Health Quality Subcommittee

Tuesday, February 19, 2013
9:00 AM - 11:00 AM
306 HOB

Will Weatherford
Speaker

Kenneth L. "Ken" Roberson
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

(AMENDED 2/15/2013 12:44:41PM)

Amended(1)

Health Quality Subcommittee

Start Date and Time:	Tuesday, February 19, 2013 09:00 am
End Date and Time:	Tuesday, February 19, 2013 11:00 am
Location:	306 HOB
Duration:	2.00 hrs

Consideration of the following bill(s):

HB 365 Pharmacy by Hudson
HB 529 Public Records by Renuart

Department of Health Presentation on Reorganization and Efficiency Measures since the passage of CS/CS/CS/HB 1263 (2012)

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members is 6:00 p.m., Monday, February 18, 2013.

By request of the chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Monday, February 18, 2013.

NOTICE FINALIZED on 02/15/2013 12:44 by Iseminger.Bobbye

HB 1263 (2012) MQA
Efficiency Plan - DOH

HB 1263 (2012)
MQA Efficiency Plan

Lucy C. Gee M.S.
Interim Deputy Secretary
Director, Division of Medical Quality Assurance

Protect, promote and improve the health of all people in Florida.

Florida HEALTH

HB 1263

The bill revises the purposes and structure of the Florida Department of Health, making substantive changes to several programs.

MEDICAL QUALITY ASSURANCE

- Section 116 of House Bill 1263 (2012) directed MQA to develop a plan to improve the efficiency of its functions and conduct an analysis of best practices from within the division and other state agencies with similar functions, consult with its regulatory boards, and explore technology and other business solutions.
  - **Completed November 2012**

EFFICIENCY IMPROVEMENT PLAN

Objective 1: Reduce the average length of time for a qualified applicant to receive initial and renewal licensure certification or registration by one-third.

Performance Measure	Baseline	Target
Average number of days to issue an initial license for a qualified applicant.	5.77 *	1
Average number of days to process a renewal application for a qualified applicant.	4.94	1

EFFICIENCY IMPROVEMENT PLAN

Objective 2: Improve the agenda process for board meetings to increase transparency, timeliness, and usefulness for board decision-making.

Performance Measure	Baseline	Target
Percentage of board members satisfied with board meeting agendas.	95%	100%

EFFICIENCY IMPROVEMENT PLAN

Objective 3: Improve the cost-effectiveness and efficiency of the joint functions of the division and regulatory boards.

Performance Measure	Baseline	Target
Annual expenditures for board meetings.	$422,551.63	$401,424.05
Percentage of complaints resulting in probable cause.	28.3%	40%
Percentage of complaints resolved through alternative dispute resolution.	6%	7%

EFFICIENCY IMPROVEMENT PLAN

Objective 3 (continued): Improve the cost-effectiveness and efficiency of the joint functions of the division and regulatory boards.

Performance Measure	Baseline	Target
Percentage of emergency actions taken within 30 days on a practitioner who poses an immediate threat to public health and safety.	41%	75%
Number of cases in prosecution services that are greater than one year old.	1,592	900
Average cost of regulation per licensee.	$72.02	$60

EFFICIENCY IMPROVEMENT PLAN

Objective 4: Identify and analyze best practices within the division and other state agencies.

Initiative	Status
Evaluate licensure, enforcement, and board meeting preparation systems and processes used at other state agencies with similar functions.	Completed Sept. 2012

EFFICIENCY IMPROVEMENT PLAN

Objective 5: Identify options for information technology improvements.

Performance Measure	Baseline	Target
Percentage of fines and costs collected from disciplined licensees with a current license.	83.2%	85%

EFFICIENCY IMPROVEMENT PLAN

Objective 6: Identify options for contracting with outside entities.

Initiative	Status
Analyze staff capacity and capability to fulfill technology and operational requirements needed to achieve maximum efficiency.	Conducted annually Completed for FY 11-12

EFFICIENCY IMPROVEMENT PLAN

Objective 7: Identify other options the division deems useful.

Performance Measure	Baseline	Target
Percentage of customer satisfaction with MQA website.	45%	80%
Monthly number of calls from consumers, applicants, and licensees.	26,302	23,671

Questions?

Protect, promote and improve the health of all people in Florida.

Florida HEALTH

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 365 Pharmacy
SPONSOR(S): Hudson
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Poche	O'Callaghan
2) Appropriations Committee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

A biological product is a virus, therapeutic serum, vaccine, protein, blood component, or other product used to prevent, treat, or cure a disease or condition in human beings. A biological product is made by using a living system or organism to essentially "grow" or create the product, which causes variation in composition of the biological product. This differs from the manufacture of a chemical drug, which is created by combining various chemicals in an easily replicated manner to produce the desired therapeutic effect.

A biosimilar biological product is highly similar to another biological product, known as a reference product, with minor differences in clinically inactive components. There are no clinically meaningful differences between a biosimilar biological product and its reference product that impact the safety, purity, and potency of the product. Biosimilar biological products have been approved and sold in Europe since 2006, as well as in other parts of the world. There is no biosimilar biological product market currently in the United States.

The Biologics Price Competition and Innovation Act (BPCIA) was passed as part of the Patient Protection and Affordable Care Act on March 23, 2010. The BPCIA creates a pathway for approval of biosimilar biological products by the federal Food and Drug Administration (FDA), which, if determined to be interchangeable, can be substituted for more expensive reference products and thereby lower health care costs.

House Bill 365 permits the substitution of biosimilar biological products for prescribed biological products by Florida pharmacists. Substitution is only permitted if the biological product to be substituted appears on a list developed and maintained by the FDA as biosimilar to and interchangeable with the prescribed biological product. The patient and the prescribing health care provider have the ability to reject substitution and request the prescribed biological product.

The bill requires a pharmacist to notify the prescribing health care provider of the substitution within a specific time frame and in a specific manner. Both the pharmacist and the prescribing health care provider are required to maintain a written record of the substitution.

The bill appears to have an undetermined, positive fiscal impact on state and local governments.

The bill provides an effective date of July 1, 2013.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

"Brand Name" Chemical Drugs and Generic Chemical Drugs

A "brand name" chemical drug is manufactured with simple chemical ingredients that have uniform, predictable structures which are easy to characterize and replicate. The potency of a "brand name" chemical drug is determined by a defined chemical process. A generic chemical drug has the identical active substance and biological effect as its "brand name" counterpart. A generic chemical drug differs from a "brand name" chemical drug by inactive ingredients contained in the chemical structure and the rate and extent of absorption by the human body.

The Federal Food, Drug and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), established the Abbreviated New Drug Application process, creating a pathway for approval of generic medications, primarily for chemical drugs.[1] Since 1984, the federal Food and Drug Administration (FDA) has approved more than 8,000 generic drugs, which has resulted in hundreds of billions of dollars in cost savings to consumers.[2] In 2009, almost 75% of pharmaceutical prescriptions dispensed in the U.S. were generic medications.[3]

Biological Products and Biosimilar Biological Products

A biological product (biologic), in contrast to a chemical drug, is a large and complex protein, generally produced using a living system or organism.[4] It is heterogeneous and difficult to characterize. The effectiveness of a biologic is expressed in a biological system, meaning the biologic interacts with the human body to produce the desired effect. A biologic can be manufactured through a biotechnological process, derived from natural sources, or completely synthesized in a laboratory setting.[5]

A biosimilar biological product (biosimilar) has a similar, but not identical, active substance to another biologic. The biological activity of a biosimilar may vary as compared to another biologic. Because of the variable nature of a biosimilar, it is critical to identify the differences and determine which differences matter clinically. The determination of clinically meaningful differences between a biologic and its biosimilar can be exhibited through animal studies that measure toxicity, clinical studies on humans, and other scientifically accepted metrics.

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[1] The Federal Food, Drug and Cosmetic Act, s. 505(b)(2); 21 U.S.C. 355(b)(2).
[2] U.S. Dept. of Health and Human Services, Food and Drug Administration, Regulatory Information, *Fact Sheet: New "Biosimilars" User Fees Will Enhance Americans' Access to Alternatives to Biologic Drugs*, July 16, 2012, available at www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm311121.htm. (last viewed on February 14, 2013).
[3] Kozlowski, S., Woodcock, J., et al., *Developing the Nation's Biosimilar Program*, N Engl J Med 365:5, 385 (August 4, 2011).
[4] U.S. Dept. of Health and Human Services, Food and Drug Administration, Sherman, M.D., Rachel, *Biosimilar Biological Products-Biosimilar Guidance Webinar*, February 15, 2012, slide 3, available at www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm292463.pdf.
[5] Id.

In 2011, roughly 25% of the $320 billion spent on drugs in the U.S., was spent on biologics.[6] Each year, patients in the U.S. receive over 200 million vaccinations, 29 million transfusions of blood and blood components, and 1.6 million transplants of musculoskeletal tissue, all of which require the use of biologics.[7]

There is no existing market for biosimilars currently in the U.S.[8] Twelve biologics with global sales exceeding $67 billion will lose patent protection by 2020, and will be open to biosimilar competition.[9] By 2015, sales of biosimilars worldwide are expected to reach between $1.9 billion and $2.6 billion, up from $378 million in the first half of 2011.[10] The U.S. is forecast to be the largest opportunity for biosimilar sales by 2020, with a market value between $11 billion and $25 billion, which represents a 4% to 10% share of the total biologics market.[11] Biosimilars are forecast to comprise up to 50% of the off-patent biological market by 2020, with an assumed price discount between 20% and 30% when compared to biologics.[12]

The U.S. Federal Trade Commission predicts that the availability of biosimilars will significantly reduce the cost of biologics and increase their accessibility.[13]

The Biologics Price Competition and Innovation Act of 2010

The Biologics Price Competition and Innovation Act (BPCIA) was enacted as part of the Patient Protection and Affordable Care Act on March 23, 2010.[14] The BPCIA amends the Public Health Service Act and other statutes to create an abbreviated licensure pathway for biologics demonstrated to be biosimilar to or interchangeable with a reference biologic.[15] The BPCIA establishes the requirements for an application for a proposed biosimilar and an application for a proposed interchangeable product.[16]

The application must include information demonstrating biosimilarity, based on data derived from, among other things, "analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components,"[17] animal studies that include an assessment of toxicity,[18] and a clinical study or studies sufficient to establish safety, purity, and potency of the biosimilar.[19] Biosimilarity means that a biologic is highly similar to the

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[6] IMS Health, *Top Therapeutic Classes by U.S. Spending-2011*, available at www.imshealth.com/deployedfiles/ims/Global/Content/Corporate/Press%20Room/Top_Therapy_Classes_by_Sales[1].pdf

[7] U.S. Dept. of Health and Human Services, Food and Drug Administration, *About FDA*, available at www.fda.gov/AboutFDA/CentersOffices/ucm193951.htm. (last viewed on Feb. 13, 2013).

[8] One product exists in the U.S. that may meet the current definition of "biosimilar" contained in the BPCIA. Omnitrope, a form of synthetic human growth hormone used to treat long-term growth failure in children and adult onset growth deficiency, and manufactured by Sandoz, was approved for sale in the U.S. under a special ruling from FDA in 2007.

[9] Genetics and Biosimilar Initiative, *US$67 billion worth of biosimilar patents expiring before 2020,* June 29, 2012 (on file with the Health Quality subcommittee staff).

[10] IMS Health, *Shaping the biosimilars opportunity: A global perspective on the evolving biosimilars landscape*, December 2011, page 1, available at www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/Documents/Biosimilars_White_Paper.pdf.

[11] Id. at pages 3 and 6.

[12] Id. at page 6.

[13] U.S. Federal Trade Commission, *Emerging health care issues: follow-on biologic drug competition*, 2009, available at www.ftc.gov/os/2009/06/P083901biologicsreport.pdf.

[14] PPACA (Pub. L. 111-148), title VII, subtitle A, §§7001 to 7003.

[15] A reference product is an existing biological product against which another biological product is compared to determine biosimilarity and interchangeability.

[16] S. 351(k) of the PHS Act (42 U.S.C. 262(k)).

[17] 42 U.S.C. §262(k)(2)(A)(i)(I)(aa).

[18] 42 U.S.C. §262(k)(2)(A)(i)(I)(bb).

[19] 42 U.S.C. §262(k)(2)(A)(i)(I)(cc).

reference biologic, even when considering the differences in clinically inactive components, and that there are no clinically meaningful differences between the biologic and the reference biologic in terms of safety, purity, and potency.[20]
The FDA will use a totality-of-the evidence approach in reviewing biosimilar applications, meaning all available data and information submitted in support of biosimilarity and the proposed biosimilar will be evaluated before a determination is made regarding biosimilarity and interchangeability.[21] To meet the standard of interchangeability, an applicant must provide sufficient information to demonstrate biosimilarity, and also demonstrate that the biologic can be expected to produce the same clinical result as the reference product in any given patient. In addition, an applicant must demonstrate that, if the biologic is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biosimilar and the reference product is not greater than the risk of using the reference product without an alternation or switch in products.[22]

Pending FDA Rules on Biosimilars and Interchangeability

On February 9, 2012, the FDA issued three draft guidance documents regarding biosimilars and interchangeability. The documents, entitled *Guidance for Industry*, answered questions regarding implementation of the BPCIA[23] and detailed scientific and quality considerations to be addressed in demonstrating biosimilarity.[24] The guidance documents have not yet been finalized by the FDA.

The Federal Food, Drug, and Cosmetic Act, as amended by the Biosimilar User Fee Act of 2012 (BsUFA), authorizes the FDA to assess and collect fees for biosimilars from October 2012 through September 2017.[25] The FDA dedicates these fees to expediting the review process for approval of biosimilars. The FDA has determined that biosimilars represent an important public health benefit, with the potential to offer life-saving or life-altering benefits at reduced cost to the patient. According to the FDA, BsUFA facilitates the development of safe and effective biosimilars for the American public.[26]

The FDA is currently meeting with sponsors of proposed biosimilars, receiving 50 requests for meetings and fulfilling 37 of those requests.[27] In addition, the FDA has approved 14 Investigative New Drug applications (INDs) for clinical development of proposed biosimilars.[28] The FDA has also noted that they are in active discussions with many sponsors at the pre-IND stage, indicating further clinical

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[20] 42 U.S.C. §262(i)(2).
[21] U.S. Dept. of Health and Human Services, Food and Drug Administration, *Biosimilars Fact Sheet: Issuance of Draft Guidances on Biosimilar Products*, available at www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm291197.htm .
[22] 42 U.S.C. §262(i)(3).
[23] U.S. Dept. of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, *Guidance for Industry, Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009*, February 2012, available at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm259797.htm. (last viewed on February 15, 2013).
[24] U.S. Dept. of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, *Guidance for Industry, Scientific Considerations in Demonstrating Biosimilarity to a Reference Product* and *Guidance for Industry, Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product*, February 2012, both documents available at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm290967.htm. (last viewed on February 15, 2013).
[25] Biosimilar User Fee Act of 2012, Pub. L. 112-144, title IV, ss. 401-408 (21 U.S.C. 379j-51 through 53).
[26] U.S. Dept. of Health and Human Services, Food and Drug Administration, *For Industry: Biosimilar User Fee Act (BsUFA)*, available at www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/default.htm. (last viewed on February 16, 2013).
[27] Comments of Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration, at Bloomberg State of Health Care 2013 Summit, February 11, 2013 (video available at www.bloomberg.com/video/fda-sees-more-breakthrough-drugs-woodcock-says-~Obd9FUMQ7qWka0CfYq3dg.html) (last viewed on February 15, 2013).
[28] Id.

development of biosimilars in the near future.[29] The FDA also does not expect to diverge greatly from the policies established by the European Medicines Agency for approval of biosimilars for sale in the European Union and other specific countries.[30]

Biosimilars in Europe

The European Medicines Agency (EMA) is a decentralized agency of the European Union (EU), located in London, England. It is the scientific body of the European Commission (EC).[31] The EMA's primary responsibility is the "protection and promotion of public and animal health through the evaluation and supervision of medicines for human and veterinary use".[32]

The EMA is responsible for the scientific evaluation of applications for EU marketing authorizations for human and veterinary medicines governed by the "centralised procedure".[33] Under the "centralised procedure", pharmaceutical companies submit a single marketing-authorization application to the EMA.[34] Medicines are then approved by the EC based on the positive scientific opinion of the EMA and its expert committee, the Committee on Human Medicinal Products.[35] Once granted by the EC, a centralized marketing authorization is valid in all EU Member States, as well as in the European Economic Area (EEA) countries of Iceland, Liechtenstein and Norway.[36] By law, a company can only market a medicine once it has received a marketing authorization.[37]

The "centralised procedure" is mandatory for:

- Human medicines for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases;
- Veterinary medicines for use as growth or yield enhancers;
- Medicines derived from biotechnology processes, such as genetic engineering;
- Advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines; and
- Officially designated medicines used for rare human diseases.[38]

Biologics and biosimilars fall within the mandatory "centralised procedure" for approval and marketing within the EU and other specified European countries.

In 2003, the EMA created a new pathway for approving biosimilar medicines.[39] The central feature of the evaluation process is the comparison of the biosimilar with its reference product to show that there

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[29] Id.
[30] Id.
[31] European Generic Medicines Association, *EGA FACT SHEET on generic medicines, FAQs about Biosimilar Medicines*, July 2011, available at www.egagenerics.com/index.php/biosimilar-medicines/faq-on-biosimilars. (last viewed on February 15, 2013).
[32] European Medicines Agency, *What we do*, available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000091.jsp&mid=WC0b01ac0580028a42. (last viewed on February 15, 2013)
[33] Id.
[34] Id.
[35] *See supra*, FN 23.
[36] Id.
[37] Id.
[38] European Medicines Agency, *Central authorization of medicines*, available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000109.jsp&mid=WC0b01ac0580028a47. (last viewed on February 15, 2013).
[39] European Medicines Agency, *Questions and answers on biosimilar medicines (similar biological medicinal products)*, available at www.ema.europa.eu/docs/en_GB/document_library/Medicine_QA/2009/12/WC500020062.pdf. (last viewed on February 15, 2013).

are no significant differences between them.[40] The EMA further explains the evaluation process to determine biosimilarity, which is very similar to the proposed pathway process in the U.S.:

> The relevant regulatory authority applies stringent criteria in their evaluation of the studies comparing the quality, safety and effectiveness of the two medicines. The studies on quality include comprehensive comparisons of the structure and biological activity of their active substances, while the studies on safety and effectiveness should show that there are no significant differences in their benefits and risks, including the risk of immune reactions.

One critical difference between the approval process established by the EMA and the proposed pathway outlined by the FDA is that the EMA does not make recommendations on whether a biosimilar can be used interchangeably with its reference product.[41] The FDA will determine interchangeability, which in turn will determine whether or not a biosimilar can be substituted for a prescription biologic by a pharmacist.

The EMA published general guidelines on biosimilars in 2005 and approved its first biosimilar in 2006.[42] As of February 2012, the EMA had approved 14 biosimilar products,[43] with reference products including filgrastim,[44] epoetin,[45] and somatropin.[46]

Pharmacist Substitution in Florida

In general, a pharmacist in Florida is required to substitute a less expensive generic medication for a prescribed brand name medication.[47] The presenter of the prescription may specifically request the brand name medication.[48] Also, the prescriber may indicate the brand name medication is "medically necessary" in writing, orally, or, in the case of an electronic transmission of the prescription, by making an overt act to indicate the brand name medication is "medically necessary."[49] The pharmacist must inform the presenter of the prescription that a substitution has been made and advise the presenter that he or she may refuse the substitution and request the brand name medication.[50]

Each pharmacy is required to establish a formulary of brand name medications and generic medications which, if selected as the drug product of choice, pose no threat to patient health and safety.[51] The Board of Pharmacy and the Board of Medicine are required to establish a formulary which lists brand name medications and generic medications that are determined to be clinically different so as to be biologically and therapeutically inequivalent.[52] Substitution of the drugs included in this formulary would pose a threat to patient health and safety.[53] The boards are required to distribute the formulary to licensed and registered pharmacies and pharmacists.[54] Each board that regulates practitioners licensed by the state to prescribe medications must incorporate the formulary into its

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[40] *See supra*, FN 38.
[41] *See supra*, FN 39.
[42] European Medicines Agency, *Guideline on similar biological medicinal products*, 2005, available at www.emea.europa.eu/pdfs/human/biosimilar/043704en.pdf .
[43] *See supra*, FN 4 at slide 23.
[44] A white blood cell booster used to reduce infection risks in persons receiving strong chemotherapy treatment.
[45] Also known as EPO, it treats anemia caused by chronic kidney disease in dialysis patients by promoting red blood cell production.
[46] Synthetic human growth hormone (hGH).
[47] S. 465.025(2), F.S.
[48] Id.
[49] Id.
[50] S. 465.025(3)(a), F.S.; *see also* Rule 64B-16-27.530, F.A.C.
[51] S. 465.025(5), F.S.; *see also* Rule 64B-16.27.520, F.A.C.
[52] S. 465.025(6), F.S.; *see also* Rule 64B-16.27.500, F.A.C.
[53] Id.
[54] S. 465.025(6)(b), F.S.

rules.[55] No pharmacist may substitute a generic medication for a brand name medication if either medication is included in the formulary.[56]

Effect of Proposed Changes

The bill allows a pharmacist to substitute a biosimilar for a prescribed biologic if the biosimilar has been determined by the FDA to be interchangeable with the prescribed biologic and the prescribing health care provider does not express a preference against substitution in writing, orally, or electronically. The ability of a pharmacist to substitute a biosimilar for a prescription biologic is permissive; substitution of a generic chemical drug for brand name chemical drug is mandatory under Florida law.[57]

The bill requires the pharmacist to notify the person presenting the prescription that he or she has substituted a biosimilar for the prescribed biologic. The presenter has the right to reject the substitution and request the prescribed biologic. This is identical to current law regarding generic chemical drugs, which permits a presenter of a prescription for a brand name chemical drug to reject substitution and request the brand name chemical drug.

The bill requires the pharmacist, within 10 days of substitution, to inform the prescribing health care provider that he or she substituted a biosimilar for the prescribed biologic. Notification can be made by telephone, voicemail, facsimile, e-mail, electronic medical record, or other electronic means. Both the pharmacist and the prescribing health care provider are required to retain a written record of the substitution for four years. The notification and recordkeeping requirements allow the health care provider to have an accurate record of a patient's medication history if needed to determine the source of an adverse reaction or ineffective treatment protocol. This provision would require a pharmacist to establish a communication policy with prescribing health care providers to ensure notification is made within the statutorily required time frame.

The bill directs the Board of Pharmacy to maintain a list on its website of biological products that the FDA has determined to be biosimilar to and interchangeable with other biologics. Changes to the list of biosimilar and interchangeable biologics made by the FDA would require the Board of Pharmacy to also update the list on its website.

Lastly, the bill adopts the definitions of the terms "biological product," "biosimilar," and "interchangeable" as they appear in the federal Public Health Service Act.[58]

B. SECTION DIRECTORY:

Section 1: Creates s. 465.0252, F.S., relating to substitution of interchangeable biosimilar products.
Section 2: Provides an effective date of July 1, 2013.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

[55] Id.
[56] Id.
[57] *See supra*, section I(A), Background, *Pharmacist Substitution in Florida*.
[58] 42 U.S.C. §262(i)(1), (2), and (3).

2. Expenditures:

While a biosimilar market does not currently exist in the U.S., it is anticipated that once biosimilars are approved by the FDA and deemed interchangeable with prescription biologics, Medicaid and the State Group Insurance program may realize cost savings due to substitution of less expensive biosimilars for prescription biologics. The estimate of cost savings is undetermined.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

While a biosimilar market does not currently exist in the U.S., it is anticipated that once biosimilars are approved by the FDA and deemed interchangeable with prescription biologics, cities and counties that are self-insured or pay a portion of employees' prescription drug insurance coverage may realize cost savings due to substitution of less expensive biosimilars for prescription biologics. The estimate of cost savings is undetermined.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill provides a pathway to establish a market for biosimilars in Florida. Companies that manufacture biosimilars for treatment or prevention of disease or conditions will be permitted to sell such products in Florida.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Department of Health and the Board of Pharmacy have appropriate rule-making authority to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

A patient may be faced with an out-of-pocket cost to obtain a second prescribed biologic if the patient's physician rejects the substitution of the biosimilar after receiving notice of such substitution.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to pharmacy; creating s. 465.0252, F.S.; providing definitions; providing requirements for a pharmacist to dispense a substitute biological product that is determined to be biosimilar to and interchangeable for the prescribed biological product; requiring the Board of Pharmacy to maintain a current list of interchangeable biosimilar products; providing an effective date.

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

Section 1. Section 465.0252, Florida Statutes, is created to read:

465.0252 Substitution of interchangeable biosimilar products.—

(1) As used in this section, the terms "biological product," "biosimilar," and "interchangeable" have the same meanings as defined in s. 351 of the federal Public Health Service Act, 42 U.S.C. s. 262.

(2) A pharmacist may only dispense a substitute biological product for the prescribed biological product if:

(a) The United States Food and Drug Administration has determined that the substitute biological product is biosimilar to and interchangeable for the specified indicated use of the prescribed biological product.

(b) The prescribing health care provider does not express a preference against substitution in writing, verbally, or

electronically.

(c) The pharmacist notifies the person presenting the prescription of the substitution in the same manner as provided in s. 465.025(3)(a).

(d) The pharmacist, within 10 business days after dispensing the substitute biological product in lieu of the prescribed biological product, notifies the prescribing health care provider of the substitution by facsimile, telephone, voicemail, e-mail, electronic medical record, or other electronic means.

(e) The pharmacist and the prescribing health care provider each retain a written record of the substitution for at least 4 years.

(3) The board shall maintain on its public website a current list of biological products that the United States Food and Drug Administration has determined are biosimilar and interchangeable as provided in paragraph (2)(a).

Section 2. This act shall take effect July 1, 2013.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 365 (2013)

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	____	(Y/N)
ADOPTED AS AMENDED	____	(Y/N)
ADOPTED W/O OBJECTION	____	(Y/N)
FAILED TO ADOPT	____	(Y/N)
WITHDRAWN	____	(Y/N)
OTHER		

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Hudson offered the following:

Amendment

Remove line 33 and insert:

(d) The pharmacist, within 5 business days after

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 529 Public Records
SPONSOR(S): Renuart
TIED BILLS: **IDEN./SIM. BILLS:** SB 60

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Guzzo	O'Callaghan
2) Government Operations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

HB 529 creates a public record exemption for information relating to the identification and location of current or former personnel of the Department of Health (DOH), whose duties include or support the:

- Investigation and prosecution of complaints filed against health care practitioners; or
- Inspection of practitioners or facilities licensed by DOH.

In addition to providing a public record exemption for DOH personnel, the bill provides that the following information relating to the families of such personnel is exempt from public record requirements:

- Names, home addresses, telephone numbers, and places of employment of the spouses and children of such personnel; and
- Names and locations of schools and day care facilities attended by the children of such personnel.

Current law provides public record exemptions for identification and location information of other public employees and their spouses and children.

The bill provides for repeal of the exemptions on October 2, 2018, unless reviewed and saved from repeal by the Legislature. In addition, the bill provides a statement of public necessity as required by the State Constitution.

The bill does not appear to have a fiscal impact.

The bill provides an effective date of upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Public Records

Article I, s. 24(a) of the State Constitution sets forth the state's public policy regarding access to government records. This section guarantees every person a right to inspect or copy any public record of the legislative, executive, and judicial branches of government. The Legislature, however, may provide by general law for the exemption of records from the requirements of Article I, s. 24(a) of the State Constitution. The general law must state with specificity the public necessity justifying the exemption (public necessity statement) and must be no broader than necessary to accomplish its purpose.[1]

Public policy regarding access to government records is addressed further in the Florida Statutes. Section 119.07(1), F.S., guarantees every person a right to inspect and copy any state, county, or municipal record. Furthermore, the Open Government Sunset Review Act[2] provides that a public record or public meeting exemption may be created or maintained only if it serves an identifiable public purpose. In addition, it may be no broader than is necessary to meet one of the following purposes:

- Allows the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption.
- Protects sensitive personal information that, if released, would be defamatory or would jeopardize an individual's safety; however, only the identity of an individual may be exempted under this provision.
- Protects trade or business secrets.

Public Record Exemptions

Current law provides public record exemptions for identification and location information of certain current or former public employees and their spouses and children.[3] Examples of public employees covered by these exemptions include law enforcement personnel, firefighters, local government personnel who are responsible for revenue collection and enforcement or child support enforcement, justices and judges, and local and statewide prosecuting attorneys. Legislation was passed in 2012 to provide a public record exemption for personal and identifying information of current or former county tax collectors, and investigators or inspectors of the Department of Business and Professional Regulation.[4]

Although the types of exempt information vary, the following information is exempt from public record requirements for all of the above-listed public employees:

- Home addresses and telephone numbers of the public employees;
- Home addresses, telephone numbers, and places of employment of the spouses and children of public employees; and

[1] Section 24(c), Art. I of the State Constitution.
[2] *See* s. 119.15, F.S.
[3] *See* s. 119.071(4)(d), F.S.
[4] CS/CS/HB1089; Chapter 2012-214, L.O.F.

- Names and locations of schools and day care facilities attended by the children of the public employees.

If exempt information is held by an agency[5] that is not the employer of the public employee, the public employee must submit a written request to that agency to maintain the public record exemption.[6]

Currently, DOH investigative staff, and their spouse's and children's personal information are not exempt from public disclosure.[7]

Department of Health – Complaints and Investigations

The Department of Health (DOH) is responsible for the regulation of health care practitioners pursuant to Chapter 456, F.S. Specific facilities and professions regulated by DOH require inspections prior to beginning practice and on a periodic basis. Specifically, these facilities and professionals include:[8]

- Pain Management Clinics;
- Pharmacies;
- Dental Laboratories;
- Massage Establishments;
- Electrolysis Establishments;
- Optical Establishments;
- Dispensing Practitioners; and
- Any place in which drugs and medical supplies are manufactured, packed, packaged, made, stored, sold, offered for sale, exposed for sale, or kept for sale.

There are a multitude of individuals that may be involved in some fashion throughout the investigation process. Section 456.073(1), F.S., requires DOH inspectors and investigators to investigate any complaint that is determined to be legally sufficient. After review of a complaint, if the allegations and supporting documentation show that a violation may have occurred, the complaint is considered legally sufficient for investigation. A complaint is legally sufficient if it contains ultimate facts that show a violation of Chapter 456, F.S., any of the practice acts relating to the professions regulated by DOH, or of any rule adopted by DOH or a regulatory board has occurred.

The Investigative Services Unit (ISU) functions as the investigative arm of DOH as it investigates complaints against health care practitioners and facilities regulated by DOH. ISU includes staff of professional investigators and senior pharmacists' who conduct interviews, collect documents and evidence, prepare investigative reports for the Prosecution Services Unit (PSU), and serve subpoenas and official orders of DOH. Upon completion of collecting information and conducting interviews, the investigator writes an investigative report and the report is forwarded to DOH's attorneys for legal review.[9]

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[5] Section 119.011(2), F.S., defines "agency" to mean any state, county, district, authority, or municipal officer, department, division, board, bureau, commission, or other separate unit of government created or established by law including, for the purposes of this chapter, the Commission on Ethics, the Public Service Commission, and the Office of Public Counsel, and any other public or private agency, person, partnership, corporation, or business entity acting on behalf of any public agency.

[6] Section 119.071(4)(d)3., F.S.

[7] *But See* s. 119.071(4)(d)2.a., F.S., re: DOH investigators of child abuse.

[8] Sections 456.069, and 465.017, F.S.

[9] Florida Department of Health, Division of Medical Quality Assurance, http://www.doh.state.fl.us/mqa/enforcement/enforce_csu.html (last visited February 15, 2013).

Attorneys, within the PSU, then review the investigative report to recommend a course of action, which may include:[10]

- Emergency orders against licensees who pose an immediate threat to the health, safety, and welfare of individuals;
- Expert reviews for complex cases that require professional health care experts to render an opinion;
- Closing orders if the investigation or the expert review does not support the allegations;[11] or
- Administrative complaints when the investigation supports the allegations.

When an administrative complaint is filed, the subject has the right to choose a hearing, consent/stipulation agreement, or voluntarily relinquish their license. In all of these instances, the case is then presented to the professional board or DOH for final agency action. If the subject appeals the final decision, the PSU attorney defends the final order before the appropriate appellate court.

According to DOH[12], recently, investigators have had to be involved in more investigations that include criminal elements. Investigators who inspect massage establishments are identifying and reporting to law enforcement possible human trafficking activities. Further, investigators have forged strong relationships with law enforcement in an effort to combat the health care concerns caused by illegal pill mills and controlled substance abuse in Florida. As DOH investigators are exposed to more and more potentially dangerous criminal situations, they have become concerned about the release of personal information that may be used by criminals, or individuals under investigation by DOH, to target investigative staff and their families.

Effect of Proposed Changes

The bill further expands the current public record exemption for identification and location information of public employees to include current and former DOH personnel whose duties include or support the investigation and prosecution of complaints filed against health care practitioners or the inspection of practitioners or facilities licensed by DOH. The bill provides that the following information is exempt from public record requirements if such personnel make a reasonable effort to protect the information from being accessible through other means available to the public:

- Home addresses, telephone numbers, and photographs of current or former DOH personnel whose duties include or support investigating complaints against health care practitioners, or inspecting practitioners or facilities licensed by DOH;
- Names, home addresses, telephone numbers, and places of employment of the spouses and children of such personnel; and
- Names and locations of schools and day care facilities attended by the children of such personnel.

The bill provides for repeal of the exemption on October 2, 2018, unless reviewed and saved from repeal by the Legislature.

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[10] *Id.*

[11] Cases closed with no finding of probable cause are generally confidential and are not available through a public records request.

[12] HB 529 Bill Analysis, Economic Statement and Fiscal Note, Department of Health, at page 3, February 1, 2013 (on file with the Health Quality subcommittee).

The bill provides a statement of public necessity as required by the State Constitution.[13]

B. SECTION DIRECTORY:

Section 1: Amends s. 119.071, F.S., relating to general exemptions from inspection or copying of public records.
Section 2: Provides a public necessity statement.
Section 3: Provides an effective date of upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is necessary to implement the provisions of the bill.

[13] *See* s. 24(c), Art. I of the State Constitution.

C. DRAFTING ISSUES OR OTHER COMMENTS:

As currently written, the bill would encompass all DOH employees whose duties are to "support" those who perform investigations and prosecutions of health care practitioners or facilities licensed by DOH.

This broad exemption may be in conflict with the constitutional requirement that the exemption must be no broader than necessary to accomplish its purpose.

It is unclear what the term "reasonable efforts" in line 191 of the bill means and what actions personnel would have to take to protect identifying information.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to public records; amending s. 119.071, F.S.; providing an exemption from public records requirements for certain identifying information of specific current and former personnel of the Department of Health and the spouses and children of such personnel, under specified circumstances; providing for future legislative review and repeal of the exemption under the Open Government Sunset Review Act; providing a statement of public necessity; providing an effective date.

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

Section 1. Paragraph (d) of subsection (4) of section 119.071, Florida Statutes, is amended to read:

119.071 General exemptions from inspection or copying of public records.—

(4) AGENCY PERSONNEL INFORMATION.—

(d)1. For purposes of this paragraph, the term "telephone numbers" includes home telephone numbers, personal cellular telephone numbers, personal pager telephone numbers, and telephone numbers associated with personal communications devices.

2.a. The home addresses, telephone numbers, social security numbers, dates of birth, and photographs of active or former sworn or civilian law enforcement personnel, including correctional and correctional probation officers, personnel of

the Department of Children and Families ~~Family Services~~ whose duties include the investigation of abuse, neglect, exploitation, fraud, theft, or other criminal activities, personnel of the Department of Health whose duties are to support the investigation of child abuse or neglect, and personnel of the Department of Revenue or local governments whose responsibilities include revenue collection and enforcement or child support enforcement; the home addresses, telephone numbers, social security numbers, photographs, dates of birth, and places of employment of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1).

b. The home addresses, telephone numbers, dates of birth, and photographs of firefighters certified in compliance with s. 633.35; the home addresses, telephone numbers, photographs, dates of birth, and places of employment of the spouses and children of such firefighters; and the names and locations of schools and day care facilities attended by the children of such firefighters are exempt from s. 119.07(1).

c. The home addresses, dates of birth, and telephone numbers of current or former justices of the Supreme Court, district court of appeal judges, circuit court judges, and county court judges; the home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of current or former justices and judges; and the names and locations of schools and day care facilities attended by the children of current or former justices and judges are exempt

from s. 119.07(1).

d. The home addresses, telephone numbers, social security numbers, dates of birth, and photographs of current or former state attorneys, assistant state attorneys, statewide prosecutors, or assistant statewide prosecutors; the home addresses, telephone numbers, social security numbers, photographs, dates of birth, and places of employment of the spouses and children of current or former state attorneys, assistant state attorneys, statewide prosecutors, or assistant statewide prosecutors; and the names and locations of schools and day care facilities attended by the children of current or former state attorneys, assistant state attorneys, statewide prosecutors, or assistant statewide prosecutors are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

e. The home addresses, dates of birth, and telephone numbers of general magistrates, special magistrates, judges of compensation claims, administrative law judges of the Division of Administrative Hearings, and child support enforcement hearing officers; the home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of general magistrates, special magistrates, judges of compensation claims, administrative law judges of the Division of Administrative Hearings, and child support enforcement hearing officers; and the names and locations of schools and day care facilities attended by the children of general magistrates, special magistrates, judges of compensation claims, administrative law judges of the Division of Administrative Hearings, and child support enforcement hearing officers are

exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution if the general magistrate, special magistrate, judge of compensation claims, administrative law judge of the Division of Administrative Hearings, or child support hearing officer provides a written statement that the general magistrate, special magistrate, judge of compensation claims, administrative law judge of the Division of Administrative Hearings, or child support hearing officer has made reasonable efforts to protect such information from being accessible through other means available to the public.

f. The home addresses, telephone numbers, dates of birth, and photographs of current or former human resource, labor relations, or employee relations directors, assistant directors, managers, or assistant managers of any local government agency or water management district whose duties include hiring and firing employees, labor contract negotiation, administration, or other personnel-related duties; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

g. The home addresses, telephone numbers, dates of birth, and photographs of current or former code enforcement officers; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt

from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

h. The home addresses, telephone numbers, places of employment, dates of birth, and photographs of current or former guardians ad litem, as defined in s. 39.820; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such persons; and the names and locations of schools and day care facilities attended by the children of such persons are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution, if the guardian ad litem provides a written statement that the guardian ad litem has made reasonable efforts to protect such information from being accessible through other means available to the public.

i. The home addresses, telephone numbers, dates of birth, and photographs of current or former juvenile probation officers, juvenile probation supervisors, detention superintendents, assistant detention superintendents, juvenile justice detention officers I and II, juvenile justice detention officer supervisors, juvenile justice residential officers, juvenile justice residential officer supervisors I and II, juvenile justice counselors, juvenile justice counselor supervisors, human services counselor administrators, senior human services counselor administrators, rehabilitation therapists, and social services counselors of the Department of Juvenile Justice; the names, home addresses, telephone numbers, dates of birth, and places of employment of spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel

are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

j. The home addresses, telephone numbers, dates of birth, and photographs of current or former public defenders, assistant public defenders, criminal conflict and civil regional counsel, and assistant criminal conflict and civil regional counsel; the home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such defenders or counsel; and the names and locations of schools and day care facilities attended by the children of such defenders or counsel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

k. The home addresses, telephone numbers, and photographs of current or former investigators or inspectors of the Department of Business and Professional Regulation; the names, home addresses, telephone numbers, and places of employment of the spouses and children of such current or former investigators and inspectors; and the names and locations of schools and day care facilities attended by the children of such current or former investigators and inspectors are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution if the investigator or inspector has made reasonable efforts to protect such information from being accessible through other means available to the public. This sub-subparagraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2017, unless reviewed and saved from repeal through reenactment by the Legislature.

l. The home addresses and telephone numbers of county tax

collectors; the names, home addresses, telephone numbers, and places of employment of the spouses and children of such tax collectors; and the names and locations of schools and day care facilities attended by the children of such tax collectors are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution if the county tax collector has made reasonable efforts to protect such information from being accessible through other means available to the public. This sub-subparagraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2017, unless reviewed and saved from repeal through reenactment by the Legislature.

m. The home addresses, telephone numbers, and photographs of current or former personnel of the Department of Health whose duties include or support the investigation and prosecution of complaints filed against health care practitioners or the inspection of practitioners or facilities licensed by the Department of Health; the names, home addresses, telephone numbers, and places of employment of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution if the personnel have made reasonable efforts to protect such information from being accessible through other means available to the public.

3. An agency that is the custodian of the information specified in subparagraph 2. and that is not the employer of the officer, employee, justice, judge, or other person specified in

subparagraph 2. shall maintain the exempt status of that information only if the officer, employee, justice, judge, other person, or employing agency of the designated employee submits a written request for maintenance of the exemption to the custodial agency.

4. The exemptions in this paragraph apply to information held by an agency before, on, or after the effective date of the exemption.

5.a. Sub-subparagraphs 2.a.-l. are ~~This paragraph is~~ subject to the Open Government Sunset Review Act in accordance with s. 119.15, and shall stand repealed on October 2, 2017, unless reviewed and saved from repeal through reenactment by the Legislature.

b. Sub-subparagraph 2.m. is subject to the Open Government Sunset Review Act in accordance with s. 119.15, and shall stand repealed on October 2, 2018, unless reviewed and saved from repeal through reenactment by the Legislature.

Section 2. The Legislature finds that it is a public necessity that the home addresses, telephone numbers, and photographs of current or former personnel of the Department of Health whose duties include or support the investigation and prosecution of complaints filed against health care practitioners or the inspection of practitioners or facilities licensed by the Department of Health; that the names, home addresses, telephone numbers, and places of employment of the spouses and children of such personnel; and that the names and locations of schools and day care facilities attended by the children of such personnel be made exempt from public record

requirements. The Legislature finds that the release of such identifying and location information might place current or former personnel of the Department of Health whose duties include or support the investigation and prosecution of complaints filed against health care practitioners or the inspection of practitioners or facilities licensed by the Department of Health and their family members in danger of physical and emotional harm from disgruntled individuals who have contentious reactions to actions carried out by personnel of the Department of Health, or whose business or professional practices have come under the scrutiny of investigators and inspectors of the Department of Health. The Legislature further finds that the harm that may result from the release of such personal identifying and location information outweighs any public benefit that may be derived from the disclosure of the information.

Section 3. This act shall take effect upon becoming a law.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 529 (2013)

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Renuart offered the following:

Amendment

Remove line 183 and insert:

duties include the investigation or prosecution of

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 529 (2013)

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Renuart offered the following:

Amendment

Remove line 183 and insert:

duties include the investigation or prosecution of

Remove line 217 and insert:

Health whose duties include the investigation or

Remove line 228 and insert:

include the investigation or prosecution of