

The Florida Senate
COMMITTEE MEETING EXPANDED AGENDA

REGULATED INDUSTRIES
Senator Bradley, Chair
Senator Margolis, Vice Chair

MEETING DATE: Wednesday, April 15, 2015
TIME: 4:00 —6:00 p.m.
PLACE: *Toni Jennings Committee Room*, 110 Senate Office Building

MEMBERS: Senator Bradley, Chair; Senator Margolis, Vice Chair; Senators Abruzzo, Bean, Braynon, Diaz de la Portilla, Flores, Latvala, Negron, Richter, Sachs, and Stargel

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	CS/SB 1486 Community Affairs / Brandes (Similar CS/H 1151)	Residential Master Building Permit Programs; Requiring local governments to create master building permit programs if requested by a licensed general, building, or residential contractor to assist builders who construct certain dwellings and townhomes on a repetitive basis; authorizing a builder to use a master building permit for individual dwellings or townhomes under certain conditions; authorizing governing bodies of local governments to set specified fees, etc. CA 04/07/2015 Fav/CS RI 04/15/2015 Favorable FP	Favorable Yeas 10 Nays 0
2	CS/SB 1180 Health Policy / Latvala (Compare H 981, CS/CS/H 1049)	Practice of Pharmacy; Providing that the Florida Pharmacy Act and rules adopted under the act do not limit a veterinarian from engaging in an activity allowed under ch. 474, etc. HP 03/23/2015 Fav/CS RI 04/08/2015 Not Considered RI 04/15/2015 Fav/CS FP	Fav/CS Yeas 10 Nays 0

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 Regulated Industries

BILL: CS/SB 1486

INTRODUCER: Community Affairs Committee and Senator Brandes

SUBJECT: Residential Master Building Permit Programs

DATE: April 15, 2015

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>White</u>	<u>Yeatman</u>	<u>CA</u>	<u>Fav/CS</u>
2.	<u>Kraemer</u>	<u>Imhof</u>	<u>RI</u>	<u>Favorable</u>
3.	_____	_____	<u>FP</u>	_____

Please see Section IX. for Additional Information:

PLEASE MAKE SELECTION

I. Summary:

CS/SB 1486 provides for the creation of local residential master building permit programs to assist builders who construct certain dwellings and townhomes on a repetitive basis. The bill directs each local government to create a residential master building permit program within 6 months of a written request made by a licensed contractor to a licensed local building official. Under the program, a builder obtains a master building permit by submitting certain documents, such as a general construction plan, to the local building department. Within 120 days after receiving a complete application, the local building department must review the general construction plan to determine compliance with the building code and approve or deny the master building permit application.

If the local building department approves the general building plan and all documents provided with the master building permit application are verified, the builder receives a master building permit and permit number. The bill provides that after approving a master building permit application, the local building department may only require the builder to submit limited documents for a site-specific building permit for a single-family or two-family dwelling.

II. Present Situation:

Florida Building Code and Local Amendments

Part IV of ch. 553, F.S., titled the “Florida Building Codes Act,” provides a mechanism for the uniform adoption, updating, amendment, interpretation, and enforcement of a single, unified state building code.¹ The Florida Building Commission (FBC) updates the Florida Building Code (code) every 3 years by selecting the most current versions of model codes to serve as the basis for the new edition of Florida’s code. During the triennial code adoption process, FBC staff integrates provisions that have been previously adopted by the commission in prior code editions that are related to state agency regulation, wind-resistance design of buildings in the high velocity hurricane zone, and other provisions required for consistency with statute.²

While the Legislature has stated its intent that the code be applied, administered, and enforced uniformly and consistently from jurisdiction to jurisdiction,³ flexibility is provided so that local governments may adopt amendments to the administrative provisions⁴ and technical provisions of the code.⁵ These local amendments, which apply solely within the jurisdiction of the local government, are:

- Required to be more stringent than the minimum standards of the code;
- Not allowed to be made more than once every 6 months;
- Not allowed to make additional requirements that are discriminatory against materials, products, or construction techniques of demonstrated capabilities;
- Not allowed to make additional requirements introducing a new subject not addressed in the code;⁶ and
- Not applicable to state or school district owned buildings, manufactured buildings or factory-built school buildings approved by the commission, or prototype buildings approved pursuant to s. 553.77(3), F.S.⁷

Section 553.73(11), F.S., requires local building code enforcement officials and local fire code enforcement officials to resolve conflicts between the Florida Building Code, the Florida Fire Prevention Code, and the Florida Life Safety Code by agreement of the officials in favor of the code requirement that offers the greatest degree of lifesafety, or alternatives that would provide an equivalent degree of lifesafety and an equivalent method of construction. These decisions may be appealed to the local administrative board with firesafety responsibilities, and are subject to further review by a joint committee composed of members of the FBC and the Fire Code Advisory Council.

¹ See ss. 553.70 - 553.898, F.S.

² See Section 553.73(7)(g), F.S., which provides in pertinent part, “[a]mendments or modifications related to state agency regulations which are adopted and integrated into an edition of the Florida Building Code shall be carried forward into the next edition of the code, subject to modification as provided in this part. Amendments or modifications related to the wind-resistance design of buildings and structures within the high-velocity hurricane zone of Miami-Dade and Broward Counties which are adopted to [the code] do not expire, and shall be carried forward into the next edition of the code, subject to review or modification”

³ Section 553.72, F.S.

⁴ Section 553.73(4)(a), F.S.

⁵ Section 553.73(4)(b), F.S.

⁶ Section 553.73(4)(b)(3), F.S.

⁷ Section 553.73(4)(c), F.S.

Local Government Permitting

The Legislature has specified that local governments have the power to inspect all buildings, structures, and facilities within their jurisdictions in protection of the public's health, safety, and welfare.⁸ Section 553.79(1), F.S., provides that it is unlawful for any person, firm, corporation, or governmental entity to construct, erect, alter, modify, repair, or demolish any building without first paying for and obtaining a permit from the appropriate enforcing agency or from such persons delegated the authority to issue permits. Typically, the appropriate enforcing agency is the local building department in the county or municipality in which the property is located. The builder is required to obtain a site-specific building permit for each individual site-specific building intended to be constructed, even if the builder expects to build multiple identical structures on a repetitive basis.

A builder is required to provide building plans and specifications at the time of application for a site-specific building permit, along with a structural inspection plan and additional supporting documents sufficient for the building code administrator or inspector to determine whether the building plans are in compliance with the code.⁹ The specific documents required to be submitted with the site-specific building permit application vary depending upon the county or municipality reviewing the documents. The City of Tallahassee requests the following documents with the application for site-specific building permit:

- Completed permit application, signed by the contractor;
- Affidavit of the owner, designating contractor as the agent;
- Disclosure statement if the owner is acting as his or her own contractor;
- Affidavit of occupancy;
- Florida Lien Law form if the owner is acting as his or her own contractor;
- Certified copy of recorded Notice of Commencement;
- Two sets of construction plans, including floor plan, elevations, foundation plan or floor framing plan, wall sections, roof plan, two gas diagrams, manufacturer's truss layout, and fire resistance framing plan;
- Two engineered wind analyses, if the structure is over 400 square feet, has openings within three feet of a corner, or is two stories; the engineer must have the subdivision name, lot, and block or complete address;
- Environmental information, including a site plan, information regarding whether the property is located in a FIRM flood zone, street name, lot dimensions, setback dimensions, north arrow, easements and restrictions, location and size of all protected trees, limits of clearing and location for placement of sediment and erosion control measures, clearly labeled existing and proposed structures, existing and proposed two-foot contour lines labeled accordingly; all grading or other methods of storm-water conveyance; and finished floor elevation;
- 2010 Florida Building Code, Energy Conservation Form 402 or 405;
- EPL Display card signed by the builder with the date and address of the home;
- Manual J form with the HVAC load sizing summary for residential buildings signed by the preparer;

⁸ Section 553.72(2), F.S.

⁹ Section 553.79(2) and (6), F.S.

- Soil test, signed by an engineer with subdivision name, lot and block or complete address; and
- Completed driveway connection application.¹⁰

Along with the application and listed documents, the builder submits a fee to cover both the review of the submitted documents and any inspection costs. The fees are based on a schedule adopted by the local government pursuant to s. 553.80(7), F.S., which provides that:

- The fees, and any fines or investment earnings related to the fees, may only be used to carry out the local government's responsibilities in enforcing the code;
- When providing a schedule of reasonable fees, the total estimated annual revenue derived from fees, and the fines and investment earnings related to the fees, may not exceed the total estimated annual costs of allowable activities;
- At the discretion of the local government, any unexpended balances are carried forward to future years for allowable activities or are refunded;
- The basis for a fee structure for allowable activities must relate to the level of service provided by the local government and must include consideration for refunding fees due to reduced services; and
- Fees charged must be consistently applied.

Section 553.80(7)(a), F.S., further specifies the types of enforcement activities that the fees may be used to fund:

- The direct costs and reasonable indirect costs associated with review of building plans;
- Building inspections;
- Reinspections;
- Building permit processing;
- Building code enforcement;
- Fire inspections associated with new construction;
- Training costs associated with the enforcement of the code; and
- Enforcement action pertaining to unlicensed contractor activity to the extent not funded by other user fees.

The FBC sets standards and criteria to authorize preliminary construction before completion of all building plans review, including, but not limited to, special permits for the foundation only. Section 105.13 (phased permit approval), of the code¹¹ provides the following:

After submittal of the appropriate construction documents, the building official is authorized to issue a permit for the construction of foundations or any other part

¹⁰ City of Tallahassee *Combination Residential Building, Environmental & Driveway Connection Permit Application*, BI FORM AP-RESIDENTIAL_BUILDING, 10/17/2012, available at http://www.tal.gov.com/Uploads/Public/Documents/growth/pdf/forms/combo_residential_bldg_env_permit_appl.pdf (last visited April 14, 2015).

¹¹ A draft of the 2014 Florida Building Code has been made available in a read-only format by the International Code Council, Inc. (ICC) at http://ecodes.biz/ecodes_support/free_resources/14FloridaDraft/Building/14FL_Building_Draft.html (last visited April 14, 2015). The ICC was founded in 1994 by the Building Officials and Code Administrators International, Inc. (BOCA), International Conference of Building Officials (ICBO), and Southern Building Code Congress International, Inc. (SBCCI). As regional building codes began to lose their usefulness in a national context, the ICC developed International Codes, which are a set of comprehensive, coordinated building safety and fire prevention codes.

of a building or structure before the construction documents for the whole building or structure have been submitted. The holder of such permit for the foundation or other parts of a building or structure shall proceed at the holder's own risk with the building operation and without assurance that a permit for the entire structure will be granted. Corrections may be required to meet the requirements of the technical codes.

III. Effect of Proposed Changes:

Section 1 creates s. 553.794, F.S., to establish the parameters for local government residential master building permit programs. Upon receipt of a written request made by a licensed general, building, or residential contractor, a local government must create a residential master building permit program within 6 months of receipt of the request. The program is intended for use by builders constructing identical homes on a repetitive basis, and must be designed to achieve standardization, consistency, and a reduction in time spent by local building departments during the site-specific building permit application process.

After a master building permit program is established by a local government, the following must be submitted to the local building department for a master building permit:

- A completed master building permit application;
- A general construction plan that complies with specified requirements;
- All general construction plan pages, documents, and drawings, including structural calculations if required by the local building department, signed and sealed by the licensed architect or engineer;
- Written acknowledgement from the licensed architect or engineer that the plan pages, documents, and drawings contained within the application will be used for future site-specific building permit applications;
- Truss specifications signed and sealed by the engineer; and
- An energy performance calculation for all building orientations that considers the worst-case scenarios for the relevant climate zone and includes component and cladding product approvals for windows, pedestrian and garage doors, glazed opening impact protection devices, truss anchors, roof underlayments, and roof coverings.

The bill provides that the general construction plan:

- May be submitted in electronic or paper format, as required by the local building department; paper plans must be a minimum of 36 inches by 48 inches or must comply with local building department requirements;
- Shall include left-hand and right-hand building orientations, including floor plans;
- Shall include a model design, with up to four alternate exterior elevations with the same living space footprint, that must:
 - Include a foundation plan;
 - Contain a truss layout sheet for each exterior elevation compatible with the roof plan;
 - Not contain more than three alternate garage layouts, with each garage limited to accommodating no more than three cars;
- Must show typical wall sections from the foundation to the roof;

- Must contain a complete set of applicable electrical, plumbing, fuel gas, and mechanical plans;
- Must contain window, door, and glaze opening impact protection device schedules, if applicable; and
- Must meet any other local building department requirements.

The local building department must review the general construction plan to determine compliance with the code, and must approve or deny the master building permit application within 120 days after receiving a completed application, unless waived by the applicant. If the local building department approves the general building plan, and all documents provided with the master building permit application are verified, the builder must receive a master building permit and permit number.

In order to build a home using a model design approved under the master building permit, the builder must apply for a site-specific building permit using the master building permit number. The bill provides that once a master building permit application has been approved, the local building department may only require the builder to submit the following documents for a site-specific building permit for a single-family or two-family dwelling or townhome:

- A completed site-specific building permit application that identifies the master building permit number and the model design to be built, including elevation and garage style;
- Three signed and sealed copies of the lot or parcel survey or site plan, indicating the Federal Emergency Management Agency flood zone, base flood elevation, and minimum finished floor elevation. The survey or site plan must conform to local zoning regulations, and lot or parcel drainage indicators must be shown with site elevations;
- An affidavit by the licensed engineer of record affirming the master building permit is a true and correct copy of the master building permit on file with the local building department, referencing the master building permit number, and affirming that the master building permit will conform to soil conditions on the specific site;
- Complete mechanical drawings of the model design, including HVAC heating and cooling load calculations and equipment specifications; and
- Specific information not included in the master building permit application addressing the HVAC system design, including duct design and heating and cooling load calculations.

The builder may submit the master building permit number an unlimited number of times with the site-specific building permit applications, so long as the master building permit is valid, and the builder uses an approved model design. Approved master building permits are valid until the code is updated as provided in s. 553.73, F.S.

Once a local building department has approved a master building permit, the local building department may:

- Not allow structural revisions to the building;
- Allow limited nonstructural revisions to the building if any revised floor plan is submitted and approved; and
- Accept limited field revisions, in its discretion.

The bill provides that fees for the master building permit program may be set by the local government body, as currently authorized by s. 553.80(7), F.S.

The bill provides that in addition to any other penalty provided by law, a builder or design professional who willfully violates the requirements of a local government's residential master building permit program are subject to a fine of \$10,000 for every dwelling or townhome that is built using the master building permit but does not conform to the master building permit on file with the local building department.

Section 2 provides an effective date of July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The bill requires cities and counties to incur expenses, as it mandates that upon request of a contractor, a local residential master building permit program be created. As set forth in Article VII, Section 18 of the Florida Constitution, cities and counties are not bound by general laws requiring them to spend funds or take an action requiring them to spend funds unless the Legislature has determined that the law fulfills an important state interest, the law is approved by two-thirds of the membership in each house of the Legislature, and the law is exempted from the requirements of the state constitution.

One such exception is for law having insignificant fiscal impact. The fiscal impact of this bill is indeterminate. Should the bill become law, cities and counties may not be bound by it without a determination by the Legislature that the law fulfills an important state interest, and a vote approving the law by a two-thirds vote of the membership of both the Senate and the House of Representatives.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

Local governments have the authority to adopt fees associated with a requested master building permit program, and may evaluate revenue impacts accordingly.

B. Private Sector Impact:

After creation of a master building permit program, both the local building department and affected residential contractors will benefit from the reduction in duplicative

documentation and time associated with building permit application reviews for large development projects. Residents and other contractors may benefit from better availability of staff time and resources resulting from reduced volume of building permit application documentation.

C. **Government Sector Impact:**

The expense of establishing master building permit programs and reviewing master building permit applications may be offset by the reduced requirements for maintaining and reviewing repetitive information, allowing more timely review of information specific to each building site and any special attributes when warranted.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 553.794 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.)

CS by Community Affairs on April 7, 2015:

Provides that a local government whose licensed local building official receives a written request from a licensed general, building, or residential contractor has 6 months to create a master building permit program, and clarifies that local governments set fees for the master building permit program pursuant to existing provisions in s. 553.80(7), F.S.

B. **Amendments:**

None.

By the Committee on Community Affairs; and Senator Brandes

578-03626-15

20151486c1

1 A bill to be entitled
2 An act relating to residential master building permit
3 programs; creating s. 553.794, F.S.; requiring local
4 governments to create master building permit programs
5 if requested by a licensed general, building, or
6 residential contractor to assist builders who
7 construct certain dwellings and townhomes on a
8 repetitive basis; defining terms; providing
9 requirements for submitting a master building permit
10 application, a general construction plan, or a site-
11 specific building permit application; specifying
12 documents that must be provided with the applications
13 and plan; requiring master building permits to be
14 approved or denied within a time certain; providing
15 duration of validity of approved master building
16 permits; authorizing a builder to use a master
17 building permit for individual dwellings or townhomes
18 under certain conditions; limiting revisions to
19 approved master building permits; authorizing
20 governing bodies of local governments to set specified
21 fees; providing for penalties under certain
22 circumstances; authorizing local governments to adopt
23 procedures to carry out master building permit
24 programs; providing an effective date.

25
26 Be It Enacted by the Legislature of the State of Florida:
27

28 Section 1. Section 553.794, Florida Statutes, is created to
29 read:

578-03626-15

20151486c1

30 553.794 Local government residential master building permit
31 program.-

32 (1) MASTER BUILDING PERMIT PROGRAM CREATION.-If a local
33 building official licensed pursuant to part XII of chapter 468
34 receives a written request from a general, building, or
35 residential contractor licensed pursuant to chapter 489
36 requesting the creation of a master building permit program, the
37 local government that employs the recipient building official
38 shall create a residential master building permit program within
39 6 months after receipt of the written request. A master building
40 permit program is intended for use by builders who expect to
41 construct identical single-family or two-family dwellings or
42 townhomes on a repetitive basis. The master building permit
43 program must be designed to achieve standardization and
44 consistency during the permitting process and to reduce the time
45 spent by local building departments during the site-specific
46 building permit application process.

47 (2) DEFINITIONS.-For purposes of this section, the term:

48 (a) "Building orientation" means the placement of a
49 building with respect to weathering elements such as sun, wind,
50 and rain and environmental factors like topography.

51 (b) "Elevation" means a construction drawing that is drawn
52 to scale and depicts the external face of the dwelling or
53 townhome to be constructed.

54 (3) MASTER BUILDING PERMIT APPLICATION.-To obtain a master
55 building permit, a builder must submit the following information
56 to the local building department:

57 (a) A completed master building permit application.

58 (b) A general construction plan that complies with

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59 subsection (4).

60 (c) All general construction plan pages, documents, and
61 drawings, including structural calculations if required by the
62 local building department, signed and sealed by the design
63 professional of record, along with a written acknowledgement
64 from the design professional that the plan pages, documents, and
65 drawings contained within the master building permit application
66 will be used for future site-specific building permit
67 applications. The design professional of record must be a
68 licensed engineer or architect.

69 (d) Truss specifications, signed and sealed by the truss
70 design engineer. The design professional of record must stamp
71 and sign the truss layout sheet as reviewed and approved for
72 each model design.

73 (e) Energy performance calculations for all building
74 orientations. The calculations must consider worst-case
75 scenarios for the relevant climate zone and must include
76 component and cladding product approvals for all windows,
77 pedestrian doors, garage doors, glazed opening impact protection
78 devices, truss anchors, roof underlayments, and roof coverings.
79 The design professional of record must stamp and sign all
80 product approvals as reviewed and approved for use with each
81 model design.

82 (4) GENERAL CONSTRUCTION PLAN.—The general construction
83 plan submitted as part of a master building permit application:

84 (a) May be submitted in electronic or paper format, as
85 required by the local building department. A plan submitted in
86 paper format must be a minimum of 36 inches by 48 inches or must
87 comply with requirements of the local building department.

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88 (b) Shall include left-hand and right-hand building
89 orientations, including floor plans.

90 (c) Shall include a model design that may include up to
91 four alternate exterior elevations, each containing the same
92 living space footprint. The model design:

93 1. May not contain more than three alternate garage
94 layouts, with each garage layout limited to accommodating no
95 more than three cars.

96 2. Must include a foundation plan.

97 3. Must contain a truss layout sheet for each exterior
98 elevation that is compatible with the roof plan.

99 (d) Must show typical wall sections from the foundation to
100 the roof.

101 (e) Must contain a complete set of applicable electrical,
102 plumbing, fuel gas, and mechanical plans.

103 (f) Must contain window, door, and glazed opening impact
104 protection device schedules, if applicable.

105 (5) MASTER BUILDING PERMIT APPROVAL PROCESS.—

106 (a) A builder may submit to the local building department a
107 master building permit application that contains the information
108 identified in subsection (3). Once a master building permit
109 application is approved as provided in this subsection, the
110 local building department may only require the builder to submit
111 the documents identified in subsection (7) for each site-
112 specific building permit application for a single-family or two-
113 family dwelling or townhome.

114 (b) The local building department shall review the general
115 construction plan submitted as part of the master building
116 permit application to determine compliance with existing

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117 building code requirements. If the general construction plan is
118 approved and all documents provided pursuant to subsections (3)
119 and (4) are verified, the builder shall receive a master
120 building permit and permit number.

121 (c) The local building department must approve or deny a
122 master building permit application within 120 days after the
123 local building department receives a completed application,
124 unless the applicant agrees to a longer period.

125 (d) A builder may use the master building permit number for
126 each dwelling or townhome as long as the builder uses the model
127 design contained in the master building permit.

128 (e) An approved master building permit will remain valid
129 until the Florida Building Code is updated as provided in s.
130 553.73.

131 (6) REVISIONS TO MASTER BUILDING PERMIT.—Once a master
132 building permit has been approved, a local building department:

133 (a) May not allow structural revisions to the master
134 building.

135 (b) May allow limited nonstructural revisions to the master
136 building so long as any revised floor plan is submitted to and
137 approved by the local building department.

138 (c) May accept limited field revisions, as determined by
139 the local building department.

140 (7) SITE-SPECIFIC BUILDING PERMIT APPLICATIONS.—Once a
141 builder has an approved master building permit, the builder is
142 only required to submit the following information for each site-
143 specific building permit application for a single-family or two-
144 family dwelling or townhome:

145 (a) A completed site-specific building permit application

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146 that includes the master building permit number and identifies
147 the model design to be built, including elevation and garage
148 style.

149 (b) Three signed and sealed copies of the lot or parcel
150 survey or site plan, as applicable. The survey or site plan must
151 indicate the Federal Emergency Management Agency flood zone,
152 base flood elevation, and minimum finished floor elevation. Lot
153 or parcel drainage indicators must be shown along with site
154 elevations.

155 (c) An affidavit by the licensed engineer of record
156 affirming that the master building permit is a true and correct
157 copy of the master building permit on file with the local
158 building department. The affidavit must reference the master
159 building permit number. The licensed engineer of record must
160 affirm that the master building permit will conform to soil
161 conditions on the specific site.

162 (d) Complete mechanical drawings of the model design,
163 including HVAC heating and cooling load calculations and
164 equipment specifications.

165 (e) Specific information that was not included in the
166 master building permit application addressing the HVAC system
167 design, including duct design and heating and cooling load
168 calculations.

169 (8) FEES.—The governing bodies of local governments may set
170 fees pursuant to s. 553.80(7).

171 (9) PENALTIES.—In addition to any other penalty provided by
172 law, a builder or design professional who willfully violates
173 this section shall be fined \$10,000 for each dwelling or
174 townhome that is built under the master building permit that

578-03626-15

20151486c1

175 does not conform to the master building permit on file with the
176 local building department.

177 (10) PROGRAM GUIDELINES.—Each local government may adopt
178 procedures to provide master building permit program guidelines
179 and requirements for the submission and approval of materials
180 and applications.

181 Section 2. This act shall take effect July 1, 2015.



The Florida Senate

Committee Agenda Request

To: Senator Rob Bradley, Chair
Committee on Regulated Industries

Subject: Committee Agenda Request

Date: April 7, 2015

I respectfully request that **Senate Bill #1486**, relating to **Residential Master Building Permit Programs**, be placed on the:

- committee agenda at your earliest possible convenience.
- next committee agenda.

A handwritten signature in black ink, appearing to read "Jeff Brandes", written over a horizontal line.

Senator Jeff Brandes
Florida Senate, District 22

THE FLORIDA SENATE
APPEARANCE RECORD

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

4-15-2015

Meeting Date

1488

Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Brian Pitts

Job Title Trustee

Address 1119 Newton Ave S.

Phone 727/897-9291

Street

St Petersburg

FL

33705

Email justice2jesus@yahoo.com

City

State

Zip

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Justice-2-Jesus

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

4-15-2015

Meeting Date

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

1486

Bill Number (if applicable)

Topic Master Buiding Permit

Amendment Barcode (if applicable)

Name Wayne Bertsch (Birch)

Job Title

Address 113 E College Ave

Phone 850 251 1835

City TLH State FL Zip 32301

Email Wayne@wayneoh.com

Speaking: [X] For [] Against [] Information

Waive Speaking: [X] In Support [] Against (The Chair will read this information into the record.)

Representing Florida Home Builders 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.

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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 Regulated Industries

BILL: CS/CS/SB 1180

INTRODUCER: Regulated Industries, Health Policy Committee and Senator Latvala and others

SUBJECT: Practice of Pharmacy

DATE: April 15, 2015

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Stovall</u>	<u>Stovall</u>	<u>HP</u>	<u>Fav/CS</u>
2.	<u>Kraemer</u>	<u>Imhof</u>	<u>RI</u>	<u>Fav/CS</u>
3.	_____	_____	<u>FP</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 1180 amends ch. 465, F.S., the Florida Pharmacy Act (Pharmacy Act), to provide that a veterinarian licensed under the Veterinary Medical Practice Act (ch. 474, F.S.) is not prohibited from administering a compounded drug to any animal under the veterinarian's care, or dispensing a compounded drug to the animal's owner or caretaker. Regulation of the practice of pharmacy as set forth in the Pharmacy Act is not affected.

The bill creates s. 465.1862 to define the terms "maximum allowable cost" (MAC) and "pharmacy benefits manager" (PBM) and to require certain provisions in contracts between a pharmacy and a PBM. A PBM contracts with health insurance plans, such as a health maintenance organization or insurer, to manage the cost and quality of the plans' drug benefits and may provide a variety of related services. The maximum-allowable cost (MAC) is the payment for the unit ingredient costs for off-patent prescription drugs (generics). The PBM, an insurer, or a health maintenance organization may develop a MAC list based on a proprietary survey of wholesale prices and other factors. The bill requires a PBM to update pricing information weekly, and to adopt procedures that will timely eliminate drugs from MAC lists, or modify drug prices to remain consistent with pricing data used to formulate prices and product availability.

II. Present Situation:

Veterinary Medical Practice

The Board of Veterinary Medicine within the Department of Business and Professional Regulation is charged with the regulation of the practice of veterinary medicine under ch. 474, F.S., the Veterinary Medical Practice Act (Veterinary Act). The legislative purpose for the Veterinary Act is to ensure that every veterinarian practicing in Florida meets minimum requirements for safe practice and veterinarians who are not normally competent or who otherwise present a danger to the public are disciplined or prohibited from practicing in Florida.

The practice of veterinary medicine¹ includes:

- Diagnosing the medical condition of animals and prescribing, dispensing, or administering drugs, medicine, appliances, applications, or treatment of whatever nature for the prevention, cure, or relief of a wound, fracture, bodily injury, or disease thereof;
- Performing any manual procedures for the diagnosis of or treatment for pregnancy or fertility or infertility of animals;
- Representing oneself by the use of titles or words, or undertaking, offering, or holding oneself out, as performing any of these functions; and
- Determining the health, fitness, or soundness of an animal.

Veterinary medicine includes, with respect to animals, surgery, acupuncture, obstetrics, dentistry, physical therapy, radiology, theriogenology,² and other branches or specialties of veterinary medicine.³

With several exceptions, a person must be licensed as a veterinarian under the Veterinary Act, prior to practicing veterinary medicine in this state.⁴ Veterinarians who hold a valid federal controlled substance registry number are authorized to prescribe and dispense controlled substances pursuant to ch. 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act.⁵

Pharmacy Practice Act

Pharmacies and pharmacists are regulated under the Florida Pharmacy Act (Pharmacy Act) found in ch. 465, F.S.⁶ The Board of Pharmacy (the board) is created within the Department of Health (DOH) to adopt rules to implement provisions of the Pharmacy Act and take other actions based upon duties conferred on it. The practice of the profession of pharmacy includes:

- Compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;

¹ See s. 474.202(9), F.S.

² Theriogenology is a branch of veterinary medicine dealing with reproduction.

³ See s. 474.202(13), F.S.

⁴ See ss. 474.203, 474.207, and 474.213, F.S.

⁵ See s. 893.02(21), F.S.

⁶ Other pharmacy paraprofessionals, including pharmacy interns and pharmacy technicians, are also regulated under the Act.

- Monitoring a patient’s drug therapy, assisting the patient in managing his or her drug therapy, and reviewing the patient’s drug therapy and communicating with the patient’s prescribing health care provider or the provider’s agent or other persons as specifically authorized by the patient, regarding the drug therapy;
- Transmitting information from persons authorized to prescribe medicinal drugs to their patients; and
- Administering vaccines to adults.⁷

Compounding

Compounding is defined under the Pharmacy Act as combining, mixing, or altering the ingredients of one or more drugs or products to create another drug or product.⁸ Under the board’s rules,⁹ compounding includes the preparation of:

- Drugs or devices in anticipation of prescriptions based on routine, regularly-observed prescribing patterns;
- Drugs or devices, pursuant to a prescription, that are not commercially available;¹⁰ or
- Commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist. The reconstitution of commercially available products pursuant to the manufacturer’s guidelines is permissible without notice to the practitioner.

The preparation of drugs or devices for sale or transfer to pharmacies, practitioners, or entities for purposes of dispensing or distribution is not compounding and is not within the practice of the profession of pharmacy.¹¹

Historically and continuing today, a practitioner might prescribe a compounded preparation when a patient requires a different dosage form, such as a liquid rather than a pill or tablet, a different dosage strength than is commercially available, a product free of certain allergens, or a product that is not commercially available. Compounding and dispensing in this manner is typically patient-specific.

More recently, the practice of compounding medications has evolved and expanded to include compounding for office use. “Office use” is not currently defined in Florida law, but is defined by rule as the providing and administering of a compounded drug to a patient in a practitioner’s office or in a health care facility, such as a hospital, ambulatory surgical center, or pharmacy.¹²

⁷ See s. 465.003(13), F.S.

⁸ See s. 465.003(18), F.S.

⁹ See Rule 64B16-27.700, F.A.C.

¹⁰ The term “commercially available products” means any medicinal product that is legally distributed in Florida by a drug manufacturer or wholesaler. See Rule 64B16-27.700, F.A.C.

¹¹ See Rule 16B16-27.700(2), F.A.C., which further provides that supplying patient-specific compounded prescriptions to another pharmacy as permitted by law and regulated by rule is authorized. These provisions pertain to centralized prescription filling for another pharmacy.

¹² See Rule 16B16-27.700(3), F.A.C.

“Office use” means the provision and administration of a compounded drug to a patient by a practitioner in the practitioner’s office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy.¹³ The rule authorizes a pharmacist to dispense and deliver a quantity of a compounded drug to a practitioner for office use by the practitioner provided:

- The quantity compounded does not exceed the amount a practitioner may use in his or her office before the expiration date of the drug;
- The quantity compounded is reasonable considering the intended use of the compounded drug and the nature of the practitioner’s practice;
- The total quantity compounded does not exceed the pharmacy’s capacity to comply with pharmaceutical standards;
- The pharmacy and practitioner enter into a written agreement that provides:
 - The compounded drug may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity;
 - The practitioner will record product identifying information in the patient’s record;
 - The practitioner will provide notification to the patient regarding the reporting of an adverse reaction or complaint in order to facilitate a recall of the compounded product;
- The pharmacy maintains records of all compounded drugs ordered by practitioners for office use;
- The pharmacy labels the compounded drug with specified information; and
- The pharmacy is an outsourcing facility and complies with those requirements.

Until recently, the regulation of compounded medications was without clear guidelines or oversight responsibility by the FDA or state agencies. The FDA traditionally regulated the manufacture of prescription drugs, which typically includes making drugs (preparation, deriving, compounding, propagation, processing, producing, or fabrication) on a large scale for marketing and distribution of the product for unidentified patients. State boards of pharmacy historically have regulated the compounding of medications by a pharmacy under the practice of pharmacy that are requested for an identified patient.¹⁴

However, after a nationwide crisis in 2012 relating to contaminated human sterile drugs that had been compounded in pharmacies, enhanced regulation of sterile compounded human drugs was enacted at the federal level. President Barack Obama signed the Drug Quality and Security Act (DQSA)¹⁵ into law on November 27, 2013. Under the DQSA,¹⁶ a compounder of human drugs may become an outsourcing facility, which is able to qualify for exemptions from, among other things, the FDA approval requirements for new drugs.

¹³ *Id.*

¹⁴ See generally U.S. Department of Health and Human Services, FDA, Guidance, Compliance & and Regulatory Information for Compounded Drugs, at:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm> (last visited April 6, 2015).

¹⁵ See <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/> (last visited April 6, 2015).

¹⁶ See Section 503B of the Food, Drug, and Cosmetic Act (known as the Compounding Quality Act) at: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376732.htm> (last visited April 6, 2015).

Compounding Animal Drugs

According to the FDA, the DQSA does not cover the compounding of animal drugs.¹⁷ The statutory and regulatory provisions governing the compounding of human drug products differ from those governing the compounding of animal products. All relevant statutory and regulatory requirements relating to the compounding of animal drug products remain in effect, subject to the requirements of section 512 of the Food Drug and Cosmetic Act.¹⁸ Section 512 of the Food Drug and Cosmetic Act addresses the new animal drug approval requirements, which correspond to the approval process for new drugs for humans.

The FDA has issued compliance policy guidance¹⁹ intended to provide guidance and instructions to FDA staff, the industry, and the public for obtaining information to help fulfill the FDA's plans regarding the compounding of drugs for use in animals. This guidance describes FDA's current thinking on what types of compounding might be subject to enforcement action, and articulates the FDA's policy that it will defer to state authorities regarding the day-to-day regulation of compounding by veterinarians and pharmacists of animal and human drugs that are intended for use in animals.

However, when the scope and nature of activities of veterinarians and pharmacists raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new animal drug, adulteration, or misbranding provisions of the Food, Drug and Cosmetic Act, the FDA will consider enforcement action. The guidance lists 13 factors, any of which may trigger enforcement action. Two of the thirteen factors involve compounding drugs for use in situations where the health of the animal is not threatened and where suffering or death of the animal is not likely to result from failure to treat, and compounding drugs for third parties who resell to individual patients.

Dispensing Practitioner

Section 465.0276, F.S., in the Pharmacy Act relates to dispensing practitioners. Under this section, a person is prohibiting from dispensing medicinal drugs unless licensed as a pharmacist or otherwise authorized under the Pharmacy Act to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section of law.

This section requires a practitioner who dispenses medicinal drugs for human consumption for fee or remuneration of any kind to register with her or his professional licensing board as a dispensing practitioner, pay a registration fee, and comply with and be subject to all laws and rules applicable to pharmacists and pharmacies. Additional responsibilities are placed on practitioners who register under this section. Because veterinarians do not dispense medicinal

¹⁷ See note 14 *supra* (response to question 12).

¹⁸ See U.S. Department of Health and Human Services, FDA, *Guidance for Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act* (July 2014) at footnote 3, at <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm377052.pdf> (last visited April 6, 2015).

¹⁹ See <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074656.htm> (last visited April 6, 2015.)

drugs for human consumption, and the Veterinary Act does not have a corresponding registration requirement, veterinarians do not register with the Board of Veterinary Medicine.

Dispensing, Prescribing, and Administering

“Dispense” means the transfer of possession of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to:

- The ultimate consumer; or
- One who represents that it is his or her intention not to consume or use the drug, but to transfer it to the ultimate consumer or user for consumption by that person.²⁰

“Prescribing” is issuing a prescription. A “prescription” includes an order for drugs that is written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a practitioner licensed by the laws of the state to prescribe such drugs, issued in good faith and in the course of professional practice, intended to be filled or dispensed by another person licensed to do so.²¹ “Administer” means the direct application of a drug, whether by injection, inhalation, ingestion, or any other means, to the body of a person or animal.²²

Prescription Drug Costs

Advances in pharmaceuticals have transformed health care over the last several decades. In 2013, retail prescription drug spending totaled \$272.1 billion which was an increase of 3.3 percent from 2012; the increase has been attributed by the Centers for Medicare and Medicaid Services to price increases for brand name and specialty drugs, increased spending on new medicines, and increased utilization.²³ The projected growth for prescription drug spending in 2014 was 6.8 percent and 6.4 percent for 2015.²⁴

Regulation of Pharmacies and Pharmacy Benefits Management Companies

Pharmacies and pharmacists are regulated under the Pharmacy Act in ch. 465, F.S. The board adopts rules to implement provisions of the pharmacy act and takes other actions according to duties conferred on it by the Pharmacy Act.²⁵ Each pharmacy is subject to inspection by the DOH and may be disciplined for violations of applicable laws and rules relating to a pharmacy.²⁶

A pharmacy benefits manager (PBM) administers the prescription drug part of a health plan on behalf of the plan sponsor (self-insured employers, insurers, and health maintenance organizations). Currently, PBMs are not subject to regulation in Florida. Some states, such as

²⁰ See ss. 465.003(6) and 893.02(7), F.S.

²¹ See ss. 465.003(14) and 893.02(20), F.S.

²² See ss. 465.003(1) and 893.02(1), F.S.

²³ See Centers for Medicare and Medicaid Services, *National Health Expenditure Projections 2013-2023*, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2013.pdf> (last visited: April 15, 2015).

²⁴ Id.

²⁵ See sections 465.005 and 465.022, F.S.

²⁶ See sections 465.015 and 465.016, F.S.

Connecticut, Georgia, Kansas, Louisiana, Maryland and South Dakota, require PBMs to either register with state insurance regulators or be licensed as third-party administrators.²⁷

Although PBMs are not subject to licensure in Florida, a PBM may obtain accreditation from various impartial, external organizations (accrediting bodies) that determine if certain national standards are being met. Accreditation is an evaluative, rigorous, transparent, and comprehensive process in which a health care organization undergoes an examination of its systems, processes, and performance by an impartial external organization (accrediting body) to ensure that it is conducting business in a manner that meets predetermined criteria and is consistent with national standards.

Pharmacy Benefits Managers and Pharmacies

While PBMs provide pharmacy claims processing and mail-order pharmacy services to their customers, many provide additional services, including rebate negotiations with drug manufacturers, development of pharmacy networks, formulary management, prospective and retrospective drug utilization reviews, generic drug substitutions, and disease management programs. The decision of plan sponsors to use PBMs to control pharmacy benefit costs, however, can shift business away from retail pharmacies.

Maximum Allowable Cost Pricing List

Contracts between a PBM and health plan sponsors specify how much the health plan sponsors will pay PBMs for brand name and generic drugs. These prices are typically set as a discount off the average wholesale price (AWP)²⁸ for brand-name drugs and at a MAC²⁹ for generic drugs (and sometimes brand drugs that have generic versions), plus a dispensing fee. The MAC represents the upper limit price that a plan will pay or reimburse for generic drugs and sometimes brand drugs that have generic versions available (multisource brands). A MAC pricing list creates a standard reimbursement amount for identical products, and is a common cost management tool developed from a proprietary survey of wholesale prices in the marketplace, taking into account market share, inventory, reasonable profits margins, and other factors.

The federal Medicare Part D program and 45 state Medicaid programs use some type of MAC price lists to reduce costs.³⁰ The MAC price lists are used by many private employer prescription drug plans for retail generic prescriptions.

The purpose of the MAC pricing list is to ensure that the pharmacy or its buying groups are motivated to seek and purchase generic drugs at the lowest price in the marketplace. If a pharmacy procures a higher-priced product, the pharmacy may not make as much profit or may lose money on that purchase. If a pharmacy purchases generic drugs at a more favorable price, it will be more likely to make a profit.

²⁷ Joanne Wojcik, *States Try to Regulate Pharmacy Benefit Managers*, Business Insurance (August 22, 2010), available at <http://www.businessinsurance.com/article/20100822/ISSUE07/308229997> (last visited April 15, 2015).

²⁸ Average Wholesale Price is the retail list price (sticker price) or the average price that manufacturers recommend wholesalers sell to physicians, pharmacies and others, such as hospitals.

²⁹ Maximum Allowable Cost is a price set for generic drugs and is the maximum amount that the plan sponsor will pay for a specific drug.

³⁰ Medicaid Drug Pricing in State Maximum Allowable Cost Programs, Office of Inspector General, OEI-03-11-00640, (August 29, 2013) available at <https://oig.hhs.gov/oei/reports/oei-03-11-00640.asp> (last visited April 15, 2015).

In addition to negotiating rebates with drug manufacturers, PBMs negotiate with retail pharmacies to obtain various discounts on prescription drug prices. Additionally, PBMs try to assure adequate access for those enrolled in the various health plans to obtain their prescription drugs. A PBM may also be responsible for the development and management of a drug formulary, which is a list of drugs that a health plan uses to make reimbursement decisions.

Many PBMs offer incentives to health plan participants to select less-costly generic drugs rather than more expensive brand-name drugs.

In November 2014, U.S. Senator Bernie Sanders (I-Vt.) led a Senate hearing about recent pricing spikes in some generic drugs. The hearing followed a joint investigation Senator Sanders led with U.S. Representative Elijah Cummings (D-Md.).³¹ One of the comments made during the hearing quoted that a small percentage of certain generic drugs increased more than 1,000 percent in the past year.³² Included in the hearing materials was data showing that one-half of generic medicines went up in price between last summer and this summer with the price of some common medicines rising by over 500 percent.³³ In such an environment, a static MAC list could result in inadequate reimbursement to a pharmacy despite its best efforts to purchase from the lowest cost source.

Federal Pharmacy Benefits Managers Transparency Requirements

On March 23, 2010, President Obama signed into law Public Law No. 111-148, the Patient Protection and Affordable Care Act (PPACA), and on March 30, 2010, President Obama signed into law Public Law No. 111-152, the Health Care and Education Affordability Reconciliation Act of 2010, amending PPACA. The law³⁴ requires Medicare Part D plans and qualified health plan issuers who either have their own PBM or contract with a PBM to report to the U.S. Department of Health and Human Services (HHS) aggregate information about rebates, discounts, or price concessions that are passed through to the plan sponsor or retained by the PBM. In addition, each plan must report the difference between the amount the plan pays the PBM and the amount that the PBM pays its suppliers (spread pricing). The reported information is confidential, subject to certain limited exceptions.

III. Effect of Proposed Changes:

The bill provides that a veterinarian licensed under the Veterinary Medical Practice Act (ch. 474, F.S.) is not prohibited by ch. 465, F.S., and the adopted rules from administering a compounded

³¹ Senator Sanders and Representative Cummings have also filed legislation that would require drug makers to extend rebates to Medicaid when drug makers raise prices greater than inflation. This is the current federal law for brand-name drugs. See <http://www.sanders.senate.gov/newsroom/press-releases/drugmakers-mum-on-huge-price-hikes> (last visited April 15, 2015).

³² Ed Silverman, *Should Generic Drug Makers Pay Medicaid Rebates Tied to Inflation?* Wall Street Journal Pharamlot (Nov. 24, 2014) <http://blogs.wsj.com/pharmalot/2014/11/24/should-generic-drug-makers-pay-medicaid-rebates-tied-to-inflation/> (last visited: Mar. 27, 2015).

³³ U.S. Senate Subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor and Pensions, *Ranking Member Cummings and Chairman Sanders Investigate Staggering Price Increases for Generic Drugs* (Oct. 2, 2014) <http://www.sanders.senate.gov/download/face-sheet-on-generic-drug-price-increases?inline=file> (last visited: Mar. 27, 2015).

³⁴ 42 U.S.C. s. 1320b-23.

drug to any animal under the veterinarian's care, or dispensing a compounded drug to the animal's owner or caretaker.

The bill creates s. 465.1862, F.S., respecting pharmacy benefits manager contracts," in the Florida Pharmacy Act, and defines the following terms:

- "Maximum allowable cost," which is the per-unit amount that a pharmacy benefits manager reimburses a pharmacist for a prescription drug excluding dispensing fees but before any application of copayments, coinsurance, and other cost-sharing charges; and
- "Pharmacy benefits manager," which is a person or entity doing business in this state which contracts to administer or manage prescription drug benefits to residents of Florida on behalf of a health insurance plan defined in s. 627.6482, F.S.³⁵

The bill provides that in each original or renewal contract between a PBM and a pharmacy, the contract must require the PBM to:

- Update MAC pricing information at least every 7 days; and
- Maintain a process to timely eliminate drugs from MAC lists, or modify drug prices to remain consistent with pricing data used to formulate prices and product availability.

The effective date of the bill is July 1, 2015.

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.

³⁵ See ss. 627.6482(6), F.S., which defines that "health insurance" as any hospital and medical expense incurred policy, minimum premium plan, stop-loss coverage, health maintenance organization contract, prepaid health clinic contract, multiple-employer welfare arrangement contract, or fraternal benefit society health benefits contract, whether an individual policy or group policy, but excluding motor vehicle policies for medical payments or personal injury protection, liability insurance supplemental coverage, or workers' compensation.

B. Private Sector Impact:

Veterinarians who are licensed and practicing under the Florida Veterinary Practice Act, ch. 474, F.S., may administer a compounded drug to any animal under the veterinarian's care, or dispense a compounded drug to the animal's owner or caretaker without concern that such activities are prohibited by the provisions of the Pharmacy Act, ch. 465, F.S., or the rules adopted thereunder.

Pharmacies and pharmacy benefits managers must absorb the cost of verifying its contracts or contract renewals include provisions requiring the update maximum allowable cost pricing information at least every 7 days, and adopt procedures that will timely either eliminate drugs from MAC lists, or modify drug prices to remain consistent with pricing data used to formulate prices and product availability.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 465.0276 of the Florida Statutes.

This bill creates section 465.1862 of the Florida Statutes.

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

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

CS by Regulated Industries on April 15, 2015:

The CS amends s. 465.0276, F.S., respecting dispensing practitioners, to provide that veterinarians who are licensed and practicing under the Florida Veterinary Medical Practice Act, ch. 474, F.S., may administer a compounded drug to any animal under the veterinarian's care, or dispense a compounded drug to the animal's owner or caretaker. The CS removes the exception stating that licensed veterinarians engaging in activities allowed by the Veterinary Medical Practice Act are not limited by the provisions of ch. 465, F.S., the Pharmacy Act, or any adopted rules.

The CS creates s. 465.1862 to define the terms "maximum allowable cost" (MAC) and "pharmacy benefits manager" (PBM) and to require certain provisions in contracts between a pharmacy and a PBM. The CS requires a PBM to update pricing information

weekly, and to adopt procedures that will timely either eliminate drugs from MAC lists, or modify drug prices to remain consistent with pricing data used to formulate prices and product availability.

CS by Health Policy on March 23, 2015:

The CS removes the new definition for office use compounding and the new provision stating that nothing in the chapter or rule prohibit a veterinarian from dispensing a compounded drug to an animal patient or its owner or caretaker. Instead, the CS provides that neither the Florida Pharmacy Act nor pharmacy rules limit a veterinarian from engaging in an activity allowed under the Veterinary Practice Act.

B. Amendments:

None.

By the Committee on Health Policy; and Senators Latvala, Soto,
and Diaz de la Portilla

588-02726-15

20151180c1

1 A bill to be entitled
2 An act relating to the practice of pharmacy; amending
3 s. 465.027, F.S.; providing that the Florida Pharmacy
4 Act and rules adopted under the act do not limit a
5 veterinarian from engaging in an activity allowed
6 under ch. 474; providing an effective date.

7

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

9

10 Section 1. Section 465.027, Florida Statutes, is amended to
11 read:

12 465.027 Exceptions.—

13 (1) This chapter may ~~shall~~ not be construed to prohibit the
14 sale of home remedies or preparations commonly known as patents
15 or proprietary preparations which, ~~when such~~ are sold only in
16 original or unbroken packages or, ~~nor shall this chapter be~~
17 ~~construed~~ to prevent businesses from engaging in the sale of
18 sundries or patents or proprietary preparations.

19 (2) No provision in this chapter or rule adopted under this
20 chapter limits a veterinarian licensed under chapter 474 from
21 engaging in an activity allowed under chapter 474.

22 Section 2. This act shall take effect July 1, 2015.



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Appropriations Subcommittee on
Transportation, Tourism, and Economic
Development, *Chair*
Appropriations
Commerce and Tourism
Governmental Oversight and Accountability
Regulated Industries
Rules

SENATOR JACK LATVALA
20th District

March 24, 2015

The Honorable Rob Bradley, Chairman
Senate Committee on Regulated Industries
330 Knott Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Dear Chairman Bradley:

I respectfully request consideration of Senate Bill 1180/Practice of Pharmacy by the Senate Regulated Industries Committee at your earliest convenience. The bill was favorably referred by the Health Policy Committee on March 23.

This bill will permit the administration of a compounded veterinary drug to a patient by a practitioner in the practitioner's office or other treatment setting or to the owner or caretaker of the patient.

If you have any questions regarding this legislation, please contact me. Thank you in advance for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Jack".

Jack Latvala
State Senator
District 20

Cc: Patrick Imhoff, Staff Director; Lynn Koon, Administrative Assistant

REPLY TO:

- 26133 U.S. Highway 19 North, Suite 201, Clearwater, Florida 33763 (727) 793-2797 FAX: (727) 793-2799
- 408 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5020

Senate's Website: www.flsenate.gov

ANDY GARDINER
President of the Senate

GARRETT RICHTER
President Pro Tempore

THE FLORIDA SENATE
APPEARANCE RECORD

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

April 15, 2015

CSSB1180

Meeting Date

Bill Number (if applicable)

~~105958~~

Topic Pharmacy Benefit Managers

Amendment Barcode (if applicable)

618008

Name Michael Jackson

Job Title Executive Vice President and CEO

Address 610 North Adams Street

Phone (850) 222-2400

Street

Tallahassee

Florida

32301

Email mjackson@pharmview.com

City

State

Zip

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Florida Pharmacy 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)

4/15/15
Meeting Date

SB 1180
Bill Number (if applicable)

618008
Amendment Barcode (if applicable)

Topic PHARMACY

Name LARRY WILLIAMS

Job Title ATTORNEY

Address 215 SOUTH MONROE SUITE 601
Street

Phone (850) 521-1980

TALLAHASSEE FL 32301
City State Zip

Email LWILLIAMS@GUNSTER.COM

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing AMERICAN PHARMACY COOPERATIVE

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

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

4/15/15

Meeting Date

1180

Bill Number (if applicable)

PL18008

Amendment Barcode (if applicable)

Topic Pharmacy

Name Cynthia Henderson

Job Title _____

Address 108 E. Jefferson St #A

Street

Phone 850-559-0855

Tallahassee FL 32301

City

State

Zip

Email Cyhenderson@ame.com

of amendment

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read ~~this~~ information into the record.)

Representing EPIC Rx

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)

4-15-2015

Meeting Date

1180

Bill Number (if applicable)

~~105958~~

Amendment Barcode (if applicable)

618608

Topic _____

Name Brian Pitts

Job Title Trustee

Address 1119 Newton Ave S
Street

Phone 727/897-9291

St Petersburg FL 35705
City State Zip

Email justree2jesus@yahoo.com

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing Justice-2-Jesus

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

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

4-15-15 Meeting Date

CS/SB 1180 Bill Number (if applicable)

Topic Pharmacy Benefits Manager Amend. Amendment Barcode (if applicable)

Name BILL MINCY

Job Title

Address 2648 BANTRY BAY DRIVE Street

Phone 850-322-7740

TALAHASSEE FL 32309 City State Zip

Email bill.mincy@ppsconline.com

Speaking: [X] For [] Against [] Information

Waive Speaking: [X] In Support [] Against (The Chair will read this information into the record.)

Representing PPSC

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

Lobbyist registered with Legislature: [] Yes [X] 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

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

5/15/2015
Meeting Date

1180
Bill Number (if applicable)

Topic Compounding Pharmacy

Amendment Barcode (if applicable)

Name Jon Rawison

Job Title Pres. - Armony Hill

Address 934 N. Magnolia Ave.

Phone 321-436-0836

Street
Orlando Fl. 32803
City State Zip

Email Jon@ArmonyHillAdvocates.com

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing FLA Coalition of Vet Compounding Pharmacies.

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

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

4-15-15

1180

Meeting Date

Bill Number (if applicable)

Topic Pharmacy

Amendment Barcode (if applicable)

Name Michael Fischer

Job Title

Address PO Box 1197

Phone 222-6344

Street

Tallahassee FL 32302

Email mile@redfishconsult.com

City

State

Zip

Speaking: [X] For [] Against [] Information

Waive Speaking: [] In Support [] Against (The Chair will read this information into the record.)

Representing FLORIDA INDEPENDENT PHARMACISTS

Appearing at request of Chair: [] Yes [X] 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.

THE FLORIDA SENATE
APPEARANCE RECORD

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

4-15-15
Meeting Date

SB 1180
Bill Number (if applicable)

Topic Pharmacy

Amendment Barcode (if applicable)

Name Pat Mison (Mison)

Job Title Consultant

Address 119 E. Park Ave.

Phone 528-4442

Tallahassee FL 32301
City State Zip

Email pat@misonandassociates.com

Speaking: For Against Information

Waive Speaking: In Support Against
(The Chair will read this information into the record.)

Representing FL Veterinary Medical 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.



435334

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/16/2015	.	
	.	
	.	
	.	

The Committee on Regulated Industries (Latvala) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Subsection (6) is added to section 465.0276,
Florida Statutes, to read:

465.0276 Dispensing practitioner.—

(6) This chapter and the rules adopted thereunder do not
prohibit a veterinarian licensed under chapter 474 from
administering a compounded drug to a patient, as defined in s.



435334

11 474.202, or dispensing a compounded drug to the patient's owner
12 or caretaker. This subsection does not affect the regulation of
13 the practice of pharmacy as set forth in this chapter.

14 Section 2. This act shall take effect July 1, 2015.

15

16 ===== T I T L E A M E N D M E N T =====

17 And the title is amended as follows:

18 Delete everything before the enacting clause

19 and insert:

20

A bill to be entitled

21

An act relating to the practice of pharmacy; amending

22

s. 465.0276, F.S.; specifying that the Florida

23

Pharmacy Act and rules adopted thereunder do not

24

prohibit a veterinarian from administering a

25

compounded drug to a patient or dispensing a

26

compounded drug to the patient's owner or caretaker;

27

providing applicability; providing an effective date.



105958

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
04/16/2015	.	
	.	
	.	
	.	

The Committee on Regulated Industries (Latvala) recommended the following:

1 **Senate Amendment to Amendment (435334) (with title**
2 **amendment)**

3
4 Between lines 13 and 14
5 insert:

6 Section 2. Section 465.1862, Florida Statutes, is created
7 to read:

8 465.1862 Pharmacy benefit managers.—

9 (1) As used in this section, the term:

10 (a) "Health insurance plan" has the same meaning as the



105958

11 term "health insurance" as defined in s. 627.6482.

12 (b) "Maximum allowable cost" means the upper limit or
13 maximum amount that a health insurance plan will pay for generic
14 prescription drugs or brand name prescription drugs that have
15 available generic versions that are included on a list of
16 products generated by the pharmacy benefit manager.

17 (c) "Pharmacy benefit manager" means a person or entity
18 doing business in this state which contracts to administer or
19 manage prescription drug benefits on behalf of a health
20 insurance plan that provides prescription drug benefits to
21 residents of this state.

22 (2) In each contract between a pharmacy benefit manager and
23 a pharmacy, the pharmacy shall have the right to obtain from the
24 pharmacy benefit manager a current list of the sources used to
25 determine the maximum allowable cost pricing. The pharmacy
26 benefit manager must:

27 (a) Update the maximum allowable cost pricing information
28 at least every 7 business days and provide a means by which a
29 contracted pharmacy may promptly review current pricing
30 information in an electronic, print, or telephonic format that
31 is readily available to a contracted pharmacy within 1 business
32 day after the pricing information is updated at no cost to the
33 contracted pharmacy.

34 (b) Maintain a procedure to eliminate products from the
35 list of products subject to maximum allowable cost pricing in a
36 timely manner in order to remain consistent with changes in the
37 marketplace.

38 (3) To place a prescription drug on a list of products, a
39 pharmacy benefit manager must ensure that the prescription drug



105958

40 is generally available for purchase by pharmacies in this state
41 from a national or regional wholesaler and is not obsolete.

42 (4) (a) Each contract between a pharmacy benefit manager and
43 a pharmacy must include a process for appeal, investigation, and
44 resolution of disputes regarding maximum allowable cost pricing.

45 The process must:

46 1. Limit the right to appeal to 30 calendar days after the
47 initial claim.

48 2. Require investigation and resolution by the pharmacy
49 benefit manager of a dispute within 7 business days after an
50 appeal is received by the pharmacy benefit manager.

51 3. Include a telephone number at which a contracted
52 pharmacy may contact the pharmacy benefit manager regarding an
53 appeal.

54 4. Require that the pharmacy benefit manager provide a
55 reason for a denial of an appeal and identify the National Drug
56 Code of a prescription drug that may be purchased by the
57 contracted pharmacy at a price at or below the maximum allowable
58 cost as determined by the pharmacy benefit manager.

59 (b) If an appeal is upheld, the pharmacy benefit manager
60 shall make an adjustment to the maximum allowable cost pricing
61 within 1 business day after the date the appeal is upheld. The
62 pharmacy benefit manager shall make the price adjustment
63 applicable to all similarly situated contracted pharmacies.

64
65 ===== T I T L E A M E N D M E N T =====

66 And the title is amended as follows:

67 Delete line 27 and insert:

68 providing applicability; creating s. 465.1862, F.S.;



105958

69 defining terms; requiring that a contract between a
70 pharmacy benefit manager and a pharmacy allow the
71 pharmacy to obtain from the manager a list of sources
72 used to determine maximum allowable cost pricing;
73 requiring a pharmacy benefit manager to periodically
74 update the maximum allowable cost pricing information
75 and to provide a means for pharmacies to review such
76 information within a specified time; requiring a
77 pharmacy benefit manager to maintain a procedure to
78 eliminate certain products from the list of products
79 subject to maximum allowable cost pricing; specifying
80 requirements for a pharmacy benefit manager to place a
81 prescription drug on a list of products; requiring
82 contracts between a pharmacy benefit manager and a
83 pharmacy to include a specified process for appeal;
84 requiring a pharmacy benefit manager to make
85 adjustments to the maximum allowable cost price within
86 a specified period if an appeal is upheld; providing
87 an effective date.



618008

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/16/2015	.	
	.	
	.	
	.	

The Committee on Regulated Industries (Latvala) recommended the following:

1 **Senate Amendment to Amendment (435334) (with title**
2 **amendment)**

3
4 Between lines 13 and 14
5 insert:

6 Section 2. Section 465.1862, Florida Statutes, is created
7 to read:

8 465.1862 Pharmacy Benefits Manager Contracts.—

9 (1) (a) "Maximum allowable cost" means the per-unit amount
10 that a pharmacy benefits manager reimburses a pharmacist for a



618008

11 prescription drug, excluding dispensing fees, prior to the
12 application of copayments, coinsurance, and other cost-sharing
13 charges, if any.

14 (b) "Pharmacy benefits manager" means a person or entity
15 doing business in this state which contracts to administer or
16 manage prescription drug benefits on behalf of a health
17 insurance plan, as defined in s. 627.6482, to residents of this
18 state.

19 (2) Each contract execution or contract renewal between a
20 pharmacy benefits manager and a pharmacy must include
21 requirements that the pharmacy benefits manager:

22 (a) Update maximum allowable cost pricing information at
23 least every 7 calendar days; and

24 (b) Maintain a process that will, in a timely manner,
25 eliminate drugs from maximum allowable cost lists or modify drug
26 prices to remain consistent with changes in pricing data used in
27 formulating maximum allowable cost prices and product
28 availability.

30 ===== T I T L E A M E N D M E N T =====

31 And the title is amended as follows:

32 Delete line 27

33 and insert:

34 providing applicability; creating s. 465.1862, F.S.;

35 defining terms; requiring that each contract or

36 contract renewal between a pharmacy benefits manager

37 and a pharmacy require the pharmacy benefits manager

38 to periodically update the maximum allowable cost

39 pricing information and to maintain a procedure to



618008

40 eliminate certain drugs from the list of those subject
41 to maximum allowable cost pricing or modify maximum
42 allowable cost prices to remain consistent with
43 changes in certain pricing data; providing an
44 effective date.



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Appropriations Subcommittee on Criminal and
Civil Justice, *Chair*
Appropriations
Banking and Insurance
Ethics and Elections
Higher Education
Regulated Industries
Rules

SENATOR JOE NEGRON
32nd District

April 15, 2015

Chairman Rob Bradley
Regulated Industries Committee
330 Knott Building
404 Senate Office Building
Tallahassee, FL 32399

HAND DELIVERED

Re: Excused Absence Request

Dear Chairman Bradley:

This letter shall serve as my formal request for an excused absence from the Senate Committee on Regulated Industries on Wednesday, April 15, 2015. This absence was necessary to conduct other Senate business.

Thank you for your consideration of this request.

Sincerely Yours,

A handwritten signature in blue ink, appearing to read "Joe Negron".

Joe Negron
State Senator
District 32

JN/hd

c: Patrick "Booter" Imhoff, Staff Director

REPLY TO:

- 3500 SW Corporate Parkway, Suite 204, Palm City, Florida 34990 (772) 219-1665 FAX: (772) 219-1666
- 412 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5032

Senate's Website: www.flsenate.gov

ANDY GARDINER
President of the Senate

GARRETT RICHTER
President Pro Tempore



THE FLORIDA SENATE

Senator Maria Lorts Sachs
Deputy Minority Whip
District 34

Committees:

Higher Education
Vice Chair

Fiscal Policy

Communications, Energy,
and Public Utilities

Appropriations
Subcommittee on
Education

Appropriations
Subcommittee on
Transportation, Tourism,
and Economic
Development

Military Affairs, Space,
and Domestic Security

Regulated Industries

STAFF:

Matthew Damsky
Legislative Assistant

Laura Jiménez
Legislative Assistant

April 14, 2015

The Honorable Rob Bradley
208 Senate Office Building
404 S. Monroe Street
Tallahassee, FL 32399-1100

Dear Chairman Bradley,

I will not be able to attend the Committee on Regulated Industries meeting taking place at 4:00 p.m. on April 15, 2015. Please excuse me from attending the meeting.

Your leadership and consideration are appreciated.

Very truly yours,

Senator Maria Lorts Sachs
District 34

CourtSmart Tag Report

Room: EL 110

Case:

Type:

Caption: Senate Regulated Industries Committee

Judge:

Started: 4/15/2015 4:05:39 PM

Ends: 4/15/2015 4:23:09 PM

Length: 00:17:31

4:05:46 PM Meeting called to order by the Chair
4:06:02 PM Roll call
4:06:40 PM CS/S1486 - Senator Brandes
4:07:00 PM Senator Brandes to explain the bill
4:07:41 PM Senator Braynon commenting
4:08:14 PM CS/SB 1486 - Passes
4:09:12 PM CS/SB 1180 - Senator Latvala
4:09:36 PM Senator Latvala to explain the bill
4:10:19 PM Amendment #435334 - Senator Latvala
4:10:38 PM Senator Stargel questioning
4:11:06 PM Amendment to the Amendment #618008 - Senator Latvala
4:11:28 PM Senator Lavala to explain the amendment
4:12:51 PM Larry Williame - American Pharmacy Cooperative
4:14:30 PM Brian Pitts - Justice-2-Jesus
4:17:52 PM Amendment to the Amendment - Adopted
4:18:09 PM Amendment as amended - Adopted
4:19:58 PM Senator Latvala to close on the bill
4:21:06 PM Cs/CS/SB 1180 - Passes
4:21:38 PM Comments by Chairman Bradley
4:22:54 PM Meeting adjourned