

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the adoption of New) NOTICE OF PUBLIC HEARING ON
Rule I and the amendment of ARM) PROPOSED ADOPTION AND
37.10.101, 37.10.104, and 37.10.105) AMENDMENT
pertaining to living wills)

TO: All Concerned Persons

1. On September 3, 2008, at 1:00 p.m., the Department of Public Health and Human Services will hold a public hearing in the Sapphire Room of the Colonial Building, at 2401 Colonial Drive, Helena, Montana, to consider the proposed adoption and amendment of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Public Health and Human Services no later than 5:00 p.m. on August 25, 2008, to advise us of the nature of the accommodation that you need. Please contact Gwen Knight, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 202951, Helena, Montana, 59620-2951; telephone (406)444-9503; fax (406)444-6744; or e-mail dphhslegal@mt.gov.

3. The rule as proposed to be adopted provides as follows:

NEW RULE I DO-NOT-RESUSCITATE PROTOCOL (1) POLST is intended to replace Comfort One as the system used by medical professionals to identify and administer appropriate care, including DNR orders, to terminally ill patients.

(2) When issuing a DNR order, medical professionals must use the POLST form and follow the DNR/POLST protocol approved by the Board of Medical Examiners and the department. The department adopts and incorporates the DNR/POLST protocol July, 2008 which can be found at www.mt.gov/dli/bsd/license/bsd_boards/med_board/licenses/med/polst.asp or upon request from the Montana Board of Medical Examiners, P.O. Box 200513, 301 S. Park, 4th Floor, Helena, MT 59620.

(3) All previously issued Comfort One identifying material, including forms, will be considered valid by health care providers.

(4) All previously issued DNR orders will be considered valid by health care providers.

AUTH: 50-10-105, MCA

IMP: 50-10-101, MCA

4. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:

37.10.101 DEFINITIONS (1) "Comfort ~~one~~ One" means a comprehensive, statewide program of identifying, providing palliative care and method withholding resuscitative measures for ~~to~~ terminally ill patients ~~who have declared living wills or~~ for whom a physician has issued a do-not-resuscitate (DNR) order. ~~Comfort one~~ may also be used as an identifying term in educational programs for pre-hospital care providers, patients, physicians, hospital, hospice, home health and other medical personnel. The Comfort One program is to be succeeded by "POLST".

(3) ~~(2)~~ "Comfort ~~one~~ One card or form" means a uniform statewide identification card or form, issued before January 1, 2010, approved by the department, indicating that a ~~comfort one form~~ DNR has been issued to the patient, and containing the following identifying information:

(a) ~~name, sex, and birth date of the patient;~~

(b) ~~comfort one logo;~~

(c) ~~signature of the patient's attending physician or representative of a~~ licensed hospice program in which the patient is enrolled; and

(d) ~~the method by which a declaration may be revoked, if desired.~~

(4) ~~(3)~~ "Comfort ~~one~~ One logo" means a standard, statewide graphic display, including the words "comfort one", approved by the department, ~~which must be~~ displayed on comfort one forms, cards, necklaces, and bracelets.

(5) ~~(4)~~ "Comfort ~~one~~ One necklace or bracelet" means a necklace or bracelet of uniform statewide design, approved by the department, ~~and indicating that a~~ comfort one form has been issued to the patient. The comfort one Comfort One necklace or bracelet must prominently display the ~~comfort one~~ Comfort One logo and may only be issued to patients on verification that they have a ~~comfort one~~ Comfort One form, or have been identified as DNR patients on the POLST form.

(5) "POLST" means Provider Orders for Life-Sustaining Treatment, a comprehensive statewide method of identifying a patient's wishes for providing palliative care, medical interventions, or withholding resuscitative measures to terminally ill patients who have declared living wills or for whom a DNR order has been issued.

(2) ~~(6)~~ "Comfort ~~one~~ "POLST form" means a uniform, single form for statewide use, approved by the department and Board of Medical Examiners, indicating either that a valid and current declaration pursuant to 50-9-103, MCA, has been executed and that the declarant is a qualified patient as defined in 50-9-102, MCA, or that a physician provider has issued a do-not-resuscitate DNR order for the patient. The form must contain the following:

(a) ~~name, sex, and birth date of the patient;~~

(b) ~~signature of the patient's attending physician or representative of a~~ licensed hospice program in which the patient is enrolled;

(c) ~~comfort one logo;~~

(d) ~~the method by which a declaration may be revoked, if desired; and~~

(e) ~~an explanation of comfort one, including the actions emergency care~~ providers will take when presented with comfort one identification.

(7) "Provider" means a physician, or advanced practice registered nurse. A physician assistant with a valid agreement with a supervising physician who has delegated the authority to sign DNR orders may also be considered a provider.

AUTH: 50-9-110, MCA

IMP: 50-9-102, 50-9-106, MCA

37.10.104 LIVING WILL PROTOCOL FOR EMS PERSONNEL (1) The living will protocol may also be designated the "POLST protocol". Providers may use POLST to implement DNR orders, or the end of life treatment decisions by a patient expressed through a living will or otherwise.

(2) For a patient who has completed a POLST or Comfort One form, Under any of the following three circumstances, emergency medical services personnel must follow the POLST protocol approved by the board of medical examiners for providing palliative care or withholding life-sustaining procedures from a patient if a patient meets the following criteria:

(a) The identity of the patient has been clearly established and the personnel have been presented with any one of the following:

(i) a POLST form for the patient;

(ii) a ~~comfort one~~ Comfort One card or form for the patient; or

(iii) a written ~~do not resuscitate~~ DNR order signed and dated by a physician.

(b) An unresponsive person is wearing a ~~comfort one~~ Comfort One necklace or bracelet identifying the existence of a DNR order (no further identification is necessary).

~~(c) A physician's do not resuscitate order has been presented, but only when:~~

~~(i) the order is in writing and the personnel have a copy of the order or have seen the order; or~~

~~(ii) a physician issues a verbal order directly to the emergency medical services personnel.~~

~~(2) The living will protocol may also be designated the "comfort one protocol".~~

~~(3) This rule applies to an inter hospital transfer of patients as well as a response to an emergency by emergency medical service personnel.~~

AUTH: 50-9-110, MCA

IMP: 50-9-102, 50-9-103, MCA

37.10.105 SOURCES OF POLST AND COMFORT ONE IDENTIFICATION

(1) POLST forms, Comfort One forms, cards, necklaces, and bracelets may be obtained only through:

(a) physicians;

(b) licensed hospice programs;

(c) licensed home health agencies;

(d) hospitals;

(e) skilled nursing facilities;

(f) long term care facilities; and

(g) any other agency entity specifically approved by the department.

AUTH: 50-9-110, MCA
IMP: 50-9-102, MCA

5. The department proposes to adopt and amend these rules in order to adopt "Provider Orders for Life-Sustaining Treatment (POLST)" as a comprehensive system for treating patients with a terminal condition. The program is designed to improve the quality of care people receive at the end of life by improving communication of patient wishes, and documenting of medical orders on a single form.

NEW RULE I

Modeled after programs implemented in several other states, Montana's Provider Orders for Life-Sustaining Treatment (POLST) form and protocol is necessary to assure that a patient's wishes for life-sustaining treatments are honored by all health care professionals in all health care settings.

The department is proposing the adoption of New Rule I to reflect that the Board of Medical Examiners and the department have adopted, and the department has approved POLST as the protocol for implementing do-not-resuscitate (DNR) orders in medical settings. POLST is a comprehensive system that will incorporate both DNR orders as well as wishes for palliative care expressed by the patient in a living will or to the patient's provider. Comfort One will continue to be used to identify patients with a DNR order.

Current studies estimated that 20-30 percent of the U.S. population has an advance directive such as a DNR order or living will to define their preferences for "end-of-life" treatment. However, advance directives are often unavailable to ambulances or hospitals. Some advance directives are not followed because the order is not transferred from facility to facility, is not specific enough, is overridden, or is not immediately recognized as a "physician order". Montana's POLST form and protocol addresses all of these issues and assures that a patient's wishes are defined and followed when a patient is in terminal condition. POLST forms accompany patients as they are transferred to and from different locations and facilities.

The POLST form and protocol were developed by the Montana Board of Medical Examiners, in consultation with the department, as well as members of the medical community. The Board of Medical Examiners has held a number of public meetings, at which public input was sought.

ARM 37.10.101

The department is proposing changes to the definitions section to reflect the adoption of the POLST system to be used in all medical settings.

Although POLST is intended to replace the Comfort One system, Comfort One is being retained to identify terminally ill patients who have been issued a DNR order. This will help assure that emergency medical service providers will quickly be able to identify those patients having a DNR order and to make patient care decisions accordingly.

The current Comfort One form is being replaced by the POLST form. As this form encompasses aspects of both the department's rulemaking responsibility and the board's POLST protocol, it is approved by both entities. A reference to 50-9-102, MCA, "qualified patient", has been added.

Upon approval of these proposed rules, the POLST form will replace the current Comfort One form and card. While every effort will be made to educate health care providers, health care facilities, and the public about the POLST program, forms that are issued before January 1, 2010 will still be valid to allow for continuity of care with respect to DNR orders that are currently in effect.

Comfort One is a registered trademark, approved by the department, that is currently used on all forms and materials. While it is necessary to retain "approved by department" in order to be in command of how the logo is used, its current use on materials will change as we transition from the Comfort One program to the POLST program.

The Comfort One bracelet and necklace are only issued to persons who have a DNR order. Under these proposed rules, the only way to document that patients have a DNR order and receive a bracelet or necklace is if they have a Comfort One form (due to be phased out by January 1, 2010) or by being identified as DNR patients on the new POLST form.

"Provider" is a new definition in these proposed rules which supports language in the Montana Rights of the Terminally Ill Act and Do-Not-Resuscitate -- Notification, 50-10-101 through 50-10-107, MCA which allows physicians and advanced practice nurses to issue DNR orders. This definition also makes it clear that physician assistants who have been delegated do-not-resuscitate authority by their supervising physician can issue such orders.

ARM 37.10.104

Proposed changes to this rule reflect the adoption of the POLST protocol as the "living will" protocol to be followed by EMS personnel in treating qualified patients and implementing DNR orders as well as other instructions for palliative care expressed in a living will or to a patient's physician and reflected in the POLST form.

Reference to a physician's DNR order (verbal or written) is being deleted as this information is clear in other parts of these proposed rules and in the POLST protocol.

ARM 37.10.105

The department is proposing to amend this rule to reflect that POLST forms as well as Comfort One identifying material must still be obtained through specific authorized sources.

6. Interested persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to Gwen Knight, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 202951, Helena MT 59620-2951, no later than 5:00 p.m. on September 11, 2008. Comments may also be faxed to (406)444-9744 or e-mailed to dphhslegal@mt.gov. The department maintains lists of persons interested in receiving notice of administrative rule changes. These lists are compiled according to subjects or programs of interest. To be included on such a list, please notify this same person or complete a request form at the hearing.

7. An electronic copy of this Proposal Notice is available through the Secretary of State's web site at <http://sos.mt.gov/ARM/Register>. The Secretary of State strives to make the electronic copy of this Notice conform to the official version of the Notice, as printed in the Montana Administrative Register, but advises all concerned persons that in the event of a discrepancy between the official printed text of the Notice and the electronic version of the Notice, only the official printed text will be considered. In addition, although the Secretary of State works to keep its web site accessible at all times, concerned persons should be aware that the web site may be unavailable during some periods, due to system maintenance or technical problems.

8. The bill sponsor notice requirements of 2-4-302, MCA, do not apply.

9. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct the hearing.

/s/ Shannon McDonald
Rule Reviewer

/s/ Russell E. Cater for
Director, Public Health and
Human Services

Certified to the Secretary of State August 4, 2008.