# HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 261 Cosmetic Product Registration
**SPONSOR(S):** Latvala
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 176

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR or BUDGET/POLICY CHIEF |
|---|---|---|---|
| 1) Health Quality Subcommittee | 9 Y, 0 N | Langston | O'Callaghan |
| 2) Government Operations Appropriations Subcommittee | | | |
| 3) Health & Human Services Committee | | | |

## SUMMARY ANALYSIS

The federal Food and Drug Administration (FDA) is responsible for regulating cosmetic products in the United States. The FDA prohibits adulterated or misbranded cosmetic products from being sold to consumers and enforces cosmetic product labeling requirements. Unlike drugs, cosmetic products are not subject to safety inspections and premarket approval. However, the FDA encourages cosmetic manufacturers to voluntarily submit information on facilities, products, and ingredients, which provides the FDA with post-market product information and assists in the assessment of product safety.

The Florida Department of Business and Professional Regulation's Division of Drugs, Devices, and Cosmetics (Division) regulates cosmetics that are manufactured and repackaged in Florida. Cosmetic manufacturers physically located in Florida are required to hold an active cosmetic manufacturer permit issued by the Division. In addition, each product produced or repackaged by such manufacturers is required to be registered with the Division.

HB 261 amends ch. 499, F.S., to remove the requirement that Florida cosmetic manufacturers register cosmetic products with the Division. The bill eliminates the fee for registration of cosmetics. The bill makes conforming changes by removing registration and renewal requirements for cosmetic products, including the requirements to submit registration applications, product labels, and registration and renewal fees. This allows cosmetic manufacturers in Florida to sell cosmetics without registering such products.

The bill removes the Division's authority to issue certificates of free sale for registered cosmetic products in s. 499.003(6), F.S.

Throughout the bill the term "Federal Drug Administration" is revised to correctly reference the federal Food and Drug Administration.

The bill has a significant negative fiscal impact on the Department of Business and Professional Regulation and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2016.

## FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

**Current Situation**

Federal Regulation of Cosmetics

In the United States more than 8 billion cosmetics are sold annually which results in over $60 billion in annual sales.[1] The federal Food and Drug Administration's (FDA) definition of cosmetics covers a broad range of products. For regulatory purposes, the term includes products for the eyes, face, nails, hair, skin, and mouth, which may be in the form of products such as makeup, polish, hair dyes, fragrances, deodorants, shave gel, oral care, lotions, bath products, and products for infants and children.[2]

The FDA regulates cosmetics under the authority of the federal Food Drug and Cosmetic Act (FDCA) and the Fair Packaging and Labeling Act (FPLA). The FDCA prohibits the adulteration and misbranding of cosmetics and the introduction, receipt, and delivery of adulterated or misbranded cosmetics into interstate commerce.[3] A cosmetic is considered to be adulterated if it contains a substance that may cause injury to users under the conditions of use prescribed on the product's labeling or if it contains a soiled or decomposed substance.[4] A cosmetic is considered to be misbranded if its labeling is false or misleading, if it does not bear the required labeling information, if the container is made or filled in a deceptive manner, or if it does not comply with child resistant packaging requirements.[5] The FDA is authorized to take action against a cosmetic on the market if a product is found to be adulterated or misbranded, as well as companies and individuals who market such products.[6] However, the FDA does not have the authority to require a manufacturer to recall a cosmetic product from the marketplace, although the agency has general regulations on voluntary recalls.[7]

*Voluntary Regulations*

The FDA's legal authority over cosmetics is less comprehensive than other products it regulates, such as drugs and medical devices, with respect to mandatory product approval, regulation, and registration. The FDA does not impose registration requirements on cosmetic manufacturers, but it allows cosmetic manufactures to follow voluntary registration regulations. These voluntary regulations include facility registration, reporting of product's ingredients, and reporting of adverse reactions to products.

Voluntary cosmetic regulation compliance is managed electronically through the FDA's Voluntary Cosmetic Registration Program (VCRP). The VCRP is an electronic reporting system for manufacturers, packers, and distributors of cosmetic products that are distributed commercially in the United States.[8] Voluntary submission to the VCRP provides the FDA with information on cosmetic

[1] Landa, Michael. "Examining the Current State of Cosmetics," testimony on March 27, 2012, before the Subcommittee on Health Committee on Energy and Commerce, U.S. House of Representatives, accessible at http://www.fda.gov/NewsEvents/Testimony/ucm297215.htm (last visited December 10, 2015).
[2] 21 C.F.R. §720.4(c)(12) (1992).
[3] Amalia Corby-Edwards, *FDA Regulation of Cosmetics and Personal Care Products*, CONGRESSIONAL RESEARCH SERVICE, July 9, 2012, available at http://asbcouncil.org/sites/default/files/library/docs/crs_report_fda_regulation_of_cosmetics_and_personal_care_products.pdf (last visited December 10, 2015).
[4] Id.
[5] Id.
[6] U.S. FOOD AND DRUG ADMINISTRATION, *FDA Authority over Cosmetics*, March 20, 2014, http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm (last visited December 10, 2015).
[7] *Supra*, note 3.
[8] U.S. FOOD AND DRUG ADMINISTRATION, *Voluntary Cosmetic Registration Program*, http://www.fda.gov/Cosmetics/RegistrationProgram/default.htm (last visited December 10, 2015).

businesses and products, which helps support product safety review processes.[9] As of December 2015, there are 2,970 active online accounts, 1,473 registered establishments, and 45,103 product formulations on file with the VCRP.[10]

The FDA does not require good manufacturing practices (GMP) for cosmetic products as it does with drugs and medical devices, unless the product is considered both a cosmetic and a drug.[11] GMPs provide standards for product development, monitoring, and control of processes and facilities, providing assurance that products meet FDA quality and safety standards. With the exception of color additives, the FDA does not require safety testing or premarket approval of the ingredients and chemicals used in cosmetic products.[12]

*Labeling*

The FPLA requires that packages and their labels provide consumers with accurate information about the quantity of contents to prevent consumer deception.[13] FPLA regulations require cosmetic product labels to disclose:[14]

- Identification of the product;
- Net quantity of contents in terms of weight, measure, or numerical count;
- Material facts about product and its use, such as directions for safe use;
- Name and place of business of the product's manufacturer, packer, or distributor;
- Warning and caution statements for products that are required to bear such statements by the FDCA and FDA regulations; and
- A list of ingredients in descending order of predominance.

*Product Ingredients*

The FDA is not statutorily authorized to approve a premarket cosmetic product. Therefore, manufactures are responsible for verifying the safety of their products before they are sold to consumers. FDA regulations prohibit or restrict the use of 10 types of ingredients in cosmetic products including chloroform, bithioniol, methylene chloride, and mercury-containing compounds[15] and require warning statements on the labels of certain types of cosmetics. Manufacturers must remove dangerous products from the market once a safety concern emerges. The FDA can pursue enforcement actions against such products or against firms or individuals who violate the law.[16] In general, except for color additives and those ingredients that are prohibited or restricted by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic, provided that the:[17]

- Ingredient and the finished cosmetic are safe under labeled or customary conditions of use;
- Product is properly labeled; and
- Use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws that FDA enforces.

State Cosmetic Laws

[9] Information from the VCRP is used by the Cosmetic Ingredient Review, an industry funded organization, to assess ingredient safety and determine priorities for ingredient safety review. *Id.*
[10] U.S. FOOD AND DRUG ADMINISTRATION, *Registration Reports*, http://www.fda.gov/Cosmetics/RegistrationProgram/RegistrationReports/default.htm (last visited December 9, 2015).
[11] In some cases products that are used for two purposes are considered both a cosmetic and a drug. For example, a shampoo is a cosmetic because its intended use is to cleanse the hair; however, an antidandruff treatment is a drug because its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug and must comply with the requirements for both cosmetics and drugs. U.S. FOOD AND DRUG ADMINISTRATION, *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?),* http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm (last visited December 10, 2015).
[12] *Supra*, note 3.
[13] 15 U.S.C. § 1451-1460 (2009).
[14] *Supra*, note 1.
[15] U.S. FOOD AND DRUG ADMINISTRATION, *Prohibited and Restricted Ingredients*, http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm (last visited December 10, 2015).
[16] *Supra*, note 1.
[17] *Supra*, note 6.

All 50 states have laws and regulations in place that conform to the FDCA, the FPLA, and FDA regulations for cosmetics.[18] Further cosmetic related laws and regulation vary state by state. Very few states, including Louisiana,[19] Nevada,[20] and Florida, have mandatory registration requirements for both cosmetic products and manufacturers. New Jersey[21] and Pennsylvania[22] require only cosmetic facilities, not products, to be registered with their respective state agencies. Other states, such as Texas[23] and Illinois,[24] authorize their respective state agencies to issue certificates of free sale for the export of in-state produced products.

California and Washington require post-market product reporting. The California Safe Cosmetics Act requires cosmetic manufacturers to notify the state of any product ingredients that are on state or federal lists of chemicals that cause cancer or birth defects.[25] Washington only requires this notification for children's cosmetic products.[26]

Florida Cosmetic Regulation

The Department of Business and Professional Regulation's Division of Drugs, Devices, and Cosmetics (Division) serves to protect the health, safety, and welfare of Florida citizens from injury due to the use of adulterated, contaminated, and misbranded drugs, drug ingredients, and cosmetics[27] by administering the provisions of ch. 499, F.S., the Florida Drug and Cosmetic Act (Act).[28]

The Act conforms to FDA cosmetic laws and regulations and authorizes the Division to issue permits to Florida cosmetic manufacturers and register cosmetic products manufactured or repackaged in Florida.

*Manufacturer Permit*

Cosmetic manufacturers physically located in Florida must obtain a cosmetic manufacturer permit through the Division.[29] Manufacture in this context means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any cosmetic.[30] Cosmetic manufacturers also repackage products by changing the container, wrapper, or label of a product, which may include altering the quantity of a product into different containers.[31] A person that only labels or changes the label of a cosmetic, but does not open the container sealed by the manufacturer of the product, is exempt from obtaining a permit.[32]

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[18] U.S. FOOD AND DRUG ADMINISTRATION, *Subchapter 3.3- State Operational Authority,* http://www.fda.gov/ICECI/Inspections/IOM/ucm122520.htm (last visited December 10, 2015).
[19] LOUISIANA DEP'T OF HEALTH AND HOSPITALS, *Cosmetics*, http://dhh.louisiana.gov/index.cfm/page/727 (last visited December 10, 2015).
[20] Nev. Rev. Stat. § 585.245; Nev. Admin. Code 585.805.
[21] NEW JERSEY DEP'T OF HEALTH, *Wholesale Food and Cosmetic Project,* http://www.nj.gov/health/foodanddrugsafety/wfcp.shtml (last visited December 10, 2015).
[22] PENNSYLVANIA DEP'T OF HEALTH, *Drug, Device, and Cosmetic Program*, https://www.portal.state.pa.us/portal/server.pt/community/drugs,_devices___cosmetics/14159 (last visited December 10, 2015).
[23] 25 Tex. Admin. Code §§ 229.301-229.306 (2010).
[24] Ill. Admin. Code Food Drug and Cosmetic 77 § 720 (2014).
[25] CALIFORNIA DEP'T OF PUBLIC HEALTH, *California Safe Cosmetic Program*, http://www.cdph.ca.gov/programs/cosmetics/Pages/default.aspx (last visited December 11, 2015).
[26] DEP'T OF ECOLOGY, STATE OF WASHINGTON, *Children's Safe Product Act*, http://www.ecy.wa.gov/programs/hwtr/RTT/cspa/index.html (last visited December 11, 2015).
[27] Florida law defines a cosmetic as an article, with the exception of soap, that is: (a) intended to be rubbed, poured, sprinkled, or sprayed on; introduced into; or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance; or (b) intended for use as a component of any such article. S. 499.003(12), F.S.
[28] FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, *Division of Drugs, Devices, and Cosmetics,* http://www.myfloridalicense.com/DBPR/ddc/index.html (last visited December 11, 2015).
[29] S. 499.01(2)(o), F.S.
[30] FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, *Cosmetic Manufacturer,* http://www.myfloridalicense.com/dbpr/ddc/CosmeticManufacturer.html (last visited December 11, 2015).
[31] Id.
[32] *Supra*, note 29.

Applicants for a cosmetic manufacturer permit must complete and submit an application, pass an onsite inspection,[33] and pay a fee. Applicants must pay a fee of $800 for a biennial permit and a one-time pre-permit inspection fee of $150.[34] As of November 2014, there were 125 establishments with Division issued cosmetic manufacturer permits.[35]

Division regulations provide guidelines for cosmetic manufacturers to ensure cosmetic product safety and quality and compliance with FDA laws and regulations. The regulations provide that: [36]

- Manufacturers must assure that personnel do not contribute to contamination or adulteration of the product;
- Any facility used for the manufacture, processing, packaging, or labeling of a cosmetic shall be of suitable size and construction to produce a product that is not adulterated or misbranded;
- Any facility and equipment used in the manufacture, processing, packaging, or labeling of a cosmetic shall be maintained in a clean and sanitary condition;
- Components, containers, and closures shall not be reactive, additive, or absorptive so as to alter the safety or purity of the cosmetic;
- Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the cosmetic product; and
- An appropriate identification or tracking system should be in place to facilitate a rapid and effective recall or market withdrawal.

*Registration of Products*

Cosmetics manufactured, packaged, repackaged, labeled or relabeled in Florida must be registered with the Division.[37] Products that are both a cosmetic and a drug must be registered as a drug.[38] Registration of cosmetic products requires a manufacturer to submit a detailed Division application, a copy of the product labels, and a fee for each product.[39] The application includes the following information:

- Manufacturer's contact and address information, type of ownership, and operating hours;
- Name of product as shown on label;
- Identification of the product, if it is for professional use only;
- Manufacturer of the product, including its name, city, and state;
- Identical cosmetic products information; and
- Signed affidavit section.[40]

New cosmetic products must be registered prior to sale. If a manufacturer has existing registered products, its registered product list must be updated through the formal application process to include any new products.[41] The registration and biennial renewal fee for each cosmetic product is $30.

Manufacturers often produce similar products or slightly alter products from an outside manufacturer; for example, they may use a different brand name, container, or scent for an almost identical product. In these instances, for registration purposes, the product is not considered separate and distinct. The

[33] If the applicant also holds an Over-the-Counter Drug Manufacturer or Prescription Drug Manufacturer permit at the same time an inspection is not required. *Supra*, note 30
[34] *Supra*, note 30.
[35] Letter from the Director of the Division of Drugs, Devices, and Cosmetics to a representative of the Florida Cosmetic Manufacturers Coalition on November 26, 2014. (on file with Health Quality Subcommittee staff).
[36] Rule 61N-1.010, F.A.C.
[37] S. 499.015(1)(a), F.S.
[38] Rule 61N-1.016(1)(a), F.A.C.
[39] S. 499.015, F.S.
[40] FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, *Application for Product Registration-Cosmetics Form No.: DBPR-DDC-228*, available at http://www.myfloridalicense.com/DBPR/ddc/documents/Product_Registration_Cosmetic_App-228.pdf (last visited December 14, 2015).
[41] Rule 61N-1.016(4)(b), F.A.C.

process for "identical products" requires submission of an application and a $15 fee and biennial renewal fee for each additional size, quantity, color, flavor, and scent of a registered cosmetic product.[42]

The Division reviews applicants' product labels to determine compliance with the requirements of the FDCA.[43] The Division reviews the ingredients of the cosmetic to determine if the ingredients are approved for use in cosmetics or otherwise safe for cosmetic products.[44] Division pharmacists or drug inspectors review products that may contain ingredients that are prohibited or may change the classification of the product to a drug.[45] Currently, there are 13,024 active cosmetic product registrations with the Division.[46]

*Inspection and Investigation of Cosmetic Manufacturers*

Passing an onsite inspection is a prerequisite to issuance of a Cosmetic Manufacturer permit, unless the applicant also holds an Over-the-Counter Drug Manufacturer or Prescription Drug Manufacturer permit at the same address.[47] Additionally, once a permit has been issued to a cosmetic manufacturer, it is subject to inspection and investigation, whether announced or unannounced, by the Division and the Department of Law Enforcement.[48] Inspections and investigations may include:

- Review and copying of all records pertaining to the manufacture, advertisement, storage, holding, and distribution of any cosmetic.
- Entry to any establishment, vehicle or space therein in which cosmetics are manufactured, processed, repackaged, sold, brokered, held or transported;
- Entry to any establishment, vehicle, or space therein in which records related to cosmetics are held;
- Surveillance of procedures related to cosmetics;
- Collection of facts and information related to cosmetics;
- Questioning of persons who may have information relating to the inspection or investigation and taking sworn statements from these persons, all related to cosmetics;
- Sampling any cosmetic, including any related product (whether or not in finished form), material, component, document, literature, label, labeling or other evidence;
- Photographing any cosmetic including any related component, materials, physical plant, storage condition, article or product;
- Observations and identification of:
    - Any cosmetic consisting wholly or in part of filthy, putrid or decomposed substances;
    - Any undesirable conditions or practices bearing on filth, contamination, or decomposition which may result in a cosmetic becoming adulterated or misbranded;
    - Any unsanitary conditions or practices which may render a cosmetic injurious to health;
    - Any faulty manufacturing, processing, packaging, or holding of cosmetics as related to current GMP including recordkeeping;
    - Any deviation from recommended processing, storage or temperature requirements for any cosmetic as specified by federal or state law;
    - Any deviation from FDA requirements for the label and labeling of any cosmetic;
    - Any other action to determine compliance with chapters 499 and 893, F.S., and chapter 61N-1, F.A.C.
- Taking of evidence related to a cosmetic that is or may be in violation of Chapter 499 or 893, F.S., or any rules adopted thereunder; and
- Securing the removal of any potentially misbranded or adulterated cosmetic from commerce or public access.

[42] Rule 61N-1.016(1)(b), F.A.C.
[43] Rule 61N-1.009, F.A.C.
[44] Florida Department of Business and Professional Regulation, 2016 Legislative Bill Analysis SB 176, September 29, 2015. (SB 176 is identical to HB 261, analysis is on file with Health Quality Subcommittee staff).
[45] *Supra*, note 35.
[46] *Supra*, note 44.
[47] *Supra*, note 30.
[48] S. 499.051(1), F.S.; Rule 61N-1.019(1)-(3), F.A.C.

*Certificates of Free Sale*

Manufacturers exporting products from the United States are often asked by foreign customers or foreign governments to supply a certificate of free sale (COFS) to ensure that products are in compliance with FDA laws and regulations. A COFS is a document issued by a regulatory agency containing information about a product's regulatory or marketing status.[49] A COFS verifies that products being exported are freely marketed without restriction and are approved for sale in the United States and Florida.[50]

A COFS can be issued by a federal, state, city office or a non-governmental association such as a Chamber of Commerce. The Division, when requested by a cosmetic manufacturer, issues a COFS for a registered cosmetic product that is to be exported to another country.[51] Enterprise Florida will prepare a COFS for firms involved in the exporting of products manufactured in, or distributed from Florida for a fee of $20.00.[52]

**Effect of Proposed Changes**

HB 261 amends ch. 499, F.S., to remove the requirement that Florida cosmetic manufacturers register cosmetic products with the Division. As such, cosmetic manufacturers located in Florida will no longer be required register cosmetic products with the Division. Florida cosmetic manufacturers' products would be treated the same as cosmetic products manufactured outside of Florida but distributed and sold into Florida. The bill makes conforming changes by removing registration and renewal requirements for cosmetic products, including the requirements to submit registration applications, product labels, and registration and renewal fees.

Florida cosmetic manufacturers would continue to be regulated. They would still be required to have their facilities permitted and be subject to inspection and investigation of their cosmetic products.

The bill also removes the Division's authority to issue COFSs for registered cosmetic products in s. 499.003(6), F.S. While COFSs would not be available from the Division for exported cosmetic products, they would continue to be available from other entities for exported cosmetic products, including Enterprise Florida.

The bill provides an effective date of July 1, 2016.

[49] U.S. FOOD AND DRUG ADMINISTRATION, *FDA Export Certificate,* December 18, 2014, http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm, (last visited December 15, 2015).
[50] Enterprise Florida, *Certificate of Free Sale*, available at https://www.enterpriseflorida.com/wp-content/uploads/certificate-of-free-sale-flyer.pdf (last visited December 14, 2015).
[51] Rule 61N-1.017, F.A.C.
[52] *Supra*, note 50.

B. SECTION DIRECTORY:

**Section 1:** Amends s. 499.015, F.S., relating to registration of drugs, devices, and cosmetics; issuance of certificates of free sale.
**Section 2:** Amends s. 499.003, F.S., relating to definitions.
**Section 3:** Amends s. 499.041, F.S., relating to schedule of fees for drug, device, and cosmetic applications and permits, product registration, and free-sale certificates.
**Section 4:** Amends s. 499.051, F.S., relating to inspections and investigations.
**Section 5:** Provides an effective date of July 1, 2016.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The Division will experience a decrease in revenues associated with no longer receiving payment of fees for cosmetic product registration, product registration renewal, and COFS.

There are 13,024 current, active registered cosmetic products. Product registrations are renewed biennially. The Division's biennial renewal fees from the 13,024 products are approximately $330,465 (or $165,232.50 annually). The bill would reduce the Division's revenue from these fees and the revenue reductions would increase the Division fund's anticipated deficit. There would also be a General Revenue service charge loss of $17,805.10 in Fiscal Year (FY) 2016-2016; $18,013.16 in FY 2017-2018; and $18,234.47 in FY 2018-2019. The reduction in the Division's revenue is estimated as follows:[53]

| | Fiscal Year 2016 – 17 | Fiscal Year 2017 – 18 | Fiscal Year 2018 – 19 |
|---|---|---|---|
| Revenue reduction from annual renewals: | ($165,232.50) | ($165,232.50) | ($165,232.50) |
| Revenue reduction from initial product registrations: | ($45,225) | ($46,545) | ($47,895) |
| Revenue reduction from COFS: | ($12,106.20) | ($13,387.04) | ($14,803.39) |
| **Total revenue reduction:** | **($222,563.70)** | **($225,164.54)** | **($227,930.89)** |

2. Expenditures:

It is unclear whether the Division will have a reduction in expenditures if resources used to implement the product registration program are no longer needed or are allocated for other Division responsibilities.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill has a positive fiscal impact for cosmetic manufacturers associated with no further payment of $30 per product registration, $15 per identical product registration, and biennial renewal fee for both to the Division.

D. FISCAL COMMENTS:

[53] *Supra*, note 44; Email from David Mica, Legislative Affairs Director, Department of Business and Professional Regulation, RE: HB 261 DBPR Analysis (December 16, 2015.

None.

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

## IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES