HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 583 Provision of Pharmaceutical Services
SPONSOR(S): Insurance & Banking Subcommittee; Mayfield and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 780

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Insurance & Banking Subcommittee	7 Y, 5 N, As CS	Peterson	Luczynski
2) Appropriations Committee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The federal Patient Protection and Affordable Care Act (PPACA) imposes many insurance requirements including required benefits, rating and underwriting standards, required review of rate increases, reporting of medical loss ratios and payment of rebates, coverage for adult dependents, internal and external appeals of adverse benefit determinations, and other requirements.

PPACA requires qualified health plans to provide coverage of essential health benefits (EHB), meet cost-sharing limits, and meet actuarial value requirements. The law directs that EHBs cover at least 10 specified categories, which includes prescription drugs. Currently, the EHB requirements apply only to plans offered in the individual or small group market (less than 50 employees). Plans offered in the large group market are not covered.

The federal Department of Health and Human Services has updated the notice of benefit and payment parameters, which establish key standards for issuers and marketplaces. These regulations include provisions relating to prescription drug coverage, formulary drug lists, the drug exception process, and access to retail pharmacies. For plan years beginning January 1, 2017, the final regulation requires health plans sold in the individual and small group markets to allow enrollees to obtain most drugs at network retail pharmacies as an alternative to mail order. Exceptions to the requirement include drugs that are subject to restricted distribution by the U.S. Food and Drug Administration, or drugs that require special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy. A plan may charge a different cost-sharing amount for drugs that are obtained at a network retail pharmacy, but all cost sharing will count towards the plan's annual limitation on cost sharing.

The bill requires insurers and health maintenance organizations that provide coverage for prescription drugs to allow patients with a diagnosis of human immunodeficiency virus to access pharmaceutical services at retail pharmacies. Qualified retail pharmacies include network pharmacies and out-of-network pharmacies that the insurer or HMO credentials for the limited purpose of providing pharmaceutical services to these patients. The bill allows an insurer or HMO to charge a fee for credentialing of up to $1,500.

An insurer or HMO may charge a higher copayment or coinsurance to patients who access services at a retail pharmacy, but must charge the same copayment or coinsurance amounts whether the patient uses a network retail pharmacy or an out-of-network pharmacy that has been credentialed for this limited purpose. All cost-sharing is credited against the annual limit imposed by PPACA. Reimbursement to a network retail pharmacy is as set forth in the contract between the pharmacy and the insurer or HMO. Reimbursement to an out-of-network pharmacy that is providing pharmaceutical services pursuant to the bill is at the mail order rate.

The bill does not appear to have a fiscal impact on local government, but will have an indeterminate negative fiscal impact on the State Group Health Insurance Program.

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Patient Protection and Affordable Care Act

The federal Patient Protection and Affordable Care Act (PPACA) was signed into law on March 23, 2010.[1] PPACA imposes many insurance requirements including required benefits, rating and underwriting standards, required review of rate increases, reporting of medical loss ratios and payment of rebates, coverage for adult dependents, internal and external appeals of adverse benefit determinations, and other requirements.[2]

Qualifying coverage may be obtained through an employer, the federal or state marketplaces or exchanges created under PPACA, or private individual or group coverage meeting the minimum essential benefits coverage standard off the exchange. Florida did not establish its own state exchange under PPACA. Premium credits and other cost-sharing subsidies are available to U.S. citizens and legal immigrants within certain income limits for qualified coverage purchased through the exchange. Premium credits are set on a sliding scale based on a percentage of the federal poverty level and reduce the out-of-pocket costs incurred by individuals and families.

Prior to an insurer offering a plan through an exchange, an exchange must certify that the plan meets certain federal essential health benefits and other requirements to be deemed a qualified health plan. Section 1302 of the Affordable Care Act requires qualified health plans to provide coverage of essential health benefits (EHB), meet cost-sharing limits, and meet actuarial value requirements. The law directs that EHBs cover at least 10 specified categories, which include prescription drugs. Currently, the EHB requirements apply only to plans offered in the individual or small group market (less than 50 employees). Plans offered in the large group market are not covered.

Final Notice of Benefit and Payment Parameters for 2016[3]

On February 27, 2015, the federal Department of Health and Human Services (HHS) published its final regulations relating to notice of benefit and payment parameters, which establishes key standards for individual and small group issuers and marketplaces for 2016. These regulations include provisions relating to prescription drug coverage, formulary drug lists, the drug exception process, and access to retail pharmacies.

Prescription Drug Coverage

Currently, for purposes of complying with the EHBs, insurers and HMOs must include in their formulary drug list the greater of one drug for each U.S. Pharmacopeia (USP) category and class; or the same number of drugs in each USP category and class as the state's essential health benefit (EHB) benchmark plan.[4,5] For plan years beginning on or after January 1, 2017, plans must also use a pharmacy and therapeutic committee system that will design formularies using scientific evidence that will include consideration of safety and efficacy, cover a range of drugs in a broad distribution of

[1] Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148. On March 30, 2010, PPACA was amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152.
[2] Most of the insurance regulatory provisions in PPACA amend Title XXVII of the Public Health Service Act (PHSA), 42 U.S.C. 300gg et seq.
[3] Dept. of Health and Human Services, *Final HHS Notice of Benefit and Payment Parameters for 2016, available at* http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2016-PN-Fact-Sheet-final.pdf (last visited Jan. 29, 2016).
[4] Florida's benchmark plan is published on the CMS website. *See* CMS.GOV, THE CENTER FOR CONSUMER INFORMATION & INSURANCE OVERSIGHT, *INFORMATION ON ESSENTIAL HEALTH BENEFITS (EHB) BENCHMARK PLANS,* https://www.cms.gov/cciio/resources/data-resources/ehb.html (last visited Jan.29, 2016).
[5] 45 CFR §. 156.122(a).

therapeutic categories and classes, and provide access to drugs that are included in broadly accepted treatment guidelines.[6]

Formulary Drug List.

The regulations require a health plan to publish an up-to-date and complete list of all covered drugs on its formulary drug list, including any tiering structure and any restrictions on the manner in which a drug can be obtained. The information must be published in a manner that is easily accessible to plan enrollees, prospective enrollees, the state, the marketplace, the HHS, and the public. Additionally, insurers and HMOs must also make this information available in a standard-readable format to provide the opportunity for third parties to create resources that aggregate information on different plans.

Drug Exceptions Process

Under current HHS regulations, plans providing EHBs must have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not included on the plan's formulary drug list. [7] The final regulation clarifies that cost sharing for the non-formulary drug provided through the exceptions process counts towards the annual limitation on cost sharing and actuarial value of the plan.

Drug Mail Order Opt Out

For plan years beginning January 1, 2017, the final regulation requires health plans to allow enrollees to obtain most drugs at network retail pharmacies as an alternative to mail order. Exceptions to the requirement include drugs that are subject to restricted distribution by the U.S. Food and Drug Administration, or drugs that require special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy. A plan may charge a different cost-sharing amount for drugs that are obtained at a network retail pharmacy, but all cost sharing will count towards the plan's annual limitation on cost sharing.[8] In effect, the requirement would prohibit a health plan that is required to cover the EHB package from offering a mail-order, only prescription drug benefit.

In its response to comments on this provision of the rule, the HHS stated:[9]

> We also believe that making drugs available only by mail order could discourage enrollment by, and thus discriminate against, transient individuals and individuals who have conditions that they wish to keep confidential.

The HHS also noted that the drugs on the specialty tier of a formulary are not necessarily the same drugs that a specialty pharmacy would provide and that exceptions will be needed for many drugs that are only accessible via a specialty pharmacy. For this reason, the HHS included the two exceptions.[10]

Cost-Sharing Limitations

PPACA requires non-grandfathered health plans to limit the amount that enrollees must pay out-of-pocket for EHBs accessed through a network provider. These limits apply to plans offered in the small group, individual, and large group markets. For 2016, these limits are $6,850 (individual)/$13,700 (family). Effective with the plan year beginning January 1, 2016, plans subject to the cost-sharing limitation are required to apply the self-only (individual) limit to each individual member of family.[11] In effect, a single enrollee will not be required to pay more than $6,850 in cost sharing for in-network

[6] *Supra* note 3.
[7] 45 C.F.R. § 156.122(c). The drug exception process is distinct from the coverage appeals process, which applies if an enrollee receives an adverse benefit determination for a drug that is included on the plan's formulary drug list. The coverage appeals process has separate requirements for its external review process and allows for a secondary level of internal review before the final internal review determination for group plans. 45 C.F.R. § 147.136.
[8] 45 C.F.R. § 156.122(e).
[9] PPACA, HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10750, 10821 ((2015).
[10] *Id.* at 10821.
[11] U.S. DEPT. OF LABOR, *FAQsabout Affordable Care Act Implementation (Part XXVII),* http://www.dol.gov/ebsa/faqs/faq-aca27.html (last visited Jan. 29, 2016).

benefits, even if the enrollee is covered by a plan that has a family out-of-pocket maximum that has not yet been met. Once the limit is reached, the plan must pay 100 percent for covered network benefits.

State Regulation of Insurance

The regulatory oversight of insurance companies is generally reserved to the states. In Florida, the Office of Insurance Regulation (OIR) is responsible for all activities concerning insurers and other risk bearing entities, including licensing, rates, policy forms, market conduct, claims, issuance of certificates of authority, solvency, viatical settlements, premium financing, and administrative supervision, as provided under the insurance code.[12]

To operate in Florida, an HMO must obtain a certificate of authority from OIR.[13] The Agency for Health Care Administration (AHCA) regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from OIR, an HMO must receive a Health Care Provider Certificate from AHCA pursuant to part III of ch. 641, F.S.[14] As part of the certification process used by AHCA, an HMO must provide information to demonstrate that the HMO has the ability to provide quality of care consistent with the prevailing standards of care.[15]

Human Immunodeficiency Virus

Human immunodeficiency virus (HIV) is an immune system virus that can lead to the fatal acquired immunodeficiency syndrome (AIDS). HIV affects specific cells of the immune system and over time the virus can destroy so many of these cells that the body cannot fight off infections and disease. There is no cure for HIV, yet with proper medical care, HIV can be controlled.[16]

HIV is typically spread by having unprotected sex with someone who has HIV, or sharing needles, syringes, or other equipment used to prepare injection drugs with someone who has HIV. As of the end of 2012, about 1.2 million people in the United States were living with HIV, including 156,300 people whose infections had not been diagnosed. Approximately 50,000 people get infected with HIV each year.[17] In 2014, the estimated number of adults and children living with AIDS in Florida was 110,000. The number of newly-diagnosed cases was 5,897.[18] Florida consistently ranks at or near the top of states for its number of reported cases and new diagnoses annually.

Effect of the Bill

The bill requires insurers and health maintenance organizations that provide coverage for prescription drugs to allow patients with a diagnosis of HIV to access pharmaceutical services at retail pharmacies. Qualified retail pharmacies include network pharmacies and out-of-network pharmacies that the insurer or HMO credentials for the limited purpose of providing pharmaceutical services to these patients. The bill allows an insurer or HMO to charge a fee for credentialing an out-of-network retail pharmacy of up to $1,500.

An insurer or HMO may charge a higher copayment or coinsurance to patients who access services at a retail pharmacy, but must charge the same copayment or coinsurance amounts whether the patient uses a network retail pharmacy or an out-of-network pharmacy that has been credentialed for this limited purpose. All cost sharing is credited against the annual limit imposed by PPACA.

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[12] s. 20.121(3)(a)1., F.S. The OIR's commissioner is the agency head for purposes of final agency action, and its rulemaking body is the Financial Services Commission (the Governor and the Cabinet).
[13] ss. 641.21(1) and. 641.49, F.S.
[14] ss. 641.21(1) and 641.48, F.S.
[15] s. 641.495, F.S.
[16] CENTERS FOR DISEASE CONTROL AND PREVENTION, *About HIV/AIDS*, http://www.cdc.gov/hiv/basics/whatishiv.html (last visited Jan. 29, 2016).
[17] CENTERS FOR DISEASE CONTROL AND PREVENTION, HIV/AIDS, *Statistics Overview*, http://www.cdc.gov/hiv/statistics/overview/ (last visited Jan. 29, 2016).
[18] FLORIDA DEPT. OF HEALTH, *State HIV/AIDS Slide Sets*, *http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/epi-slide-sets.html*.

Reimbursement to a network retail pharmacy is as set forth in the contract between the pharmacy and the insurer or HMO. Reimbursement to an out-of-network pharmacy that is providing pharmaceutical services pursuant to the bill is at the mail order rate.

The bill provides an effective date of July 1, 2016.

B. SECTION DIRECTORY:

Section 1: creates ss. 627.6442, F.S., related to pharmaceutical services.
Section 2: amends s. 641.31, F.S., related to health maintenance contracts.
Section 3: provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill may have a negative fiscal impact on the State Group Health Insurance Program (GHIP). Currently, the GHIP allows members to use any retail pharmacy that accepts the same reimbursement as a mail order pharmacy for up to a 90-day supply of all non-specialty maintenance medications. These retail pharmacies may be participating either in the pharmacy benefit manager's (PBM) retail pharmacy network or the state's specific "maintenance 90 at retail" pharmacy network. Cost sharing for a 90-day supply is the same under the GHIP for drugs accessed at a retail pharmacy or a mail order pharmacy.[19] Reimbursement to retail pharmacies is the same rate as mail order pharmacies under contract with the state.[20] The GHIP complies with these elements of the bill.

Where the GHIP differs is with respect to the specialty medications. The state's current contract with the PBM requires the state's specialty medication to be dispensed by the PBM, which is considered mail order. If the state has to renegotiate its contract to allow retail pharmacies to dispense these medications, thereby eliminating the exclusivity provision of the contract, pricing may be negatively affected.[21]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

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

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health insurers and HMOs will incur administrative costs to implement the requirements of the bill. Proponents of the filed bill estimate that 20 percent of the people living with HIV are covered by a commercial plan. The remainder are either uninsured or covered by a government-sponsored program. This would mean that the bill would affect approximately 20,000 covered lives. Thus, the financial

[19] Florida Dept. of Management Services, Agency Analysis of 2016 HB 535, p. 2 (Dec. 16, 2015). The analysis was drafted to the bill, as filed, and not the CS. However, the discussion above is still relevant to provisions in the CS.
[20] s. 110.12315(3), F.S.
[21] *Supra* note 19, at p. 3.

impact to the plans likely would be more in the cost to develop the infrastructure to administer the requirement than in the effect on drug pricing.

Out-of-network pharmacies that wish to be credentialed to provide pharmaceutical services to patients with a diagnosis of HIV will incur a fee to be credentialed of up to $1,500.

People living with HIV would benefit from the opportunity to access medications locally and to use manufacturer-offered cards that provide financial assistance with copayment and coinsurance.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

None.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not applicable. The adoption of rules is not necessary to implement the provisions of the bill

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 1, 2016, the Insurance & Banking Subcommittee adopted a proposed committee substitute (PCS) and reported the bill favorably as a committee substitute. The PCS:

- Limited the scope of the bill to patients with a diagnosis of HIV.
- Authorized insurers and HMOs to charge patients a cost-sharing amount for obtaining a covered drug at a retail pharmacy that is different from the cost-sharing amount that is is charged patients who obtain a covered drug from a mail-order pharmacy. The cost-sharing amount charged to obtain drugs at a network retail pharmacy or an out-of-network retail pharmacy that is credentialed for the limited purpose provided in the bill must be the same. All cost-sharing is made subject to the annual limit imposed by PPCAC.
- Authorized insurers and HMOs to charge a reasonable credentialing fee not to exceed $1,500.
- Removed provisions in the bill that specified required notice to policyholders regarding the availability of retail access and a comparison of the costs between mail-order and retail.

The staff analysis is drafted to reflect the committee substitute.