OHIO HOSPITAL ASSOCIATION

To: Chief Executive Officers
Emergency Department Directors
Vice Presidents of Medical Affairs
Chief Nursing Officers
Risk Managers
Society of Hospital Attorneys Members
OHA Regional Quality Collaborative Leaders
Hospital Government Relations Officers
Regional Hospital Association CEOs
Directors of Quality

From: Sean McGlone, Sr. Vice President and General Counsel, OHA SMM

Date: January 15, 2014

Re: Emergency Department Opiate Prescribing Guidelines

The Ohio Hospital Association (OHA) is contacting you regarding an important development related to the *Emergency and Acute Care Facility Opioid and Other Controlled Substances Prescribing Guidelines (ED Guidelines)* that were finalized in April, 2012 and adopted and posted in emergency departments by many hospitals across the state. *In short, CMS has concluded that posting the ED Guidelines in your facilities could create liability for hospitals under the federal Emergency Medical Treatment and Active Labor Act (EMTALA).* Please see below for more information regarding this issue.

You are aware of the prescription drug epidemic in Ohio and have seen the increased attention this problem is receiving from law enforcement and regulators across the state. The legislature passed its first law addressing the issue of "pill mills" back in 2011, has passed other legislation regarding opiates since then, and is currently debating *fifteen* bills in the legislature that touch some aspect of the opiate problem in Ohio. Needless to say, this problem has gained the close attention of Ohio's policymakers.

The ED Guidelines were developed by the multi-disciplinary Professional Education Workgroup (PEW) of Governor Kasich's Cabinet Opiate Action Team (GCOAT) to promote appropriate use of opioids and other controlled substances in emergency departments and urgent care centers. The GCOAT includes the agency directors of the Ohio Department of Health (ODH), Ohio Department of Aging, and Ohio Department of Mental Health and Addiction Services, and others. In addition to playing a key role in the development of the ED Guidelines, OHA and eight other key stakeholder organizations officially endorsed the guidelines and promoted them to their memberships throughout Ohio.

The opiate problem is not unique to Ohio, and several other states began to explore the development of their own emergency department prescribing guidelines, often using Ohio's good

work on this issue as a model. As this issue was discussed in other states, the South Carolina Hospital Association inquired with its regional office of the Center for Medicare and Medicaid Services (CMS Region 4) regarding whether posting guidelines similar to Ohio's could result in violations under EMTALA. As you know, EMTALA is a federal law that requires anyone coming to an emergency department to receive an appropriate medical screening to determine whether an emergency medical condition exists, regardless of their insurance status or ability to pay. **Unfortunately, CMS Region 4 concluded that posting such guidelines in patient waiting rooms or treatment rooms "might be considered to be coercive or intimidating to patients who present to the ED with painful medical conditions, thereby violating both the language and the intent of the EMTALA statute and regulations." Further, CMS Region 4 shared its concern that "some patients with legitimate medical needs and legitimate need for pain control would be unduly coerced to leave the ED before receiving an appropriate medical screening exam."**

Upon learning about the CMS Region 4 opinion on this matter, OHA informed ODH about the issue and shared its concerns that if CMS Region 5 (which includes Ohio) reached a similar conclusion, Ohio hospitals could find themselves exposed to EMTALA liability for posting the ED Guidelines in emergency departments. Soon thereafter, ODH submitted a request to CMS Region 5 to see if its guidance regarding Ohio's ED Guidelines would be the same as Region 4's. **Unfortunately, CMS Region 5 reached the same conclusion as its Region 4 counterpart.**

OHA is disappointed by CMS' conclusion on this issue. However, OHA wanted you to be aware of CMS' position. Accordingly, **this memorandum serves as notice to Ohio hospitals of CMS' guidance. We recommend that hospitals consider removing the ED Guidelines that may be posted in your emergency departments and consulting with your legal counsel to decide what course of action to take to educate patients on this important issue while remaining compliant with EMTALA.**

Note that it is the *posting* of the ED Guidelines in the emergency department, not the existence of the ED Guidelines, that raises CMS' EMTALA concerns. Accordingly, we believe that the content of the ED Guidelines remains good practice regarding prescribing practices in emergency departments, and we encourage you to adopt the ED Guidelines as emergency department policy if you have not already done so. In addition, the sample patient handout that was created along with the ED Guidelines is a good way to communicate with patients about the emergency department's safe prescribing practices. That handout can be provided to patients during the course of that patient's treatment in the emergency department after the patient receives an appropriate screening exam.

Ohio's hospitals have been strong partners with the state in its fight against the opiate epidemic. Though CMS' position is unfortunate, it should not deter emergency room physicians from following the ED Guidelines and having necessary conversations with patients about the risks of opiate use and the need to explore alternative treatments. Physicians should continue to use their independent clinical judgment to treat the unique needs of each patient. **The ED Guidelines were created as recommendations, not protocols or standards of care. Clinical judgment remains the key determining factor in prescribing practices**; however, there is growing

recognition among professionals and policymakers that opioid prescribing practices must change in order to address the staggering epidemic of prescription drug addiction and overdose.

Finally, you should be aware that OHA has had conversations with ODH leadership and Governor Kasich's office on this issue over the last several months, and they are aware that this communication is going out to hospitals with the recommendation to remove the ED Guidelines that may be posted in hospital emergency departments.

Thank you for your leadership as Ohio addresses the opiate problem from various angles. If you have questions, please feel free to contact me at seanm@ohanet.org or 614-384-9139.

Attachments

- Copy of the ED Guidelines (page 2 of this document is the sample patient handout)
- Letter from ODH to CMS Region 5 dated July 22, 2013
- Response letter from CMS Region 5 to ODH dated November 6, 2013 (enclosing the CMS Region 4 response to the South Carolina Hospital Association inquiry)
- Article from ACEP Now providing additional detail on CMS' position, as articulated by the CMS Region 4 Medical Director who drafted that region's initial response to this issue

- I have also attached a set of Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain. These Guidelines were adopted in the Spring of 2013 by the State Medical Board of Ohio, Ohio Board of Nursing, Ohio Dental Board, and Ohio Board of Pharmacy. Though these Guidelines do not raise the EMTALA issues identified by CMS regarding the ED Guidelines, I wanted to take this opportunity to remind you of their adoption by the licensing boards.

Ohio Emergency and Acute Care Facility
Opioids and Other Controlled Substances (OOCS) Prescribing Guidelines

These guidelines are to provide a general approach in the prescribing of OOCS. They are not intended to take the place of clinical judgment, which should always be utilized to provide the most appropriate care to meet the unique needs of each patient.

1. OOCS for acute pain, chronic pain and acute exacerbations of chronic pain will be prescribed in emergency/acute care facilities only when appropriate based on the patient's presenting symptoms, overall condition, clinical examination and risk for addiction.
    a. Doses of OOCS for routine chronic pain or acute exacerbations of chronic pain will typically NOT be given in injection (IM or IV) form.
    b. Prescriptions for chronic pain will typically NOT be provided if the patient has either previously presented with the same problem or received an OOCS prescription from another provider within the last month.
    c. IV Demerol (Meperidine) for acute or chronic pain is discouraged.

2. Emergency medical clinicians will not routinely provide:
    a. Replacement prescriptions for OOCS that were lost, destroyed or stolen.
    b. Replacement doses of Suboxone, Subutex or Methadone for patients in a treatment program.
    c. Long-acting or controlled-release opioids (such as OxyContin®, fentanyl patches, and methadone).

3. Prior to making a final determination regarding whether a patient will be provided a prescription for OOCS, the emergency clinician or facility:
    a. Should search the Ohio Automated Rx Reporting System (OARRS) database (https://www.ohiopmp.gov/portal/Default.aspx) or other prescription monitoring programs, per state rules.
    b. Reserves the right to request a photo ID to confirm the identity of the patient. If no photo ID is available, the emergency or other acute care facility should photograph the patient for inclusion in the facility medical record.
    c. Reserves the right to perform a urine drug screen or other drug screening.

4. Emergency/acute care facilities should maintain an updated list of clinics that provide primary care and/or pain management services for patients, as needed.

5. Prior to making a final determination regarding whether a patient will be provided a prescription for an OOCS, the emergency clinician should consider the following options:
    a. Contact the patient's routine provider who usually prescribes their OOCS.
    b. Request a consultation from their hospital's palliative or pain service (if available), or an appropriate sub-specialty service.
    c. Perform case review or case management for patients who frequently visit the emergency/ acute care facilities with pain-related complaints.
    d. Request medical and prescription records from other hospitals, provider's offices, etc.
    e. Request that the patient sign a pain agreement that outlines the expectations of the emergency clinician with regard to appropriate use of prescriptions for OOCS.

6. Emergency/acute care facilities should use available electronic medical resources to coordinate the care of patients who frequently visit the facility, allowing information exchange between emergency/acute care facilities and other community-care providers.

7. Except in rare circumstances, prescriptions for OOCS should be limited to a three-day supply. Most conditions seen in the emergency/acute care facility should resolve or improve within a few days. Continued pain needs referral to the primary care physician or appropriate specialist for re-evaluation.

8. Each patient leaving the emergency/acute care facility with a prescription for OOCS should be provided with detailed information about the addictive nature of these medications, the potential dangers of misuse and the appropriate storage and disposal of these medications at home. This information may be included in the Discharge Instructions or another handout.

9. Emergency/acute care facilities should provide a patient handout and/or display signage that reflects the above guidelines and clearly states the facility position regarding the prescribing of opioids and other controlled substances.

Ohio State Medical Association · Ohio Hospital Association · OAHP Ohio Association of Health Plans · Ohio Osteopathic Association · OPA · OAPA · Ohio Bureau of Workers Compensation · Ohio Department of Health · Ohio Department of Aging

Approved by GCOAT on April 18, 2012

Welcome

Pain Management in our Emergency/Acute Care Facility

Our staff understands that pain relief is important when someone is hurt or needs emergency care. However, providing ongoing pain relief is often complex. We recommend this be done through your primary health care provider such as your family doctor or pain management specialist. Because mistakes or misuse of pain medication can cause serious health problems and even death, it is important that you provide accurate information about all medications you are taking. Our emergency/acute care facility will only provide pain relief options that are safe and appropriate.

For your safety, we follow these guidelines when managing chronic pain:

1. We are trained to look for and treat an emergency or urgent condition. We use our best judgment when treating pain, and follow all legal and ethical guidelines.
2. We typically do not prescribe narcotic pain medicine for chronic pain if you have already received narcotic pain medication from another health care provider or emergency or acute care facility.
3. We may contact your primary care provider to discuss your care. Typically, we will not prescribe narcotic pain medicine if we cannot talk directly with your primary care provider. If you do not have a primary care provider, we will provide you with a list of those providers in our area.
4. We may provide only enough pain medication to last until you can contact your primary care provider. We will prescribe pain medication with a lower risk of addiction and overdose whenever possible.
5. We will ask you to show a valid photo ID (like a driver's license) when you check into the emergency/acute care facility or before receiving a prescription for narcotic pain medication. If you do not have a photo ID, we may take your picture for the medical record.
6. We may ask you to give a urine sample before prescribing narcotic pain medication.
7. Health care laws, including HIPAA, allow us to request your medical record and share information with other health care providers who are treating you.
8. Before prescribing a narcotic or other controlled substance, we check the Ohio Automated Rx Reporting System (OARRS) or a similar database that tracks your narcotic and other controlled substance prescriptions.
9. For your safety, we do not:
    a. Routinely give narcotic pain medication injections (shots or IV) for flare-ups of chronic pain;
    b. Refill stolen or lost prescriptions for narcotics or controlled substances;
    c. Provide missing Subutex, Suboxone, or Methadone doses; or,
    d. Prescribe long-acting or controlled-release pain medications such as OxyContin, MS Contin, Duragesics, Methadone, Exalgo, and Opana ER.
10. Frequent users of the emergency/acute care facility may have care plans developed to assist in improving their care. The plans may include avoiding medicines likely to be abused or addictive.
11. If you need help with substance abuse or addiction, please call this toll-free number for confidential referral to treatment between the hours of 8:00 AM and 5:00 PM Monday through Friday: 1-800-788-7254

It is against the law to attempt to obtain controlled substance pain medicines by deceiving the health care provider caring for you. This can include getting multiple prescriptions from more than one provider or using someone else's name to obtain a prescription.

Ohio State Medical Association · Ohio Hospital Association · OHP Ohio Association of Health Plans · Ohio Osteopathic Association · OPA · OAPA · Ohio Bureau of Workers Compensation · Ohio Department of Health · Ohio Department of Aging

Approved by GCOAT on April 18, 2012

OHIO DEPARTMENT OF HEALTH

246 North High Street
Columbus, Ohio 43215

614/466-3543
www.odh.ohio.gov

John R. Kasich / Governor

Theodore E. Wymyslo, M.D. / Director of Health

JUL 22 2013

Ms. Jackie Garner
Regional Director, CMS Region 5
233 North Michigan Avenue, Suite 1300
Chicago, IL 60601

Dear Director Garner,

As you may know, Ohio is in the midst of a drug overdose epidemic. From 1999 to 2011, Ohio's death rate due to unintentional drug overdose increased 440 percent. In 2011 alone, drug overdoses caused the death of 1,765 Ohioans. This is equivalent to five Ohioans dying every day or one Ohioan dying every five hours. The dramatic increase in drug overdose deaths has been driven largely by prescription opioids often used for the treatment of pain.

In 2011, the Governor's Cabinet Opiate Action Team convened a diverse group of stakeholders, led by the Ohio Department of Health, to develop guidelines for the treatment of chronic pain in a number of patient settings. The first step in this effort was the development of the Ohio Emergency and Acute Care Facility Opioids and Other Controlled Substances (OOCS) Prescribing Guidelines, which were issued in April 2012. Recent data published by the Centers for Disease Control and Prevention (CDC) indicates that between 2009 and 2010, 25 percent of ED visits in individuals aged 18 to 64 years resulted in a narcotic prescription.[1] As such, the guidelines are to provide appropriate guidance for the prescribing of opioids and other controlled substances in the unique acute care environment where the treatment of chronic pain is frequently indicated without the benefit of an established and ongoing physician-patient relationship. The guidelines clearly state they are not intended to take the place of providers' clinical judgment, which should always be utilized to provide the most appropriate care to meet the unique needs of each patient. This collaborative effort earned the endorsements of healthcare provider organizations, hospitals, urgent care representatives and health plans.[2]

The guidelines are intended not only to assist clinicians in safely treating patients using opioids and other controlled substances, but also to protect patient safety. To that end, the committee developed a standard patient hand-out and poster to inform patients of the new policies and procedures if a hospital should choose to adopt the guidelines. Copies of the guidelines, patient handouts and poster have been enclosed with this letter.

It has recently come to the attention of the Ohio Department of Health that the Region-4 CMS office has reviewed a similar effort in South Carolina and has raised concerns about a possible Emergency Medical Treatment and Active Labor Act (EMTALA) violation, specifically as it

[1] CDC/NCHS. Health, United States, 2012. Data from the National Hospital Ambulatory Medical Care Survey. Emergency Department Component.

[2] OOCS Prescribing Guidelines Endorsing Organizations: Ohio Chapter of the American College of Emergency Physicians, Ohio Association of Health Plans, Ohio Association of Physician Assistants, Ohio Bureau of Workers' Compensation, Ohio Hospital Association, Ohio Osteopathic Association, Ohio Pharmacists Association, and the Ohio State Medical Association

relates to the posted patient information. This response has caused unease among many Ohio hospitals, urgent care facilities and clinicians who value the guidelines and patient information hand-outs as effective methods to promote and protect the safety of patients. In order to allay such concerns, the Ohio Department of Health requests a determination from your office as to whether Ohio's guidelines and accompanying patient information signage present a potential violation of EMTALA.

The Opiate Action Team and our partners believe that these brochures and posted signs are essential to defining the scope of services provided by an emergency department when treating pain and often reflect existing hospital policies. All materials are clearly labeled 'for your safety' to express the intent and purpose of the communication, and reaffirm that pain relief will be provided in a safe and appropriate manner. It is our understanding that the intent of EMTALA is threefold: (1) to impose an affirmative obligation on the part of the hospital to provide the patient with a medical screening exam in order to determine whether or not an emergency medical condition is present; (2) if an emergency medical condition exists, the hospital has an affirmative duty to treat the medical condition; and (3) to impose restrictions on the transfer of patients who have been diagnosed with an emergency medical condition or who are in active labor.

It is our belief that this tool is not a deterrent to obtaining care but rather provides valuable information about the utilization of opioids for the treatment of pain. Nothing in the materials suggests that the hospital will not provide a medical screening exam to patients presenting with complaints of pain or that, if the pain is determined to be due to an emergent medical condition, the patient's pain will not be treated. Nothing in the materials is intended to discourage a patient from seeking care or receiving medical screening. We hope that you agree with us that the enclosed materials are important in Ohio's fight against prescription drug abuse and do not raise concerns under EMTALA.

I thank you in advance for reviewing the enclosed materials and look forward to your response on this issue. I hope that you will be able to provide definitive guidance on our efforts to promote patient safety while decreasing prescription drug overdose deaths in Ohio.

Sincerely,

Theodore E. Wymyslo, M.D.
Director
Ohio Department of Health

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Midwest Division of Survey and Certification
Chicago Regional Office
233 North Michigan Avenue, Suite 600
Chicago, IL 60601-5519

CENTERS FOR MEDICARE & MEDICAID SERVICES

November 6, 2013

Theodore E. Wymyslo, M.D.
Director of Health
Ohio Department of Health
246 North High Street
Columbus, OH 43215

Dear Dr. Wymyslo:

Thank you for your letter describing the drug overdose epidemic occurring in Ohio. I apologize for the delayed response; however, your original letter was not received in our office until after our staff returned from the government shutdown.

As stated in your letter, CMS specifically addressed possible Emergency Medical Treatment and Active Labor Act (EMTALA) violations regarding proposed signage and posters with one of our Region IV states. We have reviewed the information you have submitted and determined the signage or paper notices could be a deterrent to obtaining necessary care and result in possible EMTALA violations.

Enclosed, please find a copy of our letter to the South Carolina Hospital Association regarding signage and postings in emergency departments related to "Prescribing Pain Medication in the Emergency Department." The attached letter is CMS' official policy. I hope that you find this information helpful. If you have additional questions, please contact Pam L. Thomas, of my staff, at (312) 886-5561 or pam.thomas@cms.hhs.gov.

Sincerely,

Nadine Renbarger

Nadine Renbarger
Associate Regional Administrator

Enclosure

cc: Jackie Garner
Ohio Department of Community Health

Department of Health & Human Services
Centers for Medicare & Medicaid Services
Atlanta Regional Office
61 Forsyth St., Suite. 4T20
Atlanta, Georgia 30303-8909

CENTERS FOR MEDICARE & MEDICAID SERVICES
CONSORTIUM FOR QUALITY IMPROVEMENT
AND SURVEY & CERTIFICATION OPERATIONS

February 6, 2013

Diane Paschal
Director, Corporate Compliance
South Carolina Hospital Association
1000 Center Point Road
Columbia, SC 29210

Dear Ms. Paschal,

Thank you for your inquiry of January 18, 2013 regarding proposed notices that hospitals have considered posting in ED waiting rooms or ED patient examination rooms regarding "Prescribing Pain Medication in the Emergency Department".

The federal EMTALA statute (Sec 1867 of the Social Security Act, 42 U.S.C.1395dd) states that "In the case of a hospital that has a hospital emergency department, if any individual (whether or not eligible for benefits under this title) comes to the emergency department and a request is made ...for examination or treatment of a medical condition, the hospital must provide for an appropriate medical screening examination within the capability of the hospital's emergency department... to determine whether or not an emergency medical condition (within the meaning of subsection (e) (1) exists.

(e)(1) The term "emergency medical condition" means- (A) a medical condition manifesting itself by acute symptoms of sufficient severity **(including severe pain) ..... etc.** (emphasis added).

42 CFR 489.24 (b) defines "Emergency medical condition" as (1) A medical condition manifesting itself by acute symptoms of sufficient severity **(including severe pain, psychiatric disturbances and/or symptoms of substance abuse)** (emphasis added).

42 CFR 489.24 (d) (4) (iv) states that Hospitals may follow reasonable registration process.... However **"Reasonable registration processes may not unduly discourage individuals from remaining for further evaluation".** (emphasis added). Furthermore, hospitals should not deny emergency services based on diagnosis, financial status, race, color, national origin, or disability (State Operations Manual Appendix V). Such cases will additionally be referred to the HHS Office of Civil rights (OCR) for investigation of discrimination. CMS Interpretive guidelines (SOM Appendix V) state that although patients may leave the emergency department of their own free will, they should not leave based on a "suggestion" by the hospital or through coercion.

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

We share your concerns and those of the provider community about the increasing prevalence of prescription drug abuse and its harmful effects. We understand the tendency of persons seeking pain medication and controlled substances for non- legitimate purposes to approach physicians, emergency departments and other health care providers for access to these drugs. Nevertheless, the intent of the EMTALA statute is clearly to assure that all individuals who come to the emergency department for a medical condition receive an appropriate medical screening examination to determine whether or not an emergency medical condition exists. Our concern is that some patients with legitimate medical needs and legitimate need for pain control would be unduly coerced to leave the ED before receiving an appropriate medical screening exam.

While many of the points mentioned in the information you submit are appropriate points for discussion between the patient and the physician or other health care practioner, they should be discussed in the context of an appropriate medical screening exam rather than be posted in the ED before patients are provided an appropriate medical screening exam. Blanket statements or protocols should not supersede professional medical judgment in individual cases. After performing an appropriate medical screening exam, it is within the bounds of reasonable professional medical judgment and discretion for an appropriately licensed physician or other health care practioner to provide or to withhold narcotic or other methods of pain control in a particular patient depending on the specific clinical circumstances.

We hope this information is helpful to you and your member hospitals.

Sincerely,

Brenda J Dawalo, RN MSN

for

Richard E. Wild, MD, JD, MBA, FACEP
Chief Medical Officer, Atlanta Regional Office
Centers for Medicare and Medicaid Services (CMS)
Sam Nunn Atlanta Federal Center
61 Forsyth Street, SW, Suite 4T20
Atlanta, GA 30303

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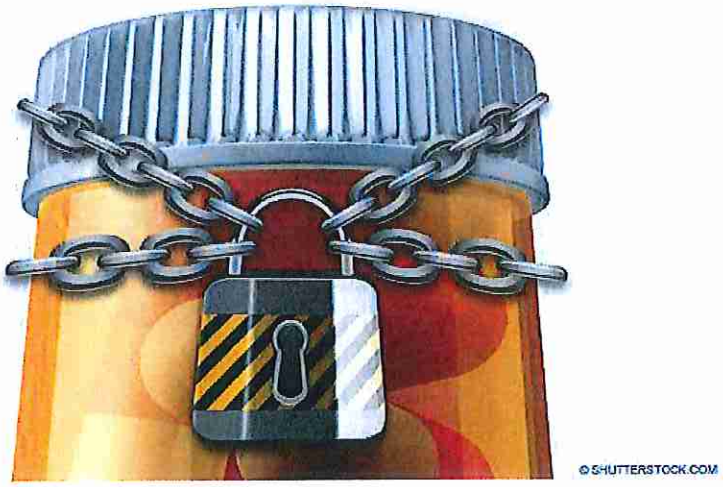
ED Waiting Room Posters on Prescribing Pain Medications May Violate EMTALA

By Richard E. Wild, MD, ‚D, MBA, FACEP | on ‚anuary 8, 2014 | 0 Comment



Statement from CMS region 4 office could have far-reaching implications for EDs nationwide

On ‚an. 18, 2013, the South Carolina Hospital Association requested an

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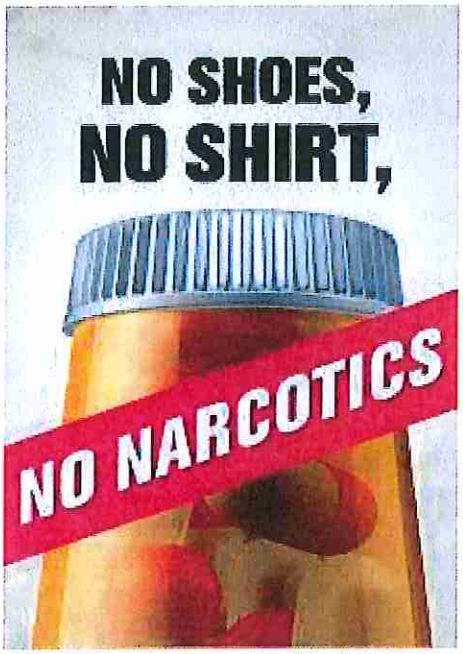
opinion from its CMS Regional Office regarding the use of Ípain postersÎ (Prescribing Pain Medication in the Emergency Department) that were developed for posting in emergency department waiting rooms and treatment areas. Despite the fact that these posters were well intentioned and proposed to deter inappropriate opioid drug seeking, concerns about CMSÍs perspective and compliance issues with EMTALA must have been contemplated. Otherwise, why would such an opinion be requested? In summary, the CMS Chief Medical Officer for the Atlanta Regional office (region 4) respondedÊ to the surprise of many. Dr. Rick Wild responded on behalf of CMS Region 4 making several observations and providing words of caution, strongly discouraging the use of such postings. In his response, Dr. Wild stated the following (summarized):



- The definition of an ÍEmergency medical conditionÎ is a medical condition manifesting itself by acute symptoms of sufficient severity including severe pain, psychiatric disturbances, and/or symptoms of substance abuse.
- ÍReasonable registration processes may not unduly discourage individuals from remaining for further evaluation.Î
- ÍAccordingly, the language regarding, ÍPrescribing Pain Medication in the Emergency Department,Í which you have provided and any similar language, which the hospital might choose to post in patient waiting rooms or treatment rooms, might be considered to be coercive or intimidating to patients who present to the ED with painful medical conditions, thereby violating both the language and the intent of the EMTALA statute and regulations.Î

These statements have generated a great deal of debate and discussion. Some say, ÍWell this is just an opinion.Î Others have said, ÍThis only impacts Region 4,Î and yet some have said, ÍWellÍ just word ours a little better.Î

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To help clarify the implications of this statement, I have asked Dr. Wild and CMS to clarify their opinion, which they have done with the written interview responses below.

Ê Kevin M. Klauer, DO, E.D, FACEF, Medical editor in chief, ACEF Now

1) Can you tell us about CMS EMTALA enforcement policy and the CMS Region 4 letter dated Feb. 6, 2013 regarding ÍPrescribing Pain Medication in the Emergency DepartmentÎ (in general)?

CMS is responsible for the enforcement of and issuance of regulations, guidance, and policies pertaining to the Emergency Medical Treatment and Labor Act (EMTALA) (Sec. 1867 of the Social Security Act, 42 U.S.C.1395dd). The CMS Central Office in Baltimore has the overall responsibility for issuing regulations, guidance and policy, and each of the ten (10) CMS regional offices are responsible for the enforcement of the EMTALA law within their areas of jurisdiction and for responding to questions regarding EMTALA enforcement policy. The individual CMS regional offices regularly communicate with CMS Central Office and also conduct regular conferences between the central office and across all the regions to ensure that CMS policies are implemented and enforced in as uniform manner as possible. Each CMS regional office works with their respective state survey agencies and quality improvement organizations (QIOs) in each enforcement investigation and action. EMTALA enforcement is complaint-driven, i.e., investigations occur in response to complaints, which suggest violations of EMTALA. Each case is investigated and decisions are rendered based on the unique facts and circumstances of that case. Each CMS region is responsible for the final determination of whether EMTALA was violated, for issuing notices of termination from the Medicare and Medicaid programs, and for approving plans of correction submitted by hospitals to avoid termination. Additionally, each region refers cases to the HHS Office of the Inspector General (OIG) for consideration of possible imposition of civil monetary penalties when appropriate.

a. History of why and when the CMS Region 4 letter regarding ÍPrescribing Pain Medication in the Emergency DepartmentÎ was drafted?

Region 4 was made aware of instances or proposals to post signage in emergency department waiting areas and distribution of informational materials pertaining to ÍPrescribing Pain Medication.Î The Region 4 letter

FOLLS

USA Today reported in October that hospitals Íare starting to cut thousands of jobs amid falling insurance payments and inpatient visits.Î Have you seen any evidence of this?

- Yes
- No
- Not Sure

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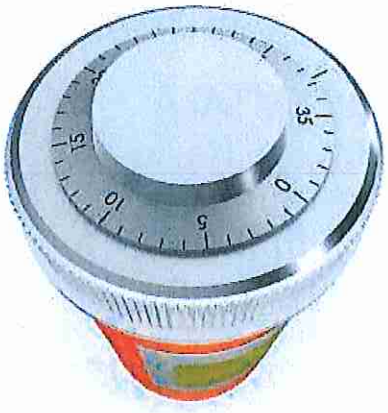
was written in response to an inquiry from a state hospital association regarding these practices and their possible violation of the EMTALA statute and regulations. Subsequently the same issue has been arising in other CMS Regions.

The Region 4 response represents current national CMS policy. This is not a new policy, but the application of the current law, regulations, and CMS policies to this particular situation.



b. What are the concerns of CMS?

CMS shares the concerns of public health organizations and the hospital industry about prescription drug abuse and its harmful effects. We understand that hospital EDs face considerable challenges in dealing with individuals seeking pain medication and controlled substances for non-legitimate purposes. We emphasize that it is within the bounds of reasonable professional judgment and discretion for a physician or other licensed healthcare practitioner to provide or withhold opioids and/or other methods of pain control, depending on the specific clinical circumstances of an individualls presentation.

However, the posting in an ED of signs and/or distribution of brochures emphasizing that certain types of pain medications will not be prescribed appears designed to indiscriminately discourage any individual seeking treatment for pain from remaining in the ED for a medical screening examination or from coming to that ED in the future. Furthermore, such signage or brochures raise questions about whether the hospital would provide stabilizing treatment in cases in which administration of opioids might be clinically appropriate. In summary, hospitals, which employ such signage or disseminate similar brochures, are at risk of being found noncompliant with EMTALA requirements.

The EMTALA statute requires that any individual who comes to the emergency department for a medical condition must be provided an

appropriate medical screening examination (not merely a triage exam) by an appropriately credentialed and qualified medical professional to determine whether or not an emergency medical condition exists. It is significant that the statute defines Íemergency medical conditionÎ to include symptoms such as severe pain. Additionally, the Medicare provider agreement statute (Section 1866(a)(1)(N)(iii)) requires hospitals to post conspicuously in any emergency department a sign that specifies the rights of individuals under EMTALA with respect to examination and treatment for emergency medical conditions and women in labor. Signs that announce restrictions on treatments, regardless of the facts of an individualls case, appear to be at odds with the signage hospitals are required by law to post in their EDs.

Further, federal EMTALA regulations (42 CFR 489.24) reiterate and expand upon these statutory requirements. For example, 42 CFR 489.24(d)(4)(iv) states that ÍReasonable registration processes may not unduly discourage individuals from remaining for further evaluation.Î Although certain signs and literature posted and distributed in emergency department waiting areas may be intended to Íeducate patients,Î they nevertheless may have the real or perceived effect of discouraging an individual from remaining for further evaluation, or stabilizing treatment and thus be in violation of EMTALA. It should also be noted that EMTALA is a federal statute, which supersedes state laws, regulations, or municipal ordinances which are in conflict with EMTALA.

In some cases, CMS is asked to pre-approve or endorse specific or ÍmodelÎ language for waiting room signs or handout materials. However, as a matter of policy, CMS does not provide prior approval to any individual hospitalls policies and procedures, nor does it review a hospitalls EMTALA policies and procedures outside the context of a specific investigation of an EMTALA complaint. Each EMTALA case complaint or investigation will be judged based on the particular facts of each case. Certain signs or materials posted or distributed in ED waiting rooms may be determined in the course of such investigation to be inconsistent with the EMTALA signage requirements and/or to have the potential to discourage individuals from remaining in the ED.

c. What was the process of drafting the Region 4 letter of Feb. 6, 2013, pertaining to Í Prescribing Pain Medication in the Emergency Department?

The Region 4 response was drafted by me, the CMS Atlanta regional chief medical officer, who is a board certified emergency medicine specialist, in

consultation with the federal statutes, regulations, and sub-regulatory guidance and with specific consultation with the CMS central office and other regional offices. The Region 4 response represents current national CMS policy. This is not a new policy, but the application of the current law, regulations, and CMS policies to this particular situation.

2) Many have reported that this is only a Region 4 opinion and have stated it is only an opinion and not policy and that this is not the position of all CMS regions. Can you speak to that?

As stated above, this letter was developed in consultation with CMSIs central office, has been shared with all CMS regional offices, and is being followed by CMS regional offices. However, given the frequency with which the issue is now arising and the questions about whether this letter represents CMS policy, CMS may issue a national memorandum on the topic.

3) Do you see alternatives to ED waiting room patient signage and flyers for chronic opiate needs when patients present to the ED?

Yes. In accordance with standard accepted medical practices and in accordance with the provisions of EMTALA, every individual who presents to the emergency department for any medical condition or complaint should first receive an appropriate medical screening exam by a properly trained and credentialed qualified medical professional. This exam is not a triage exam but is explicitly tailored to address the particular signs and symptoms of the patient. An appropriate medical screening exam uses all the available resources of the emergency department, which are appropriate to determine whether an emergency medical condition exists. After an appropriate medical screening exam is conducted, it is within the bounds of professional medical judgment and discretion for an appropriately licensed physician or other health care practitioner to provide or to withhold narcotic or other methods of pain control in a particular patient depending on the specific clinical circumstances. It is also left to the judgment of the provider as to how best to give specific patient-centered education, including handouts, policies, and institutional protocols. But again, it is emphasized that patient education should take place after a patient focused medical screening exam is completed and not by posting general policies and procedures or displaying such materials in the waiting area.

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Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain
80 mg of a Morphine Equivalent Daily Dose (MED) "Trigger Point"

These guidelines address the use of opioids for the treatment of chronic, non-terminal pain. "Chronic pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months. The guidelines are intended to help health care providers review and assess their approach in the prescribing of opioids. The guidelines are points of reference intended to supplement and not replace the individual prescriber's clinical judgment. The 80 mg MED is the maximum daily dose at which point the prescriber's actions are triggered; however, this 80 mg MED trigger point is not an endorsement by any regulatory body or medical professional to utilize that dose or greater.

Recent analysis by the Centers for Disease Control and Prevention (CDC) shows that "patients with mental health and substance use disorders are at increased risk for nonmedical use and overdose from prescription painkillers as well as being prescribed high doses of these drugs." Drug overdose deaths increased for the 11th consecutive year in 2010. Nearly 60% of the deaths involved pharmaceuticals, and opioids were involved in nearly 75%. Researchers also found that drugs prescribed for mental health conditions were involved in over half. These findings appear consistent with research previously published in the *Annals of Internal Medicine* that concluded that "patients receiving higher doses of prescribed opioids are at an increased risk for overdose, which underscores the need for close supervision of these patients" (Dunn, et al., 2010).

Health care providers are not obligated to use opioids when a favorable risk-benefit balance cannot be documented. Providers should first consider non-pharmacologic and non-opioid therapies. Providers should exercise the same caution with tramadol as with opioids and must take into account the medication's potential for abuse, the possibility the patient will obtain the medication for a nontherapeutic use or distribute it to other persons, and the potential existence of an illicit market for the medication.

Providers must be vigilant to the wide range of potential adverse effects associated with long-term opioid therapy and misuse of extended-release formulations. That vigilance and detailed attention has to be present from the outset of prescribing and continue for the duration of treatment. Providers should avoid starting a patient on long-term opioid therapy when treating chronic pain. Providers should also avoid prescribing benzodiazepines with opioids as it may increase opioid toxicity, add to sleep apnea risk, and increase risk of overdose deaths and other potential adverse effects.

Providers can further minimize the potential for prescription drug abuse/misuse and help reduce the number of unintentional overdose deaths associated with pain medications by recognizing times to "press pause" in response to certain "trigger points." This pause allows providers to reassess their compliance with accepted and prevailing standards of care. The 80 mg Morphine Equivalent Daily Dose (MED) "trigger point" is one such time.

Providers treating chronic, non-terminal pain patients who have received opioids equal to or greater than 80 mg MED for longer than three continuous months should strongly consider doing the following to optimize therapy and help ensure patient safety:

- Reestablish informed consent, including providing the patient with written information on the potential adverse effects of long-term opioid therapy.

- Review the patient's functional status and documentation, including the 4A's of chronic pain treatment
    - Activities of daily living,
    - Adverse effects,
    - Analgesia; and
    - Aberrant behavior

- Review the patient's progress toward treatment objectives for the duration of treatment.

- Utilize OARRS as an additional check on patient compliance.

- Consider a patient pain treatment agreement that may include: more frequent office visits, different treatment options, drug screens, use of one pharmacy, use of one provider for the prescription of pain medications, and consequences for non-compliance with terms of the agreement.

- Reconsider having the patient evaluated by one or more other providers who specialize in the treatment of the area, system, or organ of the body perceived as the source of the pain.

The 80 MED "trigger point" is an opportunity to review the plan of treatment, the patient's response to treatment, and any modification to the plan of treatment that is necessary to achieve a favorable risk-benefit balance for the patient's care. If opioid therapy is continued, further reassessment will be guided by clinical judgment and decision-making consistent with accepted and prevailing standards of care. The "trigger point" also provides an opportunity to further assess addiction risk or mental health concerns, possibly using Screening, Brief Intervention, and Referral to Treatment (SBIRT) tools, including referral to an addiction medicine specialist when appropriate.

For providers treating acute exacerbation of chronic, non-terminal pain, clinical judgment may not trigger the need for using the full array of reassessment tools.

Providers treating patients with acute care conditions in the emergency department or urgent care center should refer to the Ohio Emergency and Acute Care Facility Opioids and Other Controlled Substances Prescribing Guidelines. http://www.healthy.ohio.gov/ed/guidelines