

Stark County Medical Society *News*

Spring 2017

President's Message Dr. Carl Foster



Dr. Carl Foster

To even the most casual observer it is clear that the opioid epidemic is the most urgent public health problem facing our nation in general and our state in particular. Everyday news outlets are broadcasting stories about deaths that result from drug overdoses. A New York Times headline read in January "Ohio coroner's office runs out of rooms for bodies" during a particularly harrowing weekend when there were 145 opioid related deaths. It is no wonder that Ohio is tied with Kentucky for the third highest rate of deaths linked to drug overdoses at 29.9 per 100,000 population¹.

Prescription drugs have been found to be responsible for large numbers of opioid deaths. Diversion of unused and pilfered narcotics have been implicated as "gateway drugs" that introduce both youths and adults to abuse and addiction that lead to the use of street drugs. It is with this backdrop that we are anticipating new state guidelines for prescribing opioids in Ohio. There are currently two proposals under consideration. One from the Governor's office and companion proposals from both Houses of the Legislature. Of the two the Governor's is the most reasonable.

The Governor's proposal includes limits on the number of days of opioids that can be prescribed, 5-day supply for minors and a 7-day supply for adults. The proposal also limits the daily dose to 30mg. It does allow for clinical discretion if it is judged that more medication is required. In such cases the medical record must reflect that an OARRS check has been completed, that an informed consent has been obtained, and clinical justification is documented. The ICD-10 diagnosis must be included on the prescription and the pharmacy must input the ICD-10 into OARRS.

The Legislature's companion proposals allow no exception for clinical judgment and mandates clinical training and continuous medical education. For physicians treating chronic pain:

- 8 hours of training related to addiction is required
- Use of an EHR to connect to OARRS is required

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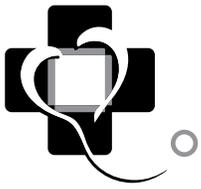
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We have access to the politicians and the state medical association. Together, we have a voice that will be heard!

Contact us at starkmedical@ameritech.net or call 330-492-3333. We look forward to hearing from you!



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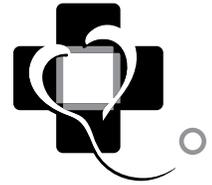
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STATE LAW CHANGES FOR PRESCRIPTIVE AUTHORITY

Scott P. Sandrock

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The state of Ohio continues to modify its regulations dealing with the prescriptive authority of physicians. The changes and proposed changes impose additional restrictions or requirements on physicians prescribing medications primarily in the areas of pain management and prescriptions of opiate medications. It is important for physicians to be aware of these changes and make sure that they are implemented within their practices. Failure to comply may result in administrative sanctions by the Medical Board, Pharmacy Board and potential criminal charges.

PROPOSED CHANGES TO PAIN MANAGEMENT CLINIC RULES.

Most physicians who practice in the area of pain management will recall the significant changes in 2011 by statute and then expanded by regulations through the State Medical Board and the State Pharmacy Board for any physician whose practice included treatment of chronic pain.

In March 2017, the State Medical Board proposed changes to the regulations concerning the operation of pain management clinics. Previously, the regulations provided that a "pain management clinic" meant a practice where the primary component of the practice is the treatment of pain or chronic pain, with the majority of those patients being treated with controlled substances. The Medical Board has changed that definition to provide that a "pain management clinic" is a facility in which the "majority of the patients are provided treatment for chronic pain that includes the use of controlled substances." The regulations go on to revise the method in which that "majority" is calculated to be a calculation on a monthly basis, and a "majority of the patients" treated that month receiving some pain medication treatment. The Board still retains the exemption in the calculation of patients being treated for some injury or illness that is expected to last 30 days or less.

The regulations will add a new provision that requires the Medical Board to conduct an on-site inspection of any facility which operates a pain management clinic, requiring the site to meet the compliance requirements outlined in the regulations. Those compliance regulations which continue from the earlier version require the clinic to maintain a log of each patient on a daily basis, specifying the date of treatment, the name of the patient, and a sign-in chart. The clinic is to maintain a quality assurance program that evaluates methods to improve patient care. The clinic is also required to have background verification of all its staff, which is required to be recertified each year. There are detailed requirements regarding patient records remain, including records to support the diagnosis, and to justify the treatment, including the medication regimen. All patients treated must also include an OARRS report, which needs to be logged.

THE GOVERNOR ANNOUNCED CHANGES ON OPIATES.

On March 30, 2017, Govern Kasich announced proposed new limits on prescriptions of opiates. While this announcement was well publicized, what was confusing is that the announced rules are not currently the law in Ohio. The announcement is merely a proposal of changes being considered by the Medical, Nursing and Dental Boards, as well as the Board of Pharmacy. Many physicians may not be fully aware that Ohio has the most aggressive Board of Pharmacy in the country concerning reviewing prescriptive activity by physicians.

The State Medical Board is working on an extremely fast track, and on April 13th issued proposed rules regarding prescriptions of opioids. Proposed Regulation 4731-11-13 provides details of various requirements of the proposed rules. First, extended release or long-acting opioid analgesics are not permitted to be prescribed for acute pain treatment. Before prescribing an opioid analgesic, the physician has to consider non-opioid treatment options and to document why non-opioid treatment options are not viable for the patient. If the physician elects to issue the prescription, there is a presumption that a three-day supply or less is medically sufficient and any deviation requires the physician to note the reasons in the patient's chart.

The proposed rule then provides that if an opioid is prescribed, that the physician may not issue a prescription or provide the medication directly with more than seven days' supply for an adult or five days with a minor, both of which cannot have refills as part of that prescription.

In the event the physician concludes that the pain being treated will last longer than seven or five days as applicable, the physician is to document the physician's conclusions into patients' medical records before writing a new prescription. If a patient is prescribed an opioid and an alternate medication becomes necessary, the burden is on the physician to provide education to the patient as to the "safe disposal of the unused medication" and again, document that education as a part of the file.

Any patient receiving a prescription for an opioid must be advised of the benefits of the medication and the risks of potential addiction, and that advice and education must be noted in the patient's medical record. The total morphine equivalent dose of any prescription shall not exceed an average of 30 MED per day.

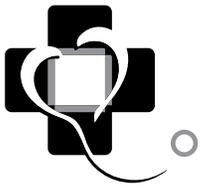
The proposed rules also reference that any violation of the rules will be deemed a "failure to maintain minimal standards." The rules also provide that if the physician fails to complete and maintain detailed medical records as required, that there will be a presumption that the prescription was not for a legitimate purpose, which can result in both sanctions through the Medical Board and can be also deemed a criminal violation for dealing in drugs. The Medical Board had set a timeline for public comments of April 28, 2017 and absent significant response from the medical community, we would anticipate the rules to go into effect within a matter of months.

While not in the proposed rules from the Medical Board, the Governor's announcement also included reference to requiring a physician to have a mandatory OARRS check with the physician being required to include both diagnosis and procedure codes to be entered into OARRS.

In addition to the Governor's announced proposed rules changes, two pieces of legislation have been introduced in the General Assembly, which also provides proposed limits on the amount of the opioid prescriptions that a physician could issue.

We will have to wait to see if the Board may provide some guidance to physicians if they were to issue a prescription for a longer duration, and if the Board "second guessed" the physician's decision. An important

continued on page 4



STATE LAW CHANGES FOR PRESCRIPTIVE AUTHORITY CONTINUED...

factor for physicians that is not discussed in these rules is the economic impact. Currently, most insurance plans will compensate a physician for an evaluation and medication visit on a 30-day cycle. If the new restrictions go into place, and a physician is required to see a patient more frequently, can a busy practitioner find additional time in their schedule for those more frequent visits, and if so, will those additional weekly visits be reimbursed by insurance plans. Unfortunately, tackling one issue may result in substantial increases in challenges for treating physicians and their practices. We will all have to wait and see how those matters evolve.

NEW RULES ADOPTED FOR TELEMEDICINE.

With the changes in technology and issues involving access to health care, an issue facing medical boards is what physicians can or should be able to do regarding the diagnosis, treatment and potential prescriptions for patients a physician has not seen in person but has talked with through electronic communications. Various states have approached the practice of telemedicine in different manners, and Ohio has been discussing the rules for telemedicine for some time.

The State Medical Board finalized its regulations regarding the prescriptive authority of physicians who treat patients through telemedicine effective March 13, 2017.

The State Medical Board regulations now provide that a physician may prescribe a drug that is not a controlled substance for a patient, even though the physician has not conducted a physical examination of that patient, only if the physician meets all of the following requirements:

1. The physician will have verified the patient's identity and physical location;
2. The physician has obtained the patient's informed consent for treatment;
3. The physician is required to ask for the patient's consent to forward records to the patient's primary health care provider or refer the patient to an appropriate health care provider. If the patient consents, the records must be sent to that provider;
4. Through interaction with the patients, the physician is required to conduct a medical evaluation which meets the "minimal standards of care," which might include portions of evaluations conducted by other health care providers;
5. The physician must establish a diagnosis and treatment plan which includes documentation for the utilization of a prescription drug;
6. The physician is required to document in a patient's medical record that the patient has consented to treatment through a remote evaluation, the pertinent history of the patient, an evaluation diagnosis treatment plan, underlying conditions, any contraindications, and any referrals by the physician to other health care providers;
7. The physician shall provide appropriate follow-up care or recommend follow-up care to the patient's primary care provider and document that activity;
8. The physician shall make the medical record of the visit available to the patient; and
9. The physician shall use appropriate technology that is sufficient for the physician to conduct all of the steps in the regulations as if the medical evaluation occurred in an in-person visit.

The regulations go on to provide additional requirements if a physician is potentially going to prescribe a controlled substance, and on whom the physician has not conducted a physical examination. In that instance, the following additional rules also apply:

1. The patient has to be an active patient of a colleague of the physician, or the physician is interacting with the patient pursuant to a call or cross-coverage agreement arranged in advance, and the physician complies with all of the steps listed above;
2. The patient is physically located at a hospital or licensed clinic at the time the physician is interacting with the patient from a remote location;
3. The patient is being treated by and is in the physical presence of another licensed physician or healthcare provider, and the patient is an actual patient of those healthcare providers.

In all instances, the burden is on the physician to document each and every requirement listed in the rules, and the failure to do so will presumptively be deemed a failure to meet the appropriate standards of care. If literally applied, a physician who is taking call for another physician and may not know the patient, will need to take additional steps, including verification of the patient's identity, obtain the patient's consent for treatment, make a detailed medical record of the phone interaction, establish a diagnosis and treatment plan prior to prescription, and obtain appropriate history and evaluate diagnosis and treatment plans. The rules are not clear as to how a doctor taking call will be able to verify the patient's identity over the phone or establish a treatment plan.

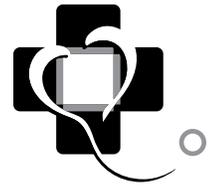
In looking at the telemedicine rules, physicians who might be involved in such a practice will definitely have to maintain appropriate records, document the conversation with the patient, make sure that that interaction is entered into the patient's chart. Keep in mind, the rules regarding prescribing controlled substances will still require the physician's requirement to have an OARRS report done and to appropriately log the encounter into the OARRS system. These circumstances will present some additional documentation challenges for physicians in group practice who may be handling call coverage for physicians in their own practice, as well as cross-coverage for physicians in other practices. The rules specifically require the physician interacting with the patient to develop a system to document the encounter and to get that information transferred into the medical record of the primary physician for that patient.

CONCLUSION.

Given the heightened public discussion of the opioid crisis in Ohio and the inference that the problem is caused by physicians' prescriptive actions, we anticipate heightened levels of enforcement activity, even for physicians acting in good faith. The failure to meet the documentation standards will be carefully reviewed by regulatory authorities, and physicians need to update their documentation procedures and practices to remain in full compliance with the regulations. Stay tuned for further changes to the rules.

If you would like copies of the regulations, need legal assistance with licensing boards, or have any questions concerning these matters, please contact Scott Sandrock at 330-253-4367, spsandrock@bmdllc.com.

4832-7161-8886, v. 1



Confidential Path to Recovery for Physicians

Physicians and other licensed medical professionals have to learn and adapt to the rapidly changing healthcare environment which leaves them more susceptible than ever to burnout and other serious conditions or illnesses. The Ohio Physicians Health Program (OPHP) envisions a medical community where physicians are supported and encouraged to obtain treatment for their mental, behavioral, and physical health. Unfortunately, physicians are not always afforded the same opportunity to utilize confidential medical treatment as the general population because they are in safety sensitive positions. Often times, when physicians seek treatment, the circumstances result in disciplinary action by their licensure board. Discipline by a licensing board can

result in suspension or loss of license which can lead to job loss, career isolation, and stigma among their peers, employers, and others. All of these consequences can make it difficult to regain employment and provide much needed healthcare to the community. When facing these obstacles, it is not uncommon for physicians to experience financial, marital, and family complications.

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CAN OPHP HELP ME?

YES! If you or a colleague are experiencing stress, burnout, depression, or other issues - or if you have concerns about drugs or alcohol use, OPHP can help.

OPHP believes it is imperative that healthcare professionals are motivated to seek treatment, have access to appropriate resources, and are provided a supportive, confidential environment for their recovery.

OPHP staff are equipped with the expertise, resources, and focus on confidentiality to inspire healthcare professionals to seek help for issues impacting their health. In addition, OPHP specializes in navigating the rules and policies of licensing agencies and employers. Physicians enrolled with OPHP for monitoring and advocacy services experience recovery and success rates significantly higher than those of the general population—on average 93 percent.

Over the past several years, OPHP has been working closely with Ohio's medical associations and the State Medical Board of Ohio with the goal of updating the confidential process known as “one-bite” that allows for early intervention and referral of impaired physicians to treatment providers without reporting them first to the Board.

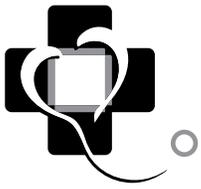
This spring, legislation was introduced to revise this law. Changes that will occur if the bill is enacted include:

- Clarity on who is eligibility to participate in the confidential program
- Expansion of those eligible to use the program which will include all licensees under the jurisdiction of the Medical Board
- Allowance for individualized treatment plans
- One entity determining eligibility into the program and providing monitoring services

We hope that through these systematic changes a more robust usage of the program will occur resulting in increased patient safety in Ohio and healthier physicians.

To learn more about OPHP or the potential impact of this new legislation please visit: www.ophp.org.

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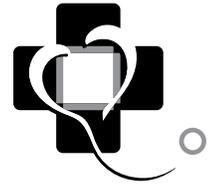
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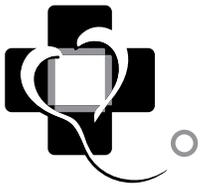
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MEMORANDUM

DATE: April 21, 2017

TO: Healthcare providers in Ohio

FROM: Sietske de Fijter, MS *Sdf*
State Epidemiologist
Chief, Bureau of Infectious Diseases

SUBJECT: Lyme disease cases in Ohio continue to increase

Cases of Lyme disease (see **Attachment 1**) have steadily increased in Ohio over the past four years (93 cases in 2013, 119 cases in 2014, 154 in 2015, and 160 in 2016). This increase in cases coincides with the increase in Ohio of the principal vector, *Ixodes scapularis* (the blacklegged tick). Prior to 2010, there were no known established populations of blacklegged ticks in Ohio. Since then, this tick has spread into Ohio and has been found so far in at least 60 counties (see **Attachment 2**), with most being found in eastern and southern regions of the state.

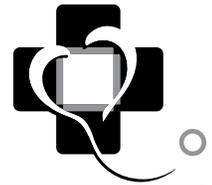
To develop a better understanding of tick-borne diseases in Ohio, the Ohio Department of Health (ODH) would like to ensure that all cases are detected. For this reason, ODH recommends that healthcare providers consider Lyme disease and other tick-borne diseases in the differential diagnosis for patients that present with appropriate symptoms. The following tick-borne diseases are reportable diseases in Ohio, and suspect or confirmed cases should be reported to the local health department where the case resides:

Anaplasmosis and Ehrlichiosis (<http://www.odh.ohio.gov/pdf/IDCM/ehrl.pdf>)
Babesiosis (<http://www.odh.ohio.gov/pdf/IDCM/babesia.pdf>)
Lyme disease (<http://www.odh.ohio.gov/pdf/IDCM/lyme.pdf>)
Rocky Mountain spotted fever (<http://www.odh.ohio.gov/pdf/IDCM/rmsf.pdf>)

Ensuring that Lyme disease cases are properly reported in Ohio

In order for Lyme disease cases to be properly confirmed and reported in Ohio, it is essential that there is **both** clinical and laboratory evidence of infection. The Centers for Disease Control and Prevention (CDC) still recommends a two-step process to properly test for evidence of antibodies against Lyme disease bacteria (see **Attachment 3**). Additional information can be found at: http://www.cdc.gov/lyme/healthcare/clinician_twotier.html

Tick-borne diseases typically occur during spring and summer, though blacklegged ticks are active and may transmit disease year-round in Ohio (see **Attachment 4**). More detailed information about blacklegged ticks and tick-borne diseases in Ohio can be found on the ODH website (<http://www.odh.ohio.gov/ticks>). Please contact your local health department or the ODH's Zoonotic Disease Program at 614-752-1029 if you have questions. Thank you for your consideration to improving tick-borne disease surveillance in Ohio.



ATTACHMENT 1:

**Lyme Disease in Ohio
Numbers-At-A-Glance
2006 - 2016**

Year	Human Cases	Deaths	Median Age (Years)	Age Range of Cases (Years)	Counties with Reported Lyme Disease Cases
2006	43	0	41	3 - 68	23
2007	33	0	37	7 - 68	24
2008	45	0	30	5 - 74	28
2009	60	0	36.5	2 - 86	28
2010	44	0	36	3 - 63	24
2011	53	0	34	6 - 84	25
2012	66	0	34	3 - 86	30
2013	93	0	43	2 - 84	34
2014	119	0	36	1 - 78	32
2015	154	0	41	1 - 85	44
2016	160	0	37	3-85	40
AVG	79	0	37	n/a	30

Source: Ohio Department of Health
Last updated: 04/19/2017

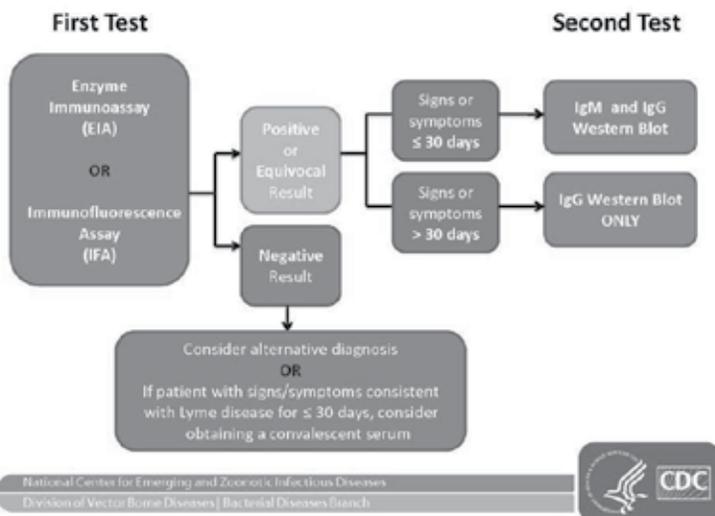
ATTACHMENT 2:

**Blacklegged Tick, *Ixodes scapularis*,
in Ohio***



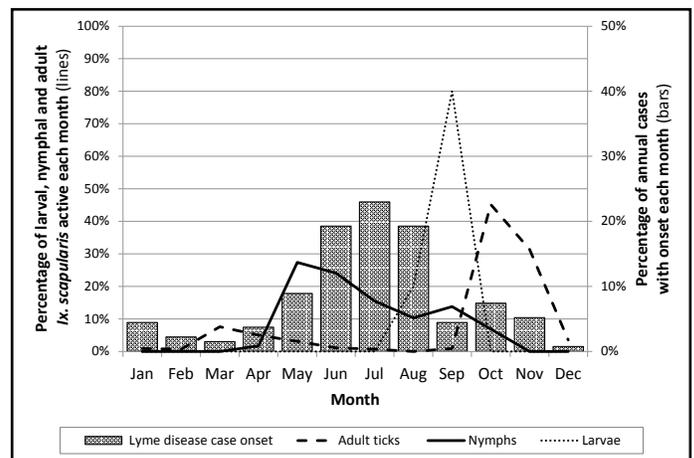
ATTACHMENT 3:

**Two-Tiered Testing for
Lyme Disease**

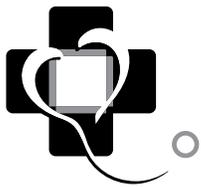


ATTACHMENT 4:

Timing of Lyme disease case onset and active blacklegged tick stages in Ohio



Blacklegged ticks are active throughout the year in Ohio. The adults are active in spring, fall and winter. The nymphs are active in the spring and summer and the larvae are active late summer. The onset of most Lyme disease cases correspond to the emergence of the nymph stage in spring. (source: ODH, Bureau of Infectious Diseases)



Stark County Medical Society

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SCMSA NEWS

Attention all SCMS members: If your spouse or domestic partner is not already a member of the SCMSA, please sign them up! The group was established as an extension to the SCMS. Our main function is to create fellowship amongst physician's families. We also raise money for our charitable fund, which gives scholarships and also does outreach in the Stark community. The dues are only \$25.00 per year and \$20.00 for the spouse or domestic partner of a resident.

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Spouse's Name: _____

Spouse's Specialty: _____

Address: _____

City: _____

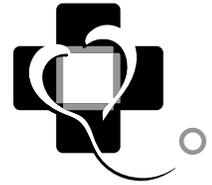
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Stark County's Reportable and Emerging Diseases Network Committee

The Spread of Syphilis in Stark County

The Centers for Disease Control and Prevention published the 2015 Sexually Transmitted Diseases Surveillance report stating that 2015 recorded the highest rate of primary and secondary stage syphilis cases across the nation since reporting began in 1941. This was at a rate of 7.5 cases per 100,000 population. During 2016 Stark County also showed an increase with 21 total cases of syphilis reported, 15 of them specifically in the primary, secondary, or early latent stages. This corresponds to a rate of 5.6 cases per 100,000 population, which



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is double the rate from the previous year for Stark County. The raw case counts for the last five years can be seen in the table to the right. Though the numbers fluctuate each year, Stark County has not previously seen case counts as high as they were in 2016.

NUMBER OF SYPHILIS CASES REPORTED IN STARK COUNTY BY YEAR FROM 2012-2016					
	2012	2013	2014	2015	2016
Total Syphilis Cases	12	13	7	7	21
Primary, Secondary, and Early Latent Syphilis Cases	3	8	7	5	15

The bacterium *Treponema pallidum* is responsible for causing Syphilis. Symptoms of syphilis vary depending on the stage of the disease, and may not present themselves for years. Without treatment, the disease will continue to progress through each stage. There are four stages of syphilis: primary, secondary, latent, and late.

➤ **PRIMARY STAGE:**

a single, painless sore (chancre) may appear at the location where syphilis entered the body within 10 to 90 days from exposure. Multiple sores may develop. With the sore(s) being painless, it can easily go unnoticed and be present for 3 to 6 weeks. Regardless of treatment, the sore(s) will heal but the patient is still highly infectious.

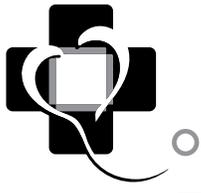
➤ **SECONDARY STAGE:**

skin rashes and/or sores in the mouth, vagina or anus can develop. The rash appears rough, red or reddish-brown, does not cause itching and can develop on both palms of the hands and/or bottoms of the feet. The rash can be indistinguishable from other rashes/diseases when present on other parts of the body. Sores appear large, raised, gray or white and tend to develop in warm, moist areas, such as the mouth, underarm or groin region. Other symptoms include fever, swollen lymph glands, sore throat, patchy hair loss, headaches, weight loss, muscles aches and fatigue. Symptoms of secondary syphilis will go away with or without treatment. The patient is still highly infectious.

➤ **LATENT AND LATE STAGES:**

begin when symptoms from the earlier stages disappear. This latent or “hidden” stage can last for years, and although syphilis is still present in the body, those who never seek treatment can develop late stage syphilis 10 to 30 years after infection. Symptoms of late stage syphilis include difficulty coordinating muscle movements, paralysis, numbness, gradual blindness, dementia and even death. The patient is potentially infectious in the early latent phase but not the late latent or late stage.

It is recommended for people who test positive for HIV and other sexually transmitted diseases, STDs, to get tested for syphilis, since syphilis can enable the transmission of HIV. Identifying potential people who may have come into contact with an infected individual and providing them with an examination is essential to the control of syphilis. Identified contacts can be prophylactically treated. Pregnant women can also transmit the disease through the placenta to the fetus or at the time of birth to their infant if left untreated. According to the CDC’s report, infected mothers may lead to infection of the baby in 80% of cases and stillborn or death in 40% of cases. Identifying cases and providing treatment is a significant factor in facilitating the decrease of this morbidity in Stark County. In addition to treatment, it should be noted that prevention includes the proper use of latex male condoms, abstinence from sexual activity or being in a long-term monogamous relationship with a partner who has been tested and is known to be uninfected. Men who have sex with men are a population disproportionately affected by syphilis; 73% of cases in our region report this as their risk factor.



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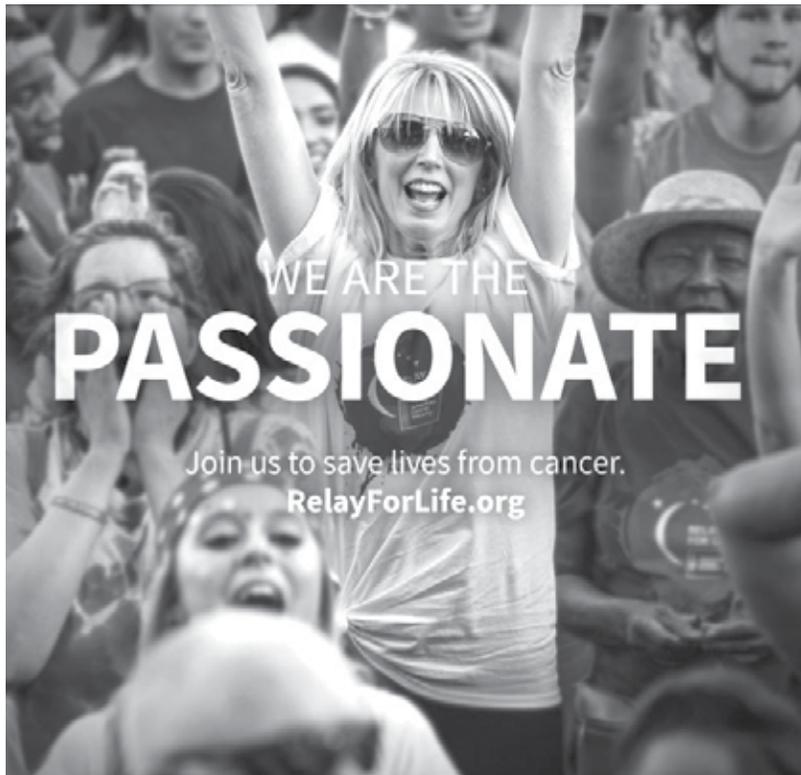
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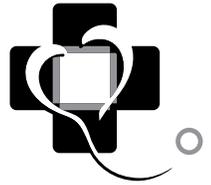
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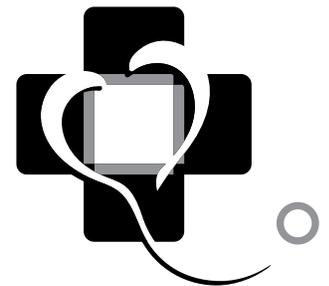
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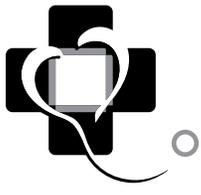
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President's Message *continued*

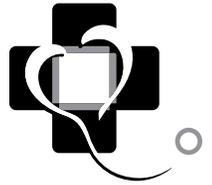
- 2 hours of CME in prescribing controlled substances is required annually
- If opioid is no longer effective CDC guidelines must be used to taper patient off opioid
- No prescription may exceed 50mg per day

For primary care physicians:

- 8 hours of training related to addiction is also mandated
- HER use to connect to OARRS is also required
- 2 hours of CME in prescribing controlled substances is also mandated
- Physicians must be able to treat addiction or must refer to another physician that can

Furthermore the Legislature's proposals include deletion of the current exception to mandatory OARRS query for scripts of less than 7 days duration and requires addiction treatment to include the offer of Naltrexone.

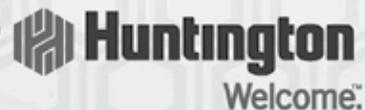
Needless to say the Governor's plan is far more desirable than the one proposed by the Legislature. The Kasich plan sets out reasonable expectations concerning limits on drug amounts while still deferring to the physician's best judgment as to the proper treatment of a particular patient. It sets up a process for exceeding the limit when it is in the best interest of that patient. The Legislature's proposal fails to do that. The OSMA has enlisted a "geographically diverse multi-specialty work group of physicians" to study both proposals as they are developed with their respective formulation processes. Through the diligence of the work group in assisting the OSMA in reviewing these proposals, the interests of all Ohio physicians will be reflected in the final new opioid prescribing guidelines.



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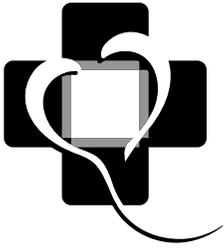
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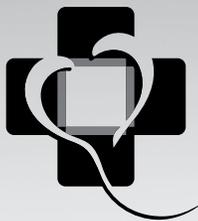
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