

STORAGE NAME: h2315.hcl

DATE: April 5, 2000

**HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE LICENSING & REGULATION
ANALYSIS**

BILL #: HB 2315 (PCB HCL 00-06)

RELATING TO: Rulemaking Authority for the Department of Health

SPONSOR(S): Committee on Health Care Licensing & Regulation and Representative Fasano

TIED BILL(S):

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:

(1) HEALTH CARE LICENSING & REGULATION YEAS 13 NAYS 0

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I. SUMMARY:

Section 120.536, F.S., establishes that a grant of rulemaking authority is necessary but not sufficient to allow an agency to adopt a rule; a specific law to be implemented is also required. As a result, state agencies are required to review the statutory authority they have for rulemaking and determine if sufficient authority exists for their rules or proposed rules.

For any rules or proposed rules that may be lacking in this authority, the Legislature shall, at the 2000 Regular Legislative Session, consider whether specific legislation authorizing the identified rules, or portions thereof, should be enacted.

This bill amends those sections of the Florida Statutes where a portion of the rule may exceed statutory authority permitted as determined by the Department of Health and the Agency for Health Care Administration (AHCA). This rule authorizing bill seeks to correct any deficiencies noted by establishing specific authority in statute. **Please see Section II.D, Section-by-section Analysis, for details.**

It is not anticipated that this legislation will have a financial impact beyond current appropriated funds.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

- | | | | |
|-----------------------------------|------------------------------|-----------------------------|---|
| 1. <u>Less Government</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 2. <u>Lower Taxes</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 3. <u>Individual Freedom</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 4. <u>Personal Responsibility</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 5. <u>Family Empowerment</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |

For any principle that received a "no" above, please explain:

B. PRESENT SITUATION:

Rulemaking Authority

In 1996, the Legislature significantly revised the Administrative Procedure Act (APA) which was designed to require executive branch agencies to more closely adhere to statutory authority when agencies adopt rules. The 1996 amendments contained a new section, s. 120.536(1), F.S., requiring existing and proposed rules to implement, interpret or make specific the particular powers and duties granted by the enabling statute. This "map-tack" provision ensures that agency rules closely relate to the enabling statute and, thus, imposes a more stringent standard.

The Legislature recognized that imposing a new statutory standard to determine the validity of rules might suddenly invalidate many rules which had previously been adopted by the agency in good faith under the older, more lenient standard. Rather than immediately invalidate existing rules, the 1996 reform legislation required each agency to examine all of its rules that had been adopted prior to the effective date of the 1996 amendments in light of the new "map-tack" provision. Agencies were required to report to the Joint Administrative Procedures Committee the list of rules which exceeded the new "map-tack" standard.

Rules placed on the list were temporarily "shielded" from legal challenges that they are invalid under the new "map-tack" provision. This "shield" left the rules in place during the 1998 legislative session, allowing the Legislature to examine the policy established by rule to determine if it is good public policy. If legislation enacted during the 1998 session provided statutory support for the rule, it remained in effect. On the other hand, the statute directed the agency to initiate repeal of any rule for which there is no authorizing legislation by January 1, 1999. Notably, an existing agency rule successfully challenged under the new APA for lack of statutory authority requires that the agency discontinue its reliance on the rule and the agency may have to pay attorney's fees and costs.

Subsequent to the 1996 amendments to the APA, several appellate cases have sought to interpret the "map-tack" standard. In *St. Johns River Water Management District v. Consolidated-Tomoka Land Co., et al*, 717 So.2d 72 (Fla. 1st DCA July 29, 1998), the petitioner land owners challenged proposed rules of the District that would create a regulatory subdistrict in the Spruce Creek and Tomoka River Hydrologic Basins, and would

create new standards for managing and storing surface waters in developments within this basin. *Tomoka* at 717 So.2d 75. An Administrative Law Judge (ALJ) in the Division of Administrative Hearings held that although the proposed rules were not arbitrary or capricious, were supported by competent and substantial evidence, and substantially accomplished the statutory objectives, the rules were invalid as a matter of law because the rules lacked the underlying statutory detail required by the new rulemaking standard in ss. 120.52(8) and 120.536(1), F.S. *Id.* at 76. The District appealed on this issue.

The First District Court of Appeal reversed the ALJ's final order, holding the proposed rules valid. In doing so, the court applied a "functional test based on the nature of the power or duty at issue and not on the level of detail in the language of the applicable statute." *Tomoka* at 717 So.2d 80.

The question is whether the rule falls within the range of powers the Legislature has granted to the agency for the purpose of enforcing or implementing the statutes within its jurisdiction. A rule is a valid exercise of delegated legislative authority if it regulates a matter directly within the class of powers and duties identified in the statute to be implemented.

Id. In applying this test, the court found that delegated legislative authority was to identify geographic areas that require greater environmental protection and to impose more restrictive permitting requirements in those areas. *Id.* at 81. The challenged rules fell within the class of powers delegated by the statute and therefore were a valid exercise of delegated legislative authority. *Id.*

The 1999 Legislature amended the Administrative Procedure Act (APA) to provide that an agency may only adopt rules that implement or interpret "specific powers and duties" granted by statute. Chapter 99-370, Laws of Florida, clarified the rulemaking standard to reflect the Legislature's intent to limit the authority of agencies to adopt rules. The 1999 revision rejected the judicial interpretation in the *Consolidated-Tomoka* case which created a functional test to determine whether a challenged agency rule is directly within their class of powers and duties. The Legislature again recognized that revising the standard to determine the validity of rules might suddenly invalidate many rules which had been adopted or reviewed under a different interpretation of the 1996 standard. Consequently, ch. 99-370 provided for another round of rule review and authorization. Agencies reviewed existing rules and provided in October 1999, to the Joint Administrative Procedures Committee (JAPC) a list of rules adopted before June 18, 1999, which exceed the new standards for rulemaking authority found in s. 120.536(1), F.S. The Legislature will consider in the 2000 Regular Session specific legislation that would authorize the identified rules. For those rules not authorized, the agencies are to initiate repeal proceedings by January 1, 2001. The JAPC or any substantially affected person may petition for repeal of an identified rule after July 1, 2001.

C. EFFECT OF PROPOSED CHANGES:

Please see Section II.D, below, Section-by-section analysis.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Amends s. 154.011, F.S., to grant authority to the department to promulgate certain rules relating to the operation of primary care programs.

Section 2. Amends s. 154.06, F.S., to include certain provisions in establishing fee schedules for public health services rendered through the county health departments.

Section 3. Amends s. 381.003, F.S., to authorize rules relating to the prevention and control of communicable diseases to include procedures for the management of specific diseases.

Section 4. Amends s. 381.004, F.S., to authorize rules implementing provisions for the testing of human immunodeficiency virus to include certain provisions.

Section 5. Amends s. 381.0051, F.S., to authorize rules relating to family planning to include certain provisions.

Section 6. Amends s. 381.0056, F.S., to authorize rules relating to the school health services program to include certain provisions.

Section 7. Amends s. 381.0057, F.S., to require services provided by comprehensive school health projects to focus on promoting student health and reducing risk-taking behavior and teen pregnancy and to declare that school health service funding provisions are supplemental to other provisions.

Section 8. Amends s. 381.006, F.S., to authorize rules relating to group-care facilities to include certain provisions.

Section 9. Amends s. 381.0062, F.S., to exempt certain public water systems from obtaining an annual permit.

Section 10. Amends s. 381.0065, F.S., to revise the definition of "onsite sewage treatment and disposal system" and to include certain provisions in the rules administering regulation of onsite sewage treatment and disposal systems. Revises the duties of the department relating to such regulation to include reference to the use and operation of sewage treatment and disposal systems.

Section 11. Amends s. 381.0072, F.S., to authorize rules creating minimum sanitation standards and manager certification requirements regarding food service establishments to include certain provisions.

Section 12. Amends s. 381.0086, F.S., to authorize rules relating to protection of the health and safety of migrant farm workers and other migrant laborers to cover field sanitation facilities and to include certain other provisions.

Section 13. Amends s. 381.0098, F.S., to authorize rules relating to regulation of biomedical waste to include certain provisions, to revise provisions relating to application for and transfer of biomedical waste permits, to prohibit the transfer of registration from one biomedical waste transporter to another, and to provide for application requirements for registration of such transporters when a change of ownership or name occurs.

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Section 14. Amends s. 381.0101, F.S., to authorize rules relating to certification of environmental health professionals to include definitions.

Section 15. Amends s. 381.02023, F.S., to authorize the adoption of rules to implement the pharmacy services program.

Section 16. Amends s. 381.89, F.S., to authorize rules implementing regulation of tanning facilities to include definitions and to provide for issuance of a stop-use order to remove a tanning device from service.

Section 17. Amends s. 383.011, F.S., to authorize rules administering the maternal and child health care program to include certain provisions.

Section 18. Amends s. 383.14, F.S., to authorize rules administering the infant metabolic screening program to include definitions.

Section 19. Amends s. 383.19, F.S., to authorize rules relating to standards for development and operation of a regional perinatal intensive care center to include certain provisions.

Section 20. Amends s. 383.216, F.S., to authorize rules implementing regulation of community-based prenatal and infant health care coalitions to include certain provisions and to provide that these coalitions need not be recognized as having federal tax exempt status.

Section 21. Amends s. 384.33, F.S., to authorize rules relating to control of sexually transmissible diseases to include certain provisions.

Section 22. Amends s. 385.207, F.S., to authorize rules relating to care and control of epilepsy to include certain provisions.

Section 23. Amends s. 391.026, F.S., to authorize rules implementing the Children's Medical Services Act to include certain provisions.

Section 24. Amends s. 392.66, F.S., to authorize rules relating to tuberculosis control to include certain provisions.

Section 25. Amends s. 395.401, F.S., to provide for the establishment by rule of processes and procedures for the formation and approval of trauma agencies, minimum requirements for conduct, and the submission of annual performance evaluations.

Section 26. Amends s. 395.402, F.S., to provide for the allocation by rule of the number of trauma centers needed for each trauma service area.

Section 27. Amends s. 401.35, F.S., to require rules relating to the regulation of medical transportation services to include definitions and requirements relating to staffing for air ambulance services, certificates of convenience and necessity, medical direction, and licensure and certification.

Section 28. Amends s. 403.862, F.S., to authorize rules relating to regulation of private and public water systems to include definitions.

Section 29. Amends s. 404.056, F.S., to provide for basic and advanced levels of certification to perform radon gas or radon progeny measurements, to authorize establishment of enforcement procedures and denial of applications for initial certification, and to provide other certification requirements.

Section 30. Amends s. 404.22, F.S., to provide for the adoption of rules relating to inspection of and standards for radiation machines and their operation.

Section 31. Amends s. 489.553, F.S., to provide for adoption of rules to implement provisions regulating septic tank contracting.

Sections 32-33. Amend ss. 491.006 and 491.0145, F.S., to provide that application fees for licensure as a clinical social worker, marriage and family therapist, or mental health counselor are nonrefundable.

Section 34. Amends s. 499.03, F.S., to define “distribute” or “distribution” for purposes of the Florida Drug and Cosmetic Act.

Sections 35-36. Amend ss. 499.024 and 499.03, F.S., to revise certain cross references.

Section 37. Amends s. 499.005, F.S., to prohibit the charging of a dispensing fee for a prescription drug sample and to prohibit the dispensing, administering, or distributing of an investigational drug except pursuant to an approved protocol.

Section 38. Reenacts s. 499.069, F.S., relating to s. 499.005, F.S., to incorporate the amendment to that section and to provide penalties.

Section 39. Amends s. 499.054, F.S., to provide that the representation or suggestion in advertising that an article is approved under the Florida Drug and Cosmetic Act is a violation of such act and to provide penalties.

Section 40. Amends s. 499.01, F.S., to require submission of the name and address of a contact person regarding access to records required to be maintained under the Florida Drug and Cosmetic Act when a permitted establishment closes.

Section 41. Amends s. 499.0121, F.S., to require vehicles containing prescription drugs to be secured from unauthorized access to such drugs.

Section 42. Amends s. 499.0122, F.S., to provide for the adoption of rules relating to prescription or order requirements for medical oxygen and veterinary legend drug retail establishments.

Section 43. Amends s. 499.013, F.S., to provide that a device manufacturer’s permit is not required if the person is engaged only in the manufacture or assembly of medical devices pursuant to a practitioner’s order for a specific patient and to require manufacturers of devices, over-the-counter drugs, or cosmetics to maintain certain records.

Section 44. Amends 499.015, F.S., to prohibit the registration of products not in compliance with the Federal Food, Drug, and Cosmetic Act and related federal regulations and to declare that registration does not mean compliance with all provisions of the act. Revises certain cross references.

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Section 45. Amends s. 499.05, F.S., to restrict rules that implement and enforce the Florida Drug and Cosmetic Act to certain provisions.

Section 46. Amends s. 499.701, F.S., to revise provisions relating to rules administering the regulation of ether to include certain requirements relating to radiation surveys.

Section 47. Amends s. 501.122, F.S., to authorize performance standards for lasers and other radiation control to include certain provisions.

Section 48. Amends s. 513.05, F.S., to authorize rules regulating mobile home parks, lodging parks, recreational vehicle parks, and recreational camps to include definitions.

Section 49. Amends s. 514.021, F.S., to authorize rules regulating public swimming and bathing facilities to include definitions.

Section 50. Amends s. 766.1115, F.S., the Access to Health Care Act, to revise the definition of "health care provider" and revise contract requirements to cover instances in which a treated individual is later found to be ineligible, to require acknowledgment in writing of receipt of the notice of agency relationship, and to authorize rules implementing the act to include services to be provided.

Section 51. Provides an effective date of upon becoming law.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

It is not anticipated that this legislation will have a financial impact beyond current appropriated funds.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

The bill does not require counties or municipalities to expend funds or take action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority that municipalities or counties have to raise revenue in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of state tax shared with counties or municipalities.

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

None.

B. RULE-MAKING AUTHORITY:

This bill establishes rulemaking authority to comply with s. 120.536, F.S.

C. OTHER COMMENTS:

None.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

None.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE LICENSING & REGULATION:

Prepared by:

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