
SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

Date: March 17, 1998 Revised: _____

Subject: Public Health Rulemaking Authority of the Department of Health (RAB)

	<u>Analyst</u>	<u>Staff Director</u>	<u>Reference</u>	<u>Action</u>
1.	<u>Williams</u>	<u>Wilson</u>	<u>HC</u>	<u>Favorable/CS</u>
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____

I. Summary:

Committee Substitute for Senate Bill 1716 is a rule authorizing bill (RAB) relating to the Department of Health's public health programs. The bill addresses those rules currently being enforced by the Department of Health which do not have the clear statutory authority needed under the revised provisions of the Administrative Procedures Act. Specific topical areas addressed in the bill are: immunizations, communicable disease control, sanitary facilities, drinking water systems, onsite sewage treatment and disposal systems, septic tank contractors, food hygiene, migrant labor housing, biomedical waste, environmental health professionals, tanning facilities, food assistance programs, emergency medical services, water quality testing, certification of water testing laboratories, radon testing, inspection of radiation machines, examinations of radiologic technologists, drugs, devices and cosmetics, mobile home parks, and public swimming and bathing facilities.

The bill amends the following sections of the Florida Statutes: 232.032(1), 381.0011(6), 381.003, 381.0031, 381.006, 381.0062(3), 381.0065(3)(b) and (m) and (4), 381.0072(1)(b) and (2)(a), 381.008(5) and (8), 381.0083, 381.0086(1), 381.0087(1) and (2), 381.0098(2)(b), (3), (4)(a), (d), and (f), and (7), 381.0101(2)(d), (f), and (g), (4)(b), (5), and (7), 381.89(4)(b), (6)(a), and (13), 383.011(1) and (2), 384.33, 384.34(4), 401.26, 401.265, 401.30, 403.0625, 403.863, 404.056(3), 404.22(1) and (2), 468.306(2), 489.553(4)(d), 489.555(1), 499.005, 499.01(1), 499.012, 499.0121, 499.0122(1)(a) and (d), 499.013(2)(e), 499.014, 499.015, 499.03, 499.05, 499.65, 499.66(2), 499.67(1), 501.122(1)(e) and (2), 513.045(1)(b), 513.05, 514.011, 514.0115, 514.03, 514.031(5) and (6), 514.033(4) and (5), and 514.05.

II. Present Situation:

During the 1996 legislative session a comprehensive rewrite of the Florida Administrative Procedures Act (APA) was adopted as CS/SBs 2290 and 2288. Among many other changes, the revised APA modified the standards which authorize rulemaking and included provision for periodic review of rules by agencies with rulemaking authority.

In the past, a number of court decisions held that a rule did not exceed the legislative grant of rulemaking authority if it was reasonably related to the stated purpose of the enabling legislation. Additionally, it was accepted that a rule was valid when it implemented general legislative intent or policy. Agencies had wide discretion to adopt rules whether the statutory basis for a rule was clearly conferred or implied from the enabling statute.

A new standard is provided in the revised APA in s. 120.536, F.S., which effectively overturns this line of cases and imposes a much stricter standard for rulemaking authority. Under the new APA, existing rules and proposed rules must *implement, interpret, or make specific* the particular powers and duties granted by the enabling statute. It is important to note that the revised APA is not intended to eliminate administrative rules or even to discourage rulemaking, but to ensure that administrative rules are no broader than the enabling statute. A grant of rulemaking authority by the Legislature is necessary, but not enough by itself, for an agency to adopt a rule. Likewise, agencies need more than a statement of general legislative intent for implementing a rule. Rules must be based on specific grants of powers and not address subjects on which the Legislature was silent.

In order to temporarily shield a rule or portion of a rule from challenge under the new provisions, agencies were to report rules which they believed did not meet the new criteria by October 1, 1997. The Joint Administrative Procedures Committee (JAPC) reports that some 5,850 rules or portions of rules were reported as exceeding the delegated rulemaking authority under s. 120.536(1), F.S. Of these, 3,610 rules were identified by various local school boards, whose rules are not contained in the *Florida Administrative Code* (FAC). However, 2,240 rules contained in the FAC were reported by various agencies as exceeding statutory authority for rulemaking under s. 120.536, F.S.

Section 120.536(2) also lays out the second step in the process, that of legislative review. The subsection provides:

The Legislature shall, at the 1998 Regular Session, consider whether specific legislation authorizing the identified rules, or portions thereof, should be enacted. By January 1, 1999, each agency shall initiate proceedings pursuant to s. 120.54 [F.S.] to repeal each rule, or portion thereof, identified as exceeding the rulemaking authority permitted by this section for which authorizing legislation does not exist.

Thus, during the 1998 legislative session, each agency has the responsibility to bring forward legislative proposals, as appropriate, which will provide statutory authorization for existing rules

or portions of rules which the agency deems necessary, but which currently exceed the agency’s rulemaking authority. The Legislature is directed to consider whether such legislation authorizing the identified rules should be enacted.

According to JAPC, there are 3500-3600 grants of rulemaking authority in the *Florida Statutes* falling roughly into two categories: (1) specific grants and (2) general grants. Most of them are specific grants of authority, that is, the grant of authority is found coupled in a sentence with a specific power or duty of the agency. General grants of rulemaking authority delegate rulemaking in the context of the agency’s mission or as it pertains to the stated purpose of the enabling legislation. Most agencies have a general grant of rulemaking authority and numerous specific grants of rulemaking authority. In most cases, it appears that existing rules exceed statutory authority because a “specific law to be implemented” is not apparent in the statute. The “character” of the referenced rules are of a degree of specificity that is too narrow to be an articulation of the general agency mission or the purpose of the enabling legislation so as to fall within the Legislature’s grant of general rulemaking authority.

As part of the JAPC - APA exercise, the Department of Health (DOH) identified a total of 489 rules relating to a variety of public health topics which lack sufficient, specific statutory authorization. Some of these rules are to be repealed by the department, while for others specific statutory authorization must be sought in order to protect existing rules from APA challenge. Many of the public health statutes which serve as the basis for these rules are fairly broad and general. The following is a list of FAC chapter citations for the rules under question which the department has indicated need immediate attention in order to ensure an adequate statutory basis for rulemaking authority:

Old Rule Number	New Rule Number	Subject Matter
10D-3	64D-3	Immunization; communicable disease control
10D-10	64E-10	Sanitary facilities
10D-4	64E-8	Drinking water systems
10D-6	64E-6	Onsite sewage treatment and disposal systems (OSDS); septic tank contractors
10D-13	64E-11	Food hygiene
10D-25	64E-14	Migrant labor camps
10D-104	64E-16	Biomedical waste
10D-123	64E-18	Environmental health professionals
10D-112	64E-17	Tanning facilities
10D-106	64F-1	WIC - supplemental food programs
10D-66	64E-2	Emergency medical services (EMS)

Old Rule Number	New Rule Number	Subject Matter
10D-41	64E-1	Testing of water quality; certification of water testing laboratories
10D-91	64E-5	Radon testing; inspection of radiation machines
10D-74	64E-3	Radiologic technology - examinations
10D-45	64F-12	Drugs, devices, and cosmetics
10D-89	64E-4	Non-ionizing radiation
10D-26	64E-15	Mobile home parks
10D-5	64E-9	Swimming pools and bathing places

III. Effect of Proposed Changes:

Section 1. Amends s. 232.032(1), F.S., relating to immunization requirements for school attendance, to specifically authorize DOH to adopt rules, including procedures for exempting a child from these immunization requirements.

Section 2. Amends s. 381.0011(6), F.S., relating to DOH duties with regard to communicable diseases, to specifically authorize DOH to adopt rules specific to the conditions and procedures relating to quarantines of animals, persons, or premises.

Section 3. Amends s. 381.003, F.S., relating to communicable diseases, to define “communicable disease” and to specify the topics to be addressed in rules relating to the prevention and control of communicable diseases.

Section 4. Amends s. 381.0031, F.S., relating to reporting of diseases of public health significance, to specify hospital and laboratory reporting, and to specify rulemaking authority relative to diseases for which reporting may be required, the methods of reporting, and overall authority for such reporting requirements.

Section 5. Amends s. 381.006, F.S., relating to DOH’s environmental health functions, to add a sanitary facilities’ function, including the specific related standards to be addressed as part of this function.

Section 6. Amends s. 381.0062(3), F.S., relating to supervision of private and certain public water systems, to impose a requirement that water suppliers give public notice of water problems and related corrective measures, and to authorize DOH to impose a reinspection fee with a range of \$25 to \$40. (This fee is included as a subset of the annual permit fee under chapter 64E-8, FAC.)

Section 7. Amends s. 381.0065(3)(b) and (m) and (4), F.S., relating to DOH onsite sewage treatment and disposal system (OSDS) duties, to: specifically authorize DOH regulation of onsite sewage treatment and disposal systems that receive an estimated commercial sewage flow of 5,000 gallons or less per day (as authorized in existing Rule 64E-6.002 (13) and (27), FAC, and per an interagency agreement with the Department of Environmental Protection); specify the rules DOH may adopt regarding portable and temporary toilet services and holding tanks; specifically authorize operating permits and annual inspections for those facilities using aerobic treatment units or generating commercial waste; require political subdivisions to issue a building or plumbing permit for a building using an OSDS only if the owner or builder has received an OSDS construction permit from DOH; prohibit building or structure occupancy until DOH approves the OSDS installation; and prohibit building change in occupancy until DOH has reviewed the change and suitability for OSDS use.

Section 8. Amends s. 381.0072(1)(b) and (2)(a), F.S., relating to DOH food service protection functions, to add to the definition of “food service establishment” facilities used at temporary food events, mobile food units, and vending machines at any facility regulated under this section; and to specify the content of DOH rules regarding sanitary standards for food service establishments.

Section 9. Amends s. 381.008(5) and (8), F.S., relating to definitions used in the regulation of migrant labor housing, to exclude from the definition of “migrant labor camp” a single family residence occupied by a single family; and clarify the definition of “residential migrant housing” with regard to the inclusion of mobile homes and proximity and ownership of certain housing stock.

Section 10. Amends s. 381.0083, F.S., relating to migrant housing permits, to require that those persons planning to construct, enlarge, remodel, use, or occupy, or convert property for use as a migrant labor camp or residential migrant housing to give DOH 45-day prior notice, and to require new owners of migrant housing to give DOH 15-day prior notice.

Section 11. Amends s. 381.0086(1), F.S., relating to migrant housing rules and variances, to include roads as a rule topic.

Section 12. Amends s. 381.0087(1) and (2), F.S., relating to migrant housing enforcement and citations, to specify a 48-hour period for the correction of major deficiencies, as defined by DOH rule, and to specify that continual or repeat violations of the same requirement will result in the issuance of a citation.

Section 13. Amends s. 381.0098(2)(b), (3), (4)(a), (d), and (f), and (7), F.S., relating to biomedical waste regulation by DOH, to: provide an exemption from the definition of “biomedical waste generator” for those funeral homes that do perform embalming; include in operating standards written operating plans for managing biomedical waste; exempt from a separate permit any generator working less than 6 hours per week in a location different than the permit location; specify that transfers of ownership be made known to DOH in the timeframe and manner

prescribed by DOH rule; provide for prorating of fees; and codify existing enforcement provisions.

Section 14. Amends s. 381.0101(2)(d), (f), and (g), (4)(b), (5), and (7), F.S., relating to environmental health professionals, to: authorize DOH to define, by rule, environmental health and sanitary conditions; authorize personnel to be field, supervisory, or administrative staff; include “Registered Environmental Specialist” as recognized personnel; authorize the DOH advisory board to establish disciplinary guidelines; specify what is to be included in DOH certification rules; include public health courses as acceptable towards certification; provide a period of time for change of address notice to DOH; and reduce the minimum fee amount from \$25 to \$10.

Section 15. Amends s. 381.89(4)(b), (6)(a), and (13), F.S., relating to tanning facilities, to: require facilities to have their most recent inspection report available to the public; specify that operators be trained in accordance with DOH rules; and specify the content of DOH rules.

Section 16. Amends s. 383.011(1) and (2), F.S., relating to maternal and child health programs administered by DOH, to: correct the name of the WIC program; authorize DOH to receive funds for administering certain federal children’s food programs; and authorize DOH to adopt specific rules for administering maternal and child health programs and the WIC program.

Section 17. Amends s. 384.33, F.S., relating to DOH rules for sexually transmissible diseases (STD), to authorize DOH to include in its rule requirements for methods of contact tracing and confidentiality.

Section 18. Amends s. 384.34(4), F.S., relating to DOH STD penalties, to specifically authorize DOH to enforce the provisions of the section and adopt rules to administer the section.

Section 19. Amends s. 401.26, F.S., relating to emergency medical services (EMS) vehicle permits, to: include in permit requirements those aircraft used in EMS transport; exempt from permit requirements those vehicles the use of which is limited to scene supervision, incident command, or supply augmentation; authorize DOH to establish criteria and time limits for substitution of vehicles out of service for maintenance; and authorize DOH to adopt and enforce rules to administer this section.

Section 20. Amends s. 401.265, F.S., relating to EMS medical directors, to authorize DOH to adopt and enforce rules to administer this section.

Section 21. Amends s. 401.30, F.S., relating to EMS records, to authorize DOH to adopt and enforce rules to administer this section.

Section 22. Amends s. 403.0625, F.S., relating to environmental laboratory certification and water quality tests conducted by certified laboratories, to: incorporate technical revisions; authorize DOH to adopt and enforce rules to administer this section and specifying the topics to be

addressed by rule; specifying those actions which constitute the grounds for disciplinary action and the penalties that can be imposed for the actions; and specify that the certification program be governed by ch. 120, FS.

Section 23. Amends s. 403.863, F.S., relating to the state public water supply laboratory certification program, to: incorporate technical revisions; specify the applicability of this section to those laboratories which conduct a water-analysis business; authorize DOH to adopt and enforce rules to administer this section and specifying the topics to be addressed by rule; specifying those actions which constitute the grounds for disciplinary action and the penalties that can be imposed for the actions; and specify that the certification program be governed by ch. 120, F.S.

Section 24. Amends s. 404.056(3), F.S., relating to certification requirements for persons performing radon measurements, to: require certification for any radon measurement or mitigation purposes; authorize DOH to establish criteria for the application, certification, and annual renewal of such individuals, including education, experience, training, examinations, and reporting, as well as training programs; provide for expiration of a certification; authorize contractual arrangements between certified and uncertified commercial businesses, including test reporting; require reporting of mitigation testing results, including report contents; and authorize DOH to establish criteria for the application, certification, and annual renewal of certification for radon measurement and mitigation businesses, including detailed requirements.

Section 25. Amends s. 404.22(1) and (2), F.S., relating to radiation machines and components, to specify additional criteria to be reviewed by DOH when inspecting radiation machines, and require those who install or service radiation machines to register and apply with DOH, using DOH forms.

Section 26. Amends s. 468.306(2), F.S., relating to radiologic technology examinations, to require applicants for examination to apply at least 75 days prior to examination date, or take a subsequently scheduled examination.

Section 27. Amends s. 489.553(4)(d), F.S., relating to septic tank contractor registration, to allow the inclusion of out-of-state work experience for those contractors licensed in another state, provided examination and continuing education requirements are comparable to those in this state; and authorizing a person employed by and under the supervision of a licensed contractor to be granted up to 2 years of related work experience.

Section 28. Amends s. 489.555(1), F.S., relating to certification of septic tank contractor partnerships and corporations, to clarify that one septic tank contractor may not be the sole qualifying contractor for more than one company; and to grant companies a 60-day period to employ a qualifying contractor when a company loses its qualifying contractor.

Section 29. Amends s. 499.005, F.S., relating to prohibited acts under the Florida Drug and Cosmetic Act, to add the notion of constructive refusal for certain actions of DOH as an illegal

act, and to add obtaining or attempting to obtain a prescription drug or device by fraud as a prohibited act.

Section 30. Amends s. 499.01(1), F.S., relating to Florida Drug and Cosmetic Act permits, to: authorize a restricted-distributor permit to a health care entity under the name of that entity's institutional pharmacy permit; prohibit the issuance of a prescription drug manufacturer, prescription drug wholesaler, or retail pharmacy wholesaler permit to the address of a health care entity; and authorizing a permitted person to change the type of permit issued, provided certain requirements are met.

Section 31. Amends s. 499.012, F.S., relating to wholesale distribution of drugs, to: incorporate technical revisions; specify that certain acts do not constitute wholesale distribution of drugs; authorize DOH to adopt rules regarding the issuing of a prescription drug wholesaler-broker permit for certain circumstances; and authorize DOH to adopt additional rules regarding the distribution of prescription drugs.

Section 32. Amends s. 499.0121, F.S., relating to storage and handling of prescription drugs, to incorporate technical revisions and to exempt from after-hours alarm system requirements entities permitted as prescription drug wholesaler-brokers and establishments that only handle medical oxygen.

Section 33. Amends s. 499.0122(1)(a) and (d), F.S., relating to medical oxygen and veterinary legend drug retail establishments, to require a medical oxygen retail establishment that refills medical oxygen to comply with all appropriate state and federal good manufacturing requirements, and to authorize DOH to adopt by rule additional labeling requirements for the sale of veterinary legend drugs.

Section 34. Amends s. 499.013(2)(e), F.S., relating to manufacturers of drugs, devices, and cosmetics, to delete the limitation that DOH rules adopted under the authority of this section only apply to cosmetics.

Section 35. Amends s. 499.014, F.S., relating to the distribution of legend drugs by hospitals, health care entities, and charitable organizations, to include comparable permitting requirements for a restricted prescription drug distributor, limited to certain specific activities.

Section 36. Amends s. 499.015, F.S., relating to registration of drugs, devices, and cosmetics, to specify that a product registration is company specific, and to impose certain notice requirements on such registrants.

Section 37. Amends s. 499.03, F.S., relating to the illegality of possessing a new drug or legend drugs without prescriptions, to authorize DOH to adopt a rule authorizing persons engaged in lawful teaching research, and testing to possess prescription drugs, and to authorize DOH to issue letters of exemption to facilitate this process.

Section 38. Amends s. 499.05, F.S., relating to DOH rules under the Florida Drug and Cosmetic Act, to authorize DOH to adopt rules regulating the storage and handling of medical devices and over-the-counter drugs, and the maintenance of distribution records to protect the public from adulterated products.

Section 39. Amends s. 499.65, F.S., relating to the prohibition of the possession of ether without a license or a permit, to authorize DOH to adopt a rule authorizing persons engaged in lawful research and testing to possess ether, and to authorize DOH to issue letters of exemption to facilitate this process.

Section 40. Amends s. 499.66(2), F.S., relating to maintenance of records for sales of ether, to delete the threshold of 2.5 gallons, below which no records are required, thus requiring all ether transactions to be recorded.

Section 41. Amends s. 499.67(1), F.S., relating to the maintenance of records relating to ether, to make it illegal for any *person*, rather than any *permittee*, to purchase, receive, store, or use ether without maintaining an inventory of same.

Section 42. Amends s. 501.122(1)(e) and (2), F.S., relating to nonionizing radiation and lasers, to incorporate technical revisions, and authorize DOH performance standards to include: qualifications, duties, and training of users; posting of warning signs and labels for facilities and devices; recordkeeping; and reporting.

Section 43. Amends s. 513.045(1)(b), F.S., relating to permit fees for mobile home and recreational vehicle parks, to specify that the permit fee for a nonexempt recreational camp be based on an equivalency rate for which two camp occupants equals one space, and to provide for the prorating of fees on a quarterly basis.

Section 44. Amends s. 513.05, F.S., relating to DOH rules for mobile home and recreational vehicle parks, to include park *modifications* in the rule requirements, and to specify rule topics.

Section 45. Amends s. 514.011, F.S., relating to definitions applicable to public swimming and bathing facilities, to add a definition for “portable pool.”

Section 46. Amends s. 514.0115, F.S., relating to public swimming and bathing facilities’ exemptions from supervision or regulation, to provide for DOH rules relating to variances from regulations for public swimming and bathing facilities.

Section 47. Amends s. 514.03, F.S., relating to DOH approval for public swimming and bathing facilities’ construction, to specify that plan approvals are valid for one year from the date of approval if construction is not commenced during the one-year period.

Section 48. Amends s. 514.031(5) and (6), F.S., relating to permits for operation of public swimming pools or bathing places, to require a permit to be posted in a conspicuous place, and to prohibit a portable pool from being used as a public pool.

Section 49. Amends s. 514.033(4) and (5), F.S., relating to fees for public swimming and bathing facilities, to specify that such fees are nonrefundable, and to provide for the prorating of the initial annual fee on a half-year basis.

Section 50. Amends s. 514.05, F.S., relating to denial, suspension, or revocation of a permit for a public swimming and bathing facility, to authorize DOH to adopt by rule the conditions under which a public pool may be closed when not in compliance with this chapter or rules adopted thereunder.

Section 51. Provides for a July 1, 1998, effective date.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Subsections 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.
