

MDHs Regulation Promulgation Process (4 - 6 months*)

(Office of Regulation and Policy Coordination – July 2017) [Information in brackets is authority for action]

Unit Decides to Promulgate Regulations

- (Varies)
- (1) Unit submits Notice of Reg. Development (NORD- concept paper) form to their Assistant Attorney General (AAG) & Deputy Secretary (DS) for sign off/approval before submitting to MDH Regulations Coordinator (RC);
 - (2) RC acknowledges approval of NORD form and gives unit a tentative schedule
 - (3) Unit writes the proposal, maybe with help of a committee or work group, depending on Unit's policy or requirements of law.
 - (4) Unit submits drafts to AAG and interested parties for input and informal comments; may also submit email version to RC for review,

***Unit Submits Proposal for Internal Sign Offs**

- (2 weeks)
- (1) Proposal reviewed (clarification or changes may be requested) and, once approved, signed off by:
 - (a) Affected parties within the Department,
 - (b) The Unit's Director, and
 - (c) The Unit's Deputy Secretary;
 - (2) Approved proposal is submitted electronically to RC and signature sheet is forwarded to RC.

Unit Submits Proposal and Background Information Form to MDH Regulations Coordinator (RC)

- (2—4 weeks)
- (1) Reviews and compares proposal to existing COMAR text, makes corrections/comments and returns to Unit for resubmission;
 - (2) Receives final draft from Unit and signs off/approves for further promulgation;
 - (3) Submits:
 - (a) Electronically to Affected Units within MDH and to Office of the Inspector General & Office of Governmental Affairs for comments;
 - (b) To Budget Management Office for sign off/approval of Estimate of Economic Impact;
 - (c) To AAG for sign off/approval as to legal sufficiency [State Government Article, §10-107(b), Annotated Code of Maryland]; and
 - (d) For Secretary's sign off/approval.

Proposal has Corresponding Federal Standards? [Executive Order 01.01.1996.03]

- (5—10 days)
- (1) Yes, but proposal is not more stringent:
 - (a) Submit proposal to Department of Commerce
 - (b) The Department of Commerce will review and respond within 10 days whether or not they agree with the analysis:
 - (i) If they agree, MDH may forward proposal to AELR; or
 - (ii) If they disagree, the Department of Commerce will forward proposal to the Governor's Office for approval.
- or
- (15+ days)
- (2) Yes, and the proposal is more stringent:
 - (a) Submit proposal to the Department of Commerce;
 - (b) The Department of Commerce will review and respond to the Dept., then forward to the Governor's Office for final determination;
 - (c) Governor's Office will advise the Department whether we may proceed or not.
- or
- (0 days)
- (3) No: Proceed to next step.

RC Electronically Submits Proposal to AELR Committee and:

- (15 days)
- (1) If proposal has an impact on environmental hazards affecting the health of children, to the Children's Environmental Health and Protection Advisory Council [SGA, §10-110(b)].
 - (2) If proposal has an impact on individuals with disabilities, to the Department of Disabilities [HSA, §7-113(c)]

RC Electronically Submits Proposal to Division of State Documents for Publication in the Maryland Register [SGA, §10-112(a)]

(15 days)

Notice and Text Published

30-day Comment Period Required [SGA, §10-111(a)(3)]

- (45 days)
- (1) If comments are received, the Unit:
 - (a) Responds in writing to the comment; and
 - (b) At end of comment period, recommends in a memo to RC, specific language changes and/or recommends proposal be:
 - (i) Adopted as proposed;
 - (ii) Adopted with non-substantive changes;
 - (iii) Reproposed with substantive changes; or
 - (iv) Withdrawn.
 - (2) If no comments are received, and no changes requested by the Unit, RC submits **Notice of Final Action** adopting the proposal as printed (unless Unit indicates otherwise).
 - (3) Notice of Final Action, copy of Proposal as printed in the Maryland Register, comments received and responses (if any), and signature sheet is sent to:
 - (a) Unit for sign off/approval through their Deputy Secretary;
 - (b) AAG for sign off/approval as to legal sufficiency; and
 - (c) Secretary for sign off/approval.

AELR can decide to delay and/or oppose adoption [SGA, §10-111(a)(2); SGA, §10-111.1]

- (Varies)
- (1) If the AELR puts a "hold" on a proposal and **DELAYS** a regulation, the Department, at the sole discretion of the Secretary, may notify AELR in writing of its intention to adopt and provide AELR with a further period of review that ends the later of:
 - (a) 30 days after the Department's written notice is provided; or
 - (b) 105th day following the initial publication of the regulation in the Maryland Register
 - (2) The Department **may not** adopt a proposal that has been put on hold by the AELR until:
 - (a) The Department receives a written release from the AELR; or
 - (b) The process and timeframes outlined in (1) above have been met.
 - (3) AELR may hold a hearing and, if majority votes to **OPPOSE** the adoption of the regulations, notice of opposition is submitted in writing to the Governor and to the Department.
 - (a) Department may:
 - (i) Withdraw or Modify the proposed regulation; or
 - (ii) Appeal the AELR's opposition to the Governor.
 - (b) If appealed, the Governor may instruct the Department to withdraw, modify, or adopt as proposed the regulation.

Adoption Possible: Regulations Coordinator Electronically Submits Final Notice to Division of State Documents for Publication in the Md.R.

(9 days) [SGA, §10-114)]

Notice Published & Effective [SGA, §10-117(a)]

(10 days after publication of Final Notice or later)

NOTE: For regulations adopted under HGA, §21-140 (Food, Drug and Cosmetic Act) effective date may not be earlier than 90 days after proposal is published.)