received a written response from Millie Suk, JD, MPP | AANEM Health Policy Director stating that "AANEM does not have any "best practices" established for pain management" and that AANEM endorses AAPMR policies. Dr. Margolin contacted AAPMR and its certifying body ABPMR and performed a voluntary practice improvement project under ABPMR guidance that showed a high level of compliance with the state and national guidelines, clear medical necessity and significant impact on patient care. This project received high reviews from the experts Dr. Wainepal and Dr. Kimura.

I would also like to mention Dr. Margolin's SBIRT protocol that is very thorough, efficient and compliant with the MLN (ICN 904084) (MLN requires physician to implement SBIRT as required by the state law (42CFR 410.20), the State of Ohio Pain Clinic (PMC) license requirements and HB 93 state law.

Dr. Margolin's practice treats high risk vulnerable patients that frequently require 30 min or more for procedures related to screening for substance use and alcohol. These procedures include face to face time spent by Dr. Margolin and his nurse practitioners, more than 30 min of telecommunication video material, structured review of several assessments including patient's history and physical examination, PADT, COMM, Flowchart form based on SMBO Administrative Rule 4731-21-02, withdrawal assessment form, point of care and conformation urine and saliva drug screen reviews, OARRS review (of note Dr. Margolin's practice obtains OARRS for every patient visit which is the highest level of compliance with the SMBO policy and HB-93 law), and several educational materials. The initial evaluations include additional assessments such as SOAPP-R and ORT and additional educational materials.

His SBIRT records document the time spent, rationale for ordering tests (i.e. urine screens), relevant history, assessment, plan of care for each encounter. Dr. Margolin identifies and manages the risk factors very efficiently (of note frequent consultation with a qualified pain psychologist, pharmacology doctors and other specialists).

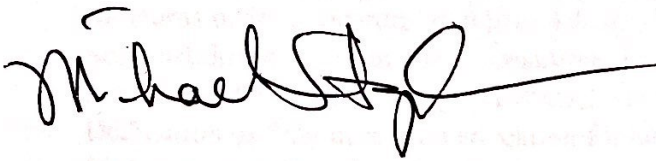
Dr. Margolin's excellence in implementation of the SBIRT protocol as related to screening for substance use and alcohol is evident by the high number of referrals from major hospitals such as OSU, Riverside, Grant, Adena Health and University Hospitals in Cleveland and even other pain management practices. It's my understanding is that Dr. Margolin is going to present his experience in this field at the State and national meetings and educational events.

MICHAEL W. STAPLES, CMBI

Finally, it should be noted that Dr. Margolin's office only sees an average of 15 patients per provider per day. This average patient number is extremely low compared to his peers that see upwards of 40-50 patients a day and does not indicate a physician that is interested more in profit than patient care.

If you have any questions or would like additional information, feel free to contact me on my cell at (513) 464-6721 or via email: Michael.Staples@practiceshields.com

Regards,



Michael Staples, CMBI

MICHAEL W. STAPLES, CMBI
(513) 464-6721 • Michael.Staples@practiceshields.com

Director of Compliance
Regulatory and Legal Health Care Compliance

Over 20 years' experience in criminal investigations, regulatory license investigations, scope of medical practice investigations, health care regulatory and legal compliance, management, conflict resolution, drug diversion investigations, and drug diversion education.

Demonstrated success record in:

- Successful investigation and prosecution of licensed health care professionals.
- Successful investigation and administrative action of licensed health care professionals for standards of care and administrative violations.
- Successful investigation and prosecution of criminal drug diverters.
- Experienced with identifying, preventing, and deterring health care drug diversion.
- Dedication to drug diversion education for health care professionals.
- Proven record of regulatory compliance excellence.

CORE COMPETENCIES

- Criminal/Administrative Investigations
 - Regulatory Compliance
 - Public Speaking
 - Drug Diversion Education
 - Drug Diversion Investigations
 - Safe Prescribing Practices
-

HIGHLIGHTED CAREER ACHIEVEMENTS

- 2+ years' experience as Director of Compliance for a large pain management office.
- 9+ years' experience as a Police Detective focusing on Criminal Drug Crimes.
- 9+ years' experience as a Medical Board Enforcement Investigator focusing on Controlled Substance Prescribing Investigations, prescriber education, scope of practice and minimum standards of care investigations.
- Earned National recognition as a Certified Medical Board Investigator "C.M.B.I." from the National Federation of Medical Boards.
- Staples, M & Practice Shields, LLC. "Comprehensive Controlled Substance Prescribing in the age of increased regulations, legal challenges, and diversion." Presented in conjunction with West Virginia Interventional Pain Physicians accredited with Commendation from the West Virginia State Medical Association for 17.25 Category 1 CME. February, 2019
- Staples, M & Practice Shields, LLC. "Comprehensive Controlled Substance Prescribing in the age of increased regulations, legal challenges, and diversion." Presented in conjunction with Tri Health Hospital for 15 Category 1 CME. February, 2019
- Staples, M. & Harding, K "APRNs and Schedule II Prescribing in Ohio." Presented in Conjunction with the Ohio Board of Nursing. Available for 6 Hours of Continuing Education Credit. Ohio Board of Nursing, Columbus, Ohio. March 31, 2014.
- Staples, M., Harding, K, & Galante, C. "APRNs and Schedule II Prescribing in Ohio." Presented in Conjunction with the Ohio Board of Nursing and Ohio State Board of Pharmacy.

Available for 6 Hours of Continuing Education Credit. Ohio Board of Nursing, Columbus, Ohio. November 25, 2013.

- Staples, M. "It Takes an Office: Protecting your Practice from Drug Diversion." Mercy Health Systems CME, June 15, 2015. <https://youtu.be/tiFrhirb93M>
- Former Director of Education and Training for Ohio Chapter of NADDI.
- Certified as a National Certified Investigator and Inspector Training (NCIT) both basic and specialized. Known as CLEAR Certification.
- Expert Report Admitted Cuyahoga County Common Pleas Court, State of Ohio, Case- CR-16-607224A-D State of Ohio vs. Rogaciano Trocio, MD, Maria Siwik, RN, Virginia Paulino, and Janet Paulino

PROFESSIONAL EXPERIENCE

Interventional Pain Specialists, Inc, 2019-Present

Crestview Hills, Kentucky

Compliance Officer

- Regulatory and Legal Compliance Management
- HIPPA Compliance Office
- Medical Records Review
- Staff Education
- Policy and Procedure Implementation
- Drug Diversion Reduction
- Standards of Care Reviews

Cincinnati Pain Physicians, LLC, 2017 – 2019

Cincinnati, Ohio

Director of Compliance

- Regulatory and Legal Compliance Management
- Identification of Drug Diversion in patient population
- Policy and Procedure Implementation
- Medical Record's Review
- Staff education
- Prevention of Drug Diversion in practice
- Standards of Care Reviews

Practice Shields, LLC

Fairfield, Ohio

2017 – 2018

Founder and Owner

- Dedication to ensuring regulatory compliance for health care practices and prescribers
- Health Care Practice and Prescriber Education
- D.R.A.P. Accreditation Program (Drug Resistant Accredited Practice)
- Practice compliance audits
- Expert Testimony
- Standards of Care Reviews
- Practice Drug Diversion Defense Techniques

State Medical Board of Ohio,

2007 – 2017

Columbus, Ohio

Enforcement Investigator

- Investigations of Ohio Regulatory Rules and Laws
- Standards of Care Investigations
- Testimony at Federal, State, Local, and Administrative Hearings
- Prescriber Controlled Substance Education
- Drug Diversion Investigations
- CME Diversion program development and implementation
- Member of drug abuse and diversion task forces

City of Monroe Police Department,

1998 – 2007

Monroe, Ohio

Police Detective

- Criminal Drug Investigations
- Warren County Drug Task Force Participant
- Federal, State, and Local Court Testimony
- CVSA Lie Detection Operator
- Butler County Child Abuse Task Force Member
- Established a strict reporting system for allegations of stolen controlled medications

EDUCATION and CERTIFICATION

Certified Medical Board Investigator (CMBI)

Basic and Specialized CLEAR Certification

OSU-Newark, Criminal Justice

Central Ohio Technical College, Criminal Justice

UC-Clermont Pre-Law

1995 Butler Tech Police Academy, Police Certification 1998