Tab 1  SB 422 by Benacquisto; (Identical to H 0363) Health Insurance Coverage For Opioids
**The Florida Senate**

**COMMITTEE MEETING EXPANDED AGENDA**

**BANKING AND INSURANCE**  
Senator Benacquisto, Chair  
Senator Richter, Vice Chair  

**MEETING DATE:** Monday, November 2, 2015  
**TIME:** 4:00—6:00 p.m.  
**PLACE:** Toni Jennings Committee Room, 110 Senate Office Building  

**MEMBERS:** Senator Benacquisto, Chair; Senator Richter, Vice Chair; Senators Clemens, Detert, Hukill, Lee, Margolis, Montford, Negron, Simmons, and Smith

<table>
<thead>
<tr>
<th>TAB</th>
<th>BILL NO. and INTRODUCER</th>
<th>BILL DESCRIPTION and SENATE COMMITTEE ACTIONS</th>
<th>COMMITTEE ACTION</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>SB 422</td>
<td>Health Insurance Coverage For Opioids; Providing that a health insurance policy that covers opioid analgesic drug products may impose a prior authorization requirement for an abuse-deterrent opioid analgesic drug product only if the insurer imposes the same requirement for each opioid analgesic drug product without an abuse-deterrence labeling claim, etc.</td>
<td>Favorable Yeas 7 Nays 0</td>
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</tbody>
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BI 11/02/2015 Favorable
HP AP

Other Related Meeting Documents
The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT
(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Banking and Insurance

BILL: SB 422
INTRODUCER: Senator Benacquisto
SUBJECT: Health Insurance Coverage For Opioids
DATE: November 2, 2015

I. Summary:

SB 422 allows a health insurance policy providing coverage for opioid analgesic drug products to impose a prior authorization requirement for an abuse-deterrent opioid analgesic drug product only if the policy imposes the same prior authorization requirement for opioid analgesic drug products without an abuse-deterrence labeling claim. The bill also prohibits a policy from requiring the use of an opioid analgesic without an abuse-deterrent labeling claim before providing coverage for an abuse-deterrent opioid analgesic drug product. Abuse deterrent formulations have characteristics that help prevent widespread abuse by impeding the delivery of their active ingredients, thereby reducing the potential for abuse, diversion, and misuse of the drug.

The fiscal impact of the bill is indeterminate.

The bill provides an effective date of January 1, 2017.

II. Present Situation:

The abuse of prescription drugs in the United States has been described as an epidemic. Every day in the United States, 44 people die because of prescription opioid overdose.1 In 2013, there were 16,235 deaths involving prescription opioid overdose.2 In Florida, 2,514 deaths were attributable to prescription opioids in 2014.3

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2 Id.
Prescription opioid analgesics are a critical component of pain management particularly for treating acute and chronic medical pain, providing humane hospice care for cancer patients, and treating patients in drug treatment programs. When used properly, opioid analgesics drugs provide significant benefits for patients. However, abuse and misuse of these products has created a serious and growing public health problem. In the United States, an estimated 4.5 million individuals who use prescription pain medications for nonmedical purposes. Recent studies indicate that pharmaceuticals, especially opioid analgesics have driven the increase in drug overdose deaths. In 2007, the total U.S. societal costs of prescription opioid abuse was estimated at $55.7 billion.

Food and Drug Administration Guidance on Abuse-Deterrent Opioids

To reduce the misuse and abuse of prescription drugs, the Food and Drug Administration released guidance to assist the pharmaceutical industry in developing new formulations and labeling of opioid drugs with abuse-deterrent properties. The goal of abuse-deterrence products is to limit access or attractiveness of the highly desired active ingredient for abusers while assuring the safe and effective release of the medication for patients. The document provides guidance about the studies that should be conducted to demonstrate that a given formulation has abuse-deterrent properties, how the studies will be evaluated, and what labeling claims may be approved based on the results of the studies.

According to the guidance, opioid analgesics can be abused in a number of ways. For example, they can be swallowed whole, crushed and swallowed, crushed and snorted, crushed and smoked, or crushed, dissolved and injected. Abuse-deterrent formulations should target known or expected routes of abuse for the opioid drug substance for that formulation. As a general framework, the FDA guidance provides that abuse-deterrent formulations are categorized in one of the following groups:

4 Medications that fall within this class include hydrocodone (e.g., Vicodin), oxycodone (e.g., OxyContin, Percocet), morphine (e.g., Kadian, Avinza), codeine, and related drugs. Hydrocodone products are the most commonly prescribed for a variety of painful conditions, including dental and injury-related pain. Morphine is often used before and after surgical procedures to alleviate severe pain. Codeine is often prescribed for mild pain. See National Institute on Drug Abuse at [http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/what-are-opioids](http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/what-are-opioids) (last accessed October 25, 2015).

5 Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, The NSDUH Report, Substance and Use and Mental Health Estimates from the 2013 National Survey on Drug Use and Health: Overview of Findings (September 4, 2014). “Nonmedical use” is defined as the use of prescription-type drugs that were not prescribed for the respondent or use only for the experience or feeling they caused. Nonmedical use of any prescription type drug does not include over-the-counter drugs.


7 Birnbaum, H.G., et al., Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States. Pain Medicine. 12:657-667. The breakout of this estimate includes the following costs: workplace $25.6 billion (46 percent), health care $25 billion (45 percent), and criminal justice $5.1 billion (9 percent). (USD in 2009).


9 The FDA has approved four extended release opioids with abuse deterrent labels (Reformulated OxyContin, Embeda ER, Hysingla ER, and Targiniq ER).
• **Physical/Chemical barriers** – Physical barriers can prevent chewing, crushing, cutting, grating, or grinding. Chemical barriers can resist extraction of the opioid using common solvents like water, alcohol, or other organic solvents.

• **Agonist/Antagonist combinations** – An opioid antagonist can be added to interfere with, reduce, or defeat the euphoria associated with abuse. The antagonist can be sequestered and released only upon manipulation of the product. For example, a drug product may be formulated such that the substance that acts as an antagonist is not clinically active when the product is swallowed but becomes active if the product is crushed and injected or snorted.

• **Aversion** – Substances can be added to a product to produce an unpleasant effect if the dosage form is manipulated prior to ingestion or is used at a higher dosage than directed.

• **Delivery System** (including depot injectable formulations and implants) – Certain drug release designs or the method of drug delivery can offer resistance to abuse.

• **New Molecular entities (NME) and prodrugs** – The properties of a NME or a prodrug could include the need for enzymatic activation or other novel effects.

• **Combination** – Two or more of the above methods can be combined to deter abuse.

• **Novel approaches** – Novel approaches or technologies that are not captured in the previous categories.

The increasing use of abuse-deterrent opioids is expected to reduce overall medical costs. One study\(^{10}\) estimated the potential cost savings from introducing abuse-deterrent opioids may be in the range of $0.6 billion to $1.6 billion per year in the United States. The study notes that cost data was extrapolated from claims data of privately insured national employers. The study also states that privately insured population accounts for approximately 60 percent of the U.S. population, and the costs and abuse patterns for Medicaid, uninsured individuals, and small employers could be different.

**Regulation of Insurers and Health Maintenance Organizations**

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, health maintenance organizations, and other risk-bearing entities.\(^ {11}\) The Agency for Health Care Administration (agency) regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from the agency pursuant to part III of ch. 641, F.S.\(^ {12}\)

**Cost Containment Measures Used by Insurers and HMOs**

Insurers use many cost containment strategies to manage medical and drug spending and utilization. For example, plans may place utilization management requirements on the use of certain drugs on their formulary, such as requiring enrollees to obtain prior authorization from their plan before being able to fill a prescription, requiring enrollees to try first a preferred drug to treat a medical condition before being able to obtain an alternate drug for that condition, or limiting the quantity of drugs that they cover over a certain period.

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\(^{10}\) Birnbaum HG, White, AG, et al. Development of a Budget-Impact Model to Quantify Potential Cost Savings from Prescription Opioids Designed to Deter Abuse or Ease of Extraction. Appl Health Econ Health Policy. 2009; 7(1); 61-70.

\(^{11}\) Section 20.121(3)(a)1., F.S.

\(^{12}\) Section 641.21(1), F.S.
Under prior authorization, a health care provider is required to seek approval from an insurer before a patient may receive a specified diagnostic or therapeutic treatment or specified prescription drugs under the plan. A preferred drug list (PDL) is an established list of one or more prescription drugs within a therapeutic class deemed clinically equivalent and cost effective. In order to obtain another drug within the therapeutic class, not part of the PDL, prior authorization is required. Prior authorization for emergency services is not required. Preauthorization for hospital inpatient services is generally required.

III. Effect of Proposed Changes:

Section 1 creates s. 627.64194, F.S., which provides requirements for opioid analgesic drug coverage. The terms “abuse-deterrent opioid analgesic drug product” and “opioid analgesic drug product” are defined. An “abuse-deterrent opioid analgesic drug product” means a brand or generic opioid analgesic drug product approved by the U.S. Food and Drug Administration with an abuse-deterrence labeling claim that indicates the drug product is expected to deter abuse. The term, “opioid analgesic drug product” means a drug product in the opioid analgesic drug class prescribed to treat moderate to severe pain or other conditions in immediate-release, extended release, or long-acting form regardless of whether or not combined with other drug substances to form a single drug product or dosage form.

The bill allows a health insurance policy that provides coverage for opioid analgesic drug products to impose a prior authorization for an abuse-deterrent opioid analgesic drug product only if the policy imposes the same prior authorization requirement for opioid analgesic drug products without an abuse-deterrence labeling claim. The bill also prohibits a health insurance policy from requiring the use of an opioid analgesic without an abuse-deterrent labeling claim before providing coverage for an abuse-deterrent opioid analgesic drug product. Abuse deterrent formulations have characteristics that help prevent widespread abuse by impeding the delivery of their active ingredients thereby reducing the potential for abuse and misuse of the drug.

Section 2 provides an effective date of January 1, 2017.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.
V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The fiscal impact on the private sector is indeterminate. The bill will provide patients with greater access to abuse-deterrent opioid analgesic drug products, which is expected to reduce opioid drug misuse, abuse, and diversion. The increased use of abuse deterrent drugs is expected to reduce emergency room and drug treatment costs associated with the misuse or abuse of opioids without such abuse deterrent formulations.

C. Government Sector Impact:

The fiscal impact on the government sector is indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 627.64194 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

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

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill’s introducer or the Florida Senate.
By Senator Benacquisto

A bill to be entitled

30-00436A-16

Be It Enacted by the Legislature of the State of Florida:

30-00436A-16

An act relating to health insurance coverage for

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opioids; creating s. 627.64194, F.S.; defining terms;

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providing that a health insurance policy that covers

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opioid analgesic drug products may impose a prior

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authorization requirement for an abuse-deterrent

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opioid analgesic drug product only if the insurer

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imposes the same requirement for each opioid analgesic

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drug product without an abuse-deterrence labeling

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claim; prohibiting such health insurance policy from

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requiring use of an opioid analgesic drug product

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without an abuse-deterrence labeling claim before

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providing coverage for an abuse-deterrent opioid

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analogesic drug product; providing an effective date.

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WHEREAS, the Legislature finds that the abuse of opioids

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is a serious problem that affects the health, social, and economic

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welfare of this state, and

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WHEREAS, the Legislature finds that an estimated 2.1

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million people in the United States suffered from substance use

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disorders related to prescription opioid pain relievers in 2012, and

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WHEREAS, the Legislature finds that the number of

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unintentional overdose deaths from prescription pain relievers

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has more than quadrupled since 1999, and

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WHEREAS, the Legislature is convinced that it is imperative

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for people suffering from pain to obtain the relief they need

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while minimizing the potential for negative consequences, NOW,

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THEREFORE,

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Section 1. Section 627.64194, Florida Statutes, is created
to read:

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627.64194 Requirements for opioid coverage.—

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(a) “Abuse-deterrent opioid analgesic drug product” means a

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brand or generic opioid analgesic drug product approved by the

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United States Food and Drug Administration with an abuse-

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deterrence labeling claim that indicates the drug product is

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expected to deter abuse.

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(b) “Opioid analgesic drug product” means a drug product in the opioid

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analgesic drug class prescribed to treat moderate to severe pain or other conditions in immediate-release, extended-

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release, or long-acting form regardless of whether or not combined with other drug substances to form a single drug product or dosage form.

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(2) COVERAGE REQUIREMENTS.—A health insurance policy that

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provides coverage for opioid analgesic drug products:

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(a) May impose a prior authorization requirement for an

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abuse-deterrent opioid analgesic drug product only if the policy

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imposes the same prior authorization requirement for each opioid

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analgesic drug product without an abuse-deterrence labeling

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claim which is covered by the policy.

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(b) May not require use of an opioid analgesic drug product

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without an abuse-deterrence labeling claim before providing

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coverage for an abuse-deterrent opioid analgesic drug product.

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Section 2. This act shall take effect January 1, 2017.

Page 1 of 2

CODING: Words [strike] are deletions; words [underline] are additions.

Page 2 of 2

CODING: Words [strike] are deletions; words [underline] are additions.
The Florida Senate
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date: 11-2-15

Bill Number (if applicable): SB 422

Amendment Barcode (if applicable):

Topic: DRUGS

Name: Mark Fontaine

Job Title: Executive Director

Address: 2868 Mahan Drive

Street: Tallahassee FL 32308

Phone: 878-2196

Email:

Speaking: [ ] For [ ] Against [ ] Information

Waive Speaking: [ ] In Support [ ] Against

(The Chair will read this information into the record.)

Representing: Florida Alcohol + Drug Abuse Association

Appearing at request of Chair: [ ] Yes [ ] No

Lobbyist registered with Legislature: [ ] Yes [ ] No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)
The Florida Senate

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date: 11-2-2015

Topic: HEALTH INSURANCE COVERAGE FOR OPIOIDS

Name: STEPHEN R. WINO

Job Title: EXECUTIVE DIRECTOR

Address: 2544 BLAIRSTONE PINES DR

Phone: 876-7463

Email:

Speaking: [ ] For [ ] Against [ ] Information

Waive Speaking: [X] In Support [ ] Against

(The Chair will read this information into the record.)

Representing: FLORIDA OSTEOPATHIC MEDICAL ASSOCIATION

Appearing at request of Chair: [ ] Yes [ ] No

Lobbyist registered with Legislature: [X] Yes [ ] No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.
November 2, 2015

Meeting Date

Topic

Relating to Health Insurance Coverage For Opioids

Name

Darrick D. McGhee

Job Title

Vice President of Government Relations

Address

537 East Park Avenue

537 East Park Avenue

Tallahassee, Florida 32301

Phone (850) 321-6489

Email darrick@teamjb.com

Speaking: ☑ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against

(The Chair will read this information into the record.)

Representing

Florida Society of Interventional Pain Physicians (FSIPP)

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.
The Florida Senate
APPEARANCE RECORD

11/2/15

Meeting Date

Bill Number (if applicable)

Topic

Name Chris Nuland

Job Title

Address 1000 Riverside Ave

Phone 904-233-3051

Email nulandlau email.com

Street Jacksonville, FL 32201

City Jacksonville, FL 32201

State  Zip

Speaking: [ ] For [ ] Against [ ] Information

Waive Speaking: [ ] In Support [ ] Against

(The Chair will read this information into the record.)

Representing Florida Chapter, American College of Physicians

Appearing at request of Chair: [ ] Yes [X] No

Lobbyist registered with Legislature: [ ] Yes [ ] No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.
October 28, 2015

The Honorable Lizbeth Benacquisto, Chair
Committee on Banking and Insurance
320 Knott Building
404 South Monroe Street
Tallahassee, FL 32399

Dear Madam Chair:

I respectfully ask to be excused from the Banking and Insurance Committee meeting scheduled for Monday November 2nd, 2015.

Thank you for your consideration.

Sincerely,

Garrett S. Richter

cc: James Knudson, Staff Director
    Sheri Green, Administrative Assistant
November 2, 2015

The Honorable Senator Lizbeth Benacquisto, Chair
Senate Banking and Insurance Committee
404 South Monroe Street
320 Knott Building
Tallahassee, FL 32399

Dear Chair Benacquisto:

I respectfully request to be excused from today’s meeting of the Senate Committee on Banking and Insurance.

Sincerely,

Tom Lee
Florida State Senator
24th District
November 2, 2015

The Honorable Lizbeth Benacquisto, Chair
Senate Committee on Banking and Insurance
320 Knott
Tallahassee, Florida 32399-1100

Dear Chair Benacquisto:

Please excuse Senator Christopher Smith from Committee on Banking and Insurance that will be held on Monday November 2, 2015 at 4:00 PM. Due to inclement weather conditions Senator Smith’s flight plans were delayed by the airline causing his arrival time to Tallahassee to fall after the scheduled committee meeting.

Thank you in advance for your consideration.

Sincerely,

Sharonda Wright-Placide
Legislative Assistant to
Senator Chris Smith, District 31
November 2, 2015

The Honorable Lizbeth Benacquisto  
Chair  
Senate Banking and Insurance Committee  
404 S. Monroe Street  
320 Knott Building  
Tallahassee, FL 32399-1100

Dear Madame Chair:

I respectfully request that I be excused from today’s Senate Banking and Insurance Committee meeting as I had car trouble on my way to Tallahassee this morning. My tire blew out and my car had to be towed all the way back to Tampa to get it repaired. I have just picked up a loaner car and am currently driving back to Tallahassee.

Thank you for your consideration of this request.

Nancy C. Detert

NCD/ca

Cc: James Knudson, Staff Director  
Sheri Green, Administrative Assistant
Meeting call to order by Chairman—quorum present
Chair turned over to Senator Simmons
Senator Benacquisto recognized to explain SB 422/Health Ins. Coverage
roll call on SB 422 - Favorable
Meeting adjourned.