PROCEDURE FOR REGULATIONS PROCESS

<table>
<thead>
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<th>ACTOR</th>
<th>ACTION REQUIRED</th>
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<tr>
<td>Proposing Unit</td>
<td>1. With its Deputy Secretary's approval, <strong>NOTIFIES</strong> 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).</td>
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<td>Regulations Coordinator</td>
<td>2. <strong>SPECIFIES</strong> 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 <strong>REQUESTS</strong> the involvement of the appropriate Assistant Attorney General, if necessary, as well as involvement of interested members of the public and/or industry, and <strong>REMINDS</strong> the Proposing Unit that the draft regulations should be sent to the appropriate advisory council or board.</td>
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<td>3. <strong>SETS</strong> target date for first draft. If date passes with no first draft, <strong>ESTABLISHES</strong> new target date. <strong>ISSUES</strong> a memorandum if second target date is missed to learn reason for delay, with copies to the appropriate Deputy Secretary and appropriate Program Director.</td>
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<tr>
<td>Proposing Unit</td>
<td>4. <strong>PREPARES</strong> the following regulations package:</td>
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<td>a. Regulation Background Information Form (DHMH 2099);</td>
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<td>b. Proposed Regulations Publication Form which includes:</td>
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<td>(i) Notice of Proposed Action statement;</td>
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(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.

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.

Director, Budget Revenue 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 does not 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) or APPROVES for legal sufficiency and RETURNS signed proposed regulations to Regulations Coordinator.

Regulations Coordinator

16. SENDS proposed regulations package (See Step #4) to the Secretary's Office for approval.
17. **Secretary of Health and Mental Hygiene**

   - **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.

18. **Regulations Coordinator**

   - 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. **Secretary of Health and Mental Hygiene**

   - 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).

22. **Department Of Business And Economic Development (DBED)**

   - **SEND**s 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.

23. **Governor's Office**

   - If necessary, **APPROVES** or **DISAPPROVES** in writing the Department's proposal.

24. **Regulations Coordinator**

   - 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:

Joshua M. Sharfstein, M.D., Secretary, DHMH  May 10, 2011
Effective Date