

# DHMH PROCEDURE

<http://www.dhmh.state.md.us/policies/inpolm.htm>

OFFICE OF REGULATION AND POLICY COORDINATION - DHMH PROCEDURE 02.10.01.P1  
Effective: May 10, 2011

## PROCEDURE FOR REGULATIONS PROCESS

<u>ACTOR</u>	<u>ACTION REQUIRED</u>
Proposing Unit	1. With its Deputy Secretary's approval, <b>NOTIFIES</b> Regulations Coordinator and, when appropriate, Deputy Secretaries and Program Directors of intent to amend, propose or repeal regulations through the Notice of Regulations Development Form (DHMH 2098).
Regulations Coordinator	2. <b>SPECIFIES</b> required style of language, format and codification system to the Proposing Unit in accordance with guidelines of the administrator of the Division of State Documents. Also <b>REQUESTS</b> the involvement of the appropriate Assistant Attorney General, if necessary, as well as involvement of interested members of the public and/or industry, and <b>REMINDS</b> the Proposing Unit that the draft regulations should be sent to the appropriate advisory council or board.  3. <b>SETS</b> target date for first draft. If date passes with no first draft, <b>ESTABLISHES</b> new target date. <b>ISSUES</b> a memorandum if second target date is missed to learn reason for delay, with copies to the appropriate Deputy Secretary and appropriate Program Director.
Proposing Unit	4. <b>PREPARES</b> the following regulations package:  a. Regulation Background Information Form (DHMH 2099);  b. Proposed Regulations Publication Form which includes:  (i) Notice of Proposed Action statement;

### Department of Health & Mental Hygiene

Office of Regulation and Policy Coordination

201 West Preston Street - Room 512 - Baltimore Maryland 21201-2301

Phone 410-767-6499 FAX 410-767-6483

- (ii) Statement of Purpose paragraphs;
    - (iii) Comparison to Federal Standards paragraphs;
    - (iv) Economic Impact Statements (Parts, A, B & C);
    - (v) Opportunity for Public Comment statement; and
  - c. Proposed regulations.
- 5. **OBTAINS** approval of the regulations package by obtaining the following signatures on a Regulations Signature Sheet (DHMH 2105):
  - a. Drafter of regulations;
  - b. Drafter's supervisor or head of unit;
  - c. Director of Unit, if not same as Step 5(b); and
  - d. Deputy Secretary / Assistant Secretary for Proposed Unit.
- 6. **FORWARDS:**
  - a. Completed Signature Sheet via email, electronically, or interoffice mail; and
  - b. The regulations package to the Regulations Coordinator electronically.
- Regulations Coordinator 7. **APPROVES** draft regulations for style and format. **RECOMMENDS** language changes, as appropriate. If changes are necessary, **RETURNS** draft to Proposing Unit for corrections.
- Proposing Unit 8. **MAKES** appropriate changes recommended by Regulations Coordinator, if any.
- Regulations Coordinator 9. Simultaneously:
  - a. **SENDS** copy of proposed regulations package to all personnel on the Regulation Coordinator's intra-departmental mailing list including, but not limited to, the Governor's Office, Budget Revenue Administration, Assistant Attorney General's Office, and the

Office of Governmental Affairs, and **REQUESTS** comments. Comments on the proposed regulations are due to Regulations Coordinator in the time frame specified in the covering memo.

- b. **SENDS** proposed regulations and Regulation Signature Sheet (DHMH 2105) to the Director, Budget Revenue Administration and **REQUESTS** approval as to fiscal impact.

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|----------------------------------------------------|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Proposing Unit                                     | 10. | <b>RESPONDS</b> to comments. In coordination with person commenting and the appropriate Assistant Attorney General, <b>MAKES</b> changes which were accepted. If changes were substantive, <b>RETURNS</b> to Step #4.                                                                                                                                                                                                                                 |
| Director, Budget Revenue Administration            | 11. | <b>DETERMINES</b> if fiscal impact of proposed regulation would result in expenditures in excess of the State budget and therefore require special approval as outlined in State Finance and Procurement Article, §7-235(b). <b>INFORMS</b> Regulations Coordinator. If fiscal impact <u>does not</u> result in expenditures in excess of the State budget, <b>APPROVES</b> and <b>RETURNS</b> signed signature sheet to the Regulations Coordinator. |
| Regulations Coordinator                            | 12. | If proposed regulations will increase expenditures beyond budgetary limitations, <b>NOTIFIES</b> the appropriate Deputy Secretary and Proposing Unit.                                                                                                                                                                                                                                                                                                 |
| Appropriate Deputy Secretary / Assistant Secretary | 13. | <b>INFORMS</b> Regulations Coordinator and Proposing Unit whether or not to abandon proposed regulations pending resolution of the problem of expenditures beyond budgetary limitations.                                                                                                                                                                                                                                                              |
| Regulations Coordinator                            | 14. | If Proposing Unit is permitted to proceed, <b>SENDS</b> proposed regulations to the Assistant Attorney General that has been assigned the primary responsibility of advising the Proposing Unit.                                                                                                                                                                                                                                                      |
| Assistant Attorney General                         | 15. | In consultation with the Proposing Unit, <b>MODIFIES</b> proposed regulations to meet legal requirements (Return to Step #4) <u>or</u> <b>APPROVES</b> for legal sufficiency and <b>RETURNS</b> signed proposed regulations to Regulations Coordinator.                                                                                                                                                                                               |
| Regulations Coordinator                            | 16. | <b>SENDS</b> proposed regulations package (See Step #4) to the Secretary's Office for approval.                                                                                                                                                                                                                                                                                                                                                       |

- Secretary of Health and Mental Hygiene
17. **REVIEWS** proposed regulations. **MAY REQUEST** a public hearing be scheduled in conjunction with the mandatory 30-day public comment period.
- a. If disapproves proposed regulations, **RETURNS** regulation package and **INDICATES** changes that need to be made by the Proposing Unit. (Return to Step #4)
- b. If approves proposed regulations, **RETURNS** signed proposed regulations to the Regulations Coordinator.
- Regulations Coordinator
18. If Secretary approves proposed regulations, but deems a public hearing is necessary, **ADVISES** the Proposing Unit that they need to conduct a public hearing. **SETS** the hearing date in conjunction with Proposing Unit and **MODIFIES** Opportunity for Public Comment statement to reflect hearing date.
19. If Secretary approves proposed regulations, but deems a public hearing is not necessary, **DETERMINES** the expiration date of the mandatory 30-day comment period.
20. If regulations do not have corresponding federal standards **PROCEED** to Step #24.
21. If regulations do have corresponding federal standards, **SUBMITS** proposal to the Department of Business and Economic Development (DBED).
- Department Of Business And Economic Development (DBED)
22. **SENDS** approval to Regulations Coordinator or **FORWARDS** the regulations to the Governor's office if DBED's review determines regulations are more stringent or restrictive than the federal standard.
- Governor's Office
23. If necessary, **APPROVES** or **DISAPPROVES** in writing the Department's proposal.
- Regulations Coordinator
24. Via the Electronic Filing System (ELF) and pursuant to State Government Article, §10-110, **SUBMITS** regulations to the Joint Committee on Administrative, Executive, and Legislative Review (AELR) for pre-review of regulations at least 15 complete days before the regulations are electronically filed with the Administrator of the Division of State Documents for publication in the Maryland Register.

25. At least 15 complete days after AELR Committee receives the regulations package, electronically **FILES** copies with the Administrator of the Division of State Documents. When proposed regulations are published in the Maryland Register, **DISTRIBUTES** copies to appropriate parties.
- Proposing Unit
26. If a hearing was determined to be necessary, **CONDUCTS** a public hearing. **EXPLAINS** proposal in specific terms, **RECEIVES** oral and written comments and **MAY MAKE** an announcement that written comments will be accepted until a specific date.
27. If comments are received by the Regulations Coordinator or the Unit during the comment period or as a result of a public hearing, **RESPONDS** in writing to all comments received within the prescribed comment period. At the end of the comment period, **SUMMARIZES** comments in a memo to the Regulations Coordinator. **RECOMMENDS** specific language changes to the proposal or **RECOMMENDS** proposal be adopted as printed. **VERIFIES** approval of the recommendation by obtaining the signatures outlined in Step #5. **FORWARDS** Signature Sheet and recommendation to the Regulations Coordinator.
- If a public hearing was held, also **FORWARDS** a transcript of the hearing, all comments submitted at the hearing and the attendance sheet to the Regulations Coordinator. (Proceed to Step #30) or
- Regulations Coordinator
28. If no comments were received during the comment period, **PREPARES** Notice of Final Action indicating proposal will be adopted as printed. **REQUESTS** Proposing Unit verify approval of the Notice of Final Action by obtaining the signatures outlined in Step #5.
- Proposing Unit
29. If no comments were received, **OBTAINS** signatures as requested in Step #5, and **RETURNS** Notice of Final Action to Regulations Coordinator.
- Regulations Coordinator
30. **FORWARDS** the final regulation package to the appropriate Assistant Attorney General to review as to legality. This package includes:
- a. Cover memo stating Proposing Unit's recommendation to make specific language changes or to adopt as proposed.

- b. Regulations Signature Sheet with signatures through the appropriate Deputy Secretary;
- c. Any comments that were received and the Proposing Unit's responses;
- d. Form memo "Re: Assistant Attorney General's Review and Response to Comments Regarding COMAR 10.\_\_\_\_," if applicable;
- e. Notice of Final Action, if applicable; and,
- f. Copy of the proposed regulations.

Assistant Attorney General

31. If comments were received, **REVIEWS** any changes recommended by Proposing Unit. **COMPLETES** the AG's Review and Response to Comments form memo. **DETERMINES** that the proposed regulations:
- a. Do not need to be amended, **SIGNS** the Regulations Signature Sheet and **ADVISES** the Regulation Coordinator to continue the process. (Proceed to Step #33.)
  - b. Do need to be amended and the changes are substantive in nature, which requires republication, and **ADVISES** Proposing Unit to begin the Reproposal process through the Regulations Coordinator immediately. (Return to Step #4.)
  - c. Do need to be amended and the changes are substantive in nature, but after consultation with the Proposing Unit, **AGREES** that it is in the best interest of the Department to adopt the regulations as proposed, **SIGNS** the Final Transmittal Sheet, but **ADVISES** the Proposing Unit to submit the recommended amendments to the Regulations Coordinator as a new proposal immediately. (Proceed to Step #33 and Proposing Unit starts a new proposed regulation that will amend original regulation. See Step #1.)
  - d. Do need to be amended, but **DETERMINES** the changes are not substantive. **ADVISES** the Proposing Unit to incorporate the changes into the Notice of Final Action in accordance with State Government Article, §10-113, and

**CERTIFIES** that the changes are not substantive, describing the nature of each change and the basis for the conclusion.

**REQUESTS** the Proposing Unit submit the amended Notice of Final Action to the Regulations Coordinator as soon as possible.

Regulations Coordinator has amended Notice of Final Action signed by the Assistant Attorney General. (See Step #33.)

32. If no comments were received, if the AAG agrees with the Proposing Unit's recommendation that no changes need to be made, or if the Notice of Final Action includes non-substantive changes which the AAG has previously reviewed, **APPROVES** for legal sufficiency and **RETURNS** signed Final Transmittal Sheets approved and Notice of Final Action to Regulations Coordinator.
- Regulations Coordinator 33. **SENDS** final regulation package (See Step #30) with the Regulation Signature Sheet (DHMH 2105) to the Secretary of Health and Mental Hygiene.
- Secretary of Health and Mental Hygiene 34. **ACCEPTS, REJECTS, or MODIFIES** regulation and **FORWARDS** decision and regulations to Regulations Coordinator.
- Regulations Coordinator 35. If regulations are rejected or modified, **ADVISES** Proposing Unit, appropriate AAG, and the appropriate Deputy Secretary, of Secretary's decision.
36. If regulations were accepted, electronically **FILES** Final Transmittal Sheets and Notice of Final Action with the Administrator of the Division of State Documents per State Government Article, §§7-201—7-222, Annotated Code of Maryland. When Notice of Final Action is published, **DISTRIBUTES** copies to appropriate parties.

**APPROVED:**



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Joshua M. Sharfstein, M.D., Secretary, DHMH

**May 10, 2011**  
**Effective Date**