MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	11/04/2016	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 12/23/2016

2. COMAR Codification

Title	Subtitle	Chapter	Regulation
10	07	01	01 and .31

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator
Michele Phinney

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410-767-5623

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5. Name of Person to Call About this Document
Amanda Thomas

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6. Check applicable items:

X- New Regulations

X- Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: February 1, 2016.

_ Repeal of Existing Regulations

_ Recodification

_ Incorporation by Reference of Documents Requiring DSD Approval

_ Reproposal of Substantively Different Text:

: Md. R

(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

_ Yes **X-** No

8. Incorporation by Reference

_ Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

_ OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

_ OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

_ Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Paul J. Ballard, Assistant Attorney General, (telephone #410-767-6918) on October 21, 2016. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Van T. Mitchell

Title

Secretary

Telephone No.

410-767-6500

Date

November 3, 2016

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 07 HOSPITALS

10.07.01 Acute General Hospitals and Special Hospitals

Authority: Health-General Article, §§19-308 and 19-308.6; Public Safety Article, §14-110.1; Annotated Code of Maryland

Notice of Proposed Action

[]

The Secretary of Health and Mental Hygiene proposes to amend Regulation .01 and adopt new Regulation .31 under COMAR 10.07.01 Acute General Hospitals and Special Hospitals.

Statement of Purpose

The purpose of this action is to establish minimum regulatory standards that reflect a consensus on quality practices for palliative care programs within Maryland's hospitals. The standards are primarily based on recommendations generated from a report developed by the Maryland Health Care Commission (MHCC) in collaboration with the Office of Health Care Quality. This regulatory action is required by Health-General Article, §19–308.9, Annotated Code of Maryland.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.

Through research and a pilot study, the Maryland Health Care Commission drafted a report providing cost estimates of implementing a palliative care program. OHCQ utilized the 2015 Maryland Health Care Commission (MHCC) report to determine the estimated cost for a large and a small hospital to implement a palliative care program. The report stated that 31 hospitals had such a program. OHCQ subtracted the number of hospitals the MHCC report identified as having a program from the total number of hospitals with 50 or more beds and determined that there were 10 hospitals remaining that would need to establish a palliative care program. These 10 hospitals were further broken down by the number of beds that are likely to need palliative care services. OHCQ estimates that a hospital with 60 or fewer beds would be able to meet the requirement by implementing a part time palliative care program, while a hospital with 60 or more beds might require a full time program. OHCQ estimates the costs to implement a palliative care program include utilizing the following staff: physician, nurse practitioner, and a social worker.

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude

A. On issuing agency:	NONE	
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:		
Affected hospitals	(-)	$2,100,000
E. On other industries or trade groups:		
Physician, Nurse Practitioners, and Social Workers	(+)	$2,100,000
F. Direct and indirect effects on public:	NONE	

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

D. The estimated implementation cost to hospitals has been determined by adding the following:
6 small hospitals x $150,000 cost for part time palliative care program = $900,000
4 large hospitals x $300,000 cost for full time palliative care program = $1,200,000
Estimated implementation cost:
Cost to small hospitals ($900,000) + Cost to large hospitals ($1,200,000) = $2,100,000
Trade group and industries will benefit as the implementation of 10 additional palliative care programs will provide additional employment opportunities.

E. See D. above.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through January 23, 2017. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2017
B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.
The proposed changes have an impact on costs to hospitals to implement the program and additional revenue to the industry and trade groups in the form of additional salary. There are no economic impacts on small businesses. Additional costs and revenue are solely attributed to the regulated industry and other industries and trade groups.

G. Small Business Worksheet:

Attached Document:

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Authority: Health-General Article, §§19-308 and 19-308.6; Public Safety Article, §14-110.1, Annotated Code of Maryland

10.07.01.01 (2/1/2016)

.01 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)—(6) (text unchanged)

(7) "Authorized decision maker" means the health care agent, guardian of the person, or surrogate decision maker who is making health care decisions on behalf of a patient in accordance with the Health Care Decisions Act, Health-General Article, §§5-601—5-618, Annotated Code of Maryland.

[(6-1)**]** *(8)*—**[**(18)**]** *(21)* (text unchanged)

(22) "Medical Orders for Life Sustaining Treatment (MOLST) form" means the form required to be developed pursuant to Health-General Article, §5-608.1, Annotated Code of Maryland.

[(19)**]** *(23)* (text unchanged)

[(20)**]** *(24)* "**[**Nonaccredited**]** *Non-accredited* hospital" means a:

(a)—(b) (text unchanged)

[(21)**]** *(25)* "**[**Nonelective**]** *Non-elective*", when applied to admission or to a health care service, means an admission or service that cannot be delayed without substantial risk to the health of the individual.

(26) "Palliative care" means specialized medical care for individuals with serious illnesses or conditions that:

(a) Is focused on providing patients with relief from the symptoms, pain, and stress of a serious illness or condition, whatever the diagnosis;

(b) Has the goal of improving quality of life for the patient, the patient's family, and other caregivers;

(c) Is provided at any age and at any stage in a serious illness or condition; and

(d) Can be provided along with curative treatment.

(27) "Palliative care program" means an interdisciplinary team that provides palliative care services.

[(22)**]** *(28)*—**[**(29)**]** *(37)* (text unchanged)

.31 Hospital Palliative Care Programs.

A. Acute general hospitals and special hospitals-chronic care with 50 or more beds shall establish an active hospital-wide palliative care program that provides consultation services to patients suffering from pain and symptoms due to serious illnesses or conditions.

B. The hospital shall:

(1) Promote the palliative care program;

(2) Provide information and referrals to patients and families when appropriate regarding the availability of palliative care services; and

(3) Inform patients of the patient's right to request a palliative care consultation.

C. Staffing.

(1) The hospital shall designate a qualified interdisciplinary care team with training in palliative care to staff the palliative care program.

(2) The hospital shall ensure that:

(a) A qualified health care professional coordinates the activities of the palliative care program with the palliative care patient's interdisciplinary care team;

(b) Staff is appropriately trained, credentialed, or certified in the staff's area of expertise;

(c) Staff receives continuing training and education; and

(d) Written policies and procedures for the hospital palliative care program are established, implemented, maintained, and updated periodically.

D. Palliative Care Education and Training. The hospital shall provide and document training to medical and other clinical staff as determined by the hospital regarding:

(1) Services provided by the palliative care program;

(2) Domains of palliative care; and

(3) Legal requirements for:

(a) Health care decisions; and

(b) MOLST as referenced in COMAR 10.01.21.

E. Interdisciplinary Plan of Care.

(1) The hospital shall incorporate the recommendations of the palliative care program into the palliative care patient's interdisciplinary care plan.

(2) The hospital shall review the interdisciplinary plan of care and revise as necessary to meet the needs of the palliative care patient.

(3) The palliative care program shall conduct care conferences as appropriate to review the plan of care with:

(a) The palliative care patient;

(b) The palliative care patient's family;

(c) The health care professionals; and

(d) Other interdisciplinary team members.

(4) Contents. The hospital shall ensure that the palliative care patient's plan of care includes at a minimum:

(a) Initial assessments conducted by the interdisciplinary palliative care team;

(b) Psychological needs assessment;

(c) Treatment goals;

(d) Choice of treatment options;

(e) Preferred care setting;

(f) Preferred site of death and after death arrangements as appropriate;

(g) Grief and bereavement plan, as appropriate;

(h) Assessment of cultural needs;

(i) Assessment of legal needs; and

(j) Assessment of discharge needs.

(5) Collaboration. The hospital shall document and provide palliative care services in collaboration with:

(a) The attending physician; and

(b) Any other health care provider managing the patient's care.

(6) Continuity of Care. The hospital shall coordinate services to ensure continuity of care for the palliative care patient. The hospital shall:

(a) Transfer the pertinent parts of the medical record, medical orders, and plan of care with the palliative care patient upon transfer to post-acute care;

(b) Ensure that MOLST forms are completed in accordance with COMAR 10.01.21;

(c) Convert a palliative care patient's treatment goals into medical orders, as appropriate; and

(d) Have reporting mechanisms to keep all staff informed and updated about care changes and treatment goals.

F. Palliative Care Services.

(1) The hospital or palliative care program shall counsel the palliative care patient or the patient's authorized decision maker regarding:

(a) Health options;

(b) Pain management options;

(c) Prognosis;

(d) Risk and benefits of treatment;

(e) Availability of grief and bereavement services, as appropriate;

(f) Psychological services;

(g) Availability of spiritual care counseling through the hospital or outpatient providers; and

(h) Hospice services, as appropriate.

(2) Referrals.

(a) As appropriate and upon request by the patient or authorized decision maker, the hospital may make timely referrals.

(b) The hospital shall document any referrals made to:

(i) Inpatient or outpatient bereavement providers;

(ii) Psychological services for the palliative care patient and the patient's family;

(iii) Inpatient or outpatient spiritual care services; and

(iv) Hospice.

(3) Pain and Symptom Management. The hospital shall:

(a) Conduct and document pain and symptom assessments using available standardized scales to appropriately manage a palliative care patient's symptoms;

(b) Provide adequate and appropriate dosage of analgesics and sedatives to meet the needs of the palliative care patient; and

(c) Educate the patient and the patient's family about the use of opioids during end-of-life care.

(4) Other Services. The hospital shall provide culturally and linguistically appropriate education and support about how to safely care for the patient at home or in an alternate residential setting as appropriate.

(5) Imminent Death. The palliative care program shall document and counsel the patient, the authorized decision maker, the patient's family, and the interdisciplinary care team about the active dying phase and imminent death as appropriate.

(6) MOLST. The hospital shall comply with the procedures and requirements of the Medical Orders for Life-Sustaining Treatment Form, which is incorporated by reference at COMAR 10.07.21.

(7) Interpreter Services. The hospital shall ensure interpreter services are available and accessible to the palliative care program.

G. Advance Directives.

(1) The hospital shall recognize the authority of:

(a) An advance directive established in compliance with Health-General Article, §5-602, Annotated Code of Maryland; and

(b) An authorized decision maker.

(2) The hospital shall ensure that any provided advance directive and authorized decision maker designation are in the patient's medical record, including the electronic medical record.

(3) The hospital shall promote advance care planning and the completion of advance directives through community outreach activities.

H. Ethics Committee. The hospital shall allow staff, patients, and the patient's family in the palliative care program access to an ethics committee to address ethical conflicts at the end of life.

I. Quality Improvement. The palliative care program shall take part in the hospital's quality improvement and performance improvement activities to the extent required by State and federal statute.

J. Departmental Oversight. The Department shall have access to all data maintained through the hospital's palliative care program to determine the hospital's compliance with State and federal regulations.

VAN T. MITCHELL

Secretary of Health and Mental Hygiene