HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 301 Cancer Treatment
SPONSOR(S): Health Innovation Subcommittee; Mayfield and others
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 422

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	12 Y, 0 N, As CS	Poche	Shaw
2) Insurance & Banking Subcommittee	11 Y, 2 N	Cooper	Cooper
3) Appropriations Committee	22 Y, 0 N	Delaney	Leznoff
4) Health & Human Services Committee	14 Y, 1 N	Poche	Calamas

SUMMARY ANALYSIS

Cancer is a group of diseases which cause the growth of abnormal cells in the body, resulting in severe sickness and death. Cancer is the second leading cause of death in the U.S. In 2010, Florida had 173,791 total deaths, of which 41,467 were caused by cancer, accounting for nearly 24 percent of all deaths in the state.

The trend in the treatment of cancer has been towards the development of oral chemotherapy medications. Experts estimate that more than 25 percent of the 400 chemotherapy drugs in the development pipeline are planned as oral medications. Although Florida law does not require health plans and health maintenance organizations (HMOs) to cover intravenous, injectable, or oral cancer treatment medications, health plans and HMOs routinely cover these treatments.

CS for HB 301 requires health insurance policies and contracts and HMO contracts that provide cancer treatment medication coverage to also provide coverage for oral cancer treatment medications. Out-of-pocket costs to the insured or member are often higher for oral cancer treatment medications than for other forms of cancer treatment. The bill requires policies and contracts to apply cost-sharing requirements for oral cancer treatment medications that are no less favorable than the cost-sharing requirements for other cancer treatment medications, such as intravenous and injectable medications. Grandfathered health plans, as that term is defined by the Patient Protection and Affordable Care Act (PPACA) and detailed in applicable regulations, are exempted from the oral cancer treatment medications coverage and cost-sharing parity requirements.

The bill prohibits insurers, HMOs, and certain other entities from taking specific actions in an effort to avoid compliance with the coverage and cost-sharing parity requirements. Prohibited actions include, but are not limited to, varying the terms of the policy in effect on the effective date of the bill and penalizing a health care provider for recommending or providing services that comply with the provisions of the bill. Cancer patients who currently have to rely on oral medications should experience cost savings. The overall impact of the bill's requirements to the cost of health insurance is unknown.

The bill may have a negative fiscal impact on local and state governmental entities when in effect; however, the amount is indeterminate.

The bill provides an effective date of January 1, 2015, and applies to policies and contracts issued or renewed on or after that date.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

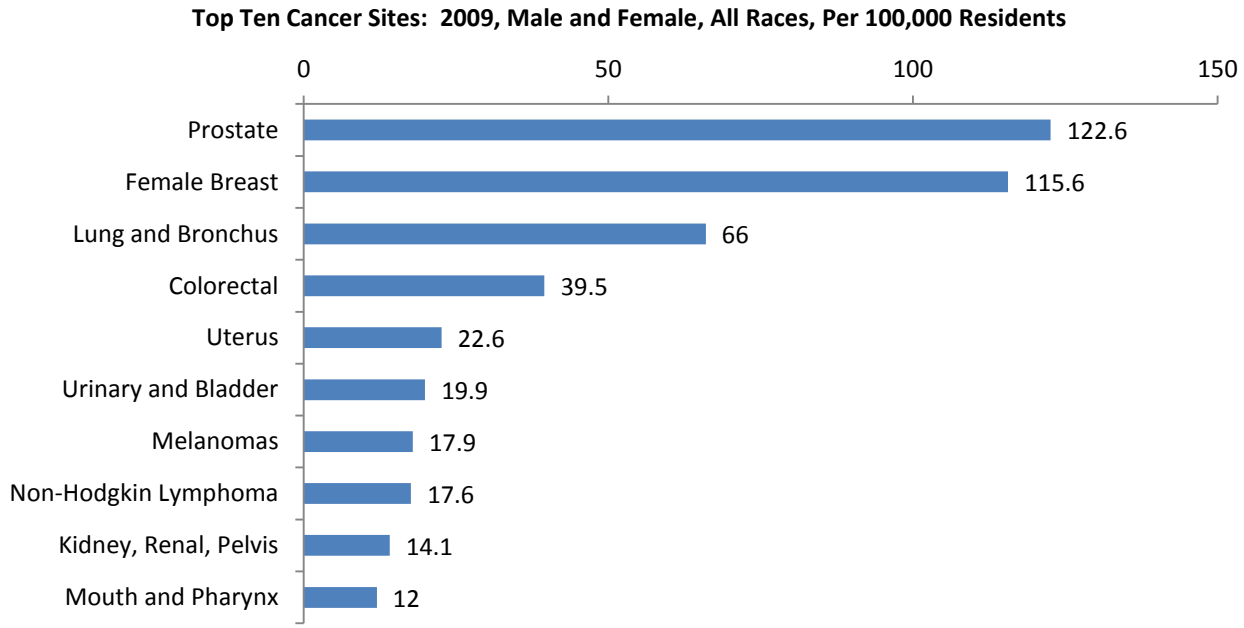
A. EFFECT OF PROPOSED CHANGES:

Present Situation

Cancer

Cancer is a group of diseases which cause the growth of abnormal cells in the body, resulting in severe sickness and death. It can be caused by external factors, such as tobacco use and exposure to certain chemicals, and internal factors, like genetics, hormones, and immune conditions. These factors may work together or separately to promote the development of cancer. Common treatments for cancer include surgery, radiation, and chemotherapy.

Cancer is the second leading cause of death in the U.S., killing 573,313 people in 2011, a decrease of 2.4% over the number of deaths in 2010.[1] It is the leading cause of death of people between the ages of 45 and 64, accounting for 161,072 of the total cancer deaths in 2011.[2] In 2010, Florida had 173,791 total deaths, of which 41,467 were caused by cancer, accounting for nearly 24 percent of all deaths in the state.[3] The following chart shows the top ten cancer sites for men and women in Florida in 2009, the last year for which complete data is available[4]:



[1] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics Report, *Deaths: Preliminary Data for 2011*, page 4, Vol. 61, No. 6 (October 10, 2012) (available at www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_06.pdf).
[2] Id. at page 30.
[3] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics Report, *Deaths: Final Data for 2010*, page 112, Vol. 61, No. 4 (available at www.cdc.gov/nchs/data/dvs/deaths_2010_release.pdf).
[4] Chart created using information from U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Program of Cancer Registries, *United States Cancer Statistics-2009 Top Ten Cancers-Florida* (available at http://apps.nccd.cdc.gov/uscs/toptencancers.aspx) (last viewed March 11, 2013).

Approximately 1,660,290 new cases of cancer are expected to be diagnosed in the U.S. in 2013.[5] Of those new cases, 118,320 cases are expected to be diagnosed in Florida.[6] From 2005 to 2009, Florida averaged 101,744 incidences of cancer each year.[7]

Cancer care expenditures have been increasing nationwide. In 2008, the National Institutes of Health estimated the direct costs of cancer, including all health care expenditures, were $77.4 billion.[8] In 2010, total costs of cancer care were $124.6 billion[9] In 2020, estimates of cancer care costs in the U.S. range from $158 billion to $207 billion.[10] It should be noted that these are estimates of direct costs of care for the treatment of cancer and do not incorporate additional types of costs related to treatment.[11]

The National Cancer Institute estimates that there were 13.7 million cancer survivors alive in the U.S. on January 1, 2012.[12] By 2020, it is estimated that there will be 18.1 million cancer survivors in the U.S., an increase of 30% over 2010.[13]

Oral Cancer Treatment Medications

The trend in the treatment of cancer has been towards the development of oral chemotherapy medications. Experts estimate that more than 25 percent of the 400 chemotherapy drugs in the development pipeline are planned as oral medications.[14]

There are a more than two dozen oral cancer treatment medications that do not have an intravenous or injectable equivalent, including tamoxifen, used to treat breast cancer, Gleevec, used to treat chronic myeloid leukemia, and anastrozole, used to treat prostate cancer.

There is a significant cost disparity to the patient between intravenous or injectable cancer treatment medications and oral cancer treatment medications. In most cases, intravenous or injectable cancer treatment medications are covered in the medical benefits portion of a health insurance plan. Due to the nature of the delivery system of the medication, a patient is required to go to the hospital, a clinic, or her doctor's office in order to have an intravenous line inserted and the medication dose administered or to have the medication injected. Because this form of treatment is covered under the medical benefits portion of insurance, the out-of-pocket expenses to the patient are limited to the office co-payment amount, which is normally a very reasonable cost, or have a cap on annual or lifetime out-of-pocket payments.

Oral cancer treatment medications, however, are covered under the pharmacy benefits portion of health insurance coverage. Many pharmacy benefit designs assign medications into tiers based on cost. Each tier carries a co-payment amount, which significantly increases as the tier, and associated drug cost, increases. Also, pharmacy benefit designs may have unlimited out-of-pocket cost-sharing requirements, meaning can be required to pay significant co-payments for as long as the patient is required to take a certain medications. Oral cancer treatment medications can run into the thousands of dollars per month in out-of-pocket costs to the patient.

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[5] American Cancer Society, *Cancer Facts & Figures 2013*, page 1.
[6] Id., *Estimated Number of New Cases for Selected Cancers by State, US, 2013*, page 5.
[7] U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, *State Cancer Profiles-Florida, Incidence Rate Tables, Incidence Rate Report for Florida by County-All Races (includes Hispanic), Both Sexes, All Cancer Sites, All Ages Sorted by Rate* (available at http://statecancerprofiles.cancer.gov/cgi-bin/quickprofiles/profile.pl?12&001).
[8] See supra, FN 4 at page 3.
[9] U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, *The Cost of Cancer*, table 1 (January 2011)(available at www.cancer.gov/aboutnci/servingpeople/cancer-statistics/costofcancer) (last viewed on March 11, 2013).
[10] Id.; $158 billion is estimated based on 2010 dollars; $173 billion is estimated assuming a 2% increase in costs over time; and $207 billion is estimated based on a 5% increase in costs over time;
[11] Id.
[12] See supra, FN 4.
[13] U.S. Department of Health and Human Service, National Institutes of Health, National Cancer Institute, *Cancer Prevalence and Cost of Care Projections- Key Facts* (available at http://costprojections.cancer.gov) (last viewed on March 11, 2013).
[14] Weingart, S.N., Bach, P.B., et al., *NCCN task force report: oral chemotherapy*, Journal of the National Comprehensive Cancer Network, 2008;6: S1-S17.

The following chart illustrates the cost of medications for serious illness, including oral oncology medications:[15]

Average Monthly Patient Out-of-Pocket Cost Per Prescription, 2011			
	Rheumatoid Arthritis	Multiple Sclerosis	Oral Oncology
Actual Out-of-Pocket (OOP) Cost	**$235**	**$227**	**$470**
Estimated OOP Cost (by Coinsurance Level)			
33% cost sharing	**$653**	**$1,100**	**$1,920**
25% cost sharing	**$495**	**$833**	**$1,454**
5% cost sharing	**$99**	**$167**	**$291**

Out-of-pocket costs for oral cancer medication treatments averaged $2,942 in 2009, which is a 17 percent increase over the costs in 2008.

Oral Cancer Treatment Parity

Between 2008 and January 2013, twenty-one states and the District of Columbia have enacted oral chemotherapy parity laws that require the same cost-sharing requirements for oral cancer treatment medications and intravenous or injectable cancer treatment medications.[16] It is anticipated that 16 states, including Florida, will have similar legislation introduced in 2013.[17]

In 2009, Milliman, Inc., in a study commissioned by GlaxoSmithKline, examined the average increase in insurance costs resulting from oral cancer treatment medication parity legislation. Such legislation requires state-regulated payers to cover oral cancer treatment medication with the same cost-sharing requirements as intravenous or injectable cancer treatment medications. Milliman found that, for most benefit plans, parity will increase plan costs less than $0.50 per member per month (PMPM).[18] Parity for some benefit plans that carry very high cost-sharing requirements for oral specialty drugs and low medical benefits may see a cost of $1.00 PMPM or more.[19] Other benefit plans that have a low cost-sharing requirement in general could see parity costs of $0.05 to $0.10 PMPM.[20]

Patient Protection and Affordable Care Act

In March 2010, the Congress passed and the President signed the Patient Protection and Affordable Care Act (PPACA).[21] 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).[22] The EHB package must cover benefits across ten general categories, including, but not limited to preventive services, maternity care, hospital services and prescription drugs.[23]

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 to offset the costs of those supplemental benefits to the enrollee.[24] Under the final rule released on February 25, 2013, a

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[15] Pharmaceutical Executive, *Who Pays for Specialty Medicines?* (citing Healthcare Analytics 2011, Amundsen Group Analysis)(available at http://license.icopyright.net/user/viewFreeUse.act?fuid=MTY5MTg4MiA%3D).
[16] *Oral Chemotherapy Parity Legislative Landscape- January 2013* (on file with Health Innovation Subcommittee staff).
[17] Id.
[18] Milliman, Client Report, Fitch, K., Iwasaki, K., Pyenson, B., *Parity for Oral and Intravenous/Injected Cancer Drugs*, page 1 (December 15, 2009).
[19] Id.
[20] Id.
[21] Pub. Law No. 111-148, H.R. 3590, 111th Cong. (Mar. 23, 2010).
[22] Id.
[23] 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 viewed March 11, 2013).
[24] 78 Fed. Reg. 12,837, 12,837-12,838 (February 25, 2013).

distinction in the proposed rule's preamble is made between changes in benefits versus changes in cost sharing. The final 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.[25]

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.[26] 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.[27]

Providing the essential health benefits are also not required of grandfathered health plans.[28] 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.[29] Grandfathered plans are required 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.[30] Even though exempt from the EHB, a grandfathered plan could still be required to meet a new a requirement under state law if otherwise required under state requirements.[31]

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.

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.

Health Insurance Mandates and Mandated Offerings

A health insurance mandate is a legal requirement that an insurance company or health plan cover services by particular health care providers, specific benefits, or specific patient groups. Mandated offerings, on the other hand, do not mandate that certain benefits be provided. Rather, a mandated offering law can require that insurers offer an option for coverage for a particular benefit or specific patient groups, which may require a higher premium and which the insured is free to accept or reject. A mandated offering law in the context of mental health can require that insurers offer an option of coverage for mental illness, which may require a higher premium and which the insured is free to accept or reject or require that, if insurers offer mental illness coverage, the benefits must be equivalent to other types of benefits.

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[25] Id.

[26] Healthcare.gov, *Grandfathered Health Plans*, available at http://www.healthcare.gov/law/features/rights/grandfathered-plans/index.html (last viewed March 11, 2013).

[27] Healthcare.gov., *Factsheet,* available at http://www.healthcare.gov/news/factsheets/2012/11/ehb11202012a.html (last viewed March 11, 2013).

[28] Barr, S., *FAQ: Grandfathered Health Plans*, December 2012, available at http://www.kaiserhealthnews.org/stories/2012/december/17/grandfathered-plans-faq.aspx (last viewed March 11, 2013).

[29] Healthcare.gov, *Keeping the Health Plan You Have: The Affordable Care Act and "Grandfathered Health Plans*, June 14, 2010, available at http://www.healthcare.gov/news/factsheets/2010/06/keeping-the-health-plan-you-have-grandfathered.html (last viewed March 11, 2013).

[30] Id.

[31] 75 Fed. Reg. 34, 538, 34,540 (June 17, 2010).

Florida currently has at least 59 mandates.[32] Higher costs resulting from mandates are most likely to be experienced in the small group market since these are the plans that are subject to state regulations. The national average cost of insurance for a family of four is $15,745.[33]

Health Insurance Mandate Report

Section 624.215, F.S., was enacted in 1987 to aid the Legislature in assessing the impact of health insurance mandates and mandated offerings on insurance policy premiums when considering proposed health insurance mandates. The statute requires that any proposal for legislation that mandates health benefit coverage or mandatorily offered health coverage must be submitted with a report to Agency for Health Care Administration and to the legislative committees having jurisdiction over the issue. The report must assess the social and financial impact of the proposed coverage to the extent information is available, and shall include:

- To what extent is the treatment or service generally used by a significant portion of the population.[34]
- To what extent is the insurance coverage generally available.[35]
- If the insurance coverage is not generally available, to what extent does the lack of coverage result in persons avoiding necessary health care treatment.[36]
- If the coverage is not generally available, to what extent does the lack of coverage result in unreasonable financial hardship.[37]
- The level of public demand for the treatment or service.[38]
- The level of public demand for insurance coverage of the treatment or service.[39]
- The level of interest of collective bargaining agents in negotiating for the inclusion of this coverage in group contracts.[40]
- To what extent will the coverage increase or decrease the cost of the treatment or service.[41]
- To what extent will the coverage increase the appropriate uses of the treatment or service.[42]
- To what extent will the mandated treatment or service be a substitute for a more expensive treatment or service.[43]
- To what extent will the coverage increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.[44]
- The impact of this coverage on the total cost of health care.[45]

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.[46]

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[32] Florida House of Representatives, Health and Human Services Quality Subcommittee, *Meeting Packet for November 15, 2011*, pages 7-9.
[33] The Henry J. Kaiser Family Foundation, Employer Health Benefits 2012 Annual Survey- Summary of Findings, page 1 (available at http://ehbs.kff.org/pdf/2012/8345.pdf) (last viewed March 11, 2013).
[34] S. 624.215(2)(a), F.S.
[35] S. 624.215(2)(b), F.S.
[36] S. 624.215(2)(c), F.S.
[37] S. 624.215(2)(d), F.S.
[38] S. 624.215(2)(e), F.S.
[39] S. 624.215(2)(f), F.S.
[40] S. 624.215(2)(g), F.S.
[41] S. 624.215(2)(h), F.S.
[42] S. 624.215(2)(i), F.S.
[43] S. 624.215(2)(j), F.S.
[44] S. 624.215(2)(k), F.S.
[45] S. 624.215(2)(l), F.S.
[46] International Myeloma Foundation, *Health Insurance Mandate Report, Parity for Oral and Intravenous Cancer Medications*, page 1, February 2013 (on file with the Health Innovation Subcommittee).

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.[47]

Effect of Proposed Changes

The bill creates a benefit mandate: it requires an individual or group insurance policy or contract or a health maintenance organization (HMO) contract that provides coverage for cancer treatment medications (intravenous or injectable cancer treatment medications) to also provide coverage for oral cancer treatment medications. In addition, the bill prohibits a policy or contract from applying cost-sharing requirements to coverage for oral cancer treatment medications that are less favorable than the cost-sharing requirements for intravenous or injectable cancer treatment medications. The bill requires that all cancer treatment medications be covered and be treated the same by health insurance policies and contracts. The bill exempts grandfathered health plans from the oral cancer treatment medication coverage and cost-sharing parity.

The bill permits a policy or contract with cost-sharing requirements for intravenous or injectable cancer medications less than $50 to apply cost-sharing requirements up to $50 to prescribed oral cancer treatment medications.

The bill prohibits the following actions by insurers, HMOs, and other specific entities designed to avoid the parity requirements of the bill:

- Varying the terms of the policy in effect on the effective date of the bill.
- Providing any incentive to a covered person to accept coverage that includes anything less than parity.
- Penalizing a provider for recommending or providing oral cancer treatment medications.
- Providing any incentive to a provider to not comply with the parity provisions.
- Changing cost-sharing requirements or classification of intravenous or injectable cancer treatment medications in effect on the effective date of the bill.

The bill provides an effective date of January 1, 2015, and applies to policies or contracts issued or renewed after that date.

B. SECTION DIRECTORY:

Section 1: Provides that the act maybe cited as the “Cancer Treatment Fairness Act.”

Section 2: Creates s. 627.42391, F.S., relating to insurance policies; cancer treatment parity; orally administered cancer treatment medications.

Section 3: Creates s. 641.313, F.S., relating to health maintenance contracts; cancer treatment parity; orally administered cancer treatment medications.

Section 4: Provides direction to the Division of Law Revision and Information.

Section 5: Provides an effective date of January 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

[47] Id. at page 2.

1. Revenues:

   None.

2. Expenditures:

   The Department of Management Services noted an indeterminate fiscal impact in its analysis of CS/HB 301.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   Local governments may experience a negative fiscal impact if health insurance premiums increase as a result of the bill. The amount is indeterminate and will vary depending on plan attributes.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health insurers and HMOs may raise premiums to address the impact of oral cancer medication treatment coverage and cost-sharing parity under the bill. As a result, policyholders and contract holders for health care coverage may see an increase in monthly premiums for the same coverage for policies and contracts issued or renewed after the effective date of the bill.

Patients receiving oral cancer treatment medications may realize less out-of-pocket expenses to obtain their medications.

D. FISCAL COMMENTS:

PPACA allows a state to require QHPs to cover additional benefits above those required under the EHB. The law also directs the state to offset the costs of those supplemental benefits to the enrollee. The bill creates a new coverage and parity requirement for oral cancer treatment medications. While PPACA requires the state to be responsible for offsetting the cost of this additional coverage and parity requirement, there are no guidelines addressing how the total cost will be determined, how it will be paid by the state, and to whom the payments will be made. As a result, the bill presents a potential indeterminate negative fiscal impact to the state.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditures of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not applicable. Rule-making authority is not required by the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES