The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Community Affairs

BILL:	SB 172
INTRODUCER:	Senator Bradley
SUBJECT:	Florida Drug and Cosmetic Act
DATE:	October 8, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Toman	Yeatman	CA	**Favorable**
2.			IT	
3.			RC	

I. Summary:

SB 172 expressly preempts to the state the regulation of over-the-counter proprietary drugs or cosmetics.

II. Present Situation:

Home Rule

Counties

A county without a charter has such power of self-government as provided by general[1] or special law, and may enact county ordinances not inconsistent with general law.[2] Counties operating under county charters shall have all the powers of local self-government not inconsistent with general law, or with special law approved by vote of the electors.[3] General law authorizes counties "the power to carry on county government"[4] and to "perform any other acts not inconsistent with law, which acts are in the common interest of the people of the county, and exercise all powers and privileges not specifically prohibited by law."[5]

Municipalities

Chapter 166, F.S., also known as the Municipal Home Rule Powers Act,[6] acknowledges the constitutional grant to municipalities of governmental, corporate, and proprietary power

[1] Chapter 125, Part I, F.S.
[2] FLA. CONST. art. VIII, s. 1(f).
[3] FLA. CONST. art. VIII, s. 1(g).
[4] Section 125.01(1), F.S.
[5] Section 125.01(1)(w), F.S.
[6] Section 166.011, F.S.

necessary to conduct municipal government, functions, and services.[7] Chapter 166, F.S., provides municipalities with broad home rule powers, respecting expressed limits on municipal powers established by the Florida Constitution, applicable laws, and county charters.[8]

Section 166.221, F.S., authorizes municipalities to levy reasonable business, professional, and occupational regulatory fees, commensurate with the cost of the regulatory activity, including consumer protection, on such classes of businesses, professions, and occupations, the regulation of which has not been preempted by the state or a county pursuant to a county charter.

Preemption

Local governments have broad authority to legislate on any matter that is not inconsistent with federal or state law. A local government enactment may be inconsistent with state law if (1) the Legislature has preempted a particular subject area or (2) the local enactment conflicts with a state statute. Where state preemption applies, it precludes a local government from exercising authority in that particular area.[9] Florida law recognizes two types of preemption: express and implied. Express preemption requires a specific legislative statement; it cannot be implied or inferred.[10] Express preemption of a field by the Legislature must be accomplished by clear language stating that intent.[11] In cases where the Legislature expressly or specifically preempts an area, there is no problem with ascertaining what the Legislature intended.[12,13]

In cases determining the validity of ordinances enacted in the face of state preemption, the effect has been to find such ordinances null and void.[14] Implied preemption is actually a decision by the courts to create preemption in the absence of an explicit legislative directive.[15] Preemption of a local government enactment is implied only where the legislative scheme is so pervasive as to evidence an intent to preempt the particular area, and strong public policy reasons exist for finding preemption.[16] Implied preemption is found where the local legislation would present the danger of conflict with the state's pervasive regulatory scheme.[17]

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[7] Florida House of Representatives, Publications, The Local Government Formation Manual 2018-2020, p. 16, *available at* https://www.myfloridahouse.gov/Sections/Documents/loaddoc.aspx?PublicationType=Committees&CommitteeId=3025&Session=2020&DocumentType=General%20Publications&FileName=2018-2020%20Local%20Government%20Formation%20Manual.pdf.
[8] Section 166.021(4), F.S.
[9] Wolf, *The Effectiveness of Home Rule: A Preemptions and Conflict Analysis*, 83 Fla. B.J. 92 (June 2009).
[10] *See City of Hollywood v. Mulligan*, 934 So.2d 1238, 1243 (Fla. 2006); *Phantom of Clearwater, Inc. v. Pinellas County*, 894 So.2d 1011, 1018 (Fla. 2d DCA 2005), approved in *Phantom of Brevard, Inc. v. Brevard County*, 3 So.3d 309 (Fla. 2008).
[11] *Mulligan*, 934 So.2d at 1243.
[12] *Sarasota Alliance for Fair Elections, Inc. v. Browning*, 28 So.3d 880, 886 (Fla. 2010).
[13] Examples of activities "expressly preempted to the state" include: operator use of commercial mobile radio services and electronic communications devices in motor vehicles, s. 316.0075, F.S.; regulation of the use of cameras for enforcing provisions of the Florida Uniform Traffic Control Law, s. 316.0076, F.S.; and, the adoption of standards and fines related to specified subject areas under the purview of the Department of Agriculture and Consumer Services, s. 570.07, F.S.
[14] *See, e.g., Nat'l Rifle Ass'n of Am., Inc. v. City of S. Miami,* 812 So.2d 504 (Fla. 3d DCA 2002).
[15] *Phantom of Clearwater, Inc.*, 894 So.2d at 1019.
[16] *Id*.
[17] *Sarasota Alliance for Fair Elections, Inc.*, 28 So.3d at 886.

Licensing and Regulation of Drugs, Devices and Cosmetics in Florida

The Florida Drug and Cosmetic Act (Act) is found in part I of ch. 499, F.S.[18] The Act's purpose is to safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.[19] The Department of Business and Professional Regulation (DBPR) is responsible for administering and enforcing efforts to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.[20] Administration of the Act must conform to the Federal Food, Drug, and Cosmetic Act[21] and the applicable portions of the Federal Trade Commission Act,[22] which prohibit the false advertising of drugs, devices, and cosmetics.[23]

Chapter 2010-161, s. 27, Laws of Fla., shifted responsibility for operation and enforcement of the Act from the Department of Health to DBPR. Administration of the provisions in the Act occur within DBPR's Division of Drugs, Devices and Cosmetics (division).[24] The division carries out its responsibilities through two program areas:[25]

- The Permitting Program is responsible for the review and approval of permitting applications for multiple permit categories including categories for over-the-counter drug manufacturers and cosmetic manufacturers.[26]
- The Bureau of Compliance & Enforcement is responsible for initial permitting and compliance inspections for permitted facilities and investigation of complaints related to violations of the Act.

In addition to the above, the Act also provides for:[27]

- Criminal prohibitions against distribution of contraband and misbranded prescription drugs;
- Regulation of the advertising and labeling of drugs, devices, and cosmetics; and
- Enforcement avenues for DBPR, including seizure and condemnation of drugs, devices, and cosmetics.

[18] Section 499.001, F.S., provides that ss. 499.001-499.94 is the Florida Drug and Cosmetic Act.
[19] Section 499.002(1)(a), F.S.
[20] Section 499.002(2), F.S.
[21] 21 U.S.C. ss. 301 *et seq*.
[22] *See* 15 U.S.C. §§ 41-58, as amended.
[23] Section 499.002(1)(b), F.S.
[24] E-mail from Colton Madill, Deputy Legislative Affairs Director, DBPR (Oct. 3, 2019) (on file with Senate Committee on Community Affairs).
[25] *Id.*
[26] Section 499.01, F.S., outlines 18 distinct permits based on the type of entity and intended activity, and includes permits for entities within the state, out of state, or even outside of the United States. These are: an out-of-state prescription drug wholesale distributor; a retail pharmacy drug wholesale distributor; a restricted prescription drug distributor; a complimentary drug distributor; a freight forwarder; a veterinary prescription drug retail establishment; a veterinary prescription drug wholesale distributor; a limited prescription drug veterinary wholesale distributor; an over-the-counter drug manufacturer; a device manufacturer; a cosmetic manufacturer; a third party logistics provider; or a health care clinic establishment.
[27] *See* ss. 499.0051, 499.0054, 499.062, F.S.

Over the Counter Drugs and Cosmetics

Part I of Ch. 499, F.S., Definitions

Section 499.003(43), F.S., defines "proprietary drug," or "OTC drug," to mean a patent or over-the-counter drug in its unbroken, original package, which is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof, is not misbranded, and can be purchased without a prescription. Section 499.003(12), F.S., defines "cosmetic" to mean an article, with the exception of soap that is: a) intended to be rubbed, poured, sprinkled, or sprayed on or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance; or (b) intended for use as a component of any such article.

U.S. Food and Drug Administration Role and Guidance

As mentioned, Florida's drugs, devices and cosmetics regulations conform to the Federal Food, Drug, and Cosmetic Act.[28] The U.S. Food and Drug Administration (FDA) defines "over-the counter drug products" as nonprescription drugs that are safe and effective for use by the general public without seeking treatment by a health professional.[29] FDA reviews the active ingredients and the labeling of classes of drugs instead of individual drug products. Examples of these classes of drugs include those related to acne, allergy, cold and cough, laxative, insect repellant, nasal decongestant, and sunscreen. For each class, an OTC drug monograph[30] is developed and published in the Federal Register. OTC drug monographs are a kind of "recipe book" covering acceptable ingredients, doses, formulations, and labeling.

FDA defines "cosmetic products" in a fashion similar to the definition of cosmetic in Part I of ch. 499, F.S.[31] Examples of cosmetics include skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, and deodorants. Cosmetic products and ingredients do not need FDA premarket approval, with the exception of color additives.[32]

Over the Counter Sunscreen

UV Ray Sun Protection from Sunscreen

According to the American Academy of Dermatology (AAD),[33]one in five Americans will develop skin cancer in their lifetime, and nearly 20 Americans die from melanoma[34] every day.

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[28] 21 U.S.C. ss. 301 *et seq*.
[29] U.S. Food and Drug Administration, *Drug Applications for Over-the-Counter (OTC) Drugs*, *available at* https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs (last visited Oct. 8, 2019).
[30] An OTC monograph establishes conditions under which certain OTC drugs may be marketed without approved new drug applications because they are "generally recognized as safe and effective" (GRASE) and not misbranded.
[31] *See* U.S. Food and Drug Administration, *FDA Authority over Cosmetics: How Cosmetics Are Not FDA-Approved, but Are FDA-Regulated, available at https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated#What_kinds* (last visited Oct. 8, 2019).
[32] *Id*.
[33] *See* American Academy of Dermatology, *Is Sunscreen Safe*, *available at* https://www.aad.org/public/spot-skin-cancer/learn-about-skin-cancer/prevent/is-sunsceen-safe (last visited Oct. 8, 2019). Information and guidance provided in this section of the analysis is drawn from the cited webpage.
[34] The American Cancer Association describes melanoma as a type of skin cancer that develops when melanocytes (the cells that give the skin its tan or brown color) start to grow out of control. While melanoma is much less common than some other

To prevent exposure to the sun's harmful UV rays, the AAD recommends protecting your skin by "seeking shade, wearing protective clothing and generously applying sunscreen."[35] ADA identifies two types of sunscreen:

- Physical sunscreen which works like a shield and sits on the surface of your skin, and
- Chemical sunscreen which works like a sponge absorbing the sun's rays.[36]

For physical sunscreen, ADA advises looking for the active ingredients zinc oxide and/or titanium dioxide. For chemical sunscreen, it recommends looking for one or more of the following ingredients: oxybenzone, avobenzone, octisalate, octocrylene, homosalate and octinoxate.

FDA Proposed Rule on Sunscreen Products for Over-the-Counter Human Use[37]

On February 26, 2019, the FDA published a proposed rule on Sunscreen Products for Over-the-Counter Human Use.[38] The proposed rule classifies the safety and effectiveness of certain active ingredients and dosage forms, updates sunscreen testing and recordkeeping requirements, and addresses new uses of sunscreens, including the sale of combination sunscreen-insect repellant products. The deadline for the rule comment period has passed and the final rule publication is due by November 26, 2019.

The most recent FDA rule on sunscreens from 1999 identified 16 active ingredients "generally recognized as safe and effective" (GRASE) in sunscreen. In information from the 2019 proposed rule, FDA summarized the existing safety data of these ingredients as follows:

- Zinc oxide and titanium dioxide were proposed to be categorized as GRASE.
- Para-aminobenzoic acid and trolamine salicylate as no longer GRASE.
- The remaining 12 ingredients, which include oxybenzone and octinoxate, were identified as not having enough information to determine whether they are GRASE and the FDA asked the industry for additional data.[39]

City of Key West Ordinance on Sunscreen Products containing Oxybenzone or Octinoxate

In February of 2019, the City Commission of Key West passed an ordinance making it unlawful to sell, offer for sale, or distribute for sale in the City of Key West any SPF sunscreen protection personal care product that contains oxybenzone or octinoxate, or both, without a medically

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types of skin cancers it is considered more dangerous because it's much more likely to spread to other parts of the body if not caught and treated early. *See* American Cancer Society, *What is Melanoma Skin Cancer? available at* https://www.cancer.org/cancer/melanoma-skin-cancer/about/what-is-melanoma.html (last visited Oct. 8, 2019).

[35] According to the ADA, as long as a sunscreen is broad spectrum (provides protection from UVA (aging) and UVB (burning) rays), water resistant (the length of time sunscreen stays on wet skin) and has a SPF 30 or higher (SPF 30 filters out 97% of the sun's UVB rays), it can effectively protect people from the sun.

[36] ADA suggests opting for physical sunscreen if you have sensitive skin and states that chemical sunscreen formulations tend to be easier to rub into the skin without leaving a residue.

[37] 84 C.F.R. § 6204 (2019), *available at* https://www.federalregister.gov/documents/2019/02/26/2019-03019/sunscreen-drug-products-for-over-the-counter-human-use. Information in this section of the analysis is derived from the FDA proposed rule.

[38] According to FDA, changed conditions since publication of the previous final rule (64 FR 27666, May 21, 1999) (now stayed) necessitated additional data review to establish that certain active ingredients listed in the Stayed 1999 Final Monograph are GRASE for use in sunscreen products

[39] While the FDA is asking for more data, it has not said that these ingredients are unsafe.

licensed prescription.[40] The ordinance cites significant harmful impacts from the two chemicals on the marine environment and residing ecosystems around the waters of Key West, including coral reefs that protect the shoreline of Key West, and the Florida Keys. The ordinance definition of "SPF sunscreen protection personal care product" includes but is not limited to lotion, paste, balm, ointment, cream, solid stick applicator, brush applicator, roll-on applicator, aerosol spray, non-aerosol spray pump, and automated and manual mist spray.

A first time violation of the ordinance shall result in one written warning. Second and subsequent violations are punishable pursuant to the city's civil citation procedure, which could result in a maximum civil penalty not to exceed $500.[41] The effective date of the specified sunscreen products prohibition is January 1, 2021.[42]

OPPAGA Research of Sunscreen Chemical Effects on Corals[43] and Marine Life

As directed by the Legislature, the Office of Program Policy Analysis and Government Accountability (OPPAGA) compiled recent peer-reviewed research about the effects of oxybenzone and octinoxate on corals and marine life.[44] In the overview of its findings presented to the Legislature in September of 2019, OPPAGA stated that:

> A small number of scientific studies have shown negative effects[45] of oxybenzone and octinoxate on corals and marine life at concentration levels generally not observed in nature. Sunscreens are not the only source of these chemicals; they also may be introduced to seawater from wastewater effluent, leaching from plastics, and leaching from hull paints on ships. Setting aside the effects of these chemicals, a number of stressors would continue to affect corals, including natural threats such as hurricanes and increases in average ocean temperatures, air pollution, and land-based pollution.

[40] Chapter 26, Article VII., Sec. 26-311, Code of Ordinances, City of Key West Florida (Ord. No.19-03, § 1, 2-5-2019).
[41] Chapter 2, Article VI, Division 3, Code of Ordinances, City of Key West Florida.
[42] Both the state of Hawaii (Senate Bill 2571 (2018)) and the U.S. Virgin Islands (Bill No. 33-0043 (2019)) have passed legislation prohibiting the sale or distribution of sunscreens containing oxybenzone or octinoxate. The Hawaii ban begins on January 1, 2021. The prohibition in the U.S. Virgin Islands begins after March 30, 2020, and includes a ban on the use or possession of sunscreen products containing oxybenzone and octinoxate. Both laws contain findings referencing the chemicals' impacts on marine life and coral.
[43] According to the United States Environmental Protection Agency, Florida's coral reefs represent the third largest barrier reef ecosystem in the world. The Florida Reef Tract extends from St. Lucie Inlet in Martin County to the Dry Tortugas west of the Florida Keys. Roughly two thirds of the Florida Reef Tract lie within Biscayne National Park and the Florida Keys National Marine Sanctuary. *See* United States Environmental Protection Agency, *America's Coral Reefs, available at* https://www.epa.gov/coral-reefs/americas-coral-reefs (last visited Oct. 8, 2019).
[44] Office of Program Policy Analysis and Government Accountability, *Summary of Peer-Reviewed Research on the Effects of Selected Sunscreen Chemicals on Corals and Marine Life, 2008 to Present* (Sept. 2019) (on file with Senate Committee on Community Affairs).
[45] Identified negative effects that may be occurring include the bleaching of coral fragments and coral cells from hard coral and damage to coral DNA and reduced reproductive success.

III. Effect of Proposed Changes:

Section 1 amends s. 499.002, F.S., to --- notwithstanding any other law, local ordinance or regulation to the contrary --- expressly preempt to the state, the regulation of over-the-counter proprietary drugs or cosmetics.

Section 2 provides an effective date of July 1, 2020.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None identified.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Manufacturers and distributors of over-the-counter proprietary drugs and cosmetics will only be subject to statewide regulations of their products.

C. Government Sector Impact:

Local government entities will be unable to adopt or enforce over-the-counter proprietary drugs and cosmetics regulations.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 499.002 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.