MDH's Regulation Promulgation Process (4 - 6 months*)
(Office of Regulation and Policy Coordination – January 2018) [Information in brackets is authority for action]

Unit Decides to Promulgate Regulations

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),

(Varies) 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, requirements of law, or whether change is substantive or not.

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

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; and

2. Approved proposal and signature sheet are submitted electronically to RC.

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

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; and

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.

RC Electronically Submits Proposal to AELR Committee and:

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)]

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.

(45 days)

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]

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.

(Varies) 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.)