

DHMH PROCEDURE

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OPERATIONS –Office of Regulation and Policy Coordination (ORPC)

DHMH PROCEDURE 02.10.01.P

Version Effective: April 7, 2016

PROCEDURE FOR REGULATIONS PROCESS

<u>ACTOR</u>	<u>ACTION REQUIRED</u>
Proposing Unit	1. With its Deputy Secretary's approval, NOTIFIES Regulations Coordinator and, when appropriate, Deputy Secretaries and Program Directors of intent to amend, propose or repeal regulations through the Notice of Regulations Development (NORD) Form . SETS Draft Due date.
Regulations Coordinator	2. SPECIFIES 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 REQUESTS the involvement of the appropriate Assistant Attorney General, if necessary, as well as involvement of interested members of the public and/or industry, and REMINDS the Proposing Unit that the draft regulations should be sent to the appropriate advisory council or board. 3. If draft due date passes with no first draft, ESTABLISHES new target date. ISSUES 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. PREPARES the following regulations package to be submitted electronically to Regulations Coordinator: a. Regulation Background Information Form ; b. Proposed Regulations Publication Form which includes: (i) Notice of Proposed Action statement; (ii) Statement of Purpose paragraphs;

Department of Health & Mental Hygiene

OFFICE OF REGULATION AND POLICY COORDINATION (ORPC)

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- (iii) Comparison to Federal Standards paragraphs;
 - (iv) Economic Impact Statements (Parts, A, B & C);
 - (v) Opportunity for Public Comment statement; and
 - c. Proposed regulations in the format prescribed by the Division of State Documents.
- 5. **OBTAINS** approval of the regulations package by acquiring the following signatures on a [Regulations Signature Sheet](#):
 - 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 electronically, by fax 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, and **RETURNS** corrected draft to Regulations Coordinator.
- 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, Financial Management 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](#) to the Chief Financial Officer, Financial Management Administration and **REQUESTS** approval as to fiscal impact.

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| Proposing Unit | 10. | RESPONDS to comments. In coordination with person commenting and the appropriate Assistant Attorney General, MAKES changes which were accepted. If changes were substantive, RETURNS to Step #4. |
| Chief Financial Officer, Financial Management Administration | 11. | DETERMINES 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) . INFORMS Regulations Coordinator. If fiscal impact <u>does not</u> result in expenditures in excess of the State budget, APPROVES and RETURNS signed signature sheet to the Regulations Coordinator. |
| Regulations Coordinator | 12. | If proposed regulations will increase expenditures beyond budgetary limitations, NOTIFIES the appropriate Deputy Secretary and Proposing Unit. |
| Appropriate Deputy Secretary / Assistant Secretary | 13. | INFORMS 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, SENDS 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, MODIFIES proposed regulations to meet legal requirements (Return to Step #4) <u>or</u> APPROVES for legal sufficiency and RETURNS signed proposed regulations to Regulations Coordinator. |
| Regulations Coordinator | 16. | SENDS proposed regulations package (See Step #4) along with any internal comments received and Proposing Unit's responses to the Secretary's Office for approval. |

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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 Commerce for review.

Department Of Commerce

22. **SENDS** approval to Regulations Coordinator or **FORWARDS** the regulations to the Governor's office if Department of Commerce'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 and within 3 business days, **POSTS** Proposal on DHMH website as required by [State Government Article, §10-112.1, Annotated Code of Maryland](#).
- 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. Notice of Final Action, if applicable; and,
 - e. Copy of the proposed regulations.
- Assistant Attorney General 31. If comments were received, **REVIEWS** any changes recommended by Proposing Unit as follows:
- a. If no changes are recommended by the Proposing Unit, **SIGNS** the Regulations Signature Sheet and **ADVISES** the Regulation Coordinator to continue the process. (Proceed to Step #33.)
 - b. If changes are recommended by the Proposing Unit, **DETERMINES** if changes are substantive or non-substantive.
 - c. If changes are determined to be substantive in nature, **ADVISES** Proposing Unit to begin the Reproposal process through the Regulations Coordinator immediately. (Return to Step #4.)
 - d. If changes are recommended by the Proposing Unit and the AG has determined that 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 Regulations Signature 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.)
 - e. If changes are recommended by the Proposing Unit and the AG has determined that 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, and **SIGNS** the Regulations Signature Sheet. **REQUESTS** the Proposing Unit submit the amended Notice of Final Action and Regulations Signature Sheet to the Regulations Coordinator as soon as possible. (See Step #33.)

32. If no comments were received, if the Proposing Unit recommends and the AAG agrees that legally no changes are needed, or if the Notice of Final Action includes changes which have been determined to be non-substantive, **APPROVES** for legal sufficiency and **RETURNS** signed Regulations Signature Sheet 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** Final 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 the Secretary's decision.
36. If regulations are accepted, electronically **FILES** Final Transmittal Sheet 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:



Van T. Mitchell Secretary, DHMH

April 7, 2016
Effective Date