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AMCNO and AMEF Collaborate with CWRU School of Medicine to Address the Opioid Crisis in Ohio

By Theodore V. Parran, Jr., MD

The current opioid epidemic is a top priority for physicians and for organized medicine in Ohio. One important approach to addressing this epidemic is to provide the highest-quality education to Ohio physicians in the areas of prudent prescribing of controlled drugs; pain management; differential diagnosis and management of anxiety insomnia and attention deficit disorder (ADD); opioid and benzodiazepine pharmacology; and strategies to maintain professional boundaries while maintaining a therapeutic relationship.

The Academy of Medicine of Cleveland & Northern Ohio (AMCNO) and its foundation, the Academy of Medicine Education Foundation (AMEF), has partnered with the CWRU School of Medicine Program in Continuing Medical Education (CME) to provide this type of online course. The course is designed for physicians in all specialties, to help them increase their knowledge and ability to effectively prescribe controlled medications that have abuse potential, with the intention to curb opioid and other controlled drug abuse and addiction. Through the AMEF, an educational grant has made this program possible. The AMEF is the charitable component of the AMCNO—the regional medical society that has united Northern Ohio physicians to respond to the needs of the profession since 1824.

CWRU School of Medicine: a National Leader in Controlled Drug Prescribing Education

Since 1994, CWRU School of Medicine has sponsored an "Intensive Course in Controlled Drug Prescribing" for the educational needs of all clinicians, as well as for those who have developed problems in their prescribing practices. More than 3,200 physicians and other prescribers have been referred to this 3-day, category 1 CME course by medical boards in 48 states and four Canadian Provinces, as well as by hospital systems and group practices. The course has received national acclaim as one of a very few high-quality educational offerings in the principles and practice of prescribing controlled drugs. Based on this expertise, several hospital systems requested that aspects of the course that most apply to typical medical practice be developed into an online offering so that clinicians in their systems could more easily

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The Supreme Court Resolves Split Between Ohio Appellate Courts: Statements of Fault are Inadmissible Under the Ohio Apology Statute

By Susan Audey, Christina Marino, and Brandon Cox, Tucker Ellis LLP

Despite a healthcare provider's best efforts, a patient may experience an unexpected medical outcome, even death. It is an elemental human characteristic to want to offer some expression of sympathy or benevolence—even to apologize for the unanticipated turn of events.

An apology may go a long way to diffuse a difficult situation, facilitate healing, preserve relationships, and even avoid later litigation. Yet a healthcare provider may be wary that any such statements would be used later as evidence of negligence or liability in a malpractice suit. To encourage conversations and transparency between healthcare providers, patients, and their families after unanticipated outcomes, Ohio and more than 30 other states have adopted what are often referred to as "apology statutes." Ohio's apology statute—R.C. 2317.43—provides that a healthcare provider's "statements,

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The Supreme Court Resolves Split Between Ohio Appellate Courts: Statements of Fault are Inadmissible Under the Ohio Apology Statute

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affirmations, gestures, or conduct expressing apology, sympathy, commiseration, condolence, compassion, or a general sense of benevolence" that relate to an unanticipated outcome during medical care are inadmissible as evidence when made to the patient, her family, or her representative.

Ohio's statute does not define "apology," or any of the other forms of expression, and does not distinguish between a healthcare provider's statement of sympathy and one acknowledging fault. One appellate court—*Wooster Orthopaedics & Sportsmedicine, Inc.*[1] — has said that statements of apology do not include statements of fault, while another—*Stewart v. Vivian*[2]—has said that they do. The Supreme Court agreed to resolve this conflict by accepting *Stewart* for review. In a 5-2 decision released on Sept. 12, 2017, Justice Kennedy, writing for the majority, found that statements admitting liability or fault made during the course of apologizing or commiserating do indeed fall within the statute's protections.[3]

Stewart was a medical-malpractice and wrongful-death action filed by Dennis Stewart on behalf of the estate of his wife, Michelle. Following a suicide attempt, Michelle was admitted to Mercy Hospital under the care of Dr. Rodney Vivian, who entered orders requiring hospital staff to visually check on Michelle every 15 minutes. During an unmonitored period, Michelle again attempted suicide. Her attempt caused irreversible brain damage and she eventually died. Dr. Vivian spoke to Dennis and Michelle's sister after the event. Dr. Vivian did not remember the conversation, although he later recalled saying he was sorry. Dennis and Michelle's sister provided differing accounts of the statements made by Dr. Vivian:

- According to Dennis, Dr. Vivian said he "didn't know how it happened; it was a terrible situation, but she had just told him that she still wanted to be dead, that she wanted to kill herself."
- Michelle's sister remembered that Dr. Vivian asked the family what they thought had happened. In response, Dennis said that Michelle "had obviously tried to kill herself." Dr. Vivian commented, "Yeah, she said she was going to do that. She told me she would keep trying."[4]

Despite differences between the family's statements, the trial court nonetheless found that Dr. Vivian's statements were an "attempt at commiseration" and therefore inadmissible under the apology statute.[5] The case proceeded to trial without the statements and the jury eventually returned a defense verdict.[6] The appellate court affirmed, finding that the Ohio General Assembly's intent was to protect all statements of apology, including those admitting fault.[7]

On appeal to the Supreme Court, the Court acknowledged that the statute does not define "apology."[8] The Court therefore relied on its ordinary dictionary meaning—"an acknowledgment intended as an atonement for some improper or injurious mark or act: an admission to another of a wrong or discourtesy done accompanied by an expression of regret."[9] Relying on that dictionary meaning, the statute was "susceptible of only one reasonable interpretation"—i.e., "a statement expressing apology is a statement that expresses a feeling of regret for an unanticipated outcome of the patient's medical care and may include an acknowledgment that the patient's medical care fell before the standard of care."[10] The Court's ruling makes clear that statements of fault come within the evidentiary protections of R.C. 2317.43 and are inadmissible.

Two justices dissented, in part. Chief Justice O'Connor, joined by Justice O'Neill, agreed that statements of fault come within the statute's protections, but disagreed that the statements made by Dr. Vivian were statements of fault.[11] To the Chief Justice, Dr. Vivian merely summarized statements Michelle made to him and "added a description of his own state of mind."[12] She concluded that Dr. Vivian's statements were an expression of shock and surprise that did not have an indicia of apology, commiseration, or regret.[13]

The Chief Justice acknowledged that a healthcare provider need not expressly say "I apologize" or "I sympathize," but she expressed concern about relying on the speaker's intent and not on the "actual content" of the statements made. She believes that a healthcare provider "could render any statement inadmissible simply by affirming a subjective intent to apologize or console."[14]

But this conclusion fails to consider that the statute's protections are not limited to statements expressing apology or sympathy, but include statements expressing commiseration, compassion, and a general sense of benevolence. However Dr. Vivian's statements are construed, there should be no doubt that statements made by a healthcare provider after an unanticipated outcome that are consistent with commiseration, compassion, and benevolence—as well as statements of apology and fault—are inadmissible under the statute. The statements Dr. Vivian made here fall within those parameters and the statute's protections.

In any event, although *Stewart* resolves an important issue regarding the applicability of Ohio's apology statute to statements of fault, Chief Justice O'Connor's dissent is likely to become a focus for further litigation as courts grapple with which statements fall under the statute and which do not. In fact, it already has. Dennis's counsel filed a motion asking the Supreme Court to reconsider the September 12 decision. Counsel did *not* take issue with the Supreme Court's conclusion that statements of fault come within the statute's protections and are inadmissible. They claim—much like the Chief Justice—that Dr. Vivian's statements are not statements of fault. The Court has yet to rule on the motion.

For now, however, the Court's decision puts to rest whether statements of fault are inadmissible under the apology statute. They are. This is good news for AMCNO members and all healthcare providers.

The AMCNO participated in providing amicus support for Dr. Vivian at the Supreme Court by jointly submitting an amicus brief with the Ohio State Medical Association, Ohio Hospital Association, and the Ohio Osteopathic Association. ■

1. 193 Ohio App.3d 581, 2011-Ohio-3199, 952 N.E.2d 1216 (9th Dist.).
2. 2016-Ohio-2892, 64 N.E.3d 606 (12th Dist.).
3. *Stewart v. Vivian,* Slip Opinion No. 2017-Ohio-7526, ¶ 2.
4. *Id.* at ¶ 13-15.
5. *Id.* at ¶ 16.
6. *Id.* at ¶ 17.
7. *Id.* at ¶ 18.
8. *Id.* at ¶ 26.
9. *Id.* at ¶ 27-28.
10. *Id.*
11. *Id.* at ¶ 33.
12. *Id.* at ¶ 41.
13. *Id.* at ¶ 42.
14. *Id.* at ¶ 43.

AMCNO/AMEF ADDRESSES OPIOID CRISIS

AMCNO and AMEF Collaborate with CWRU School of Medicine to Address the Opioid Crisis in Ohio *(Continued from page 1)*

access the content. Based on these requests, the AMEF decided to support this initiative with an educational grant.

The Current Opioid Crisis

Opioids are a class of medications that have long been used in patient care. They have also been involved in periodic epidemics of abuse and addiction since the Civil War era of the 1860s. According to the Centers for Disease Control and Prevention (CDC), the United States is in the midst of its worst opioid abuse and overdose epidemic. Prescription opioids continue to play a major role in the current epidemic, with at least half of the more than 28,000 opioid-associated deaths in 2014 involving a prescription.

As a consequence, Ted Parran, MD, a board-certified internal medicine and addiction medicine specialist, the Isabel and Carter Wang Professor and Chair in medical education at CWRU, and an AMCNO member, is especially busy combining his expertise in addiction medicine and medical education to teach the principals of safe opioid prescribing to students, residents and practicing clinicians.

"The current epidemic started in the early 1990s when there was a belief system shift, a so-called paradigm shift, regarding the treatment of chronic pain," says Dr. Parran. "Before 1990, chronic pain was typically treated without opioid medications—and it was pretty effectively managed. In the 1990s palliative care physicians presented the hypothesis that if malignant pain could respond to more aggressive opioid prescribing, resulting in an improvement in patient quality of life … then perhaps they could also be useful in chronic pain management. This hypothesis—without substantial clinical data to support it—combined with intensive pharmaceutical company marketing, and an emphasis on pain screening from accreditation organizations like the Joint Commission, resulted in a massive increase in the prescribing of high-dose, long-term opioids for chronic pain. In retrospect, a significant proportion could be termed 'over-prescribing.' Tragically, the potential risks of opioid prescribing were largely unknown, and when they did become known, they tended to be downplayed," he said.

As a consequence, opioid prescribing in the U.S. has quadrupled since 1999, with an accompanying upsurge of availability on the secondary, so-called "street market." Since 2014 physicians have gradually begun decreasing opioid prescriptions in the face of widespread misuse and fatal overdoses. One unexpected, and disastrous, result has been that many patients have turned to heroin, which is significantly less expensive and more easily available than prescription opioids. This in turn triggered a spike in fatal heroin overdoses. A confounder is that heroin is frequently mixed with fentanyl or even carfentanyl, which are synthetic opioids illegally produced and imported from China through Mexico. Fentanyl can be 100 times more potent than heroin, playing a major role in rampant accidental opioid overdoses in cities throughout Ohio and the nation.

The CWRU – AMCNO/AMEF Response

The current crisis is a perfect time for initiatives like the CWRU – AMCNO/AMEF online educational series. This series focuses on teaching a systematic approach that is time efficient, clinically effective, and evidence-based to help physicians make sound decisions regarding the acute and chronic prescribing of all controlled drugs. In effect it is a way to implement a "Universal Precautions" clinical practice-based approach to prescribing that clarifies the risk/benefit factors present in each patient situation, and also provides a systematic way to follow-up with monitoring and documentation. Basic aspects of this online curriculum cover topics such as cost-effective and efficient patient assessment, starting/continuing/stopping/or avoiding controlled drugs, doctor-patient relationship maintenance, medical board requirements, and medical record documentation. Also covered are basic principles of controlled drug pharmacology, physical dependence, withdrawal management, pain/anxiety/insomnia/ADD diagnosis and treatment, and mandatory aspects of documentation and record keeping.

Dr. Parran reports that "the CDC has referred to the current opioid epidemic as the most serious iatrogenic epidemic of our new century." Course material in this new online series will clearly help all clinicians with controlled drug prescribing decisions, will help with better balanced prescribing patterns, and will result in better patient and community safety. CWRU School of Medicine, the AMCNO and AMEF are pleased to make this outstanding clinical education resource available to the prescribing clinicians of our region. ■

AMCNO ADDRESSES OPIOID CRISIS

AMCNO Assists in Promoting Know The Risks Campaign

The AMCNO is pleased to partner with the "Opioids: Know the Risks" (#KnowTheRx) campaign in our community. This campaign is a collaborative ongoing effort among local agencies and organizations, production companies, hospitals, and media outlets, and organizations like the AMCNO which intends to address the opioid epidemic. A full list of the community partners can be found on the AMCNO website, www.amcno.org.

The campaign has included news coverage, public service announcements, commercials, print advertisements and social media outreach on the risks associated with prescription opioids. It is organized by the Cuyahoga County Opioid Marketing Task Force, which is comprised of officials from Cuyahoga County, the City of Cleveland, the medical examiner's office, the U.S. Attorney's Office and local hospitals.

The campaign is intended to supplement ongoing efforts that have focused on treating those with an addiction, supporting their families, and stopping the spread of drugs.

Many people do not realize the risks that they are taking when they take that first pill. It is a fine line between appropriate prescription use and addiction abuse. Physicians are prescribing drugs appropriately but there are risks attached to this practice, and this campaign is meant to open up a dialogue between patients and providers. **This is not a campaign against doctors.**

Hospitals are already providing information to patients about prescription drugs, and the AMCNO is looking to supplement that education.

To obtain a copy of the brochure that is part of the Know the Risks campaign and is branded with the AMCNO logo, visit www.amcno.org/pdf/KnowtheRx.pdf. We encourage our members to share it with their patients to open the lines of communication about the issue.

If you would like to learn more about the campaign from the Cuyahoga County Office of the Executive website and review the additional materials available in the toolkit, log on to http://executive.cuyahogacounty.us. In addition, KnowtheRx.org is hosted by cleveland.com and is locally focused. It contains additional resources for patients and providers. ■

AMCNO Attends HOPES Task Force Roundtable

The Task Force on HOPES (Heroin, Opioids, Prevention, Education and Safety) recently held a regional meeting at MetroHealth Medical Center. Chaired by Rep. Robert Sprague (R-Findlay), a panel of state and local leaders involved in combating Ohio's opioid crisis gathered to discuss the issue.

During Rep. Sprague's opening remarks, he played a video of Ohio House Speaker Cliff Rosenberger (R-Clarksville) from January 1, when he introduced the HOPES agenda, which was formed as a response to the crisis. "This is our burden, our challenge," Rep. Rosenberger said. "We must confront it."

Rep. Sprague said that $180 million has been allocated in the budget for HOPES, which is divided into four categories that focus on:

- Workforce development
- Prevention
- Mental health
- Treatment and child services

In addition to Rep. Sprague, the panel consisted of: **Rita Andolsen,** Director, Systems Communications at Metro; **Rep. Dave Greenspan** (R-Westlake); **Rep. Steve Hambley** (R-Brunswick); **Valeria Harper,** CEO of the Alcohol, Drug, and Mental Health Services (ADAMHS) Board; **Jen Johns,** Director, Government Relations at Cleveland Clinic; **Rep. Sarah LaTourette** (R-Chesterland); **Dr. Joan Papp,** physician at Metro and AMCNO member; **Dr. Ted Parran,** addiction specialist at Rosary Hall at St. Vincent and AMCNO member; and **Hugh Shannon,** Administrator, Cuyahoga County Medical Examiner's Office.

Rep. Sprague wanted to convene for an effective roundtable discussion. "We're searching for new ideas and answers so that Ohio doesn't stay No. 1 in the country for opioid deaths," he said.

The HOPES Task Force convenes at MetroHealth Medical Center to discuss the opioid crisis.

He asked each panel member to explain what they're working on. Andolsen reported on the Know the Rx campaign, which was created to raise awareness of the risks of prescription opioids, to be at the forefront of the problem. A Detroit-based company agreed to provide marketing pieces *pro bono*. The materials have been sent to numerous media outlets, and many of them have picked it up. (For more information on this initiative, see page 4.)

Dr. Papp discussed Metro's prevention programs. Project DAWN (Deaths Avoided With Naloxone) launched in 2013. To date, the kits have saved more than 1,000 lives. A medication-assisted treatment (MAT) location is now open. The Office of Opioid Safety has also opened at Metro, of which Dr. Papp serves as the Medical Director. It is the first of its kind in Northeast Ohio, and the goal is to educate physicians and the public on opioid addiction. "We need to take a comprehensive approach to address [the crisis]," she said. Providers will receive education on opioids to help avoid potentially unsafe prescribing practices. Tools will also be available for providers to get patients into treatment. An education coordinator was recently hired, and the office received a $2 million grant to work with local communities. (To learn more about the Office of Opioid Safety, see page 7.)

Johns reported that Cleveland Clinic is working on MAT practices, specifically a pilot program for patients with substance abuse disorder who need access to MAT. The Clinic is finding that shared appointments, which focus on peer support, have been successful so far.

Harper said that the ADAMHS Board took a role in this issue from the onset. Some of the programs they offer include reaching out to youths and adolescents on prevention through education, and having a faith-based outreach committee that informs and trains members on Project DAWN and other initiatives.

Rep. Greenspan asked the panel about successful programs that can be used statewide. Harper cited two examples: quick response teams and peer recovery support programs. Dr. Parran said outpatient counseling also works, and when it's combined with patients receiving buprenorphine, there is a 60% success rate.

During the meeting, community leaders were asked to come to the podium to share their testimony or experiences.

Rep. LaTourette said that access to care continues to be an issue, and asked if there was legislation that could address it. Dr. Papp said that peer support and behavioral treatment have success in our region. Dr. Parran stated that education and counseling are also important, and the drug court movement is essential.

Rep. Greenspan asked Shannon about his work at the medical examiner's office and what concerns he may have. "Despite all of the good work and solutions, the end results are not where we want them to be," Shannon said. He reported that so far this year, there have been 500 deaths (20-25% of all fatalities) from fentanyl containing carfentanil. If trends continue, there will be 2,000 of these deaths by next year. Last year, they saw 56 carfentanil deaths, and there have been more than 100 already this year. "This is a serious threat to the community if these trends continue," he concluded.

Community leaders and citizens then provided comments from the floor. At the close of the meeting, Rep. Greenspan stressed the importance of working together to make the issue manageable.

The AMCNO will continue to follow these task force meetings and report updates to our members. ■

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MetroHealth Office of Opioid Safety

By Joan Papp, MD, Director, Office of Opioid Safety, MetroHealth

Opioid overdose continues to be the greatest threat to public health in Northeast Ohio and has been the leading cause of injury-related deaths statewide since 2007. This crisis, which started with an epidemic of prescription opioid abuse, has accelerated at an unprecedented pace, with the widespread availability of illicit heroin and fentanyl in Cuyahoga County over the past two years. This rate of acceleration represents a dire public health emergency and MetroHealth Medical Center is leading the fight with its new Office of Opioid Safety, led by Dr. Joan Papp. The mission of the new office is to improve opioid safety throughout the MetroHealth System and in the community through education, advocacy and treatment.

Since 2013, Dr. Papp has led MetroHealth's Project DAWN (Deaths Avoided With Naloxone) overdose prevention program, which is responsible for distributing the opioid antidote naloxone to more than 7,000 individuals and is credited with more than 1,000 lives saved with opioid overdoses reversed. The new office will continue to manage Project DAWN, but will address opioid safety and overdose prevention in a much more comprehensive way. The immediate goals of the office are to educate healthcare professionals on state and federal opioid guidelines, promote safer opioid prescribing and educate healthcare professionals on how to identify and treat opioid use disorder. The office is currently staffed with a full-time program manager, two Project DAWN outreach professionals and a full-time senior medical educator to work alongside Dr. Papp. The office aims to hire additional staff in 2018 to educate the community and collect data on outcomes. The senior medical educator is tasked with developing a curriculum to carry out the educational goals. Some early successes addressing education include a regional *SCOPE of Pain* safe opioid prescribing conference attended by more than 80 healthcare providers in the region, DATA 2000 waiver training of more than 75 prescribers who are now able to prescribe buprenorphine for treatment of opioid use disorder, and the development of a simulation training program to teach communication skills on how to lead difficult conversations with patients about opioid use. An education module on opioid best practice was also created for all providers to promote compliance with state and federal rules and guidelines.

MetroHealth recognizes that some healthcare providers are struggling to manage complex patients, and this new office aims to identify these providers and direct additional resources to them to support providers and to improve patient safety. MetroHealth is identifying the providers by analyzing prescribing patterns like high frequency and high morphine equivalent doses (MED) of opioids or concurrent prescriptions for benzodiazepines that may place patients at risk. If a provider is identified, additional tools and resources are provided to assist them. Some of these tools are clinical care pathways for both pain management and treatment of opioid use disorder, provider and patient education and better access to specialty services. Providers are also encouraged to participate in the communication skills simulation training.

The new office continues to work alongside the AMCNO, striving for improved state and federal policy that supports physicians and increases access and reimbursement for treatment of opioid use disorder. In October, the MetroHealth Office of Opioid Safety hosted the Task Force on HOPES (Heroin, Opioids, Prevention, Education and Safety) meeting led by Speaker of the Ohio House, Clifford Rosenberger, and chaired by State Representative Robert Sprague, in a roundtable discussion to share successful ongoing work in the community and ways in which that work can be spread and supported by the General Assembly across the state. An open hearing followed the roundtable discussion that allowed community members to discuss concerns and ideas to address the opioid epidemic. The office will also work closely will the Center for Health Affairs and its newly appointed Executive Director of the Northeast Ohio Hospitals Consortium on Opioid Addiction to advocate for sensible policy changes and to aid in spreading successful programs to all local hospitals. (For more information on the HOPES session see page 5.)

To better serve the community's growing need for addiction treatment, MetroHealth is now offering expanded outpatient addiction treatment services at its Parma campus located on Snow Road. The treatment program currently offers medication-assisted treatment with buprenorphine and a 6-week intense outpatient behavioral health treatment program. These services can be accessed by scheduling through the Department of Psychiatry, and walk-in assessment hours are available on Thursday mornings.

Lastly, the Office of Opioid Safety aims to open a physical space for the public early in 2018, which will serve as a one-stop resource for patients and families seeking help and for professionals on all matters related to addressing the opioid epidemic in our community. ■

Editor's note: *Dr. Joan Papp is a current member of the AMCNO and she was the recipient of our Special Honors Award in 2015.*

New Medical Marijuana Rules Allow Ohio Physicians to *Recommend* Marijuana in Patient Care

By Isabelle Bibet-Kalinyak and Richard C. Cooper, McDonald Hopkins LLC

On Sept. 8, 2017, the Ohio State Medical Board (the "Board") issued the new administrative rules[1] that will govern how Ohio physicians can now officially *recommend* medical marijuana for patients with certain qualifying conditions, such as amyotrophic lateral sclerosis ("ALS"), aka Lou Gehrig's disease, and fibromyalgia. The long-anticipated new rules follow the 2016 legalization of medical marijuana under Ohio law.[2]

Federation of State Medical Boards Model Guidelines

Over the last two decades, beliefs, attitudes, and laws in the United States have grown more tolerant toward the use of marijuana—medical or otherwise.[3] Between 2001 and 2013, the number of adults using marijuana has doubled. On the clinical front, as a patchwork of laws developed since the passage of Proposition 215 in California in 1996,[4] the Federation of State Medical Boards designated the Workgroup of Marijuana and Medical Regulation to evaluate current medical and osteopathic rules and regulations dealing with marijuana and draft model guidelines to assist state medical boards in regulating physicians, who are licensed to *recommend* marijuana treatment options, such as marijuana or marijuana-infused products to patients.[5] The new Ohio rules closely follow these nine model guidelines.[6]

Application and Requirements for Physicians

Under the new rules, Ohio physicians who meet certain requirements can obtain a certificate to recommend medical marijuana (the "Certificate") by applying to the Board.[7] The requirements delineated by the new rules include all the following:

1. Active and unrestricted Ohio license to practice medicine and surgery (MD or DO).
2. Access to the Ohio Automated Rx Reporting System ("OARRS").
3. Active DEA registration.
4. Never have been denied a license to prescribe, possess, dispense, administer, supply or sell a controlled substance by the DEA due to inappropriate prescribing, furnishing, dispensing, administering, supplying or selling a controlled substance, or never have had a DEA or state prescribing license restricted for the same.
5. Never have been subject to disciplinary action by any licensing entity based on prescribing, furnishing, dispensing, diverting, administering, supplying or selling a controlled substance or other dangerous drug.
6. Completion of at least two hours of Continuing Medical Education ("CME") in courses that assist in the diagnosing of a qualifying medical condition for medical marijuana and treating qualifying conditions with medical marijuana.
7. No ownership or investment interest in, or compensation agreement with, a medical marijuana entity licensed or seeking licensure in Ohio.

The Board will investigate all applications and may require applicants to appear in-person in Columbus to support their application. Once initially granted by the Board, the Certificate will automatically renew with the physician's license, although an additional two hours of CME will be required prior to automatic renewal. The current rules do not permit mid-level providers such as physician assistants or nurse practitioners to apply for a certificate.

Qualifying Conditions for Patients

The new rules clearly limit the qualifying conditions for which a physician may recommend medical marijuana under Ohio law. To apply for a medical marijuana card, the patient must demonstrate that he or she suffers from one of the following conditions or diseases: AIDS, Alzheimer's disease,[8] ALS, cancer, chronic traumatic encephalopathy, Crohn's disease, epilepsy or other seizure disorder, fibromyalgia, glaucoma, hepatitis C, inflammatory bowel disease, multiple sclerosis, pain that is either chronic and severe or intractable, Parkinson's disease, positive HIV status, post-traumatic stress disorder, sickle cell anemia, spinal cord disease or injury, Tourette's syndrome, traumatic brain injury, ulcerative colitis, or any other disease or condition added by the Board pursuant to Section 4731.302 of the Ohio Revised Code.

Forms and Routes of Administration

The new rules prohibit patients from growing medical marijuana and limit cultivation, processing, testing, and distribution to licensed growers, processors, testing laboratories, and retail dispensaries, respectively. They also define the only acceptable forms and routes of administration:[9]

1. Oral administration: Oil, tincture, capsule, or edible form.
2. Vaporization: Metered oil, solid preparation, or plant material (with use of vaporizing devices).
3. Transdermal: Patches.
4. Topical: Lotions, creams, or ointments.

Standard of Care for Physicians

The new rules also define a minimum standard of care Ohio physicians must adhere to in order to ensure patient and public safety:[10]

1. Establish and maintain bona fide physician-patient relationship, including an initial in-person visit and ongoing follow-up care.
2. Documentation in the medical records must include at least the following:
   - The patient's name and the dates of the office visits.
   - A description of the current medical condition being treated.
   - A detailed medical, prescriptive, and substance use disorder history.
   - A review of diagnostic test results, prior treatment and current medications.
   - Drug screen at physician's discretion if the physician unveils evidence of drug abuse.
   - A physical exam and diagnosis of the patient's medical condition.
   - Diagnosis or confirmation of prior diagnosis of a qualifying medical condition for medical marijuana. If

the patient has already been diagnosed with a qualifying condition, the physician must verify such diagnosis with the prior provider of record that made such diagnosis and document this step in the medical records.

The physician must terminate or decline to issue a new medical marijuana recommendation under any of the following circumstances:[11]

1. The diagnosis or symptoms of the qualifying condition no longer exist.
2. The physician no longer holds a valid certificate to recommend medical marijuana.
3. The patient or caregiver is abusing or diverting medical marijuana based on the physician's clinical judgment.
4. The patient is deceased.

Documentation in the Medical Records

In addition, if the physician recommends medical marijuana, he or she must document in the medical records[12] compliance with all the following actions:[13]

1. Development of a treatment plan.
2. Review of OARRS report covering at least the preceding 12 months.
3. A discussion with the patient regarding possible abuse or drug diversion of any drugs listed in the OARRS report.
4. Explanation of the risks and benefits of medical marijuana treatment.
5. Patient's consent or the consent of a legal representative.
6. Whether the patient needs a caregiver to assist in the administration of medical marijuana.
7. Confirmation of the patient's active registration with the Ohio Board of Pharmacy registry.
8. A statement from the physician certifying the following:
   - The patient has been diagnosed with at least one of the qualifying medical conditions.
   - A bona fide physician-patient relationship exists between the physician and the patient.
   - A description of the qualifying medical condition and whether it is a terminal illness associated with a life expectancy of six months or less.
   - The physician or authorized delegate has queried OARRS to obtain a report covering at least the past 12 months.
   - The physician has informed the patient of the risks and benefits of medical marijuana as related to the patient's specific medical condition and history.
9. Plan for follow-up care to assess efficacy and determine whether the terminal illness, as applicable, continues to be a terminal condition.

As illustrated by the detailed requirements set forth in newly published Ohio administrative rules, the decision to recommend medical marijuana to patients with a qualifying condition is riddled with pitfalls and risks for providers and employers. Failure to comply with (and document) all the regulatory requirements can lead to disciplinary actions by the Board, including fees, fines, civil penalties, suspension of the medical marijuana certificate, practice limitations, etc.[14] Physicians should therefore carefully weigh the risks and benefits for their patients and themselves alike. On the background of the opioid crisis and the battle for health care reform, the legalization of medical marijuana adds yet another layer of complexity for physicians, employers, and the court system momentarily. ■

Isabelle Bibet-Kalinyak and Richard Cooper are business attorneys with the corporate law firm of McDonald Hopkins LLC (www.McDonaldHopkins.com). Isabelle's practice focuses on health care law (transaction and compliance) and business immigration, primarily in health care settings; and Richard is the manager of the firm's National Healthcare Practice Group and the Co-Chair of its Healthcare Restructuring Practice Group.

1. Ohio Administrative Code ("OAC") Chapter 4731-32, Medical Marijuana.
2. Ohio Revised Code ("ORC") Chapter 3796.01 et. seq.
3. Isabelle Bibet-Kalinyak, Elizabeth Sullivan, Rick Cooper, Marijuana In Patient Care – Nine Model Guidelines From The Federation of State Medical Boards, The Ohio Physician, Academy of Medicine September/October 2017, available at http://www.amcno.org/pdf/3838%20Sept%20Oct%20Final.pdf.
4. At least 23 states have established medical marijuana programs at the time of publication. The states and territories that have enacted comprehensive marijuana programs are: Alaska (AS 17.37.070), Arizona (A.R.S. § 36-2801), California (Cal. Health & Safety Code § 11362.7 et seq.), Colorado (Colo. Rev. Stat. § 25-1.5-106), Connecticut (Conn. Gen. Stat. §420f-21a-408), Delaware (Del. Code tit. 16 § 4901A et seq.), District of Columbia (D.C. Code § 7-1671.01 et seq.), Guam (10 Guam Code Ann. § 122501 et seq.), Hawaii (Haw. Rev. Stat. § 329-121), Illinois (410 Ill. Comp. Stat. § 130/10), Maine (Me. Stat. tit. 22, § 2422 et seq.), Maryland (Md. Code, Health Gen. § 13-3301 et seq.), Massachusetts (105 Code of Mass. Regs. 725.000), Michigan (Mich. Comp. Laws § 333.26423), Minnesota (Minn. Stat. § 152.21 et seq.), Montana (Mont. Code Ann. § 50-46-301 et seq.), Nevada (NRS 453A), New Hampshire RSA 126-X), New Jersey (N.J.S.A. C.24:6I-3), New Mexico (N.M. Stat. § 26-2B-1 et seq.), New York (NY Pub Health Law § 3360), Oregon (Or. Rev. Stat. § 475.300 et seq.), Rhode Island (R.I. Gen. Laws § 21-28.6-3), Vermont (18 V.S.A. § 4472 et seq.), and Washington (RCS 69.51A). Recreational Marijuana Ballot Initiatives: Alaska (2014); Colorado (2012); District of Columbia (2014); Oregon (2014); Washington (2012). The states that have enacted laws permitting limited use of cannabidiol oils are: Alabama, Florida, Georgia, Iowa, Kentucky, Louisiana, Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming.
5. Report of the Federation of State Medical Boards ("FSMB") Workgroup on Marijuana and Medical Regulation, available at https://www.fsmb.org/Media/Default/PDF/BRD_RPT_16-2_Marijuana_Model_Guidelines.pdf.
6. Bibet-Kalinyak, supra note 3.
7. OAC § 4731-32-02.
8. ORC § 3796.01(6).
9. ORC 3796-06.
10. OAC § 4731-32-03(B).
11. OAC § 4731-32-03(F).
12. The statutory record retention period is three years.
13. OAC § 4731-32-03(C)-(E).
14. OAC § 4731-32-04.

NORTHERN OHIO PHYSICIAN

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AMCNO State Legislation and Administration Update

Ohio Department of Health Releases 2016 Ohio Infant Mortality Report

A new report released by the Ohio Department of Health (ODH) shows that the number of Ohio infants who died before their first birthday increased from 1,005 in 2015 to 1,024 in 2016, but it also shows that there were 22% fewer sleep-related infant deaths in 2016 than in 2015. That decline can be attributed to Ohio's focus on preventing sleep-related infant deaths through public awareness campaigns and programs to provide free cribs to eligible parents.

Prematurity-related conditions are the leading causes of infant deaths in Ohio. Although the number of prematurity-related infant deaths increased from 2015 to 2016, Ohio's prematurity infant mortality rate (the number of preterm infant deaths per 1,000 live births) has not changed significantly in the past decade.

Ohio is addressing many of the contributing factors related to premature births, such as smoking, and identifying and treating women at risk of developing diabetes and high blood pressure during pregnancy—conditions which increase the risk of having a preterm or low-birth-weight baby. One successful intervention is the use of progesterone (a hormone medication) in at-risk women to help reduce the likelihood of preterm birth.

The current state budget dedicates almost $50 million to improving birth outcomes and reducing racial and ethnic disparities, and it builds on almost $87 million in investments made during the past six years. The majority of state funding is dedicated to supporting local community-driven proposals to combat infant mortality in high-risk areas.

During the next two years, additional community-based pilot programs with proven track records in reducing infant mortality will be launched, according to ODH, and the evidence-based CenteringPregnancy group prenatal care model will be expanded.

Ohio will also leverage federal grants to support local infant mortality initiatives during the next year to assist 27 Ohio counties at risk for poor birth or childhood developmental outcomes to expand local voluntary, evidence-based home visiting services to women during pregnancy, and to parents with young children; and to assist 14 Ohio counties with the highest infant mortality rates for African-American babies to promote healthy pregnancies, positive birth outcomes, and healthy infant growth and development.

The state's goal is to reach the national objective of a 6.0 infant mortality rate or lower in every race and ethnicity group. Although Ohio's overall (all races) infant mortality rate increased from 7.2 deaths per 1,000 live births in 2015 to 7.4 in 2016, its infant mortality rates are trending downward over time.

The complete 2016 Ohio Infant Mortality Report is available on the Ohio's infant mortality website, www.PreventInfantMortality.ohio.gov. The website also contains additional information on this important topic.

NOTE: *The AMCNO executive staff and Past President Dr. Laura David have been on the board of First Year Cleveland, our local initiative to combat infant mortality, since its initial stages. We will continue to participate in FYC meetings and report new information on this campaign to our members.*

SMBO's Changes to Licensure Application Fees and Training Certificates Took Effect Sept. 29

Two changes from the State Medical Board of Ohio (SMBO) that impact physician applicants and those with training certification took effect September 29.

The first change is a reduction in the physician licensure application fee for MDs, DOs, and DPMs, from $335 to $305—per a provision in the budget bill, HB 479.

The other change is that training certificates are valid for three years instead of one. Training certificates that have been issued since September 29 will be valid until 2020; those issued before September 29 expire in 2018. Questions about this change can be emailed to certificates@med.ohio.gov.

SMBO Issues Guidance Document on Telemedicine Rule

The State Medical Board of Ohio (SMBO) has issued a frequently-asked-questions (FAQ) guidance document to facilitate compliance with Rule 4731-11-09, Ohio Administrative Code. The rule describes the circumstances under which a physician or physician assistant can prescribe medication to a patient whom the physician or physician assistant has never personally examined when the patient is at a different location from the prescriber. Although most frequently referred to as the "telemedicine prescribing" rule, 4731-11-09 applies in all situations where the physician or physician assistant is in one location and the patient is in another and the physician or physician assistant has never personally examined the patient. To view the FAQ guidance document go to the SMBO website at http://med.ohio.gov.

SMBO Creates Informed Consent Form for Treatment with an Investigational Drug, Product or Device

In accordance with R.C. 4731.97 (I), the State Medical Board of Ohio (SMBO) has created a template of an informed consent form for treatment with investigational drugs, products or devices. Physicians who are providing these types of treatments for terminally ill patients need to use this form to secure informed consent; formatting or stylistic changes can be made to the form, but all of the components required by the law must be included. The template is available on the SMBO website, http://med.ohio.gov.

AMCNO Sends Comments to the Ohio Board of Pharmacy Regarding Compounding Rules

During October, after a lot of pushback from medical associations across the state, including the AMCNO, the Ohio Board of Pharmacy (BOP) reopened the compounding regulations for public comment.

The proposed rules would permit prescribers to compound (or prepare) certain products without needing to obtain a Terminal Distributor of Dangerous Drugs (TDDD) license from the pharmacy board, such as the preparation of combination products, the compounding of sterile dangerous drugs in accordance with the manufacturer's labeling for preparation (with no intervening steps), and the compounding of non-hazardous, non-sterile dangerous drug preparations. Prescribers must adhere to the beyond-use dating on the manufacturer's label and, if none exists, the compounded drug products may only be used for 6 hours following compounding. The AMCNO sent comments to the BOP regarding these new rules noting that although the AMCNO is appreciative of these proposed exclusions, we still have concerns about the proposed rules' impact on the ability of physicians to provide high-quality patient care in the most efficient and cost-effective manner.

In addition, the AMCNO believes that the proposed rule should add several low-risk

compounding activities to the list of compounding procedures that do not require a TDDD license such as: buffering lidocaine with epinephrine and sodium bicarbonate for in-office surgical procedures, diluting prescription drugs with sterile saline for injection, tumescent anesthesia, diluting a steroid with lidocaine or saline, and diluting or creating allergens for injection, to name a few.

The proposed rule package also contains a new rule that places onerous medical record requirements on prescribers who are compounding. The AMCNO commented that we were concerned with the extensive medical record requirements that will be placed upon prescribers in this new rule. This proposed rule is unnecessary and redundant. Physicians are already required to follow Ohio Administrative Code 4729-9-22, Records of Dangerous Drugs. Creating more cumbersome regulations without evidence-based-proven correlating enhancements in patient safety has the potential to create inconsistency and confusion in the regulation of compounding drugs and has the potential to unnecessarily increase the cost of medical care in some clinical areas.

We also noted that the BOP's drafted rules would restrict a physician's ability to practice medicine. Physicians need to be given the discretion to compound medications as dictated by their training, the patient's condition and the standard of care. Physicians and other healthcare providers in Ohio have a long track record of safety with both intradermal and intramuscular injections, and the proposed rules only add additional barriers to care without improving patient safety.

The AMCNO believes that BOP regulations such as these heavily impact physician practices and the patients for whom they provide care. Physicians and their practices are already regulated by the State Medical Board of Ohio (SMBO), yet we continue to see more regulatory burdens placed on the practice of medicine by the BOP. There are national standards and best practices that physicians follow when compounding—and in the event a physician's compounding competency is questioned, the SMBO has the opportunity to investigate the physician and take appropriate disciplinary action, if needed. The AMCNO will continue to monitor this situation as these rules move through the approval process.

Board of Pharmacy Receives Federal Funding to Address Prescription Drug Abuse

The State of Ohio Board of Pharmacy (BOP) has received a grant from the U.S. Department of Justice, in the amount of $399,918, to fund a two-year pre-criminal intervention program to address prescription drug abuse.

The program will use data from the Ohio Automated Rx Reporting System (OARRS) to identify individuals who are exhibiting possible signs of prescription drug abuse, including those who are seeing multiple prescribers to illegally obtain controlled substances (known as "doctor shopping"). Once these individuals are identified, they will be contacted by specially trained BOP agents, with the help of local law enforcement and county treatment agencies, to assist them with limiting their overutilization of the healthcare system, and they will be connected to appropriate drug treatment or other support services. The intervention program is funded through the U.S. Department of Justice's Harold Rogers Prescription Drug Monitoring Program.

Board of Pharmacy Announces Important OARRS Upgrade

Ohio is deploying a new tool in the fight against prescription drug abuse, according to the State of Ohio Board of Pharmacy (BOP), which announced an upgrade to Ohio's prescription drug monitoring program, known as the Ohio Automated Rx Reporting System (OARRS).

Starting Nov. 20, the new platform will be available at no cost to all Ohio healthcare providers who access OARRS through electronic health records and the OARRS website. Ohio is the first state in the country to provide this new resource.

The upgrade will provide Ohio prescribers and pharmacists with advanced analytics and tools to promote patient safety and assist in clinical decision-making. It offers several key features, including scores that calculate a patient's possible risk of overdose and addiction, red flags to alert prescribers of a potential patient safety issue, interactive visualization of prescription data, a messaging option to communicate with other healthcare providers, and the ability to search for local addiction treatment providers.

Under the Kasich administration, Ohio has strengthened its prescription drug monitoring program to offer prescribers and pharmacists a greater ability to prevent opiate abuse. During a 4-year period, "doctor shopping" has decreased substantially and the total number of opiates dispensed to patients has decreased by 20%, according to the BOP.

For more information on OARRS, visit www.pharmacy.ohio.gov/oarrs.

Implementation of the upgrade is supported by the Health Information Technology for Economic and Clinical Health (HITECH) Act administered by the Centers for Medicare & Medicaid Services (CMS).

Provider Advisory Group Meeting Covers Key Points for Physicians and Their Staff

The Ohio Provider Outreach and Education Advisory Group (POE AG), of which the AMCNO has been a longstanding member, met in September.

In summary, the group learned that the Centers for Medicare & Medicaid Services (CMS) has finalized a data collection strategy to gather information needed to value global surgical services. Effective as of July 1, 2017, some practitioners are required to report claims showing that a visit occurred during the post-operative period for select global services. The Quality Payment Program (QPP) and its two designated tracks were also discussed in more detail during the meeting. Clinicians can now submit QPP hardship exception applications, if they meet one of the defined qualifications set by CMS. Some eligible physicians who are considered "Special Status" will be automatically reweighted and do not need to submit a hardship request. Also discussed were the Physician Quality Reporting System (PQRS) and Value-Based Payment Modifier (VPM). In addition, the Social Security Number Removal Initiative (SSNRI) has been renamed as the New Medicare Card Project. New Medicare cards, without SSN-based identifiers, will be mailed between April 2018 and April 2019. They will contain a new Medicare Beneficiary Identifier (MBI), which is a randomly generated "non-intelligent" 11-character alpha/numeric identifier. There will be a transition period for using either the MBI or SSN-based number for transactions, but beginning Jan. 1, 2020, only the MBI can be used. Additional information was shared during the meeting and can be reviewed in the CGS Administrators' newsletter.

The CGS Administrators' newsletter is provided to the AMCNO on a regular basis. It contains a wealth of information for providers and their staff. The primary function of the POE AG is to assist in the creation, implementation, and review of provider education strategies and efforts. Members provide input and feedback on training topics, provider education materials, and dates and locations of provider education workshops and events. The group also identifies widespread

(Continued on page 12)

AMCNO State Legislation and Administration Update

(Continued from page 11)

provider education needs and assists in developing solutions and sharing information. A link to the CGS Administrators' newsletter is available on the AMCNO website at www.amcno.org.

Ohio Department of Medicaid Releases Annual Managed Care Report Card

The Ohio Department of Medicaid has released its annual report card of the state's managed care plans. The report compares each plan against the average in five different performance areas: how the plan helps members get care, the quality of doctors' communication and service, how well the plan keeps kids healthy and helps people living with illness, and the level of coverage for women's health.

This year's grades show variations in some of the categories compared to the 2016 report card.

CareSource and Molina Healthcare were the only two plans that did not score below average in any category. CareSource was above average in two categories—doctors' communication and service and keeping kids healthy—and Molina was above average in helping members live with illness. These rankings are consistent with last year's findings.

Buckeye Health Plan was below average in living with illness again this year, but improved to average in two of the other categories compared with last year (ie, getting care and keeping kids healthy), and once again scored above average in women's health.

UnitedHealthcare Community Plan scored below average in both living with illness and women's health, but was above average in getting care, as it was in the 2016 report.

Paramount Advantage was below average in getting care and doctors' communication and service compared to its average rankings in these categories last year, but it remained as average in the other three categories. To view the complete 2017 report card, visit the ODM website at http://medicaid.ohio.gov.

Report Evaluates the Use of MAT for Opioid Addiction in Ohio's Drug Court Programs

A report released by the Department of Mental Health and Addiction Services has found that Ohio's drug court programs benefit from the addition of medication-assisted treatment (MAT) for opioid addiction. Individuals who receive MAT showed higher rates of drug court retention and lower expenses from medical care and criminal justice services.

The report, conducted by the Treatment Research Institute, found that people who received MAT spent more on substance use disorder treatment but used less healthcare services overall. Those on MAT spent an average of $4,384 less on Medicaid health expenditures, but spent $606 more on all treatment compared with those who did not receive MAT. The full report is available on the Ohio Department of Mental Health Services website at http://mha.ohio.gov.

Legislation Update

HB 326 – Psychologists – This bill would allow psychologists to prescribe. Physician groups are of the opinion that if psychologists are to be allowed to prescribe, they should have the same type of training as an APRN that is focused in mental health with a limited formulary and have collaboration with a physician. This bill would also allow psychologists to prescribe medication-assisted treatment without physician collaboration. The AMCNO, along with many other medical associations, oppose this bill.

HB 273 – Prohibit requiring physicians to have maintenance of certification (MOC)
This bill would prohibit physicians from being required to secure maintenance of certification in order to obtain licensure, reimbursement, employment, or admitting privileges. At this point in time, when a physician has obtained their initial board certification in a particular specialty, in order to maintain that specialty designation, he or she is required by their specialty board to participate in certain types of continuing education, known as MOC. The need for MOC is being questioned by physicians across the country, even resulting in the passage of legislation similar to HB 273 in eight states. Testimony from physicians supporting HB 273 questioned the value of the current MOC process and whether or not it actually measures continuing competency in their specialty. Opponents of the legislation noted that this was not an issue for the legislature to decide while others stated that MOC is an important process. The AMCNO has taken this legislation under advisement and we will continue to provide information to our members as the debate continues in the legislature.

HB 226 – Fireworks
HB 226, legislation to legalize consumer fireworks in the state, pending an ad hoc committee's recommendations, has passed in the Ohio House and now moves to the Ohio Senate for debate. The bill deals with a state law which allows for the sale of fireworks in the state but prohibits their use in the state. Under current law, in-state purchasers must agree to transport the fireworks out of state within 24 hours.

The legislation would eliminate this requirement as of July 1, 2020, unless a study committee comprised of legislators, fireworks industry officials, police and fire representatives, and members from the Prevent Blindness Ohio and Ohio Optometric Association develop new regulations which are then approved by the General Assembly.

Opponents—including public safety officials, organizations and associations, including the AMCNO—have warned that the proposal would lead to more fireworks-related injuries and fires. If enacted, opponents are concerned that the bill would legalize the discharge of consumer-grade fireworks, including bottle rockets, firecrackers and missiles, 24 hours a day, 7 days a week, 365 days a year, with only minimal safety restrictions in place. We have also indicated to the legislature that although we have no objection to establishing a study committee to discuss this matter further, we cannot place faith in that process so long as the default position of the bill is full legalization of consumer fireworks.

SB 56 and HB 72 – Step Therapy
The AMCNO was pleased to participate in another Step Therapy Advocacy Day held at the Ohio Statehouse in September. SB 56 and HB 72

Senator Peggy Lehner, sponsor of SB 56 (Step Therapy), provides her comments on the bill.

AMCNO LEGISLATIVE ACTIVITIES

AMCNO EVP/CEO Elayne Biddlestone meets with Senator John Eklund about SB 56.

demonstrate a bipartisan approach to improve the current step therapy process used by health insurers. SB 56 is sponsored by Senator Peggy Lehner (R-Kettering) and Senator Charleta Tavares (D-Columbus). HB 72 is sponsored by Representative Terry Johnson (R-McDermott) and Representative Nickie Antonio (D-Lakewood). During the event, Rep. Johnson and Senator Lehner addressed the members of the Ohioans for Step Therapy Reform coalition who were on hand to participate in meetings with legislators. The coalition is comprised of more than 60 members representing thousands of providers and patients throughout Ohio.

SB 56 improves the one-size-fits-all application of step therapy. Step therapy protocols require the use of a specific medicine without knowing the patient's medical history. Excluding physicians' clinical judgment from patients' treatment plans creates a barrier to getting the right care at the right time. Step therapy can undermine physicians' ability to effectively treat patients and lower quality of care, resulting in set-backs and disease progression for patients. SB 56 does **not** prohibit insurers from using step therapy and does not require insurers to cover any specific medication. It seeks to improve the step therapy process by balancing cost containment with patient needs.

The legislation improves the step therapy process to ensure that patients get access to the medications they need in a timely manner. **It does not mandate that insurers cover any medications that are not already part of a patient's plan.** For more information about step therapy please go to www.reformsteptherapy.com, www.prescriptionprocess.com/steptherapy, or Ohio Physicians for Step Therapy Reform at ooanet.org/aws/OOSA/pt/sp/STEP_home_page.

SB 129 – Prior Authorization Legislation Implementation

This new law, which was enacted in 2016, was strongly supported by the AMCNO, and we were part of a broad-based coalition formed by the Ohio State Medical Association (OSMA) representing more than 80 provider and patient advocacy organizations who supported this legislation. The bill applies to health insuring corporations, sickness and accident insurers, and Medicaid managed care plans (the law excludes ERISA self-insured plans or Medicare Advantage plans). The bill also prohibits an insurer from including in their provider contracts any provision that is contrary to what is contained in the bill. The main provisions that became effective in January 2017 were covered in the March/April issue of the *Northern Ohio Physician* (available on our website at www.amcno.org).

There are numerous provisions of the bill that will become effective beginning in January 2018, including the following.

Insurers must have a web-based system through which to receive prior authorization (PA) requests: for prescription benefits, the system shall accept and respond to PA requests through a secure electronic transmission, and for medical benefits, the system shall accept and respond to PA requests through a secure electronic transmission—meeting specific standards.

There will be faster turnaround times for PA requests: for urgent situations, which are defined as those where a delay in patient care could seriously jeopardize the life, health or safety of the patient, or if a practitioner with knowledge of the patient's condition believes a delay would subject the patient to adverse health consequences without the care, the insurer shall approve or deny the PA request in 24 hours. For non-urgent situations, the insurer shall approve or deny the PA request within 10 calendar days.

There is to be more clarity when an insurer responds to a PA request—namely, an insurer must provide an electronic receipt to the provider showing that the PA request was received. In addition, if the PA is denied, the insurer must provide the specific reason for the denial, and if the PA request is incomplete, the insurer shall indicate the specific information that is needed to process the request.

The bill also provides for faster turnaround times for PA appeals: for urgent care services, appeals must be considered within 48 hours after the insurer receives the appeal, and for non-urgent services, appeals must be considered within 10 calendar days after the insurer receives the appeal. All appeals shall be between the healthcare provider requesting the service and a "clinical peer" (a provider in the same, or similar, specialty that typically manages the medical condition under review) within the insurer's internal utilization review operation. In addition, if the internal appeal does not resolve the disagreement, either the patient or an authorized representative may request an external appeal, which will be decided by a neutral, independent medical expert not associated with the insurer.

NOTE: *If you are experiencing an issue with a payer not complying with the provisions of this law, you may file a complaint with the Ohio Department of Insurance. Forms to file a complaint are available on the ODI website at www.insurance.ohio.gov.* ■

Are you Interested in Running for the AMCNO Board of Directors in 2018?

Directors are elected to represent their district, which is determined by primary hospital affiliation or at large for a two-year term. Members of the Board are responsible for addressing issues of importance to physicians and the patients we serve, and setting policy for the AMCNO. If you are interested in running for the Board of Directors please return this form with your name and contact information to the AMCNO, 6100 Oak Tree Blvd., Suite 440, Cleveland, Ohio, 44131. You may also FAX your information to Elayne Biddlestone at (216) 520-0999 OR call her at (216) 520-1000, ext. 100. Deadline: 12/31/17.

Yes, I am interested in running as a candidate for the AMCNO Board of Directors:

_____

Name and contact information: _____

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PS Form **3526**, August 2012 (Page 2 of 3)

Hospitals Team Up to Fight Northeast Ohio Opioid Epidemic

Over the summer months, the Northeast Ohio Hospital Consortium on Opioid Addiction was pleased to announce that it had hired Allisyn Leppla to serve as its executive director. In her new position, housed at The Center for Health Affairs, Leppla will be responsible for coordinating hospital activities aimed at stemming the Northeast Ohio opioid epidemic.

The Consortium is a partnership of The Center for Health Affairs, Cleveland Clinic, MetroHealth, St. Vincent Charity Medical Center and University Hospitals and is the result of years of work by community leaders and hospitals to reduce the widespread effect of the Northeast Ohio opioid epidemic. Thanks to efforts led by the Cuyahoga County Opiate Task Force** and the United States Attorney's Office for the Northern District of Ohio,** hospital CEOs from the region agreed in late 2016 to fund a full-time position to lead a hospital-specific response to the crisis. This decision was born out of years of discussions that led to the production of the Heroin and Opioid Action Plan, which included recommendations around a variety of reforms, including:

- Improved prescribing practices
- Increased use of medication-assisted treatment
- Expanded use of Naloxone

For more information about the Northeast Ohio Hospital Consortium on Opioid Addiction, contact The Center for Health Affairs at (216) 255-3614.

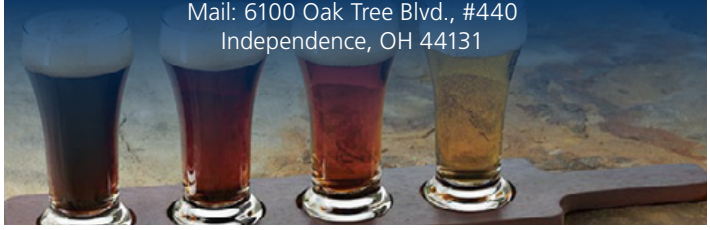
***Editor's note:** The AMCNO is a longstanding member of both the Cuyahoga County Opiate Task Force and the United States Attorney's Heroin and Opioid Action Plan Committee and we regularly participate in their meetings.*

SAVE THE DATE

The Academy of Medicine Cleveland & Northern Ohio (AMCNO) Membership Committee cordially invites physician members, residents, medical students and spouses to attend our 2018 beer tasting experience. This is the perfect opportunity for you to mingle with your colleagues.

TREMONT TAPHOUSE
2572 Scranton Rd, Cleveland, OH 44113
Sunday, February 11, 2018 • 5 – 7 p.m.

Cost:
$45 per member/spouse
$25 residents & medical students
RSVP by 2/5/2018
Email: abell@amcno.org • Phone: (216) 520-1000
Fax: (216) 520-0999
Mail: 6100 Oak Tree Blvd., #440
Independence, OH 44131



AMCNO Pollen Line – 2017 Review

By David McGarry, DO; Ranya Doll, DO; Nancy Joseph, DO; Devi Jhaveri, DO; Theodore Sher, MD; Haig Tcheurekdjian, MD; and Robert Hostoffer, DO

Allergy/Immunology Associates remains dedicated to serving patients of the Greater Cleveland area reporting daily pollen counts on the AMCNO Pollen Line. We continued to use a Rotorod Aeroallergen device to obtain the samples, which then allowed us to calculate the daily pollen levels throughout the 2017 pollen season. Pollen counts not only benefit patients but allow allergists and physicians to better direct therapy for their patients to achieve symptom relief. For those who suffer from allergic rhinitis, allergic conjunctivitis, and asthma, the pollen season can be miserable. By following yearly trends, we can predict the timing of certain allergens and prepare our patients so that they can maximize their quality of life.

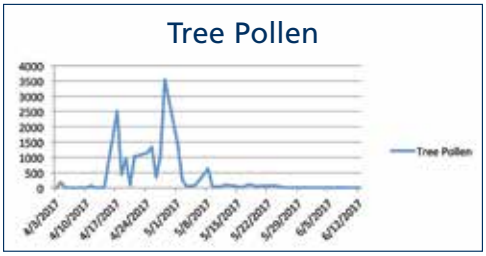
The 2017 pollen levels were significantly higher than levels seen in 2016. The greatest contributor to this substantial increase was likely the large amount of precipitation throughout the spring and early summer months. Through the first seven months of 2017 Cleveland had 11 more inches of precipitation compared to the same period last year.

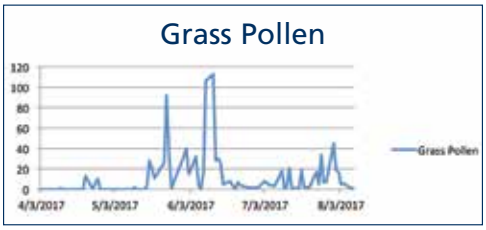
In the Greater Cleveland area, the pollen season begins in April with the blooming trees. This spring the tree season showed two peaks which correlate to similar peaks in previous years. This year the tree pollen maximum peak occurred on April 28, just two days later than last year. The calculated maximum tree pollen count was nearly 40% higher than last year.

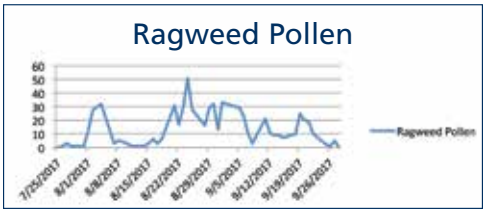
Grass pollen is known to be the main allergen of the summer months. Grass pollen in Northeast Ohio was present from May through early August, similar to previous years. The grass pollen peaked on June 12, which was just three days earlier than last year. However, the grass pollen level was nearly three times higher as compared to last year.

As the days begin to shorten and the temperature starts to cool we move into the fall ragweed season. Ragweed appeared in late July this year, just slightly earlier than last year. The ragweed peak occurred on August 24, which is slightly earlier than last year. The peak pollen count this year was twice as high as was seen in 2016.

Each year, Allergy/Immunology Associates, in coordination with the AMCNO, is proud to provide the pollen count for the Greater Cleveland area from April 1 to October 1. The counts are made available to the Pollen Line, (216) 520-1050, as well as www.amcno.org. Stay healthy and warm this winter, and we look forward to helping you prepare for next year's pollen season on April 1, 2018! ■







The Ohio Supreme Court Declines to Accept Jurisdiction of the 10th Appellate District Decision in *Pontius v. Riverside Radiology & Interventional Assoc., Inc.*

By Chris Mars, Esq., and Bret C. Perry, Esq., Bonezzi Switzer Polito & Hupp Co. LPA

The Ohio Supreme Court recently declined to review the decision of the Tenth District Court of Appeals in the case of *Pontius v. Riverside Radiology & Interventional Assocs., Inc.* The AMCNO filed an amicus brief urging the Ohio Supreme Court to review the decision of the Tenth District. The Tenth District's decision in *Pontius* subjects healthcare providers to potential liability for the actions of a rogue employee who accesses protected patient information for no other purpose other than the employee's own curiosity. Notwithstanding the *Pontius* decision, there are measures healthcare entities and providers can take to minimize and potentially eliminate the impact of *Pontius.*

By way of background, the decedent in *Pontius* presented to the Riverside Methodist emergency department complaining of urinary discomfort and lower abdominal pain. Notably, the decedent had a vena cava filter implanted due to his history of deep vein thrombosis and pulmonary embolism. A CT scan was taken of his abdomen and pelvis and were found to be negative for clots, and he was discharged. He died the following morning from a pulmonary embolism. A part-time radiologist with privileges at Riverside Methodist and acquaintance of the decedent's family accessed the decedent's CT scans, despite not being involved with the decedent's care, and determined that the original reading of the CT scan missed the clot. He then informed the decedent's mother and friend of this fact.

At trial, the court precluded any evidence of the part-time radiologist's discussion with the plaintiff that clots were missed in the CT scans, and the jury reached a verdict in favor of the defendants. The appeals court reversed the verdict and ordered a new trial, finding that the part-time radiologist's statements were admissible because they constituted a party admission. To be considered a party admission, a statement must be made by a party's agent or servant concerning a matter within the scope of the agency or employment. Astonishingly, the court found that notwithstanding the lack of directive by Riverside to review the decedent's case, the radiologist's statements were *within the scope of his employment* with Riverside because his duties included peer-review of other radiologists and that his review of the decedent's scans constituted peer review.

The *Pontius* decision makes it ever so important for healthcare entities to be vigilant to ensure that those who have access and are accessing a patient's protected information are providers who provided care to the patient or are peer-reviewing the information at the direction of the healthcare entity. Moreover, written guidelines and policies that delineate precisely under what circumstances a provider can access a patient's protected health information can be helpful to argue that conduct like that of the rogue radiologist in *Pontius* is not within the scope of employment. Furthermore, guidelines providing that peer-reviewers are prohibited from reviewing the protected information of any patient absent an express directive from the quality assurance or peer-review committee, and that such conduct is sanctionable and is not within the scope of employment could be beneficial should litigation ensue. Lastly, healthcare entities can include language in employee contracts or contracts with independent contractors to protect against liability by expressly providing that a provider accessing a patient's protected information in violation of HIPAA laws is not conduct within the scope of their employment with the healthcare entity. Although not fool-proof, the aforementioned steps can curtail the impact of the *Pontius* decision. ■

This Issue Highlights What the AMCNO and AMEF are Doing About the Opioid Crisis

It is certainly not news that an opioid epidemic has taken hold in our country. But, you may not know that we are working tirelessly on doing something about it.

The Academy of Medicine of Cleveland & Northern Ohio (AMCNO) and its foundation, the Academy of Medicine Education Foundation (AMEF), are trying to tackle the issue of opioid abuse in our community.

The AMCNO and AMEF are working with CWRU School of Medicine to address prescribing practices with online CME courses. (See the front cover article.)

The AMCNO has signed on to promote the Know the Rx campaign, and is working with AMCNO member Dr. Joan Papp as she serves as the Medical Director of the new MetroHealth Office of Opioid Safety. (See pages 4 and 7 for more information.)

We also continue to report on any legislative work that is being done with respect to those with drug-related problems, including intervention programs and Ohio's drug courts. (See pages 11 and 12.)

Of course, the opioid epidemic is not the only issue that is of concern for our organizations. The AMCNO and AMEF continue to work on other issues that are important to the physicians we serve and the patients under their care. You'll see examples of this fact throughout the rest of this magazine.

Rest assured that we are doing all that we can to make sure your voice is heard. And, in turn, we thank you for your continued support in 2017. We will continue our hard work in 2018, and beyond. ■