

PROPOSAL

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Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 32 BOARD OF PHYSICIANS

10.32.12 Delegation of Acts by a Licensed Physician [to an Assistant Not Otherwise Authorized under the Health Occupations Article or the Education Article]

Authority: Health General Article, §§19-114 and 19-118; Health Occupations Article, §14-205(a) and §14-306; Annotated Code of Maryland

Notice of Proposed Action

[21-126-P]

The Secretary of Health proposes to amend Regulations .01—.05 and adopt new Regulations .06 and .07 under **COMAR 10.32.12 Delegation of Acts by a Licensed Physician**. This action was considered at a public meeting held on September 25, 2019, notice of which was given by publication on the Board's website at <https://www.mbp.state.md.us/forms/Sep19Bagenda.pdf> from September 13, 2019, through September 25, 2019, pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

This action also was considered at a public meeting held on October 30, 2019, notice of which was given by publication on the Board's Website at from October 15, 2019, through October 30, 2019, pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to update regulations to reflect statutory changes, effective October 1, 2019, pursuant to Ch. 445 (H.B. 924), Acts of 2019, "State Board of Physicians — Registered Cardiovascular Invasive Specialists," 2019.

Specifically, the proposal includes but is not limited to:

- (1) Updates of the title and scope of the chapter;
- (2) The addition of statutory citations to the authority for the chapter;
- (3) Revisions and additions of definitions in Regulation .02;
- (4) In Regulation .05, an update of the title and the addition of civil penalty language;
- (5) The addition of a new Regulation .06, addressing matters regarding education and training of registered cardiovascular invasive specialists (RCIS); RCIS assistance in licensed physicians' performance of fluoroscopy; and the responsibilities of the RCIS, delegating physicians, and hospitals;
- (6) The addition of a new Regulation .07 regarding enforcement matters; and
- (7) Technical changes or corrections.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

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 Jason Caplan, Director, Office of Regulation and Policy Coordination, Maryland Department of Health, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499 (TTY 800-735-2258), or email to mdh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through October 12, 2021. A public hearing has not been scheduled.

.01 Scope.

A. This chapter governs the delegation of *technical* acts by a *licensed* physician [to an assistant not otherwise authorized under the Health Occupations Article or the Education Article, Annotated Code of Maryland.] *to an:*

(1) *Assistant not otherwise authorized under the Health Occupations Article or the Education Article, Annotated Code of Maryland; and*

(2) *RCIS assisting in the physician's performance of fluoroscopy during a cardiac catheterization procedure under certain circumstances as authorized under Regulation .06 of this chapter.*

B. This chapter may not be construed:

(1) As establishing the licensure, certification, or registration *by the Board* of assistants *or registered cardiovascular invasive specialists;*

(2)—(3) (text unchanged)

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1) "Assistant" means an individual to whom only routine technical acts are delegated by a *licensed* physician and who is:

(a) Trained as defined in [§B(9)] §B(17) of this regulation and not certified, registered, or licensed by the Board or any other State health occupation board; or

(b) (text unchanged)

(2) "Board" means the *State Board of Physicians*.

(3) (text unchanged)

(4) "Delegating physician" means a physician possessing an active license to practice medicine in this State who directs an assistant *or RCIS* to perform technical acts.

(5) "Direct supervision" means oversight exercised by a delegating physician who is:

(a) (text unchanged)

(b) In the presence of the [assistant and the patient.] *patient and the:*

(i) *Assistant; or*

(ii) *RCIS.*

(6) "*Fluoroscopy*" means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images.

(7) "*Hospital*" has the meaning stated in Health-General Article, §19-301, Annotated Code of Maryland.

(8) "*Licensed physician*" means, unless the context requires otherwise, a physician, including a doctor of osteopathy, who is licensed by the Board to practice medicine.

(9) "*MDE*" means the Maryland Department of the Environment.

[(6)] (10)—[(7)] (11) (text unchanged)

(12) "*Perform fluoroscopy*" means the energizing of a fluoroscopic x-ray system by an individual authorized in accordance with MDE regulations.

(13) "*Readily retrievable*" means maintained in a method by which a hospital can retrieve and produce the record for the Board upon request.

(14) "*Registered cardiovascular invasive specialist (RCIS)*" means an individual who is credentialed by Cardiovascular Credentialing International or another credentialing body approved by the Board to assist in cardiac catheterization procedures under the direct, in-person supervision of a licensed physician.

[(8)] (15)—[(9)] (16) (text unchanged)

[(10)] (17) "Trained" means possessing the knowledge, skills, and abilities, as determined by the *licensed* physician, to perform delegated acts.

.03 Standards for the [Delegating] Licensed Physician Delegating to an Assistant.

A. A *licensed* physician who delegates shall:

(1) (text unchanged)

(2) Delegate only those technical acts that are customary to the practice of the [supervising] *licensed* physician;

(3)—(5) (text unchanged)

B. The responsibility for the delegated act cannot be transferred from the delegating physician to another *licensed* physician without:

(1)—(2) (text unchanged)

.04 Scope of Delegation to an Assistant.

A. A *licensed* physician may not delegate to an assistant technical acts which are exclusively limited to any individual required to be licensed, certified, registered, or otherwise recognized pursuant to any provision of the Health Occupations Article and the Education Article, Annotated Code of Maryland.

B. A *licensed* physician may delegate technical acts consistent with national standards in the medical community and the approved policies and procedures of the sites for the delivery of health services in the following categories:

(1) (text unchanged)

(2) Nonsurgical technical acts while the assistant is under the *licensed* physician's direct supervision or on-site supervision if the assistant performs the act in accordance with procedures of the site.

C. At sites included in Health-General Article, §§19-114 and 19-3B-01(b), Annotated Code of Maryland, or any unit of those sites, a *licensed* physician may delegate technical acts in compliance with State regulations and the policies, procedures, and supervisory structures of those sites.

D. At sites not included in Health-General Article, §§19-114 and 19-3B-01(b), Annotated Code of Maryland, when providing the following specified levels of supervision, a *licensed* physician may delegate to an assistant technical acts which include but are not limited to:

(1) Without on-site supervision:

(a)—(d) (text unchanged)

(e) Laboratory tests that the *licensed* physician is satisfied the assistant is qualified to perform under State and CLIA regulations;

(f)—(g) (text unchanged)

(h) Providing sample packets of medication, selected by a *licensed* physician who is physically present at the time of selection, to patients as directed by the delegating physician and in conformance with Health Occupations Article, §12-102(a), (d), and (f), Annotated Code of Maryland;

(i)—(j) (text unchanged)

(2)—(3) (text unchanged)

E. A *licensed* physician who possesses a dispensing permit may delegate the dispensing functions in accordance with the requirements of COMAR 10.32.23.

F. A *licensed* physician may not delegate to an assistant acts which include but are not limited to:

(1)—(3) (text unchanged)

(4) Giving medical advice without the consult of a *licensed* physician; and

(5) (text unchanged)

.05 Prohibited Conduct and Penalties.

A. An assistant or RCIS acting beyond the scope of this chapter may be:

(1)—(2) (text unchanged)

B. A delegating physician, through either act or omission, facilitation, or otherwise enabling or forcing an assistant or RCIS to practice beyond the scope of this chapter, may be subject to discipline for grounds within Health Occupations Article, §14-404(a), Annotated Code of Maryland, including, but not limited to, practicing medicine with an unauthorized person or aiding an unauthorized person in the practice of medicine.

C. A delegating physician may not [require an assistant to perform a delegated act.]:

(1) *Require an assistant or RCIS to perform a delegated act; or*

(2) *Permit an assistant or RCIS to delegate any act to another individual.*

D. *A hospital that fails to comply with the requirements of Health Occupations Article, §14-306, Annotated Code of Maryland, and this chapter may be assessed a civil penalty of up to \$5,000 for each instance.*

.06 RCIS Assistance in the Delegating Physician's Performance of Fluoroscopy.

A. *Scope of Regulation.*

(1) *This regulation governs:*

(a) *A licensed physician's delegation of technical acts to an RCIS assisting in the physician's performance of fluoroscopy provided the delegation is in accordance with the entirety of this chapter; and*

(b) *The responsibilities of the hospital in which the cardiac catheterization laboratory is located to verify and document the qualifications of an RCIS and to ensure that all requirements of Health Occupations Article, §14-306, Annotated Code of Maryland and this regulation are met for each procedure.*

(2) *This regulation does not limit a licensed physician from delegating technical acts to an RCIS who is not assisting in the physician's performance of fluoroscopy provided the delegation is in accordance with Regulations .01—.05 of this chapter.*

B. *An RCIS assisting in a delegating physician's performance of fluoroscopy shall:*

(1) *Possess an active RCIS certification issued by Cardiovascular Credentialing International or another credentialing body approved by the Board;*

(2) *Complete 40 hours of:*

(a) *Accredited didactic education in fluoroscopic radiation physics and fluoroscopic patient safety; and*

(b) *Clinical fluoroscopic training supervised by a radiologist, radiographer, or radiologist assistant who is physically present in the room with the RCIS to instruct the clinical fluoroscopic training;*

(3) *In the hospital, wear an identification badge displaying in readily visible type:*

(a) *The name of the RCIS; and*

(b) *A designation by the hospital of verification of the RCIS' credentials and completion of requirements to assist in a physician's performance of fluoroscopy; and*

(4) *Comply with any additional requirements as established by:*

(a) *MDE;*

(b) *The Joint Commission; and*

(c) *Federal and State laws and regulations.*

C. *Responsibilities.*

(1) *The hospital shall:*

- (a) Verify that the RCIS has met the requirements in §B of this regulation before permitting an RCIS to assist in a delegating physician's performance of fluoroscopy;
 - (b) Issue to the RCIS an identification badge in accordance with §B(3) of this regulation;
 - (c) Keep on-site all documentation of the RCIS' certification and the additional training required under this regulation;
 - (d) Permit the Board, at any reasonable hour, to inspect the hospital's documentation of the RCIS' certification and training to ensure compliance with this regulation;
 - (e) Regarding radiation machines and fluoroscopy services, comply with any additional requirements as established by:
 - (i) MDE;
 - (ii) The Joint Commission; and
 - (iii) Federal and State laws and regulations; and
 - (f) Verify that the acts delegated to the RCIS are in accordance with the scope of this chapter.
- (2) The delegating physician shall:
- (a) Exercise direct supervision of the RCIS when the RCIS is assisting the delegating physician in the delegating physician's performance of fluoroscopy;
 - (b) Delegate only technical acts involved in the physician's performance of fluoroscopy in accordance with Regulation .03 of this chapter; and
 - (c) Verbally direct each technical act performed by the RCIS.
- (3) The RCIS:
- (a) May not perform fluoroscopy;
 - (b) Shall perform technical acts to assist the delegating physician in the delegating physician's performance of fluoroscopy only upon verbal direction from the delegating physician;
 - (c) May not delegate any act to another individual; and
 - (d) May not engage in prohibited conduct as set out in Regulation .05 of this chapter.

.07 Enforcement.

A. The Board shall conduct any necessary investigation regarding the failure to comply with the requirements of Health Occupations Article, §14-306, Annotated Code of Maryland, and this chapter.

B. Any matter regarding a hospital's failure to comply with the requirements of Health Occupations Article, §14-306, Annotated Code of Maryland, and Regulation .06 of this chapter shall be adjudicated in accordance with COMAR 10.32.02.

DENNIS R. SCHRADER
Secretary of Health