

**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.)

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Prepared By: The Professional Staff of the Health and Human Services Appropriations Committee

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BILL: CS/SB 2618

INTRODUCER: Health Regulation Committee and Senator Jones

SUBJECT: Public Health

DATE: April 8, 2008

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Garner	Wilson	HR	<b>Fav/CS</b>
2.	Fabricant	Peters	HA	<b>Favorable</b>
3.				
4.				
5.				
6.				

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**Please see Section VIII. for Additional Information:**

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|------------------------------|-------------------------------------|---|
| A. COMMITTEE SUBSTITUTE..... | <input checked="" type="checkbox"/> | Statement of Substantial Changes        |
| B. AMENDMENTS.....           | <input type="checkbox"/>            | Technical amendments were recommended   |
|                              | <input type="checkbox"/>            | Amendments were recommended             |
|                              | <input type="checkbox"/>            | Significant amendments were recommended |

**I. Summary:**

The bill repeals the requirement that the Department of Health (DOH or department) conduct environmental health programs in all places used for the incarceration of prisoners and inmates, unless it is a state institution for the mentally ill. The bill repeals the requirement that the Institutional Review Board (IRB) within the DOH review all biomedical and behavioral research on human subjects which is funded or supported in any manner by the department, conforming the role of the department's IRB to federal regulations and guidance. The bill repeals the Florida Biomedical and Social Research Board, its functions and duties. The bill also repeals the requirement that the DOH establish maximum allowable levels for contaminants in compressed air for recreational diving, and the requirement that persons or entities that provide compressed air for recreational diving submit a copy of their air quality testing results on a quarterly basis to the DOH.

This bill amends ss. 381.006 and 381.86, F.S., and repeals ss. 381.85 and 381.895, F.S.

## **II. Present Situation:**

### **Environmental Health Programs in Correctional Facilities**

Section 381.006, F.S., requires the DOH to conduct environmental health programs as part of its responsibility to protect the public health. These programs include surveillance and enforcement of regulations pertaining to issues as broad as drinking water to biohazardous waste management to disease quarantines. One of the department's functions is to ensure sanitary practices relating to state, county, municipal, and private institutions serving the public.<sup>1</sup>

Chapter 64E-26, Florida Administrative Code (F.A.C.), was promulgated to implement the public facilities function in s. 381.006, F.S., establishing standards for sanitary practices relating to the construction, operation and maintenance of state and local detention facilities. The standards address: water supply; food service operations; waste water disposal; plumbing fixture requirements; storage, collection and disposal of garbage and rubbish; design of housing areas; laundry and dry cleaning; bedding, clothing and personal items; housekeeping; insect and rodent control; and outdoor areas.<sup>2</sup>

The DOH does not have specific statutory authority to perform routine physical plant inspections of state or local detention facilities to assess compliance with all of the standards addressed in Chapter 64E-26, F.A.C. However, the DOH does have specific authority to do certain kinds of inspections such as food service and biomedical waste. These inspections are performed by the DOH's county health department staff located in each of the 67 counties.

Under a memorandum of agreement with the Florida Department of Corrections (DOC), the DOH refers environmental health complaints that it receives against state detention facilities to the DOC. The DOC has the authority the DOH lacks to inspect their own facilities and follow-up on the referred complaints. The DOC also has stand-alone environmental health standards that apply to its detention facilities.

### **The DOH's Institutional Review Board and the Florida Biomedical and Social Research Board**

An institutional review board/independent ethics committee (IRB/IEC) (also known as ethical review board) is a group of medical professionals, researchers, or professional experts in a particular field of study that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the goal of protecting the rights and welfare of the subjects.

In the United States, regulations protecting human subjects first became effective on May 30, 1974. Promulgated by the Department of Health, Education and Welfare (DHEW), those regulations raised to regulatory status National Institutes of Health's (NIH's) Policies for the Protection of Human Subjects, which were first issued in 1966. The regulations established the IRB as one mechanism through which human subjects would be protected.<sup>3</sup>

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<sup>1</sup> S. 381.006(6), F.S.

<sup>2</sup> Found at: <https://www.flrules.org/gateway/ChapterHome.asp?Chapter=64E-26> (last visited on March 16, 2008).

<sup>3</sup> Found at: [http://www.hhs.gov/ohrp/irb/irb\\_introduction.htm](http://www.hhs.gov/ohrp/irb/irb_introduction.htm) (last visited on March 16, 2008).

In Florida, the DOH operates an IRB under the Ethics and Human Research Protection Program pursuant to s. 381.86, F.S., in order to satisfy the federal requirements under 45 C.F.R. part 46 and 21 C.F.R. parts 50 and 56. In this role, the Ethics Program has a mission of protecting volunteers in research and developing capacity to assess, analyze and resolve ethical issues in public health practice. The program provides education and support for the department's IRB, technical assistance and regulatory analysis concerning research ethics, ethics consultations concerning public health ethics, and ethical issues in public health practice.<sup>4</sup>

The DOH conducts IRB review of all research involving human subjects according to requirements in federal regulations to protect the health and safety of Floridians participating in research and to maintain public trust. An IRB review is required for the DOH to receive federal grants and funding.

Review by the IRB is required by federal law when the DOH is engaged in research (department staff directly conducts research), but not when the only involvement of the DOH is funding research through a grants-in-aid program or a statutory pass through of state dollars to another entity. Based on new federal guidelines, the department's IRB will not review human subject research funded by these types of mechanisms.

The NIH funds two types of research: intramural (the NIH funds its own employees' research) and extramural (the NIH awards grants to fund research at other institutions). The NIH uses its own IRB to review intramural research, but not extramural research. Instead, the NIH requires a review of extramural research by the grantee's institution.

The grants-in-aid programs administered by the DOH and the pass-through of funds to external entities are considered extramural projects, and as such, the department's IRB no longer has to review all research conducted with funds passing through the department. The DOH will continue to require a review of extramural research by the IRB at the institution receiving funding.

Florida also has the Florida Biomedical and Social Research Board pursuant to s. 381.85, F.S. Created in 1975, after the first federal regulations were enacted to address the use of human subjects, the board is responsible for developing criteria for human subject research guided by the ethical standards for human research set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. However, over the years, the functions and activities of the board have often overlapped with those of the department's IRB which was put into statute to conform with federal law. As such, the Board and the IRB exist in conflicting statutes that the department believes should be resolved.

### **Standards for Compressed Air Use for Recreational Diving**

Compressed air has many applications, including its use in Self-Contained Underwater Breathing Apparatus (SCUBA) for recreational diving in Florida. Clean, natural air is an odorless, colorless

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<sup>4</sup> Ethics and Human Research Protection Program, Florida Department of Health. Found at <http://flpublichealthethics.net/> (last visited on March 16, 2008).

gas mixture. Excluding water vapor (H<sub>2</sub>O) levels, which vary greatly, three major elements make up about 99.97 percent of dry air: nitrogen (N<sub>2</sub>) at 78.09 percent, oxygen (O<sub>2</sub>) at 20.95 percent and argon (Ar) at 0.93 percent. An important minor component of natural air is carbon dioxide (CO<sub>2</sub>) at 0.03 percent (300 ppm). Trace gases in clean, natural air include: methane (CH<sub>4</sub>) at 0.0002 percent (2 ppm) and less than 0.0001 percent (1 ppm) of hydrogen (H<sub>2</sub>), nitrous oxide (N<sub>2</sub>O), ozone (O<sub>3</sub>) and some noble gases. Synthetic air is also used in SCUBA applications. This type of air is produced by blending N<sub>2</sub> and O<sub>2</sub> gas in the proper proportions.<sup>5</sup>

Compressed air contamination can have many causes including industrial emissions near the compression equipment, vehicle exhaust, combustion heating activities and local environmental conditions. These factors can all seriously degrade the quality of intake air used during compression. Compressor equipment, malfunctions and poor maintenance or operational practices can also introduce contaminants into SCUBA air tanks. Many of these factors can be avoided or controlled by proper compression procedures and equipment (i.e., CO<sub>2</sub> filters). If however, these procedures are not followed, compressed air contamination can result in gas toxicity, which could lead to illness or death.

Florida law<sup>6</sup> requires the DOH to establish maximum levels of contaminants in compressed air used for recreational sport diving. Persons and entities providing compressed air for sports diving are required to ensure that the compressed air they provide is tested quarterly by a laboratory that is accredited by either the American Industrial Hygiene Association or the American Association for Laboratory Accreditation and that the results of such tests are provided quarterly to the DOH. The DOH is required to maintain these test results, but is not required to assess their validity or accuracy.

However, the DOH states that the requirement is obsolete. It reports that since enactment of this section in 1999, the DOH has collected approximately 9,000 quarterly test reports from approximately 250 commercial compressed air providers in Florida. To date, no reports show any contamination of compressed air sold by the dive shops, nor has the DOH received any reports of injury, illness, or death associated with contaminated compressed air.

### III. Effect of Proposed Changes:

**Section 1.** Amends s. 381.006, F.S., repealing the requirement that the DOH conduct environmental health programs in all places used for the incarceration of prisoners and inmates, unless it is a state institution for the mentally ill. The DOC will continue to enforce environmental health standards in these facilities.

**Section 2.** Amends s. 381.86, F.S., repealing the requirement that the Institutional Review Board within the DOH review all biomedical and behavioral research on human subjects which is funded or supported in any manner by the department. This language is sometimes inconsistent with recent federal guidance on when the DOH IRB approval is required. The DOH will

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<sup>5</sup> Found at

<http://www.libertymutual.com/omapps/ContentServer?cid=1058291359083&pagename=CMInternet%2FPage%2FCorpGene ricDarkBlue&c=Page> (last visited on March 16, 2008).

<sup>6</sup> S. 381.895, F.S.

continue to use its IRB for research it conducts and will require grantees to use the IRB at the institution receiving the funding.

**Section 3.** Repeals s. 381.85, F.S., pertaining to the Florida Biomedical and Social Research Act. Specifically, the bill repeals: legislative intent regarding how research on human beings funded by the department is to be conducted; the creation and function of the Review Council for Biomedical and Social Research; the requirement that all research conducted on human beings conducted under the authority of the department be reviewed by the Review Council for Biomedical and Social Research; and the rule-making authority pertaining to this section. This section is in conflict with s. 381.86, F.S., under which the DOH IRB operates.

The bill also repeals s. 381.895, F.S., pertaining to: the requirement that the DOH establish maximum levels of contaminants in compressed air used for recreational sport diving; limitations on the application of these standards; the requirement that each person or entity providing compressed air for sports diving conduct a quarterly test for contaminants which are certified and reported to the DOH; the requirement that the DOH maintain these test results; the penalties associated with providing compressed air without having valid certification or posting the certification; and the rule-making authority necessary to carry out the provisions of this law.

**Section 4.** The bill provides an effective date of July 1, 2008.

#### **IV. Constitutional Issues:**

##### **A. Municipality/County Mandates Restrictions:**

The DOH reports that while the repeal of the provision of environmental programs in places used for the incarceration of prisoners and inmates does apply to county jails and Juvenile Justice facilities, the department never had an enforcement role in those environmental programs beyond setting standards, and do not inspect those facilities. Based on this information, it appears that 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, Section 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. Fiscal Impact Statement:**

##### **A. Tax/Fee Issues:**

None.

**B. Private Sector Impact:**

The repeal of s. 381.895, F.S., will relieve 250 Florida dive shops of the expense involved in sampling compressed air quality quarterly and submitting testing results to the DOH. The total fiscal impact is indeterminate at this time.

**C. Government Sector Impact:**

These changes in the bill should reduce administrative cost within the DOH. The amount of administrative reductions that will be achieved by the DOH are likely minimal and are indeterminate at this time.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Additional Information:****A. Committee Substitute – Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

**CS by Health Regulation on March 19, 2008:**

The CS corrects the title to reflect the elimination of DOH's environmental health program responsibility for sanitary practices in places used for the incarceration of prisoners and inmates.

**B. Amendments:**

None.