

INSTRUCTIONS — NOTICE OF PROPOSED ACTION FORM **(2018)**

FORM IS IN BOLD / INSTRUCTIONS ARE IN ITALICS AND UNBOLDED

Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle __ (INSERT 2 digit number and name of Subtitle in all CAPS)

10. __ . __ . __ (INSERT Subtitle number and chapter number and name of Chapter)

Authority: _____ **Article, §** __ - __ ,
Annotated Code of Maryland

Authority

(Required by State Government Article, §10-106, Annotated Code of Maryland)

In general, authority lines are to be presented as follows:

Authority: State Government Article, §7-201, Annotated Code of Maryland

However, considerable variation may occur. Citations to publications other than the Annotated Code may be appropriate, including cites to the United States Code (U.S.C.), the Code of Federal Regulations (CFR), Executive Orders, and Attorney General Opinions.

Since 99% of all authorities are to the Annotated Code, the following guidelines are keyed to Annotated Code references.

- 1) For new chapters, the authority should appear according to the above example.*
- 2) For amendments, start with the cite that already appears in COMAR. Customize the reference by omitting those references which do not apply to the regulations being amended. Only the sections of the Annotated Code applicable to the regulations being amended, or to new regulations being adopted under the same chapter, should appear in the Register. The sections not included will not be deleted from COMAR.*
- 3) To add entries to an existing authority, type the new entries. It is not possible in ELF fields to underline text.*
- 4) To repeal existing authority entries that currently appear in COMAR, use brackets around the entries to be repealed.*
- 5) If the proposal contains more than one chapter, the authority does not appear with the proposal heading, but should be placed after the chapter number and name and immediately before the actual text of the regulation. In this instance, type the words "See below" in the Authority field.*

6) Do not abbreviate either the Article name or Annotated Code of Maryland.

Is There Emergency Text That Is Identical To The Proposed Text:

Yes No

Is There An Incorporation By Reference Document Associated With This Proposal?

Yes No

General Information

This is general information that the Office of Regulations and Policy Coordination (ORPC) needs in order to complete the Electronic Filing (ELF) document. This section is not printed in the Maryland Register.

Does This Proposal Have An Impact On Environmental Hazards Affecting The Health Of Children As Defined In Health-General Article, §13-1501(c)?

Yes (explain) No

Children's Environmental Health and Protection Advisory Council

(Required by State Government Article, §10-110(b), Annotated Code of Maryland)

In 2000, the Children's Environmental Health and Protection Advisory Council was created with the duty of reviewing proposed regulations that have an impact on environmental hazards affecting the health of children.

The term "environmental hazard" is defined in Health-General Article, §13-1501(c), Annotated Code of Maryland which states, in part: Environmental hazard.- "Environmental hazard" means one or a group of toxic chemical, biological, or physical agents in the environment, resulting from human activities or natural processes, that may impact the health of exposed children, including such pollutants as lead, pesticides, air pollutants, contaminated drinking water, polluted waters, toxic waste, polychlorinated biphenyls, secondhand tobacco smoke, and industrial and home chemicals.

There is no publication or analysis associated with this requirement. Identify whether the proposal being drafted meets the definition of environmental hazard. If it does, check yes and explain. ORPC will email the proposal to Clifford Mitchell of the Children's Environmental Health and Protection Advisory Council when internal comments are requested. This section is not printed in the Maryland Register.

Does This Proposal Include An Increase Or Decrease In A Fee For A License?

Yes, complete (1)—(8) No, skip (1)—(8) and proceed to Notice of Proposed Action.

- (1) Explain/justify why an increase or decrease is necessary:**
 - (2) How much money is needed to operate effectively or to eliminate an operating fund deficit?**
 - (3) In what year was the most recent fee increase?**
 - (4) Is the fee revenue retained by the Proposing Unit or passed through to a national organization that administers a uniform licensing exam?**
 - (5) Describe any measures taken to mitigate the need for increased revenue:**
 - (6) Describe any special circumstances that have had an adverse impact on the Proposing Unit's operating expenses.**
 - (7) Describe any consideration given by the Proposing Unit as to the hardship a fee increase may have on the regulated profession.**
 - (8) Describe any efforts to solicit the opinions of licensees regarding the Proposing Unit's effectiveness and performance.**
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Fee Justification

(Required by State Government Article, §10-110(c)(2), Annotated Code of Maryland)

IF the proposal has an increase or a decrease in fees, complete this section. ORPC will submit this information separately to the AELR Committee via email to the Department's AELR Committee Counsel at the same time the ELF document is submitted to the AELR. This section is not printed in the Maryland Register.

Notice of Proposed Action

The Secretary of Health proposes to

Notice of Proposed Action

(Required by State Government Article, §10-112(a)(2), Annotated Code of Maryland)

The Notice of Proposed Action describes what the Department is doing. The drafter basically chooses one or more of the following five options:

- adopt new regulations;*
- amend existing regulations;*
- repeal existing regulations;*
- recodify regulations;*
- amend and recodify regulations.*

The notice should take the following form:

The Secretary of Health proposes to [adopt new/amend/repeal/recodify/amend and recodify] Regulation(s) xx under COMAR [codification number and name of chapter].

Combinations of the five action choices (adopt new, amend, repeal, recodify, or amend and recodify) are frequently used.

Proposals which affect more than one chapter should itemize and number the actions, with each chapter numbered separately.

Statement of Purpose

The purpose of this proposal is to

Statement of Purpose

(Required by State Government Article, §10-112(a)(3)(ii), Annotated Code of Maryland)

All proposed regulations must include one or more purpose paragraphs that adequately describe the content and purpose of the proposed action. This section should be a fair summary of what the proposed action provides.

The extent to which the Department must go in stating the purpose of its proposal depends on the circumstances of each case. A brief regulatory proposal will require a brief purpose statement. A lengthier and more complex proposal will require a more developed purpose statement that adequately summarizes what the regulatory changes aim to accomplish.

*Examples of the sort of purpose statements that, standing alone, are **not** adequate follow:*

- 1) The purpose of this action is to bring the regulations into line with recent statutory enactments.*
- 2) The purpose of this action is to implement the recommendations of the ABC Report as required by the DEF Article of the Annotated Code of Maryland.*
- 3) The purpose of the action is to simplify certification requirements. (NOTE: In some cases, this would be appropriate. For example, if the proposal is brief and the change is readily apparent, this statement would suffice. If, however, the proposal contains extensive changes that add to or alter much in existing regulations, this statement would not be adequate.)*
- 4) The purpose of this action is to bring more order to the existing regulatory standards in accordance with the Regulatory Review and Evaluation Act.*

- 5) *The purpose of this action is to ensure that the application process is being conducted fairly and in the best interests of all parties.*
- 6) *The purpose of this action is to establish guidelines within which regulated institutions are to conduct business.*
- 7) *The purpose of this action is to clarify current regulations.*

What these examples all share is that they tell little or nothing about the content or purpose of the regulations being proposed.

Also note that if regulations are being repropose, it is not adequate to refer the reader back to the purpose statement in the original proposal. A reproposal requires a fresh statement of purpose because the reproposal may contain provisions that were not in the original proposal and may substantially alter their purpose.

Summarizing the purpose of new regulations, as well as the purpose of changes to existing regulations, will help the reader develop an overview and understanding of what the Department intends to accomplish.

In addition, the Statement of Purpose section may be used to explain the reasons for the action, including any scientific data used in formulating the proposal.

**Comparison to Federal Standards
(Check one option)**

There is no corresponding federal standard to this proposed action.

or

There is a corresponding federal standard to this proposed action, but the proposed action is not more restrictive or stringent.

The corresponding federal standard is: _____

EXPLAIN why the proposed action is not more restrictive or stringent than the corresponding federal standard:

or

This proposed action is more restrictive or stringent than corresponding federal standards as follows:

- (1) **Regulation citation and manner in which it is more restrictive than the applicable federal standard:**
- (2) **Benefit to the public health, safety or welfare, or the environment:**
- (3) **Analysis of additional burden or cost on the regulated person:**
- (4) **Justification for the need for more restrictive standards:**

Comparison to Federal Standards

1) If there are no federal standards (statutes or regulations) which govern the same program or conduct which is the subject of the proposed action, check the first option.

2) If there are corresponding federal standards, but the proposed action is not more restrictive or stringent, check the second option

3) If there are corresponding federal standards and the proposed action is more restrictive or stringent, check the third option and complete the justification. Note that the justification does not require creative drafting, but merely a recitation of one of the four justifications listed below:

- (a) The benefit from the more restrictive standard exceeds the burden or cost of the more restrictive standard on the regulated person or business;
- (b) Conditions or circumstances specific or special to Maryland require that Maryland enact a more restrictive standard;
- (c) The applicable federal standard is not sufficient to protect the public health, safety, or welfare of Maryland citizens; or
- (d) State law requires the adoption of a more restrictive standard.

Impact Statements
Part A
(check one option)

Estimate of Economic Impact

___ **The proposed action has no economic impact.**

Or

___ **The proposed action has an economic impact. (IF this is checked, complete the following form in its entirety)**

I. Summary of Economic Impact. (INSERT SHORT SUMMARY)

II. Types of Economic Impact.

	Revenue (R+/R-)	
	<u>Expenditure (E+/E-)</u>	<u>Magnitude</u>

- A. On issuing agency:**
- B. On other State agencies:**
- C. On local governments:**

	Benefit (+)	
	<u>Cost (-)</u>	<u>Magnitude</u>

- D. On regulated industries or trade groups:**
- E. On other industries or trade groups:**
- F. Direct and indirect effects on public:**

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

*Estimate of Economic Impact
Impact Statement Forms Part A*

(Required by State Government Article, §10-112(a)(3)(i) and (4), Annotated Code of Maryland)

General: If the proposed regulation produces no economic impact, check the first option. If there is economic impact, check the second option and complete the form in its entirety.

I. Summary of Economic Impact:

This summary is not a synopsis of the substance of the proposal. Do not repeat what is in the Statement of Purpose. Summarize briefly the economic impact only.

II. Types of Economic Impact:

This section is a breakdown of the economic impact under six categories. The form consists of three columns.

In the first column, the Proposing Unit should list or catalog the various entities subject to impact under each of the six categories. For example, if there is more than one regulated industry in Category D, list each industry separately under Category D and number them using numbers in parentheses.

The second column should contain only a symbol indicating the direction of the impact, or the word "NONE". For the government Categories A — C, use (R+) for increased revenue, (R-) for decreased revenue, (E+) for increased expenditure, and (E-) for decreased expenditure. For Categories D — F, use (+) for a benefit and (-) for a cost for each item listed.

If there is no impact within a particular category, use the word NONE.

The third column must contain a dollar amount or a word if the second column contains a symbol. Explanations are reserved for Section III. Words which are acceptable include "Indeterminable", "Minimal", and "Unquantifiable".

Note on Category C: If the proposal imposes a mandate on local government, categorize the impact in the first column, use a symbol in the second column, and give the dollar amount for the Statewide impact in the third column. Use Section III to describe the mandate, break down the impact by county (if possible), state whether the mandate is a federal requirement, and estimate the effect on the property tax rates, if applicable.

III. Assumptions:

This section should describe how the figures under Section II were derived.

No discussion for a category is required if "NONE" appears in that category under Section II. Agencies may choose, however, to discuss why there is no impact under a particular category.

If a symbol appears in the second column, however, a discussion of that impact must appear in the Assumption section. Each discussion must follow the numbering structure of Section II; for example, A, C, D(1), D(2).

Formulas can be used if they can be expressed briefly and within the limits of the format.

Check your math!

Part B
Economic Impact on Small Businesses
(check one option)

___ **The proposed action has minimal or no economic impact on small businesses.**

or

___ **The proposed action has a meaningful economic impact on small businesses. An analysis of this economic impact follows.**

Economic Impact on Small Businesses
Impact Statement Forms Part B
(Required by Executive Order 01.01.2017.33)

State Government Article, §2-1505.2, includes the following definitions which are relevant to the analysis:

“Economic impact analysis” means an estimate of the cost or the economic benefit to small businesses that may be affected by a regulation proposed by the Department pursuant to Title 10, Subtitle 1 of this article.

“Small business” means a corporation, partnership, sole proprietorship, or other business entity, including its affiliates, that: (i) is independently owned and operated; (ii) is not dominant in its field; and (iii) employs 50 or fewer full-time employees.

Conduct an economic impact analysis of the proposal on Maryland small businesses by utilizing the Guidelines for Estimating and Minimizing the Economic Impact of Regulations on Small Businesses (2017) and, if necessary, the “Spreadsheet of Trade Associations and Organizations for Soliciting Small Business’ input on Regulations” – available on MDH Standard Forms webpage under “Regulations”- https://health.maryland.gov/Pages/sf_rf.aspx.

Based on the analysis, make a determination as to whether the proposal will have minimal or no economic impact on Maryland small businesses OR will have a meaningful economic impact on Maryland small businesses.

If there is minimal or no impact, check the first option. If there is meaningful impact, check the second option and prepare a concise but comprehensive summary narrative of the economic impact for publication. Make sure to include estimates of the type and number of affected small businesses and costs and benefits to small businesses, if possible.

Please retain all documents resulting from your analysis and explain in detail on the Background Information form.

Impact on Individuals with Disabilities

(check one option)

The proposed action has no impact on individuals with disabilities.

or

The proposed action has an impact on individuals with disabilities as follows:
(Agency to complete this assessment)

Impact on Individuals with Disabilities

(Required by State Government Article, §10-112(a)(3)(iii), Annotated Code of Maryland)

The Maryland Department of Disabilities was created by statute effective July 1, 2004. Human Resources Article, §7-113(c), Annotated Code of Maryland, requires the Secretary of Disabilities to review new or proposed changes to regulations with regard to the provision of resources and services to individuals with disabilities. That section also requires the regulations to contain “an assessment that describes the impact of the proposed regulations on individuals with disabilities.”

Definition of Disabilities

An individual with a disability is defined by the Americans with Disabilities Act (ADA) as a person who has a physical or mental impairment that substantially limits one or more major life activities, a person who has a history or record of such impairment, or a person who is perceived by others as having such impairment.

The United States Census identifies these primary disabilities based on the existence of long lasting conditions:

- 1) Sensory disability, such as blindness, deafness, or a severe vision or hearing impairment;*
- 2) Physical disability — a condition that substantially limits one or more basic physical activities, such as walking, climbing steps, reaching, lifting, or carrying;*
- 3) Mental disability — difficulty learning, remembering, or concentrating;*
- 4) Self-care disability — difficulty performing activities, such as dressing, bathing, or getting around inside the home;*
- 5) Lack of mobility — difficulty going outside the home alone, such as shopping and visiting a doctor’s office;*
- 6) Employment disability – difficulty working at a job or business*

The ADA Amendments Act (ADAAA) of 2008 refined this definition in light of court decisions that looked at mitigating measures and their impact

- The definition of disability is construed in favor of broad coverage to the maximum extent permitted;*
- The term “substantially limits” is to be interpreted consistently with the ADAAA;*
- An impairment that substantially limits one major life activity need not limit other major life activities to be considered a disability;*
- An impairment that is episodic or in remission is a disability if it would substantially limit a major life activity when active; and*
- Mitigating measures shall not be a factor when determining whether an impairment substantially limits a major life activity. The only mitigating measures that can be considered*

are ordinary eyeglasses or contact lenses that fully correct visual acuity or eliminate refractive error.

Disability Impact Assessment

To determine whether and to what extent a proposal may impact individuals with disabilities, consider the following questions. Do the proposed regulations impact the following? If so how?

Will more people be served?

Will fewer people be served?

Will existing limitations on services be increased or reduced?

Have eligibility requirements changed such that fewer individuals with disabilities will qualify for/ have access to services under the proposed regulations?

Have eligibility requirements changed such that more individuals with disabilities will qualify for/ have access to services under the proposed regulations?

Does the program increase or reduce opportunities for employment for individuals with disabilities?

Does the regulation impact payment for services or payments to service providers?

Does the proposed regulation impact workforce development/ expansion for service providers?

Does the proposed regulation limit allowable services or choices available under similar federal programs?

Do the proposed regulations have unintended consequences that impact people with disabilities?

Do the proposed regulations facilitate one or more of the following outcomes?

- Program or process consolidation*
- Expansion of services for people with disabilities*
- Increased employment opportunities for people with disabilities*
- Enhanced coordination among State agencies*
- Reduction of the number individuals or families waiting for services*

Will the proposed regulations result in one or more of the following outcomes?

- Reduced administrative expenditures*
- Reduced operational expenditures*
- Savings derived from improved outcomes*

Describe how the proposed regulations incorporate the following principles.

- Expanded choice and options for individuals with disabilities*
- Self-directed or person-centered planning control*
- Increased community capacity*
- Involvement of individuals with disabilities or their families in policy-making implementation*
- Involvement of individuals with disabilities in program evaluation*

The above description relates to the provision of resources and services to individuals with disabilities. Note that proposed regulations having a direct impact on individuals with disabilities should also be reported on this impact statement.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Maryland Department of Health, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499 (TTY 800-735-2258), or email to

mdh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through (leave blank). A public hearing has not been scheduled.

Opportunity for Public Comment

(Required by State Government Article, §10-112(a)(3)(v), Annotated Code of Maryland)

The Administrative Procedure Act allows two methods to be used to receive public comments for proposed regulations.

*First, the Department may hold a hearing. MDH generally does not hold public hearings on regulations. **IF** you believe MDH **SHOULD** hold a hearing on your proposal contact the Office of Regulations and Policy Coordination at 410-767-6499 ASAP.*

Second, in lieu of a hearing, the Department is required to accept written and telephone comments. The MDH Regulation Coordinator is the point person for accepting public comments and including them as part of the Department's official record. Comments are accepted for 30 days following the publication of the proposal. Since the proposal is time-sensitive, leave this space blank. ORPC will insert the appropriate date at the time of submission.

Part C

(For legislative use only; not for publication)

- A. Fiscal Year in which regulations will become effective: FY _____**
- B. Does the budget for fiscal year in which regulations become effective contain funds to implement the regulations?**
___ Yes ___ No ___ N/A
- C. If “yes”, state whether general, special (exact name), or federal funds will be used:**
- D. If “no”, identify the source(s) of funds necessary for implementation of these regulations:**
- E. If these regulations have no economic impact under Part A, indicate reason briefly:**
- F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason.**
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Impact Statement Part C—Legislative Information

Part C requests agencies to provide information required by the Department of Legislative Services in its report to the AELR Committee. Answer the questions in the space provided. Part C is not printed in the Maryland Register.

**USING THE ELF INSTRUCTIONS, INSERT AMENDMENTS FROM ON-LINE
COMAR OR TYPE NEW MATERIAL AND DELETE THIS SENTENCE.**

ROBERT R. NEALL
Secretary of Health
