

DHMH POLICY

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OFFICE OF REGULATION & POLICY COORDINATION

DHMH POLICY 02.10.01

Effective: May 10, 2011

POLICY ON REGULATIONS PROCESS

I. EXECUTIVE SUMMARY

This policy states that the adoption of regulations which implement laws pertaining to the Department is the prerogative of the Secretary of Health and Mental Hygiene.

This policy does not apply to regulations adopted by the Kidney Disease Commission, the Health Services Cost Review Commission, and the Maryland Health Care Commission.

Units formulating regulations are instructed to conform to the Administrative Procedures Act, the State Documents Law, this policy and the accompanying procedure.

The Regulations Coordinator is responsible for managing the regulation making process and, in coordination with the proposing unit, requesting comments from interested members of the State, public at large, and industry. The DHMH Secretary shall determine whether a public hearing shall be conducted to examine the merits of the proposed regulation.

The Director of the Budget Management Office, or designee, shall determine if the fiscal impact of the proposed regulation results in expenditures in excess of the limitations in the State budget, pursuant to State Finance and Procurement Article, §7-235(b).

The Attorney General of Maryland, or designee, is responsible for reviewing the proposed regulation for approval as to its legality.

II. BACKGROUND

Both this policy, DHMH 02.10.01, and accompanying procedure, DHMH 02.10.01.P1, effective (*will insert date when known*) updates DHMH Policy 04.01.01 and 04.01.02, which became effective March 6, 1998 and which superseded Policy DHMH 1300 and Procedure DHMH 1300.1. This version updates hyperlinks and makes other minor technical changes.

With certain exceptions, the General Assembly and the Governor have given to the Secretary the power to adopt regulations which implement legislatively authorized programs empowered by Maryland Health-General Article and Maryland Health Occupations Article. The regulations, when properly formulated and adopted, have the force of law. Because regulations impact on the personal and business lives of the public, the General Assembly and the Governor have seen fit to establish a structured system for the adoption of regulations.

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Furthermore, the Secretary of Health and Mental Hygiene has determined that in order to comply with legal requirements governing the adoption of regulations, to ensure that Department regulations reflect sound policy analysis and coordination, and to ensure that regulations are adopted on a timely basis, it is necessary to establish a Departmental procedure for formulating regulations.

III. POLICY STATEMENTS

A. The adoption of regulations which implement laws contained in Health-General Article and Health Occupations Article, with the exception of the regulations adopted by the Kidney Disease Commission pursuant to Health-General Article, §13-308, the State Health Services Cost Review Commission pursuant to Health-General Article, §19-207, and the Maryland Health Care Commission, pursuant to Health-General Article, §19-109, is the prerogative of the Secretary of Health and Mental Hygiene under the authority granted by Health-General Article, §2-104(b).

B. All regulations formulated by units within the Department shall conform to the requirements of the Administrative Procedure Act (State Government Article, §§10-101 — 10-129) and the State Documents Law (State Government Article, §§7-201 — 7-222).

C. All regulations shall be developed in accordance with the process set forth in this policy and any accompanying procedures.

D. The Regulations Coordinator is responsible for managing the regulation-making process of the Department.

E. The Regulations Coordinator, with the proposing unit, is responsible for requesting substantive comments on proposed regulations from units of the Department, other State agencies, and interested members of the public or industry as required.

F. The Secretary of the Department of Health and Mental Hygiene is responsible for determining if a public hearing is needed to examine the merits of the proposed regulation.

G. The Director of the Budget Management Office, or designee, is responsible for determining if the fiscal impact of the proposed regulation(s) results in expenditures in excess of the limitations in the State budget, pursuant to State Finance and Procurement Article, §7-235(b).

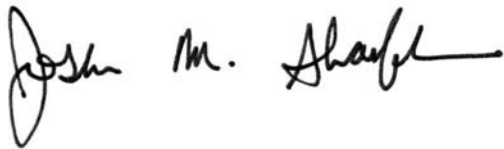
H. The Attorney General of Maryland, through his/her assistant(s) as appropriate, is responsible for reviewing the proposed regulations for approval as to legality (State Government Article, §§10-106 — 10-107).

IV. REFERENCES

- State Government Article, §§10-101 — 10-129 (Administrative Procedures Act)
<http://www.michie.com/maryland/lpext.dll/mdcode/20422/210a0?fn=document->
- State Government Article, §§7-201 — 7-222 (State Documents Law)
<http://www.michie.com/maryland/lpext.dll/mdcode/20422/2095e?fn=document->

- State Finance and Procurement Article, §7-235(b)
<http://www.michie.com/maryland/lpext.dll/mdcode/1f342/1faa1/1fb1b/1fbb5?fn=document-frame.htm&f=templates&2.0#>
- Health-General Article, §§2-104(b), 13-308, 19-109, 19-207
<http://www.michie.com/maryland/lpext.dll/mdcode/12fde/12ff7/12ff9/1300a?fn=document-frame.htm&f=templates&2.0#>
<http://www.michie.com/maryland/lpext.dll/mdcode/12fde/13a51/13ab3/13ad7?fn=document-frame.htm&f=templates&2.0#>
<http://www.michie.com/maryland/lpext.dll/mdcode/12fde/14508/1450a/1453c?fn=document-frame.htm&f=templates&2.0#>
<http://www.michie.com/maryland/lpext.dll/mdcode/12fde/14508/14616/14636?fn=document-frame.htm&f=templates&2.0#>
- Style Manual for Maryland Regulations, Division of State Documents, Office of the Secretary of State, (2009)
<http://www.dsd.state.md.us/stylemanual.PDF>
- DHMH Procedure 02.10.01.P1, Procedure for the Adoption of or Amendment to Regulations Affecting the Public
<http://www.dhmh.state.md.us/policies/021001p1.htm>

Approved:



Joshua M. Sharfstein, M.D., Secretary, DHMH

May 10, 2011
Effective Date