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 Health Regulation Committee

BILL:	CS/SB 1006
INTRODUCER:	Health Regulation Committee and Senator Latvala
SUBJECT:	Health Care
DATE:	February 24, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wilson	Stovall	HR	**Fav/CS**
2.			CM	
3.			BC	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

The bill requires licensed hospitals and birth centers that provide maternity and newborn care to screen all newborns, prior to discharge, for Critical Congenital Heart Disease (CCHD). For home births, the health care provider in attendance is responsible for the screening. A parent or legal guardian may object to the screening, in which case the screening must not be completed. The bill defines "screening" and requires hospitals and birth centers to designate certain licensed practitioners to be responsible for programmatic oversight of the screening and to ensure that appropriate referrals are completed.

The bill modifies several definitions used in part I of chapter 499, F.S., the Florida Drug and Cosmetic Act (the Act), and organizes various exceptions to the permit requirements into a single subsection. It eases existing restrictions on the limited distribution of active pharmaceutical ingredients to Florida permitted prescription drug manufacturers and restrictions on prescription drug distributions to permitted prescription drug manufacturers and researchers.

The bill authorizes dentists to purchase prescription drugs through a professional corporation or limited liability company composed of dentists and still be exempt from the requirement to obtain a health care clinic establishment permit. The bill provides an exemption from the

prescription drug repackager permit requirement and the product registration requirements for a restricted prescription drug distributor permitholder that is a health care entity that repackages prescription drugs in this state for its own use or distributes prescription drugs to a hospital or other health care entity in the state for its own use if it meets certain conditions.

This bill substantially amends the following sections of the Florida Statutes: 499.003 and 499.01. The bill creates s. 383.146, F.S.

II. Present Situation:

Congenital Heart Disease

Congenital Heart Disease (CHD) is a term that embraces a variety of defects that are present in the structure of the heart at birth. These congenital defects change the normal flow of blood through the heart, leading to a range of conditions and symptoms. CHD affects about 7 to 9 of every 1,000 live births in the United States and Europe and is the most common cause of death in the first year of life, with defects accounting for 3 percent of all infant deaths and more than 40 percent of all deaths due to congenital malformations.[1]

Current methods for detecting CHD generally include prenatal ultrasound screening and careful and repeated clinical examinations, both in the hospital nursery and as part of routine well-child care. CHD is often missed by hospital discharge and post-discharge clinical exams of infants. Pulse oximetry screening can identify some newborns with CHD. A pulse oximeter is a medical device that measures the percentage of hemoglobin in the blood that is saturated with oxygen. The device indirectly monitors the oxygen saturation of a patient's blood without the need to take a blood sample. It is estimated that one quarter of congenital heart defects could be detected and potentially treated by measuring blood oxygen saturation.[2]

Neonates with abnormal pulse oximetry screening results need confirmatory testing for the cause of the low oxygen saturation, and immediate intervention, often involving a surgical procedure. Any infant with a positive screen should have a diagnostic echocardiogram. The infant's pediatrician should be notified immediately and the infant might need to be seen by a cardiologist for follow-up.[3]

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[1] Letter dated October 15, 2010, to The Honorable Kathleen Sebelius, Secretary of Health and Human Services, from R. Rodney Howell, M.D., Chairperson of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children. Found at: <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/correspondence/criticalcongenital.pdf> (Last visited on January 23, 2012).

[2] Letter dated September 21, 2011, to R. Rodney Howell, M.D., Chairperson of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, from The Honorable Kathleen Sebelius, Secretary of Health and Human Services. Found at: <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendations/correspondence/cyanoticheartsecre09212011.pdf> (Last visited on January 23, 2012).

[3] *Pulse Oximetry Screening for Critical Congenital Heart Defects*, Centers for Disease Control and Prevention. Found at: <http://www.cdc.gov/ncbddd/pediatricgenetics/pulse.html> (Last visited on January 23, 2012).

Newborn Screening

All babies born in the United States are checked for certain medical conditions soon after birth. This is called newborn screening. Over 4 million infants are screened each year. Newborn screening identifies conditions that can affect a child's long-term health or survival. Early detection, diagnosis, and intervention can prevent death or disability and enable children to reach their full potential. All babies are screened, even if they look healthy, because some medical conditions cannot be seen by just looking at the baby. Each state runs its own newborn screening program.

Newborn screening usually takes place before a newborn leaves the hospital. Most tests use a few drops of blood from pricking the baby's heel. The blood specimen is placed on a special filter paper and, in Florida, the specimen card is sent to the Department of Health (DOH) Newborn Screening Laboratory in Jacksonville for testing. The laboratory receives about 250,000 specimens annually from babies born in Florida. The majority of the test results are reported within 24-48 hours. The DOH Children's Medical Services program provides the follow-up for all abnormal screening results.

Section 383.14, F.S., requires the Florida DOH to promote the screening of all newborns born in Florida for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect, *as screening programs accepted by current medical practice become available and practical in the judgment of the department*.

Most states screen for a standard number of conditions, but some states may screen for more conditions. Florida currently screens for 35 disorders, including hearing impairment, but does not screen for CHD.[4] The National Newborn Screening and Genetics Resource Center provides a current list of conditions included in each state's newborn screening program. As of December 19, 2011, only one state (New Jersey) requires screening of all newborns for CHD, but the requirement has not yet been implemented.[5]

Adding Conditions to Required Screening

The DOH is required, after consultation with the Genetics and Newborn Screening Advisory Council, to adopt rules requiring every newborn in this state, prior to becoming 1 week of age, to be subjected to a test for phenylketonuria and, at the appropriate age, to be tested for other metabolic diseases and hereditary or congenital disorders *as the department deems necessary*.[6]

At the national level, the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children advises the Secretary, U.S. Department of Health and Human Services, on the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and standards. The advisory committee recommends conditions that should be added to the Recommended Uniform Screening Panel.

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[4] *See* Department of Health Bill Analysis, Economic Statement and Fiscal Note for SB 1052 – on file with the Senate Health Regulation Committee.
[5] National Newborn Screening Status Report, updated 11/21/11. Found at: <http://genes-r-us.uthscsa.edu/nbsdisorders.pdf> (Last visited on January 23, 2012).
[6] s. 383.14(2), F.S.

On September 17, 2010, the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children recommended that Critical Congenital *Cyanotic* Heart Disease be added to the Recommended Uniform Screening Panel.[7] Secretary Sebelius accepted the committee's recommendation on September 21, 2011, and Critical CHD screening was added to the Recommended Uniform Screening Panel as a core condition.[8]

On January 20, 2012, the Florida Genetics and Newborn Screening Advisory Council recommended that CHD be added to the panel of disorders screened in the Florida Newborn Screening Program.

Hospital, Birth Center, and Home Deliveries

In 2010 there were 214,519 resident live births in Florida.[9] Of these births, 211,485 (98.6 percent) occurred in hospitals and physicians attended 88.5 percent of the hospital births.[10] Midwives attended 10.9 percent of live births in hospitals. Birth centers accounted for 1,377 births (0.64 percent of live births) and midwives attended 96.9 percent of birth center births. Physicians attended 2.8 percent of birth center births. In 2010, there were 1,508 births in an identified place other than a hospital or birth center and 149 births where the place of delivery was unknown.[11]

Hospitals are licensed and regulated under ch. 395, F.S., and part II of ch. 408, F.S. Birth centers are licensed and regulated under ss. 383.30-383.335, F.S., and part II of ch. 408, F.S. There are 23 licensed birth centers in Florida.

Health Insurance

Section 627.6416, F.S., requires individual health insurance policies that provide coverage on an expense-incurred basis, which provide coverage for a member of a family of the insured or subscriber, to include, for children, coverage for child health supervision services. These services are covered from the moment of birth to age 16 years. The term "child health supervision services" means physician-delivered or physician-supervised services that include, at a minimum, periodic visits including a history, a physical examination, a developmental assessment and anticipatory guidance, and appropriate immunizations and laboratory tests. These services must be provided in accordance with prevailing medical standards consistent with the Recommendations for Preventive Pediatric Health Care of the American Academy of Pediatrics. The recommendations currently include newborn metabolic and hemoglobin screening.

The same child health supervision requirements applicable to individual health insurance policies are also applied to group, blanket, and franchise health insurance policies under s. 627.6579, F.S., and to health maintenance organization contracts under s. 641.31(30), F.S.

[7] Supra, fn 1.
[8] Supra, fn 2.
[9] Department of Health, *2010 Florida Vital Statistics Annual Report – Live Births*. Found at: <http://www.flpublichealth.com/VSBOOK/pdf/2010/Births.pdf> (Last visited on January 23, 2012).
[10] *Id.*
[11] *Id.*

Insurance Mandates

Pursuant to s. 624.215, F.S., every person or organization seeking consideration of a legislative proposal which would mandate a health coverage or the offering of a health coverage by an insurance carrier, health care service contractor, or health maintenance organization as a component of individual or group policies, must submit to the Agency for Health Care Administration (Agency) and the legislative committee having jurisdiction a report which assesses the social and financial impacts of the proposed coverage.

Medicaid

Medicaid is the medical assistance program that provides access to health care for low-income families and individuals. Medicaid also assists aged and disabled people with the costs of nursing facility care and other medical expenses. The Agency is responsible for Medicaid. Medicaid serves approximately 3.19 million people in Florida, with over half of those being children and adolescents 20 years of age or younger. Estimated Medicaid expenditures for FY 2011-2012 are approximately $20.3 billion.

The total number of live births paid for by Medicaid through fee for service and health maintenance organizations during FY 2010-2011 was 130,989.[12]

Under s. 383.145(3)(j), F.S., which establishes the requirements for newborn and infant hearing screening, the Medicaid program must cover the initial procedure for screening the hearing of newborns or infants and any medically necessary follow-up reevaluations leading to diagnosis. These services are reimbursable under Medicaid as an expense compensated supplemental to the per diem rate for Medicaid patients enrolled in MediPass or Medicaid patients covered by a fee for service program. For Medicaid patients who are enrolled in a health maintenance organization, Medicaid must reimburse providers directly at the Medicaid rate. These services may not be considered a covered service for the purposes of establishing the payment rate for Medicaid health maintenance organizations. Nonhospital-based providers are eligible to bill Medicaid for the professional and technical component of each procedure code.

Medicaid pays hospitals a per diem rate for hospital inpatient services based on hospital cost reports. Cost reports are submitted annually and rates are adjusted as appropriate. Standard testing of a patient's vital signs is included in the per diem rate regardless of the Medicaid recipient's age. Measuring blood oxygen saturation using pulse oximetry is considered a standard part of testing a patient's vital signs. A separate screening for newborns for congenital heart disease is not currently reimbursed by Medicaid other than as a part of the hospital per diem rate. Medicaid currently does not reimburse separately for the screening of newborns for congenital heart disease in any other setting either.

[12] See Agency for Health Care Administration 2012 Bill Analysis and Economic Impact Statement for SB 1052 – on file with the Senate Health Regulation Committee.

Florida Drug and Cosmetic Act

One purpose of the Act 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. Another purpose of the Act is to promote uniformity between state and federal laws and their administration and enforcement, throughout the United States.

In 2003, the Legislature enacted the Prescription Drug Protection Act,[13] which put in place additional safeguards for the distribution of prescription drugs in, into, and from this state. This legislation was predicated on the findings and recommendations of the report of the Seventeenth Statewide Grand Jury in its First Interim Report to the Legislature.[14] That grand jury was called to examine, among other matters, the safety of prescription drugs in Florida. In particular, they examined the situation concerning the sale and re-sale of prescription drugs in the wholesale market.

Section 499.003, F.S., defines terms that are used in the Act. The bill amends the following terms in s. 499.003, F.S.: "distribute" or "distribution," "drug," "establishment," "prescription drug," and "wholesale distribution."

Section 499.01, F.S., requires a variety of manufacturers, distributors, and other business entities involved in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics to obtain a permit prior to operating. Permits that are addressed in the bill include:

- *Nonresident prescription drug manufacturer permit*, which is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the wholesale distribution in this state of such prescription drugs;
- *Out-of-state prescription drug wholesale distributor permit*, which is required for a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state; and
- *Health care clinic establishment permit*, which is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number.

Section 499.012(8), F.S., sets forth the application requirements for an out-of-state prescription drug wholesale distributor. Generally, the applicant must identify the business (name and trade names, address, and telephone number); and provide information about the ownership, operations and affiliated groups,[15] including the name and address of each shareholder of a corporation that owns 5 percent or more of the corporation; a background statement and

[13] *See* ch. 2003-155, L.O.F.
[14] The report is available at: <http://myfloridalegal.com/pages.nsf/Main/09558F82389E020785256CDA006DB01A> (Last visited on February 6, 2012).
[15] "Affiliated group" is defined in s. 499.003(2), F.S., to mean an affiliated group as defined by s. 1504 of the Internal Revenue Code of 1986, as amended, which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group. The affiliated group must disclose the names of all its members to the department.

fingerprint card for affiliated persons;[16] the estimated or actual annual dollar volume of certain activities pertaining to prescription drugs by the applicant; a copy of the deed or lease for the business property; a list of all licenses and permits issued to the applicant by any other state which authorize the applicant to purchase or posses prescription drugs; and documentation of the credentialing policies and procedures for customers if the applicant intends to sell Schedule II or Schedule III controlled substances to physicians in Florida.[17]

Effective October 1, 2011, all of the statutory powers, duties, and functions, records, personnel, property, and unexpended balances of appropriations, allocations, or other funds for the administration of ch. 499, F.S., relating to drugs, devices, cosmetics, and household products were transferred from the Department of Health to the Department of Business and Professional Regulation (DBPR).[18]

III. Effect of Proposed Changes:

Section 1 creates s. 383.146, F.S., to require each licensed hospital and birth center that provides maternity and newborn care services to screen all newborns, prior to discharge, for CCHD. This requirement must be implemented by October 1, 2012. For home births, the health care provider in attendance is responsible for the screening. The bill defines screening to mean measuring blood oxygen saturation using pulse oximetry to determine whether the newborn needs additional diagnostic evaluation for CCHD.

A parent or legal guardian may object to the screening by providing a signed written objection, in which case the screening must not be completed. The physician, midwife, or other person who is attending the newborn is required to maintain a record that the screening has not been performed and attach the written objection.

Appropriate documentation of the screening completion, results, interpretation, and recommendations must be placed in the medical record within 24 hours after completion of the screening procedure.

The bill requires each hospital to formally designate a lead physician to be responsible for programmatic oversight of the newborn CCHD screening and to ensure that the appropriate referrals are being completed following a positive screening test result. The bill requires each birth center to designate a licensed health care provider to be responsible for programmatic oversight and to ensure that the appropriate referrals are being completed.

The DOH is provided with specific rulemaking authority. The bill requires the department to administer and provide services pursuant to this newly created section of law and specifically to:

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[16] "Affiliated party" is defined in s. 499.003(3), F.S. In summary, it means a director, officer, trustee, partner, or committee member or a subsidiary or service corporation of the permittee or applicant; a person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant; and the five largest natural shareholders that own at least five percent of the permittee or applicant.

[17] The specific application requirement is for documentation of the credentialing policies and procedures requirements by s. 499.0121(14), F.S., However, that subsection addresses reporting requirements. Subsection (15) addresses credentialing requirements for physician-customers for certain controlled substances.

[18] *See* s. 27, ch. 2010-161, L.O.F.

- Furnish all physicians, county health departments, perinatal centers, birthing centers, and hospitals forms on which the results of tests for CCHD are to be reported to the department.
- Charge and collect fees sufficient to administer the newborn screening program for CCHD.

Section 2 amends s. 499.003, F.S., which provides definitions for the Act.

The bill amends the definition of "*distribute*" or "*distribution*" to specify that the term does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction. Under s. 499.003(54), F.S., "wholesale distribution" is defined as "distribution of prescription drugs to persons other than a consumer or patient," with certain specified exceptions. References in the law that require wholesale distributions to be backed up using documents that show each transaction from the manufacture of the drug through each distribution may conflict with the change in the definition of "distribution."

Specifically, s 499.0121(6), F.S., requires wholesale distributors to establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records must provide a complete audit trail from receipt to sale or other disposition. One component of the required records is any financial documentation supporting the transaction.[19] The change in the definition of "distribution" appears to have the effect of no longer requiring wholesale distributors to comply with the requirement to keep financial documentation available for inspection by the department.

Also, s. 499.01212, F.S., requires each person engaged in the wholesale distribution of a prescription drug to provide a pedigree paper to the person receiving the drug prior to or simultaneous with the distribution. The wholesale distributor must also maintain and make available to the department, upon request, the invoice numbers from the manufacturer. Pedigrees have to be authenticated in accordance with Rule 64F-12.013(5)(d), F.A.C., using invoices and shipping documents. If a wholesale distribution does not include billing and invoicing activities, the pedigrees, which have to be authenticated using shipping documents and invoices, cannot be authenticated.

The bill amends the definition of "*drug*" to specifically include active pharmaceutical ingredient as a component of a drug. The bill defines "active pharmaceutical ingredient," for purposes of the definition of "drug," to include any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or other animals.

The definition of "*establishment*" is amended to modify the meaning of "one physical location," at which the place of business is located, to clarify that the location may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common exclusive ownership, operation, and control, an intervening thoroughfare does not affect the contiguous

[19] *See* s. 499.0121(6)(a)5., F.S.

nature of the buildings. For purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application.

The bill amends the definition of "*prescription drug*" to specify that an active *pharmaceutical* ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in Florida are also prescription drugs. The U.S. Food and Drug Administration determines the classification of drugs, whether prescription or not, and this definition may not be consistent with the federal classification.

The exception from the definition of "*wholesale distribution*" for the sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or entity that is eligible to purchase prescription drugs at public health services prices to a contract provider or its subcontractor for eligible patients of the agency or entity is amended to no longer require a contract provider or subcontractor to maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.

Section 3 amends s. 499.01, F.S., to modify the exemption from the requirement to obtain a health care clinic establishment permit for a licensed practitioner who purchases a prescription drug under his or her license, so that a professional corporation or limited liability company composed of dentists may pay for prescription drugs obtained by a licensed dentist and the licensed dentist is deemed the purchaser and owner of the prescription drugs.

Section 499.01, F.S., is further amended to repeal the exemption from obtaining a nonresident prescription drug manufacturer permit for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state in limited quantities intended for research and development and not for resale, or human use other than authorized clinical trials and biostudies authorized and regulated by federal law.

The bill also repeals the exemption from obtaining an out-of-state prescription drug wholesale distributor permit for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is licensed as a prescription drug wholesale distributor in its state of residence to a licensed prescription drug wholesale distributor in Florida, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name.

The bill creates a new subsection (3) to provide exemptions from the required permits. A permit is not required:

- To distribute prescription drug active pharmaceutical ingredient from an establishment located in the United States to an establishment that is located in Florida and permitted as a prescription drug manufacturer under the following conditions.
    - The active pharmaceutical ingredient is for use by the prescription drug manufacturer in preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in Florida where the product is received.
    - The manufacturing must be under an approved and otherwise valid New Drug Approval, Abbreviated New Drug Approval, New Animal Drug Approval, or Therapeutic Biologic Application.

  - The application, active pharmaceutical ingredient, or finished dosage form must not have been withdrawn or removed from the U.S. market for public health reasons.
  - The distributor claiming an exemption must maintain a license, permit or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.
  - The distributor claiming an exemption and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient must comply with recordkeeping requirements, but not the pedigree paper requirements.

- To distribute limited quantities of a prescription drug that has not been repackaged from an establishment located in the United States to an establishment located in this state that is permitted as a prescription drug manufacturer for research and development or to a holder of a letter of exemption issued by the department for research, teaching, or testing.
  - The department must define "limited quantities" by rule, and may include the allowable number of transactions within a given period of time and the amounts of prescription drugs distributed into the state for purposes of this exemption.
  - The distributor claiming an exemption must maintain a license, permit or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.
  - All purchasers and recipients of any prescription drugs under this exemption must ensure that the products are not resold or used, directly or indirectly, on humans except in lawful clinical trials and biostudies authorized and regulated by federal law.
  - The distributor claiming an exemption and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient must comply with recordkeeping requirements, but not the pedigree paper requirements.
  - The immediate package or container of any active pharmaceutical ingredient distributed into the state intended for teaching, testing, research, and development must bear a label prominently displaying the statement "Caution: Research, Teaching, or Testing Only – Not for Manufacturing, Compounding, or Resale."

- For an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is licensed as a prescription drug wholesale distributor in its state of residence to a licensed prescription drug wholesale distributor in Florida.
  - Both wholesale distributors must conduct wholesale distributions of prescription drugs under the same business name.
  - The recordkeeping requirements and the pedigree paper requirements must be followed for such transactions.

The bill requires persons who receive prescription drugs from a source claimed to be exempt from permitting to maintain on file the following information for all distributors and establishments from whom they purchase or receive prescription drugs under an exemption:

- A record of the FDA establishment registration number, if any;
- The resident state prescription drug wholesale distribution license, permit, or registration number; and
- A copy of the most recent resident state or FDA inspection report.

All persons claiming an exemption from the permitting requirements of the Act who engage in the distribution of prescription drugs in or into Florida are subject to the Act. They must make available, within 48 hours, to the department on request all records related to any prescription drugs distributed under an exemption, regardless of the location where the records are stored.

The bill requires a person who purchases or receives a prescription drug from a person claimed to be exempt from the permitting requirements to report to the department in writing within 14 days after receiving any product that is misbranded or adulterated or that fails to meet minimum standards set forth in the official compendium or state or federal good manufacturing practices for identity, purity, potency, or sterility, regardless of whether the product is thereafter rehabilitated, quarantined, returned, or destroyed.

The bill authorizes the department to adopt rules to administer the exemption provisions in the bill. The bill declares that the failure to comply with the requirements of the exemption provisions, or rules adopted by the department to administer these provisions is a violation of:

- Section 499.005(14), F.S., which makes the purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient an unlawful act; and
- For knowing failure, s. 499.0051(4), F.S., which states that a person who knowingly purchases or receives a prescription drug in a wholesale distribution transaction from a person not authorized to distribute prescription drugs commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, F.S.

The exemption provisions in the bill do not relieve any persons from any requirement prescribed by law with respect to controlled substances.

The bill provides an exemption from the prescription drug repackager permit requirement for a restricted prescription drug distributor permitholder that is a health care entity that repackages prescription drugs in this state for its own use or distributes prescription drugs to a hospital or other health care entity in the state for its own use if it meets certain conditions. The restricted prescription drug distributor is also exempt from product registration requirements for the drugs it repackages and distributes.

Section 4 provides an effective date of July 1, 2012.

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 the 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.

D. Other Constitutional Issues:

The requirement in the bill that the objection to screening must contain the parent's or guardian's signature may violate the right of privacy under the Florida Constitution, Article I, Section 23.

The bill may impair existing contracts since the requirement for health insurers and health maintenance organizations to cover screening CCHD takes effect on October 1, 2012, and does not provide an exemption for existing contracts.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

The DOH currently collects a maximum hospital fee of $15 per live birth, as authorized in s. 383.14(3)(g), F.S., to cover the cost of newborn screening. Adding CCHD to the list of newborn screenings could require an increase in the hospital fee from $15 to $15.78 per live birth.

B. Private Sector Impact:

Hospitals, birth centers, and health care practitioners attending home births will have additional screening and reporting requirements.

Early detection with prompt early treatment may lead to a better outcome for babies born with severe heart disease. Detection prior to hospital discharge may also prevent unexpected events such as death or an emergency health crisis in the home setting.

An unknown, but probably small, number of specialty distributors providing a narrow category of products to Florida customers would be exempt from permitting fees.

C. Government Sector Impact:

The DOH will need to create and implement a system to track CCHD test results within the existing program structure. The CCHD screening is similar to newborn hearing screening in that the birthing facility conducts the actual testing and the DOH tracks the results and provides surveillance activities for infants who fail the screening test.

The main costs of adding CCHD to the Florida Newborn Screening Program are related to the necessary modifications of the current data system to add the screening results and staff time to track infants who fail the screening test. Follow-up actions would include communicating with physicians and parents regarding the outcome of the confirmatory

testing and obtaining the final diagnosis and outcome. The department estimates its expenditures to be $166,191 in FY 2012-2013 and $154,922 in FY 2013-2014.

Funding for the program could come from surplus revenue generated from billing for other disorders tested in the Newborn Screening program. The department must be provided budget authority to spend the surplus funding for this purpose. As of November 22, 2011, the Newborn Screening program had a surplus of revenue in FY 2010-2011 totaling $2,110,778.[20]

The DBPR estimates that the potential reduction in license fees as a result of the exemptions in the bill would be minimal, if any. The bill may require changes to the inspection application and the associated violation codes, but this can be done with existing resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The requirement for a written signature for objecting to screening by a parent or guardian at lines 57 and 58 is more prescriptive than a similar requirement under s. 383.14(4), F.S., which does not require a signature.

Section 624.215, F.S., requires every person or organization seeking consideration of a legislative proposal mandating health coverage to submit to the Agency for Health Care Administration and the appropriate legislative committees having jurisdiction a report assessing the social and financial impacts of the proposed coverage. Neither the Committee on Health Regulation nor the Committee on Banking and Insurance received a report analyzing newborn screening for CCHD as created by the bill.

Section 499.0121(6)(c), F.S., requires that the records wholesale distributors are required to maintain be readily available for authorized inspection. The modified definition of "establishment," with no requirement to designate in the permit application the location where the records will be kept, could create conflicts with the requirement that records be readily available.

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 February 22, 2012:
Instead of establishing a permit by endorsement for certain out-of-state prescription drug wholesale distributors, the CS:

[20] *See* Department of Health Bill Analysis, Economic Statement and Fiscal Note for SB 1052 – on file with the Senate Health Regulation Committee.

- Establishes a newborn screening requirement for critical congenital heart disease;
- Amends definitions in the Florida Drug and Cosmetic Act; and
- Provides certain exemptions from the permitting requirements of the Act.

B. Amendments:

None.