HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 591 Health Insurance
SPONSOR(S): Health Care Regulation Policy Committee; Roberson and others
TIED BILLS: **IDEN./SIM. BILLS:**

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee	7 Y, 5 N, As CS	Holt	Calamas
2)	Insurance, Business & Financial Affairs Policy Committee			
3)	Full Appropriations Council on Education & Economic Development			
4)	General Government Policy Council			
5)				

SUMMARY ANALYSIS

The bill mandates that state regulated health plans include antiretroviral (ARV) drugs on their drug formulary or preferred drug list. The bill prohibits health plans from restricting access to ARVs by requiring prior authorization, step therapy, or any other limitation that limits access. Health insurance plans, and health maintenance organizations are required to comply with the provisions of the bill. The bill has no impact on Medicaid health plans.

The bill will have a significant negative fiscal impact to the state and no fiscal impact to local governments (See Fiscal Analysis).

The bill takes effect July 1, 2010.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

The bill requires state-regulated health plans to include antiretroviral (ARV) drugs on their drug formulary or preferred drug list[1] (PDL). In addition the bill prohibits health plans from restricting access to ARVs by requiring prior authorization[2], step therapy[3], or any other limitation that limits access.

HIV/AIDS

HIV stands for Human Immunodeficiency Virus. HIV is the virus that causes AIDS. A person with HIV is called HIV positive (HIV+).[4] HIV weakens the immune system by killing "CD4 cells" or "T cells" which help protect the body from disease.[5]

Since the disease was first reported over 20 years ago, an estimated 944,306 people have developed AIDS in the United States.[6] According to the Centers for Disease Control and Prevention (CDC), estimated 55,000 - 58,500 new HIV infections occur in the United States each year.[7] In 2008, there were 7,111 reported new HIV cases in Florida.[8]

HIV/AIDS Life Expectancy, Treatment and Cost

The main drug treatment for people with HIV is Highly Active Antiretroviral Therapy (also called HAART). HAART drugs help to slow the growth of HIV in the body. HAART combines three or more

[1] A list in which an insurance company has categorized into prescription drugs into tiers.
[2] The process of obtaining advanced approval of coverage for a health care service or medication.
[3] A treatment process that is designed to encourage utilization of select medication(s) before other medication(s) is used due to cost, safety and medical appropriateness. (e.g., first step use of generic drug; and second step use of name brand drug).
[4] U.S. Food and Drug Administration, HIV and AIDS - Medicines to Help You, available at: http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSActivities/ucm118966.htm (last viewed March 6, 2010).
[5] *Id.*
[6] Centers for Disease Control and Prevention, National Prevention Information Network, HIV/AIDS Today, available at: http://www.cdcnpin.org/scripts/hiv/hiv.asp (last viewed March 2, 2010).
[7] *Id.*
[8] Florida Department of Health, Community Health Assessment Resource Tool Set (CHARTS), Communicable Diseases, HIV Cases (March 10, 2010).

ARVs in a daily regimen and is the recommended treatment for HIV infection.[9] HAART is made up of seven different types of medicines:[10]

1. Nucleoside Reverse Transcriptase Inhibitors (NRTIs) are faulty versions of building blocks that HIV needs to replicate. When HIV uses an NRTI instead of a normal building block, reproduction of the virus is stalled. The U.S. Food and Drug Administration (FDA) has approved the following NRTIs for treatment of HIV:[11]

Brand Name	Generic Name	Manufacturer Name	Approval Date
Combivir	lamivudine and zidovudine	GlaxoSmithKline	27-Sep-97
Emtriva	emtricitabine, FTC	Gilead Sciences	02-Jul-03
Epivir	lamivudine, 3TC	GlaxoSmithKline	17-Nov-95
Epzicom	abacavir and lamivudine	GlaxoSmithKline	02-Aug-04
Hivid	zalcitabine, dideoxycytidine, ddC (no	Hoffmann-La Roche	19-Jun-92
Retrovir	zidovudine, azidothymidine, AZT,	GlaxoSmithKline	19-Mar-87
Trizivir	abacavir, zidovudine, and	GlaxoSmithKline	14-Nov-00
Truvada	tenofovir disoproxil fumarate and	Gilead Sciences, Inc.	02-Aug-04
Videx EC	enteric coated didanosine, ddI EC	Bristol Myers-Squibb	31-Oct-00
Videx	didanosine, dideoxyinosine, ddI	Bristol Myers-Squibb	9-Oct-91
Viread	tenofovir disoproxil fumarate, TDF	Gilead	26-Oct-01
Zerit	stavudine, d4T	Bristol Myers-Squibb	24-Jun-94
Ziagen	abacavir sulfate, ABC	GlaxoSmithKline	17-Dec-98

2. Nonnucleoside Reverse Transcriptase Inhibitors (NNRTIs) bind to and disable reverse transcriptase, a protein that HIV needs to replicate. The FDA has approved the following NNRTIs used in the treatment of HIV infection:[12]

Brand Name	Generic Name	Manufacturer Name	Approval Date
Intelence	etravirine	Tibotec Therapeutics	18-Jan-08
Rescriptor	delavirdine, DLV	Pfizer	4-Apr-97
Sustiva	efavirenz, EFV	Bristol Myers-Squibb	17-Sep-98
Viramune	nevirapine, NVP	Boehringer Ingelheim	21-Jun-96

3. Protease Inhibitors disable protease, a protein that HIV needs to replicate. The FDA has approved the following protease inhibitors used in the treatment of HIV infection:[13]

Brand Name	Generic Name	Manufacturer Name	Approval Date
Agenerase	amprenavir, APV	GlaxoSmithKline	15-Apr-99
Aptivus	tipranavir, TPV	Boehringer Ingelheim	22-Jun-05
Crixivan	indinavir, IDV,	Merck	13-Mar-96
Fortovase	saquinavir (no longer marketed)	Hoffmann-La Roche	7-Nov-97

[9] Agency for Health Care Administration, 2010 Bill Analysis & Economic Impact Statement, House Bill 591, March 1, 2010.
[10] U.S. Food and Drug Administration, Antiretroviral drugs used in the treatment of HIV infection, available at: http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSActivities/ucm118915.htm (last viewed March 9, 2010).
[11] *Id.*
[12] *Id.*
[13] *Id.*

Invirase	saquinavir mesylate, SQV	Hoffmann-La Roche	6-Dec-95
Kaletra	lopinavir and ritonavir, LPV/RTV	Abbott Laboratories	15-Sep-00
Lexiva	Fosamprenavir Calcium, FOS-APV	GlaxoSmithKline	20-Oct-03
Norvir	ritonavir, RTV	Abbott Laboratories	1-Mar-96
Prezista	darunavir	Tibotec, Inc.	23-Jun-06
Reyataz	atazanavir sulfate, ATV	Bristol-Myers Squibb	20-Jun-03
Viracept	nelfinavir mesylate, NFV	Agouron Pharmaceuticals	14-Mar-97

4. Fusion Inhibitors block HIV entry into cells; these drugs require specialized laboratory testing in order to evaluate the appropriate use and efficacy of treatment. The FDA has approved the following fusion inhibitors used in the treatment of HIV infection:[14]

Brand Name	Generic Name	Manufacturer Name	Approval Date
Fuzeon	enfuvirtide, T-20	Hoffmann-La Roche & Trimeris	13-Mar-03

5. Integrase Inhibitors disable integrase, a protein that HIV uses to insert its viral genetic material into the genetic material of an infected cell. The FDA has approved the following integrase inhibitors used in the treatment of HIV infection:[15]

Brand Name	Generic Name	Manufacturer Name	Approval Date
Isentress	raltegravir	Merck & Co., Inc.	12--Oct-07

6. Entry Inhibitors block HIV entry into cells (similar function as fusion inhibitors). The FDA has approved the following entry inhibitors used in the treatment of HIV infection:[16]

Brand Name	Generic Name	Manufacturer Name	Approval Date
Selzentry	maraviroc	Pfizer	06-August-07

7. Combination Drugs combine two types of one class or two or more classes into one pill to help improve treatment adherence and tolerance. The FDA has approved the following combination used in the treatment of HIV infection:[17]

Brand Name	Generic Name	Manufacturer Name	Approval Date
Atripla	efavirenz, emtricitabine and tenofovir	Bristol-Myers Squibb and Gilead Sciences	12-July-06

Regulation of Health Plans

Health plans are regulated at both the state and federal level. At the federal level, the Employee Retirement Income and Security Act (ERISA) regulates the operation of voluntary employer-sponsored benefits including pension plans and health plans. ERISA provides an explicit exemption from state regulation for health plans that are self-funded. State regulations apply to health benefits purchased through private health insurance plans and health maintenance organizations (HMOs).

[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*

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 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.

Florida currently has at least 52 mandates.[18] The Council for Affordable Health Insurance estimates that mandated benefits currently increase the cost of basic health coverage from a little less than 20 percent to perhaps 50 percent, depending on the number of mandates, the benefit design and the cost of the initial premium.[19] Each mandate adds to the cost of a plan's premiums, in a range of less than 1 percent to 10 percent, depending on the mandate.[20] 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 $13,375.[21]

Health Insurance Mandate Report

Florida enacted section 624.215, F.S., to take into account the impact of insurance mandates and mandated offerings on premiums when making policy decisions. That section requires that any proposal for legislation that mandates health benefit coverage or mandatorily offered health coverage must be submitted with a report to AHCA and the legislative committee having jurisdictions. The report must assess the social and financial impact of the proposed coverage to the extent information is available, shall include:

- To what extent is the treatment or service generally used by a significant portion of the population.[22]
- To what extent is the insurance coverage generally available.[23]
- If the insurance coverage is not generally available, to what extent does the lack of coverage result in persons avoiding necessary health care treatment.[24]
- If the coverage is not generally available, to what extent does the lack of coverage result in unreasonable financial hardship.[25]
- The level of public demand for the treatment or service.[26]
- The level of public demand for insurance coverage of the treatment or service.[27]
- The level of interest of collective bargaining agents in negotiating for the inclusion of this coverage in group contracts.[28]
- To what extent will the coverage increase or decrease the cost of the treatment or service.[29]
- To what extent will the coverage increase the appropriate uses of the treatment or service.[30]

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[18] Office of Insurance Regulation list of state health insurance mandates on file with Health Care Regulation Policy Committee staff; and "Health Insurance Mandates in the States 2009," Council for Affordable Health Insurance; *available* at: http://www.cahi.org/cahi_contents/resources/pdf/HealthInsuranceMandates2009.pdf. *(*last viewed March 9, 2010)
[19] "Health Insurance Mandates in the States 2009," Council for Affordable Health Insurance; *available* at: http://www.cahi.org/cahi_contents/resources/pdf/HealthInsuranceMandates2009.pdf. *(*last viewed March 9, 2010)
[20] *Id.*
[21] Kaiser Family Foundation, Employer Health Benefits 2009 Annual Survey, *available* at: http://ehbs.kff.org/?CFID=20695941&CFTOKEN=84763322&jsessionid=6030bac21268c605c7863526585a397e6175 (last viewed March 9, 2010).
[22] s. 624.215(2)(a), F.S.
[23] s. 624.215(2)(b), F.S.
[24] s. 624.215(2)(c), F.S.
[25] s. 624.215(2)(d), F.S.
[26] s. 624.215(2)(e), F.S.
[27] s. 624.215(2)(f), F.S.
[28] s. 624.215(2)(g), F.S.
[29] s. 624.215(2)(h), F.S.
[30] s. 624.215(2)(i), F.S.

- To what extent will the mandated treatment or service be a substitute for a more expensive treatment or service."[31]
- To what extent will the coverage increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders."[32]
- The impact of this coverage on the total cost of health care."[33]

Effects of the Bill

The bill mandates that state regulated health plans include ARV drugs on their drug formulary or preferred drug list. The bill prohibits health plans from restricting access to ARVs by requiring prior authorization, step therapy, or any other limitation that limits access. All health insurance plans (ss. 627.6404, 627.6515, and 627.6572, F.S.), and health maintenance organizations (s.641.31093, F.S.) are required to comply with the provisions of the bill. The bill has no impact on Medicaid health plans.

The health insurance mandate report[34] was submitted by the AIDS Healthcare Foundation, the proponent of House Bill 591.[35]

Extent to which the treatment or service generally used by a significant portion of the population.[36]

According to proponents, the provisions in the bill will directly affect services provided to 30,000 HIV/AIDS patients. However, the proponents could not provide sufficient documentation to support this projection. In addition it is unclear what percentage of the 30,000 patients have been denied coverage for ARVs.

Extent to which the insurance coverage is generally available.[37]

The proponent did not have adequate data to support a definite conclusion but believes that the majority of providers approve payment for ARVs without utilizing administrative procedures that impose delay or access to a particular ARV.

Extent to which the lack of insurance coverage results in persons avoiding necessary health care treatment, if insurance coverage is not generally available.[38]

Documentation was not provided suggesting that patients are not being provided coverage outright. Thus, there is not a way to determine if persons are avoiding necessary health care treatment. Anecdotal examples have been provided where a particular ARV was denied.

Extent to which insurance coverage is generally not available and results in an unreasonable financial hardship.[39]

The proponents could not provide documentation showing that coverage is not generally available. The proponent provided examples where a particular ARV was denied. Under these situations, it is unclear if a patient paid for the drugs out-of-pocket, went without using the particular ARV, or whether an

[31] s. 624.215(2)(j), F.S.
[32] s. 624.215(2)(k), F.S.
[33] s. 624.215(2)(l), F.S.
[34] The Health insurance mandate report is on file with Health Care Regulation Policy Committee staff.
[35] The AIDS Healthcare Foundation is based in Los Angeles and is the nation's largest provider of HIV/AIDS medical care. AHF offers cutting-edge medicine and advocacy, regardless of ability to pay to more than 27,000 people in the United States, Africa, Central America and Asia. Domestically, AHF operates 14 healthcare centers, 11 pharmacies, a disease management program in Florida serving the state's HIV/AIDS Medicaid population (Positive Healthcare Florida) and the first capitated Medicaid managed care program for people with AIDS (Positive Healthcare California). *See* AIDS Healthcare Foundation, Organization, *available* at: http://www.aidshealth.org/about-us/organization/ (last viewed March 10, 2010).
[36] s. 624.215(2)(a), F.S.
[37] s. 624.215(2)(b), F.S.
[38] s. 624.215(2)(c), F.S.
[39] s. 624.215(2)(d), F.S.

alternative drug was taken.[40] The proponents provided examples for eleven patients who utilized four different health plans[41] where ARVs were denied, later approved, or approved with limitations. The ARVs that were denied or later approved were: Isentress, Intelence, Prezista, and Truvada.[42] The ARVs that were approved with limitations were: Norvir, Lexiva, and Atripla.[43]

The level of public demand for the treatment or service.[44]

Insufficient documentation was provided to determine a level of public demand.

The level of public demand for insurance coverage of the treatment or service.[45]

The proponent provides no data on the level of public demand for insurance coverage of all ARVs without utilization limits.

The level of interest of collective bargaining agents in negotiating for the inclusion of this coverage in group contracts.[46]

Insufficient documentation was provided to determine the interest of collective bargaining agents in negotiating for the inclusion of this coverage in group contracts.

Extent to which the coverage increase or decrease the cost of the treatment or service.[47]

The provisions of the bill may increase the cost to health plans since they are restricted from using prior authorization or step therapy, which health plans commonly use to reduce utilization. In addition, a health plan might experience an increase in costs if the health plan's formulary does not currently contain all ARVs. However, according to the proponents, properly managed HIV/AIDS patients with appropriate ARVs can lead healthy, productive lives without risk of the complications that can result without treatment—in particular, opportunistic infections that result in increased hospitalizations. According to proponents, timely access to the correct ARV regimen reduces the likelihood that patient will develop a drug resistance that results in the need for newer and often more expensive ARVs. The projected life expectancy for HIV infected individual, if they remain in optimal HIV care, is 24.2 years, and the lifetime per person HIV care cost is $618,900 per person.[48]

Extent to which the coverage increase the appropriate uses of the treatment or service.[49]

Since, the proponents could only provide a few examples where HIV/AIDS patients were denied coverage it is difficult to project the extent to which changes in coverage will increase the use of a treatment or service.

Extent to which the mandated treatment or service be a substitute for a more expensive treatment or service.[50]

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[40] Schackman BR et al. The lifetime cost of current human immunodeficiency virus care in the United States. *Med Care* 2006 Nov; 44:990-7.
[41] The two health plans: Vista, Total Health Choice. The two Medicaid plans: Insurance Universal, Insurance Sunshine.
[42] Examples of health plan denials of ARVs on file with Health Care Regulation Policy Committee staff.
[43] *Id.*
[44] s. 624.215(2)(e), F.S.
[45] s. 624.215(2)(f), F.S.
[46] s. 624.215(2)(g), F.S.
[47] s. 624.215(2)(h), F.S.
[48] Schackman BR et al. The lifetime cost of current human immunodeficiency virus care in the United States. *Med Care* 2006 Nov; 44:990-7.
[49] s. 624.215(2)(i), F.S.
[50] s. 624.215(2)(j), F.S.

Insufficient information was provided to determine if more expensive treatment would be substituted. Depending upon what combination of ARVs a patient is prescribed would determine actual costs for service. Typically, newer drugs cost more.

Extent to which the coverage increases or decreases the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.[51]

Health plans should experience a decrease in administrative reviews and appeals associated with approving a particular drug therapy.

The impact of this coverage on the total cost of health care.[52]

The actual impact to the cost of health care is unknown, since it is not known how many ARVs would have to be added to formularies, or the variety and value of utilization limits used by different plans. Based on the Department of Management Services fiscal analysis, two state employee health maintenance organizations that require prior authorization have projected an increase in cost of $0.10 to $0.90 per member per month.[53]

The bill takes effect July 1, 2010.

B. SECTION DIRECTORY:

Section 1. Creating s. 627.6404, F.S., relating to HIV treatment.
Section 2. Amending s. 627.6515, F.S., relating to out-of-state groups.
Section 3. Creating s. 627.6572, F.S., relating to HIV treatment.
Section 4. Creating s. 641.31093, F.S., relating to HIV treatment
Section 5. Provides that the bill takes effect July 1, 2010.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   According to the Department of Management Services, the state contracts with two health maintenance organizations (HMOs) in the state employee group plan which require prior authorization for ARVs. Cost estimates provided by the two HMOs affected are: [54]

   Vendor 1: $0.10 per member per month
   Vendor 2: $0.90 per member per month

   Based on projected enrollment and the above estimates provided by the HMO vendors, the fiscal impact would be: [55]

	(FY 10-11)	(FY 11-12)	(FY 12-13)
Vendor 1 cost:	$9,152	$9,510	$9,865
Vendor 2 cost:	$330,847	$343,624	$356,324
Total cost estimate:	$339,999	$353,134	$366,189

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

[51] s. 624.215(2)(k), F.S.
[52] s. 624.215(2)(l), F.S.
[53] Department of Management Services, 2010 Bill Analysis & Economic Impact Statement, House Bill 591, March 3, 2010.
[54] Department of Management Services, 2010 Bill Analysis & Economic Impact Statement, House Bill 591, March 3, 2010.
[55] *Id.*

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The provisions of the bill may increase the cost to health plans since they are restricted from using prior authorization or step therapy, which health plans commonly use to reduce utilization and cost. In addition, a health plan might experience an increase in costs if the health plan's formulary does not currently contain all ARVs. Usually, increases in cost are passed on to policyholders.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

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

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On March 16, 2010, the Health Care Regulation Policy Committee adopted one amendment and reported the bill favorably as a committee substitute. The amendment removed section one of the bill relating to Medicaid plans (s. 409.912, F.S.). Therefore, the bill has no impact on Medicaid health plans.

This analysis is drafted to the committee substitute.