



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Care Safety and Quality
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Circular: DHCQ 17-1-668

To: Acute Care Hospitals; Long-Term Care Facility Administrators; Massachusetts Controlled Substance Registrants; Ambulance Services and their Emergency Medical Services Personnel; Substance Use Treatment Providers; Licensed Nurses

From: Eric Sheehan, Director, Bureau of Health Care Safety and Quality
James Lavery, Director, Bureau of Health Professions Licensure

CC: Allison F. Bauer, JD, LICSW, Director, Bureau of Substance Abuse Services

Date: January 24, 2017

Re: Implementation of the STEP Law: Voluntary Non-Opioid Directive Form

Purpose

The purpose of this Circular is to provide guidance regarding Voluntary Non-Opioid Directives as established in Chapter 52 of the Acts of 2016, an act relative to substance use, treatment, education and prevention (“the STEP Act”).

Background

The STEP Act sets out a process enabling individuals to decline in advance any treatment option that includes opioids. The Bureau of Health Care Safety and Quality is actively working with the Bureau of Substance Abuse Services to ensure Massachusetts residents and the substance use disorder (“SUD”) treatment communities are aware that this new resource is available in our fight to eliminate opioid misuse.

Under the STEP Act, the Department of Public Health (“DPH” or “the Department”) is responsible for creating a Voluntary Non-Opioid Directive form (“Directive”) and publishing it on the Department’s website for public use. In addition, prior to discharge, SUD treatment providers will inform persons under their care about the option to file a Directive.

Any person who wishes to decline future treatment with opioids may fill out the form and give it to their care provider, who will record it in the patient’s electronic health record (“EHR”), or medical record if the

patient does not have an EHR, or responding emergency medical services (“EMS”) personnel. The patient, or the patient’s guardian or health care proxy, may revoke the Directive, orally or in writing, for any reason, at any time.

This guidance sets out how the Department will implement the new law until such time as regulations are promulgated.

Non-Opioid Directive Form

The Directive developed by DPH is attached to this document as Appendix A. It is also available on the Department’s website at <http://www.mass.gov/eohhs/gov/departments/dph/programs/substance-abuse/>.

If a person does not want opioids to be administered to them or offered as a treatment option, they may fill out and present the signed Directive to a care provider or responding EMS personnel at any time.

DPH encourages patients to complete the Directive in consultation with their primary care provider or SUD treatment provider. However, consultation it is not necessary to the validity of the Directive.

Provider Responsibilities

If a care provider receives a signed Directive, it must be recorded in the patient’s EHR, or medical record if the patient does not have an EHR.

Prior to prescribing, administering, or offering an opioid drug product to a patient, a provider should check the individual’s medical record to determine whether a Directive has been recorded. In the case of an EMS response, EMS personnel should ask the patient or patient’s on-scene representative(s) if the patient has such a Directive. Unless revoked by the patient verbally or in writing, a provider should consider a signed Directive as the patient’s non-consent to opioid treatment. The existence of a signed Directive does not prohibit offering, prescribing or administering opioid medications for the purpose of medication assisted SUD treatment, as approved for such use by the FDA.

If the patient has filed a Directive, or otherwise expresses his or her wish not to be treated with opioids, the provider is encouraged to consult the List of Non-Opioid Drug Products for Pain Management, as developed by the Drug Formulary Commission, for alternative pharmacological treatment options, available on the Department’s website at <http://www.mass.gov/eohhs/docs/dph/quality/drugcontrol/drug-formulary/non-opioid-drug-list-and-letter-july2016.pdf> . In the case of an EMS response, EMS personnel may consult with their service’s medical control physician.

Any board of professional licensure may limit, condition, or suspend the license of, or assess fines against a licensee who recklessly or negligently fails to comply with a person’s Directive.

Exemptions

Pharmacists

A written prescription that is presented at, or electronically transmitted to, a pharmacy shall be presumed to be valid. A pharmacist in an outpatient setting shall not be held in violation of this section of 94C for dispensing a controlled substance in contradiction to a person’s Directive except upon evidence that the pharmacist acted knowingly against that person’s Directive.

Health Care Professionals

No health care provider or employee of a health care provider acting in good faith, using appropriate clinical judgement, shall be subject to criminal or civil liability or be considered to have engaged in

unprofessional conduct if they do not offer or administer a prescription or medication order for an opioid pursuant to a person's Directive.

Emergencies

If an individual is unconscious or otherwise incapacitated, and consultation with a guardian, health care agent, or the medical record would impede the provision of timely emergency care or provides no evidence that a voluntary non-opioid directive form has been filed, emergency administration of an opioid drug product will not be considered a violation of the law.

Contact Information

Questions or concerns regarding this information should be directed to the Drug Control Program:
dcp.dph@state.ma.us.

Resources

- List of Non-Opioid Drug Products for Pain Management
<http://www.mass.gov/eohhs/docs/dph/quality/drugcontrol/drug-formulary/non-opioid-drug-list-and-letter-july2016.pdf>
- CDC Guideline Information for Prescribers:
<http://www.cdc.gov/drugoverdose/prescribing/providers.html>
- CDC Guideline for Prescribing Opioids for Chronic Pain:
<https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

Appendix A: Non-Opioid Directive Form



MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH VOLUNTARY NON-OPIOID DIRECTIVE (VNOD)

DCPFORM
DHCQ-17-1-668

PATIENT'S LAST NAME		PATIENT'S MIDDLE NAME OR INITIAL
PATIENT'S FIRST NAME		
DATE OF BIRTH (MM/DD/YYYY)		

STREET OR RESIDENTIAL ADDRESS		
CITY	STATE	ZIP CODE (5 or 9 digits)

LAST NAME OF GUARDIAN OR HEALTH CARE AGENT (If applicable)		MIDDLE NAME OR INITIAL
FIRST NAME OF GUARDIAN OR HEALTH CARE AGENT		

PATIENT/GUARDIAN/HEALTH CARE AGENT STATEMENT (SIGNATURE AND DATE REQUIRED)	
<p>I _____ (<input type="checkbox"/> patient <input type="checkbox"/> guardian <input type="checkbox"/> health care agent)</p> <p>certify that I am refusing at my own insistence the offer or administration of any opioid medications including in an emergency situation where I am unable to speak for myself. I understand the risks and benefits of my refusal, and hereby release the health care provider(s) or emergency medical service, its administration and personnel, from any responsibility for all consequences, which may result by my abstinence under these circumstances. I further certify my understanding that I may effectively revoke this certification at any time orally or in writing.</p> <p>I hereby direct that health care provider(s) or emergency medical service(s), their administration and personnel, comply with the Massachusetts Department of Public Health Voluntary Non-Opioid Directive regulations and guidance with regard to the above named patient.</p>	
Signature of Patient/Guardian/Health Care Agent	Date

SIGNATURE AND DATES (ALWAYS REQUIRED)	
<p>I am a health care practitioner for the above named patient. I verify that the above named patient has a current and valid Voluntary Non-Opioid Directive (VNOD)</p> <p>issued on _____</p>	
Signature of Health Care Practitioner	
Print Name of Health Care Practitioner	Effective Date of VNOD certification
Address of Health Care Practitioner	
Telephone Number of Health Care Practitioner	

First Copy: To be kept by patient
Second Copy: To be kept in patient's permanent medical record

If the person completing this form is currently enrolled in substance use treatment, appropriate consents must comply with HIPAA and 42 CFR Part 2.