

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 Health Policy

BILL: SB 422

INTRODUCER: Senator Benacquisto and others

SUBJECT: Cancer Treatment

DATE: March 4, 2013

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	Pre-meeting
2.	_____	_____	BI	_____
3.	_____	_____	AP	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

SB 422 creates the “Cancer Treatment Fairness Act.” The bill requires individual and group health insurance or health maintenance policies that provide coverage for cancer treatment medications to provide coverage for oral medications in a manner no less favorable than those provided intravenously or as injectables.

The bill also prohibits insurers and health maintenance organizations (HMOs) from increasing or varying the cost sharing for intravenous or injectable medications in order to comply with the changes in this legislation. Insurers and HMOs are also prohibited from providing any incentive, recommending a service, or changing the classification of any medication in order to meet the requirements of this bill.

The bill includes a directive to the Division of Law Revision and Information to replace references in the bill to the effective date to the actual date the bill becomes effective. The bill provides a specific effective date of July 1, 2013.

This bill creates two new sections of law, sections 627.42391 and 641.313, Florida Statutes.

II. Present Situation:

Cancer is the general name for a group of more than 100 unique diseases, but they share a common thread in that all cancers start because abnormal cells grow out of control.¹ Half of all

¹ American Cancer Society, *What is Cancer?*, <http://www.cancer.org/cancer/cancerbasics/what-is-cancer> (last visited Feb. 6, 2013).

men and one-third of all women in the United States will develop some form of cancer during their lifetime.² The National Cancer Institute estimates that approximately 13.7 million Americans with a history of cancer were alive on January 1, 2012, and about 1,660,290 new cancer cases are expected in 2013.³ In Florida, the number of new cases in 2013 is expected to be 118,320.⁴

After diagnosis, a cancer treatment plan is developed based on a number of factors, including the type of cancer, the stage of the disease, the patient's age and overall health.⁵ Treatment options include surgery, radiation therapy or anticancer drug therapy; some plans may also include stem cell transplantation.⁶ Anticancer drug therapy is further broken down into three types: cytotoxic agents (chemotherapy), biologic agents and hormonal agents.⁷ These agents can include oral and intravenous or injectable products.⁸

Chemotherapy is a specific type of cancer treatment that uses drugs to kill cancer cells. It works by stopping or slowing the growth of cancer cells.⁹ Historically, intravenous therapies have been the most common method for administering anticancer drug therapies.¹⁰

A 2010 Texas Department of Insurance report found that 28 percent of the oral anticancer medications approved by the Food and Drug Administration had intravenous/injected substitutes and 23 percent had generic equivalents.¹¹ However, treatment delivery systems are changing and pills are quickly becoming a more prevalent option.¹² At least 25 percent of the drugs in the oncology development phase are oral medications.¹³ Not all oral medications have an injectable or IV equivalent.

Intravenous medications are usually administered in a physician's office or outpatient hospital setting, but an oral medication is typically dispensed as a prescription and most often provided

² American Cancer Society, *How Common is Cancer?*, <http://www.cancer.org/cancer/cancerbasics/what-is-cancer>, (last visited Feb. 6, 2013).

³ American Cancer Society, *Cancer Facts & Figures, 2013*, (1), <http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-036845.pdf> (last visited Feb. 6, 2013).

⁴ American Cancer Society, *Cancer Facts & Figures*, *supra* note 3 at 5.

⁵ National Cancer Institute at the National Institutes of Health, *What You Need to Know About Cancer: Treatment*, <http://www.cancer.gov/cancertopics/wyntk/cancer/page8>, (last visited Feb.8, 2013).

⁶ *Ibid.*

⁷ Milliman, NY, Kathryn Fitch et al., *Parity for Oral and Intravenous/Injected Cancer Drug*, 3, (Jan. 25, 2010), <http://publications.milliman.com/research/health-rr/pdfs/parity-oral-intravenous-injected.pdf> (last visited Feb. 6, 2013).

⁸ *Ibid.*

⁹ Washington State Department of Health, *Oral Chemotherapy Drug Coverage Mandated Benefit Sunrise Review*, 7 (Publication Number 631-014) (December 2010), <http://www.doh.wa.gov/portals/1/Documents/Pubs/631014.pdf> (last visited Feb.6, 2013).

¹⁰ National Cancer Institute at the National Institutes of Health, *Oral Chemotherapy: Potentials and Misconceptions*, <http://www.nccn.com/understanding-cancer/233-oral-chemotherapy.html>, (last visited Feb.15, 2013).

¹¹ Texas Department of Insurance, *Patient Cost Disparity between Orally and Intravenously Administered Chemotherapies*, Report on Senate Bill 1143, Section 3, (12), 81st Legislature, Regular Session, 2009, August 2010.

¹² Michelle Andrews, *Some States Mandate Better Coverage of Oral Cancer Drugs*, Kaiser Health News, May 14, 2012, <http://www.kaiserhealthnews.org/features/insuring-your-health/2012/cancer-drugs-by-pill-instead-of-iv-michelle-andrews-051512.aspx>, (last visited on Feb.6, 2013).

¹³ *Ibid.*

through a pharmacy.¹⁴ The intravenous or injectable medication is usually covered as a medical benefit as an office or hospital outpatient service.¹⁵

In contrast, coverage for an oral cancer drug generally falls under a plan's prescription benefit.¹⁶ The patient's out of pocket cost for an office visit or outpatient hospital visit compared to the co-payment, co-insurance or deductible for a prescription can differ by thousands of dollars, depending most frequently on the cost of the drug.¹⁷ And, unlike the medical portion of many health plans, the prescription drug benefit may not include a maximum out of pocket limit.¹⁸ In addition, when the prescription costs reach a certain level, patient compliance drops and prescriptions remain unfilled.¹⁹ Beginning in January 2014, federal law prescribes out of pocket limits for many health insurance plans under the federal Patient Protection and Affordable Care Act (PPACA).²⁰

As of January 2013, 21 states plus the District of Columbia had passed oral oncology parity laws.²¹ Parity laws generally require that insurance coverage for orally administered chemotherapy medication be provided on a basis no less favorable than coverage for intravenous or injected medications.²²

The National Comprehensive Cancer Network (NCCN) notes that oral chemotherapy is a more attractive option for those patients for whom cancer is a chronic disease.²³ Moreover, oral medications can be less costly to administer since they are taken at home and not in a physician's office or hospital setting.²⁴ While a physician or the physician's nursing staff may not be present for the dosing of the oral medication, there can still be a significant investment made in education and support of the patient to ensure appropriate use of the medication.²⁵

The NCCN website includes a list of misconceptions about the use of oral chemotherapy drugs.²⁶ The NCCN notes that oral chemotherapy is not for everyone and patients should be aware that oral chemotherapy is not simple to administer nor does it automatically have fewer side effects than intravenous treatment.²⁷

Patient advocacy groups for oral chemotherapy parity argue that oral medications reduce the amount of time that family members and caregivers miss work for appointments as well as

¹⁴ Milliman, *supra* note 7 at 7.

¹⁵ *Ibid.*

¹⁶ Milliman, *supra* note 7 at 1.

¹⁷ Milliman, *supra* note 7 at 12.

¹⁸ Milliman, *supra* note 7 at 4.

¹⁹ Andrews, *supra* note 12.

²⁰ *See infra* note 30.

²¹ Alliance for Access to Cancer Care, *Fact Sheet* (February 2013); On file in the Senate Health Policy Committee.

²² Milliman, *supra* note 7 at 12.

²³ National Comprehensive Cancer Network, *Oral Chemotherapy: Potentials and Misconceptions*, <http://www.nccn.com/understanding-cancer/233-oral-chemotherapy.html> (last visited: Feb. 7, 2013).

²⁴ Texas Department of Insurance, *Patient Cost Disparity between Orally and Intravenously Administered Chemotherapies*, Report on Senate Bill 1143, Section 3, (11-12), 81st Legislature, Regular Session, 2009, Aug. 2010.

²⁵ *Ibid.*

²⁶ National Comprehensive Cancer Network, *Oral Chemotherapy: Potentials and Misconceptions*, <http://www.nccn.com/understanding-cancer/233-oral-chemotherapy.html> (last visited: Feb. 7, 2013).

²⁷ *Ibid.*

provide the patient with a sense of empowerment.^{28,29} More than a quarter of employees are acting as caregivers to family members who are experiencing an illness, including cancer.³⁰

Patient Protection and Affordable Care Act

In March 2010, the Congress passed and the President signed the Patient Protection and Affordable Care Act (PPACA).³¹ Under PPACA, qualified health plans (QHP) would be available from the state or federal Exchange beginning January 1, 2014. PPACA required the Secretary of Health and Human Services to establish for those QHP's a minimum package of essential health benefits (EHB).³² The EHB package must cover benefits across ten general categories from preventive services, maternity care, hospital services to prescription drugs.³³

Section 1311(d)(3)(B) of PPACA allows a state to require QHPs to cover additional benefits above those required under the EHB; however, the law also directs the state or the issuer to offset the costs of those supplemental benefits to the enrollee.³⁴ Under the proposed rule released on November 26, 2012, a distinction in the proposed rule's preamble is made between changes in benefits versus changes in cost sharing. The proposed rule limits the offset requirement only to "care, treatment and services," thereby excluding a state's obligations to defray costs relating to changes relating to provider types, cost-sharing or reimbursement.³⁵

In addition to these provisions, certain plans under PPACA received "grandfather status." A grandfathered health plan is a plan that existed on March 23, 2010, the date that PPACA was enacted, and that at least one person had been continuously covered for one year.³⁶ Some consumer protection elements do not apply to grandfathered plans that were part of PPACA but others are applicable, regardless of the type of plan.³⁷

Providing the essential health benefits are also not required of grandfathered health plans.³⁸ A grandfathered plan can lose its status if significant changes to benefits or cost sharing changes are made to the plan since attaining its grandfathered status.³⁹ Grandfathered plans are required

²⁸ Patients Equal Access Coalition, *White Paper: Cost Effectiveness of Oral Chemotherapy*, <http://www.readbag.com/myeloma-pdfs-advocacy-peac-cost-effectiveness-oral-chemo> (last visited Feb. 15, 2013).

²⁹ Texas Department of Insurance, *supra* note 24 at 12.

³⁰ National Business Group on Health and National Comprehensive Cancer Network, *An Employer's Guide to Cancer Treatment and Prevention*, 1, (2011).

³¹ Pub. Law No. 111-148, H.R. 3590, 111th Cong. (Mar. 23, 2010).

³² *Ibid.*

³³ Center for Consumer Information and Insurance Oversight, *Essential Health Benefits Coverage Bulletin*, (1), Dec. 16, 2011, available at: http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf (last visited: Feb. 18, 2012).

³⁴ 77 Fed. Reg. 70,644, 70,647, (Nov. 26, 2012), available at: <http://www.gpo.gov/fdsys/pkg/FR-2012-11-26/pdf/2012-28362.pdf> (last visited Feb. 18, 2013).

³⁵ *Ibid.*

³⁶ Healthcare.gov, *Grandfathered Health Plans*, <http://www.healthcare.gov/law/features/rights/grandfathered-plans/index.html> (last visited Feb.11, 2013).

³⁷ Healthcare.gov., <http://www.healthcare.gov/news/factsheets/2012/11/ehb11202012a.html>, (last visited Feb. 11, 2013).

³⁸ Sarah Barr, *FAQ: Grandfathered Health Plans* (Dec. 2012), <http://www.kaiserhealthnews.org/stories/2012/december/17/grandfathered-plans-faq.aspx> (last visited Feb. 12, 2013).

³⁹ Healthcare.gov, *Keeping the Health Plan You Have: The Affordable Care Act and "Grandfathered Health Plans* (June 14, 2010), <http://www.healthcare.gov/news/factsheets/2010/06/keeping-the-health-plan-you-have-grandfathered.html> (last visited Feb. 12, 2013).

to disclose their status to their enrollees every time plan materials are distributed and to identify the consumer protections that are not available as a grandfathered plan.⁴⁰ Even though exempt from the EHB, a grandfathered plan could still be required to meet a new requirement under state law if otherwise required under state requirements.⁴¹

The PPACA's provisions include annual limitations on cost sharing in section 1302(c)(1) and an annual limitation on deductibles in section 1302(c)(2) of the Affordable Care Act effective January 1, 2014. The type of plan an individual is enrolled in and the level of benefits selected or "medal plan," will determine the amount of out of pocket costs that an individual may incur; however, out of pocket costs must still remain within certain guidelines.

The federal law further prohibits the imposition of annual and lifetime benefit limits, except for certain grandfathered plans, effective January 1, 2014. These protections went into effect for children earlier, September 23, 2010, and apply to grandfathered group health insurance plans. These restrictions would impact any out of pocket costs applied to prescription drug coverage whether delivered as an oral or an injectable medication.

Florida Mandates

A "mandate" is usually defined as required health coverage for specific type of treatments, benefits, providers or categories of dependants.⁴² In Florida, health insurance coverage mandates are spread throughout the insurance statutes depending on the coverage type and insurance product. In addition, some types of health insurance coverage are exempt from state mandates, such as self-funded plans.⁴³ As a result, specific mandates may not be applicable to all insured persons as not all benefits are applicable to all insurance coverage types.⁴⁴ Florida has at least 52 different "mandates" falling across the small group, individual or large group health insurance market, including health maintenance organizations (HMOs).⁴⁵

Under current state law, s. 627.4239, F.S., coverage for the use of drugs in the treatment of cancer is mandated under any individual or group policy that covers cancer if that drug is recognized for treatment of that indication in a standard reference compendium or recommended in the medical literature.⁴⁶ Coverage is also required for the administration of the medically necessary services to administer those drugs.⁴⁷ Current state law does not specifically address coverage under

⁴⁰ Ibid.

⁴¹ 75 Fed. Reg. 34, 538, 34,540 (June 17, 2010)

⁴² National Conference of State Legislatures, *Mandated Health Insurance Benefits and State Laws*, <http://www.ncsl.org/issues-research/health/mandated-health-insurance-benefits-and-state-laws.aspx> (last visited Feb. 20, 2013).

⁴³ Florida Department of Financial Services, *Insurance Library*, available at: http://www.myfloridacfo.com/consumers/insuranceLibrary/Insurance/L_and_H/Health_Care/Self-Funded_Medical_Plans/Self-Funded_-_Regulation.htm (last visited Feb. 20, 2013).

⁴⁴ Florida Department of Financial Services, *Insurance Library*, available at: http://www.myfloridacfo.com/consumers/insuranceLibrary/Insurance/L_and_H/Health_General/MandatedHealthInsAndHMOBenefits.pdf (last visited Feb. 20, 2013).

⁴⁵ Ibid.

⁴⁶ See s. 627.4239(2)(a), F.S.

⁴⁷ See s. 627.4236(2)(b), F.S..

HMOs or parity for any co-insurance, deductible or copayment that may be related to how cancer treatment medicine is delivered.

Required Study by Advocates

Section 624.215, F.S., requires every person or organization seeking consideration of a legislative proposal that would mandate specific health coverage to submit to the Agency for Health Care Administration and the appropriate legislative committee a report reviewing the social and financial impacts of the proposed coverage. The statute lists twelve components for assessment, if available:

- To what extent is the treatment or service generally used by a significant portion of the population?
- To what extent is the insurance coverage generally available?
- If the insurance coverage is not generally available, to what extent does the lack of coverage result in persons avoiding necessary health care treatment?
- If the coverage is not generally available, to what extent does the lack of coverage result in unreasonable financial hardship?
- The level of public demand for the treatment or service.
- The level of public demand for insurance coverage of the treatment or service.
- The level of interest of collective bargaining agents in negotiating for the inclusion of this coverage in group contracts.
- To what extent will the coverage increase or decrease the cost of the treatment or service?
- To what extent will the coverage increase the appropriate uses of the treatment or service?
- To what extent will the coverage increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders?
- The impact of this coverage on the total cost of health care.

The International Myeloma Foundation (Foundation) delivered a report to the Senate Health Policy Committee on February 21, 2013, assessing SB 422 and HB 301 against the criteria of s. 624.215, F.S., while specifically not admitting, that the bill's directives mandate any specific health coverage.⁴⁸

According to the Foundation, insurance coverage of oral cancer medications is not the precise issue. The issue is the out of pocket cost differential to patients between intravenous or injectables and oral treatments as most insurance plans already cover the medication.⁴⁹ The report states that there is a direct correlation between the levels of out of pocket costs and the number of prescriptions left abandoned. For example, claims with patient cost sharing over \$500 had more than four times the likelihood of abandonment as opposed to those that cost less than \$100.⁵⁰ In addition, one in five persons uses all or most of their savings to pay for cancer treatment.⁵¹

⁴⁸ International Myeloma Foundation, Health Insurance Mandate Report, *Parity for Oral and Intravenous Cancer Medications*, 1, (February 2013) (on file with the Senate Committee on Health Policy).

⁴⁹ International Myeloma Foundation, *supra* note 48 at 2.

⁵⁰ International Myeloma Foundation, *supra* note 48 at 3.

⁵¹ International Myeloma Foundation, *supra* note 48 at 3.

The report indicates that for some cancers, oral treatment is the only standard treatment.⁵² More treatments are being approved as over 40 oral medications have been approved for 54 different types of cancer.⁵³ The report argues that oral medications are less costly to administer at home, may have fewer side effects, provide patient empowerment and are more convenient for the patient and the patient's caregivers.⁵⁴

With reduced copayments, the report points out that fewer prescriptions would be abandoned or unfilled leading to greater medication compliance.⁵⁵ The Foundation argues that by keeping these out of pocket costs affordable and making prescription drug compliance easier that the overall costs of cancer will decrease.⁵⁶

As to the potential for increased costs, the report notes that minor increases in administrative expenses may be incurred by insurance companies, but that administrative expenses saved from fewer office visits may offset those costs.⁵⁷ Citing the Milliman study, the Foundation report restates an estimate of not more than \$0.50 per member per month for the cost of implementing cancer treatment parity. The Foundation report also notes that in a survey of nine other states plus the District of Columbia with a similar parity provision, the legislation's impact on premiums was zero to negligible.⁵⁸

III. Effect of Proposed Changes:

Section 1 of the bill names the act the "Cancer Treatment Fairness Act."

Sections 2 and 3 of the bill create new sections of law, ss. 627.42391 and 641.313, F.S., to address cancer treatment parity for orally administered medications under individual and group insurance and HMO insurance policies, respectively. Under these sections, the bill adds definitions for "cancer treatment medication" and "cost sharing."

In addition, the bill provides that for any individual, group, or HMO policy that is delivered, issued, renewed or amended in Florida that includes major medical or other comprehensive coverage that also provides cancer treatment, such policy must also provide coverage for orally prescribed cancer medications. The bill provides that cost sharing provisions for those orally prescribed medication may not be less favorable than any cost sharing required for intravenous or injected cost sharing medications. Insurers are prohibited from taking certain actions to thwart the intent of this bill, specifically:

- Varying the terms of their policies as they exist on the effective date of this act in order to comply with this requirement. In effect, insurers may not increase cost sharing on

⁵² International Myeloma Foundation, *supra* note 48 at 1.

⁵³ International Myeloma Foundation, *supra* note 48 at 1.

⁵⁴ *Ibid.*

⁵⁵ International Myeloma Foundation, *supra* note 48 at 5.

⁵⁶ *Ibid.*

⁵⁷ International Myeloma Foundation, *supra* note 48 at 6.

⁵⁸ *Ibid.*

intravenous medications or injections rather than reduce cost sharing on orally prescribed cancer treatments to meet this requirement.

- Offering an incentive that would encourage any person to accept less than the minimum protections offered under this act.
- Penalizing a health care practitioner through a reduction in compensation for recommending or providing services to a person covered under this section of law.
- Incentivizing a health care provider to not comply with this act.
- Changing the classification of any intravenous or injected cancer treatment medication.
- Increasing the cost sharing for any intravenous or injectable medications to comply with this act.

Section 4 provides a directive to the Division of Law and Information to replace any instances of “the effective date of this act” with the final effective date once this act becomes law.

Section 5 specifies the effective date of the act is July 1, 2013.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

SB 422 may impact the cost of health insurance coverage provided in the private sector. A 2010 report by Milliman estimated that for most commercial benefit plans, the cost for oral cancer treatment parity would be under \$0.50 per member per month.⁵⁹ The actual cost would vary based on the benefit plan and the level of cost sharing incurred by the employee or patient.⁶⁰

⁵⁹ Milliman, *supra* note 7 at 1.

⁶⁰ *Ibid.*

The statutorily mandated study submitted by the International Myeloma Foundation cites both the Milliman report for cost estimates as well as other state survey data that shows nominal cost impacts.

C. Government Sector Impact:

The bill's provisions may impact the cost of health insurance coverage provided to employees across all groups in the government sector.

A 2010 report by Milliman estimated that for most commercial benefit plans, the cost for oral cancer treatment parity would be under \$0.50 per member per month.⁶¹ The actual cost would vary based on the benefit plan and the level of cost sharing incurred by the employee or patient.⁶²

The statutorily mandated study submitted by the International Myeloma Foundation cites both the Milliman report for cost estimates as well as other state survey data that shows nominal cost impacts.

VI. Technical Deficiencies:

The Office of Insurance Regulation (OIR) identified a potential conflict with current law at section 627.4239, F.S.,⁶³ which governs coverage of drugs for the treatment of cancer. This law currently requires insurers to cover these drugs as well as the administration of those drugs by a licensed health care practitioner in the small group, large group and individual markets. It is unclear how a health plan could comply with the "no less favorable" provisions of this bill given the current requirements that costs also be covered for the administration of the same drug by a licensed health care practitioner.

Additionally, the OIR recommends that the current section of law be amended to accommodate this change rather than create a new section of law.

VII. Related Issues:

The bill includes a directive to add an effective date once the act takes effect; however, the bill already includes an effective date in Section 5. It is unclear why Section 4 is necessary when an effective date has been provided and no conflicting effective dates are included in the bill.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

⁶¹ Ibid.

⁶² Ibid.

⁶³ Florida Office of Insurance Regulation, *Senate Bill 422 Bill Analysis and Fiscal Impact* (January 23, 2013) (on file with the Senate Committee on Health Policy).

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
