MARYLAND REGISTER

Proposed Action on Regulations

Date Filed with AELR Committee	TO BE COMPLETED BY DSD
12/02/2014	Date Filed with Division of State Documents
	Document Number
	Date of Publication in MD Register
	Committee

1. Desired date of publication in Maryland Register: 1/9/2015

2. COMAR Codification

Title Subtitle Chapter Regulation

10 09 55 01-.10

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator	Telephone Number
Michele Phinney	410-767-5623

Mailing Address

201 W. Preston Street

City	State	Zip Code
Baltimore	MD	21201

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5. Name of Person to Call About this Document	Telephone No.
Michael Cimmino	410-767-0579

Email Address

michael.cimmino@maryland.gov

6. Check applicable items:

- X- New Regulations
- _ Amendments to Existing Regulations
- Date when existing text was downloaded from COMAR online: .
- _ 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 State Government Article, §10-506(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 David Lapp, Assistant Attorney General, (telephone #410-767-5292) on November 13, 2014. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Joshua M. Sharfstein, M.D.	
Title	Telephone No.
Secretary	410-767-6500
Date	
December 2, 2014	

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 09 MEDICAL CARE PROGRAMS

10.09.55 Physician Assistants

Authority: Health-General Article, §§2-104(b), 15-103, and 15-105, Annotated Code of Maryland

Notice of Proposed Action

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The Secretary of Health and Mental Hygiene proposes to adopt new Regulations .01—.10 under a new chapter, COMAR 10.09.55 Physician Assistants.

Statement of Purpose

The purpose of this action is to allow Physician Assistants (PAs) to enroll in the Medical Assistance Program.

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 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 February 9, 2015. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2015

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:

Physician Assistants are currently receiving payment from the Medicaid program through the physician for whom they work so there is no anticipated financial impact.

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

See E.

G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 09 MEDICAL CARE PROGRAMS

10.09.55 Physician Assistants

Authority: Health-General Article, §§2-104(b), 15-103, and 15-105, Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Advanced duties" means medical acts that require training and certification beyond the basic physician assistant education program.

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

(3) "Delegation agreement" means a document that is executed by a licensed physician and a physician assistant containing the requirements of Health Occupation Article, §15-302, Annotated Code of Maryland and COMAR 10.32.03.05.

(4) "Department" means the Department of Health and Mental Hygiene, the single State agency designated to administer the Maryland Medical Assistance Program under Title XIX of the Social Security Act, 42 U.S.C. §1396 et seq.

(5) "Dispense" means to dispense starter dosages or drug samples.

(6) "Medical Assistance Program" means the program of comprehensive medical and other health-related care for indigent and medically indigent persons.

(7) "Physician" means an individual who meets the licensure requirements and conditions of participation of COMAR 10.09.02.

(8) "Physician assistant" means an individual who is licensed to practice medicine with physician supervision.

(9) "Practice as a physician assistant" means the performance of medical acts that are:

(a) Delegated by a supervising physician to a physician assistant;(b) Within the supervising physician's scope of practice; and

(c) Appropriate to the physician assistant's education, training, and experience.

(10) "Program" means the Maryland Medical Assistance Program.

(11) "Provider" means a licensed physician assistant who, through appropriate agreement with the Department, has been identified as a Program provider by the issuance of a provider number.

(12) "Participant" means a person who is certified as eligible for, and is receiving, Medical Assistance benefits.

(13) "Supervision" means the responsibility of the physician to exercise on-site supervision or provide immediate available direction for the physician assistants performing delegated medical acts, and includes:

(a) Oversight of the physician assistant and acceptance of direct responsibility for the patient services and care rendered by the physician assistant;

(b) Continuous availability to the physician assistant either in person, by telephone, electronic means, or by some other form of telecommunication; and

(c) Designation of one or more alternate supervising physicians.

.02 License and Certification Requirements.

A. The provider shall meet all license requirements as set forth in COMAR 10.09.36.02.

B. A physician assistant applying for provider status shall:

(1) Be licensed to practice as a physician assistant in Maryland or in the state or jurisdiction in which the service is provided;

(2) Be in compliance with requirements set forth in COMAR 10.32.03; and

(3) If practicing in Maryland, have a delegation agreement with a supervising physician that outlines the

physician assistant's duties within the medical practice or facility which has been filed with and approved by the Board of Physicians.

C. A physician having a written agreement to supervise a physician assistant shall:

(1) Be licensed to practice medicine in the state in which the physician assistant is providing services;

(2) Practice primarily in the area of specialization in which the physician assistant is licensed and certified;

(3) Accept Program reimbursement as payment in full for services provided;

(4) Establish and review drug and other medical guidelines with the physician assistant;

(5) Participate with the physician assistant in reviewing and discussing medical diagnoses and the therapeutic and corrective measures employed in the practice setting;

(6) Jointly sign records to document accountability of both the physician and the physician assistant;

(7) Be available for consultation in person, by telephone, electronic means, or by some other form of telecommunication; and

(8) Designate an alternate supervising physician if the physician identified in the delegation agreement temporarily becomes unavailable.

D. For hospitals, correctional facilities, detention centers, or public health facilities, the primary supervising physician shall keep an ongoing list of all approved alternate supervising physicians within the alternate supervising physicians' scopes of practice, with each alternate supervising physician's signature and date.

.03 Conditions for Participation.

A. A physician assistant shall meet all conditions for participation as set forth in COMAR 10.09.36.03. *B.* A physician assistant shall:

(1) Have a written and executed delegation agreement with a licensed physician approved by the

Board, or as required by the state in which services are provided; and

(2) If the primary supervising physician delegates the prescribing of controlled dangerous

substances to a physician assistant, the physician assistant shall:

(a) Obtain a Maryland Controlled Dangerous Substance (MCDS) license from the Maryland Division of Drug Control; and

(b) After obtaining an MCDS license:

(i) Register with the Drug Enforcement Administration (DEA); and

(ii) Obtain a license from the DEA.

C. To continue to participate as a provider, the physician assistant shall submit to the Program periodically as necessary as copy of the provider's:

(1) Current physician assistant certification;

(2) Current approved delegation agreement: and

(3) Current license to practice in the state in which services are provided.

D. Modification of Delegation Agreement.

(1) The physician assistant and supervising physician shall notify the Program within 5 days in writing, if the provider's approved written delegation agreement with the physician is modified or terminated by either party.

(2) If the delegation agreement is modified, the physician assistant and the supervising physician shall submit to the Program a copy of the modified or new written agreement.

(3) If the duties of the physician assistant are limited, reduced, or result in other changes of employment that might be grounds for disciplinary actions under Health Occupations Article, §15-314, Annotated Code of Maryland, the supervising physician, hospital, alternative health care system, or employer shall notify the Program immediately or within 5 days in writing.

E. A physician assistant may practice in Maryland:

(1) Only in the area of specialization in which the physician assistant is licensed and certified by the Board; or
(2) If out-of-State, only in the area of specialization allowed by the licensing authority in the state in which services are provided.

.04 Covered Services.

A. The Program covers medically necessary services rendered to participants in accordance with:

(1) The functions allowed under:

(a) The Physician Assistant's Practice Act;

(b) COMAR 10.32.03; and

(c) The physician assistant's written delegation agreement with a physician; or

(2) If out-of-State, those functions authorized in the state in which the services are provided.

B. The services in §A of this regulation shall be described in the participant's medical record in sufficient detail to support the invoice submitted for those services.

.05 Limitations.

The Program does not cover the following under these regulations:

A. Services not encompassed by the physician assistant's written delegation agreement with the physician, if required by the state in which services are provided;

B. Services not medically necessary;

C. Services prohibited by the Board;

D. Services prohibited in the state in which services are provided;

E. Physician assistant services included as part of the cost of an inpatient facility, hospital outpatient department, or freestanding clinic;

F. Visits by or to the physician assistant solely for the purpose of the following:

(1) Prescription, drug, or food supplement pickup;

(2) Recording of an electrocardiogram;

(3) Ascertaining the patient's weight;

(4) Interpretation of laboratory tests or panels; or

(5) Prescribing or administering oral medications;

G. Drugs and supplies which are acquired by the licensed and certified physician assistant at no cost;

H. Injections and visits solely for the administration of injections, unless medical necessity and the patient's inability to take appropriate oral medications are documented in the patient's medical record;

I. More than one visit per day per participant unless adequately documented as an emergency situation;

J. Services paid under the free-standing dialysis program described in COMAR 10.09.22;

K. Physician assistant billings for those laboratory or X-ray services performed by another facility, which shall bill the Program directly;

L. Immunizations required for travel outside the continental United States;

M. Acupuncture;

N. Hypnosis;

O. Travel expenses;

P. Prescriptions and injections for central nervous system stimulants and anoretic agents when used for weight control;

Q. Investigational or experimental drugs and procedures;

R. Services denied by Medicare as not medically justified;

S. Services for which the supervising physician has not reviewed and signed the patient's medical record;

T. Services for which the patient has not signed a written attestation permitting the physician assistant to perform advanced duties; and

U. Services for which the patient specifically requests to see a physician.

.06 Payment Procedures.

A. The provider shall submit the request for payment in the format designated by the Department.

B. The Department reserves the right to return to the provider, before payment, all invoices not properly signed, completed, and accompanied by any properly completed forms required by the Department.

C. A physician assistant shall charge the Program their usual and customary charge to the general public for similar services and charge their acquisition cost for injectable drugs or dispensed medical supplies.

D. The Department shall reimburse the physician assistant for covered services at the lower of their usual and customary charge or the maximum rates according to COMAR 10.09.02.07. E. Payments on Medicare claims are authorized, if:

(1) Services are covered by the Program;

(2) The provider accepts Medicare assignments;

(3) Medicare makes direct payment to the provider;

(4) Medicare has determined that services were medically justified; and

(5) Initial billing is made directly to Medicare according to Medicare guidelines.

- F. The Department shall make supplemental payments on Medicare claims subject to the following provisions: (1) Deductible insurance shall be paid in full; and
 - (2) Coinsurance shall be paid at the lesser of:
 - (a) 100 percent of the coinsurance amount; or
 - (b) The balance remaining after the Medicare payment is subtracted from the Medicaid rate.

G. The provider may not bill the Program for:

(1) Completion of forms and reports;

(2) Broken or missed appointments;

(3) Professional services rendered by mail or telephone;

(4) Services which are provided to the general public at no charge; and

(5) Providing a copy of a participant's medical record when requested by another licensed provider on behalf of the participant.

H. The Program may not make direct payment to participants.

I. Billing time limitations for claims submitted pursuant to this chapter are set forth in COMAR 10.09.36.

J. Physician assistants who are employed by or under contract to any physician, clinic, or hospital may not bill for any service for which reimbursement is sought by the physician, clinic, or hospital.

.07 Recovery and Reimbursement.

Recovery and reimbursement are as set forth in COMAR 10.09.36.07.

.08 Cause for Suspension or Removal and Imposition of Sanctions.

Cause for suspension or removal and imposition of sanctions is as set forth in COMAR 10.09.36.08.

.09 Appeal Procedures.

Providers filing appeals from administrative decisions made in connection with these regulations shall do so according to COMAR 10.09.36.09.

.10 Interpretive Regulation.

State regulations shall be interpreted in conformity with COMAR 10.09.36.10.

JOSHUA M. SHARFSTEIN, M.D.

Secretary of Health and Mental Hygiene