HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 289 Provision of Pharmaceutical Services
SPONSOR(S): Health Innovation Subcommittee; Raschein
TIED BILLS: **IDEN./SIM. BILLS:** SB 492

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	14 Y, 0 N, As CS	Grabowski	Crosier
2) Insurance & Banking Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Mail order pharmacy is a service used by insurers and employers to reduce prescription drug costs. Current state law does not prohibit an insurer from requiring insureds to use mail order pharmacy, or prohibit insurers from incentivizing its use by charging higher copayments to use a retail pharmacy.

HB 289 prohibits an insurer or health maintenance organization (HMO) from requiring an insured living with a chronic illness to use mail-order pharmacy, except for certain excluded drugs. The bill defines "chronic illness," as human immunodeficiency virus infection (HIV).

In addition, the bill prohibits insurers and HMOs from requiring different copayments or conditions to use a retail pharmacy, if the pharmacy agrees to the same terms, conditions, and reimbursement amounts applicable to a mail order pharmacy. The bill requires insurers and HMOs to provide insureds with a chronic illness an explanation of the payment or reimbursement method and charges applicable to a mail order pharmacy and a comparison of such method and charges applicable to other providers of pharmaceutical services.

The bill requires mail order pharmacy contracts with insurers or HMOs to include a contract provision requiring the mail-order pharmacy to disclose to an insured living with a chronic illness the availability of pharmaceutical services from retail pharmacies and that the exclusive use of a mail order pharmacy is not required.

The bill has no impact on state government, but may have an indeterminate negative impact on local government employee health plans.

The bill has an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

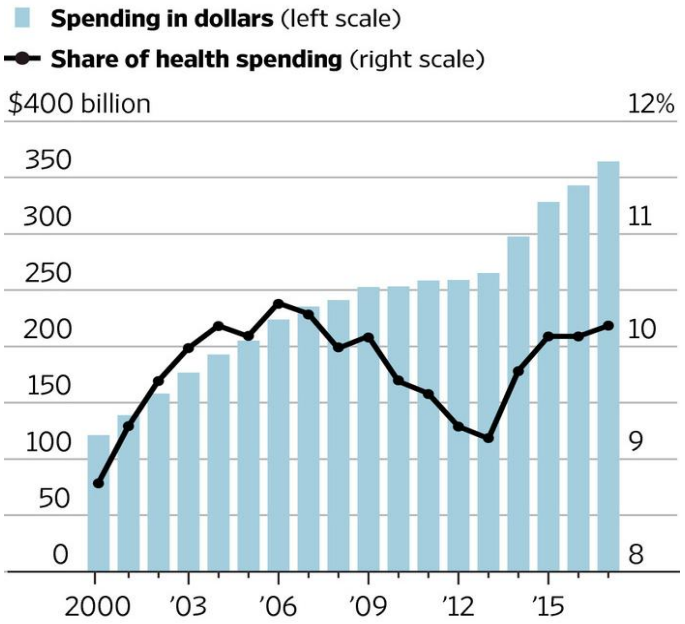
A. EFFECT OF PROPOSED CHANGES:

Background

Prescription Drug Costs

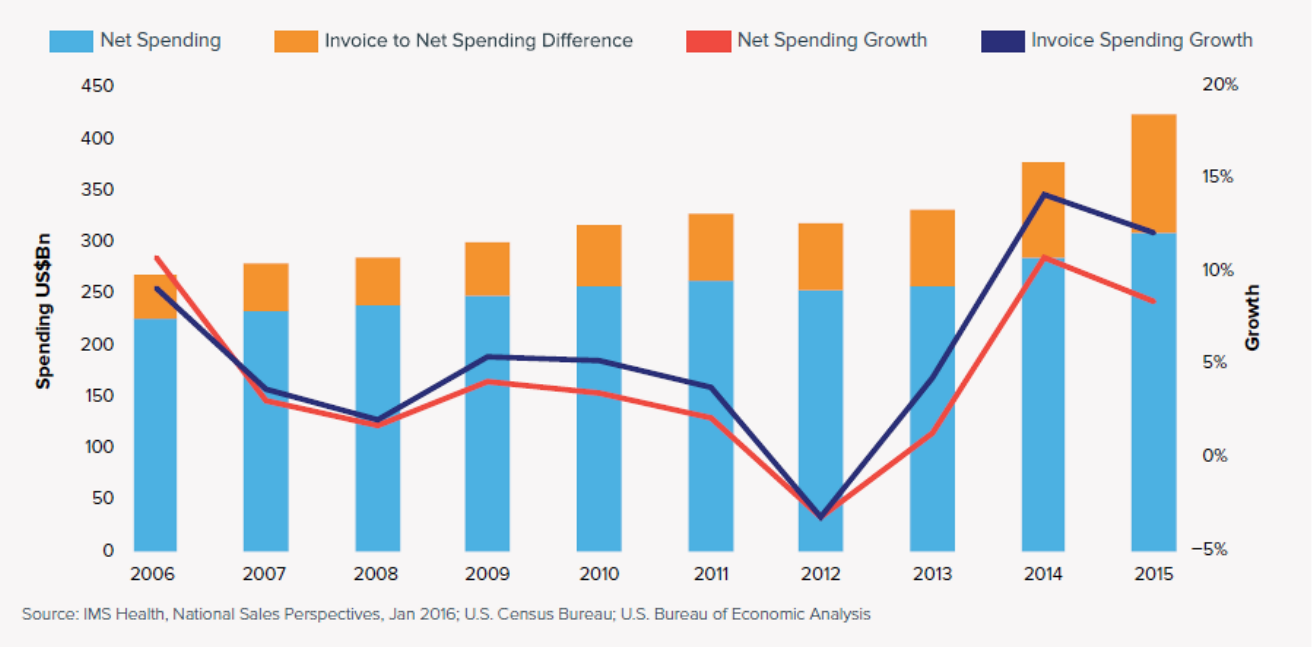
Spending on prescription drugs has risen sharply in the United States over the past few years.[1] From 2013 to 2015, out-of-pocket costs for prescription drugs rose 20 percent,[2] to an average cost of $44 per brand name prescription drug.[3] Additionally, prescription drug prices increased an average of almost 10 percent from June 2015 to May 2016.[4] Specialty prescription drug prices are projected to increase 18.7 percent in 2017, accounting for 35 percent of the prescription drug spending trend even though they account for less than one percent of prescriptions.[5] Recent increases in prescription drug prices are not only an increase in spending in terms of dollars, but also as a percentage of total healthcare spending.[6]

Prescription Drug Spending as a Share of Health Spending 2000-2017[7]

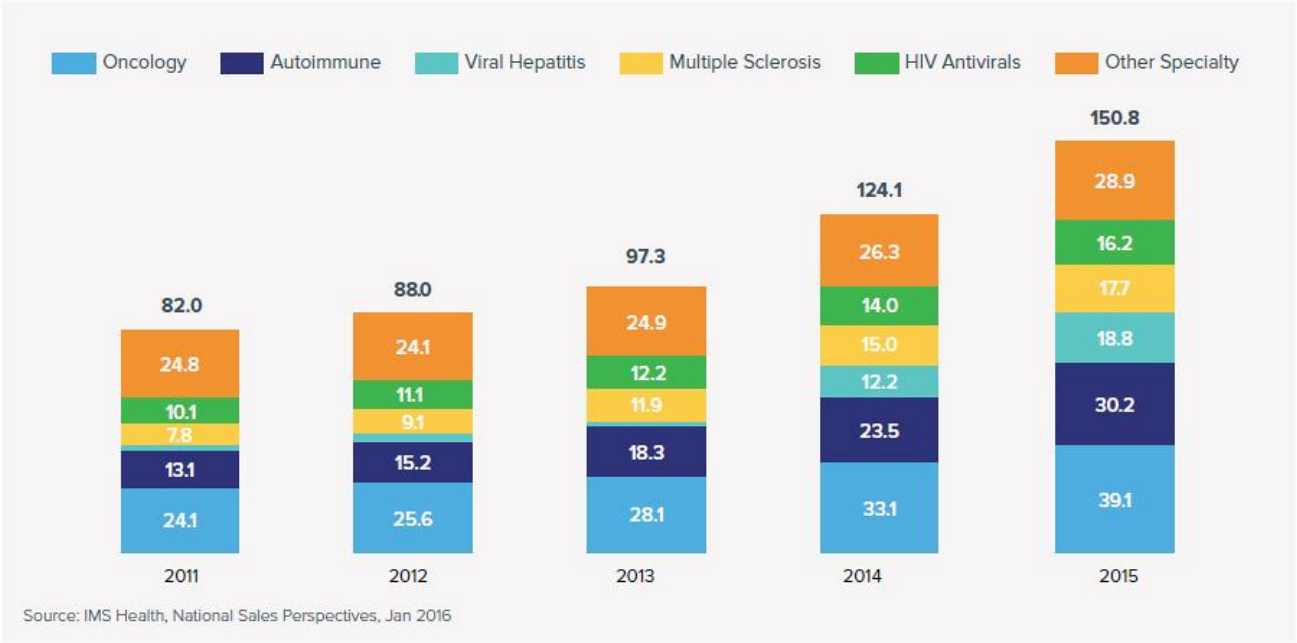


[1] Ameet Sarpatwari, Jerry Avorn, and Aaron S. Kesselheim, *State Initiatives to Control Medication Costs — Can Transparency Legislation Help?*, N. ENGL. J. MED. 2016; 374:2301-2304 Jun. 16, 2016, http://www.nejm.org/doi/full/10.1056/NEJMp1605100#t=article (last visited March 13, 2017).
[2] Troy Parks, *Drug pricing needs transparency, physicians say*, AMA WIRE, Jan. 26, 2017, https://wire.ama-assn.org/ama-news/drug-pricing-needs-transparency-physicians-say (last visited March 10, 2017).
[3] 2017 Segal Health Plan Cost Trend Survey, *available at*, https://www.segalco.com/media/2716/me-trend-survey-2017.pdf (last visited March 13, 2017)
[4] TRUVERIS, *Americans faced double digit increases in prescription drug prices in 2014, according to Truveris National Drug Index*, https://truveris.com/press-releases/ndi-americans-faced-double-digit-increases-in-prescription-drug-prices-in-2014/ (last visited March 13, 2017)
[5] *Supra*, note 3. Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions and often require special handling and administration.
[6] CENTERS FOR MEDICARE AND MEDICAID SERVICES, *National Health Expenditures by Type of Service and Source of Funds: Calendar Years 1960 to 2015*, .zip file available at, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (Last visited March 13, 2017).
[7] Jonathan D. Rockoff, *How Do We Deal With Rising Drug Costs?,* THE WALL STREET JOURNAL, Apr. 10, 2016, https://www.wsj.com/articles/how-do-we-deal-with-rising-drug-costs-1460340357 (last visited March 13, 2017).

Total U.S. Spending on Prescription Drugs, 2015[8]



Total U.S. Spending on Specialty Prescription Drugs, 2015[9]



[8] *Medicines Use and Spending in the U.S. – A Review of 2015 and Outlook to 2020,* QUINTILESIMS, APR. 2016, http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020 (last visited March 13, 2017).

[9] Id.

Prescription Drug Benefits

The federal Patient Protection and Affordable Care Act[10] (PPACA) requires qualified health plans to cover of essential health benefits (EHBs), meet cost-sharing limits, and meet actuarial value requirements. The law directs that EHBs cover at least 10 specified categories, one of which is prescription drugs.

Health insurers and employers increasingly work with pharmacy benefit managers (PBMs) to provide a range of services related to the acquisition and distribution of prescription drugs.[11] PBMs negotiate with drug manufacturers to purchase drugs at reduced prices or with the promise of additional rebates. This negotiation process often involves the development of drug formularies that incentivize the use of some drugs over others.[12] PBMs also establish pharmacy networks for insurers and employers, which involves negotiating with pharmacies to set reimbursement amounts for prescription drugs dispensed to patients.

Mail-Order Pharmacy

PBMs often encourage the use of mail order programs to manage clients' rising prescription drug expenditures. This promotion is often coupled with copayment incentives and sometimes with benefit mandates for use of mail order pharmacy. For most major PBMs, mail order is an important component of the business model and represents a significant portion of overall profitability.[13]

PBMs and other proponents of mail order pharmacy argue that mail order options offer consumers both convenience and the potential for savings, relative to what would be paid at traditional retail pharmacies. Most mail order prescriptions are for maintenance-type medications, and they are typically dispensed in a 90-day supply via mail order versus 30-day dispensing that is common at retail pharmacies.[14] Mail order use improves medication adherence – a term that refers to situations in which a patient take his or her medication as directed by a physician.[15] One recent study examined a large cohort of diabetes patients and found that patients using mail order pharmacy demonstrated significantly higher rates of adherence than those who filled their anti-diabetic medications at a traditional pharmacy.[16]

Proponents of traditional retail pharmacies have identified drawbacks associated with the use of mail order pharmacy programs. Some consumers may benefit from face-to-face interactions with pharmacists when filing prescriptions that may prevent medication errors. Others may be less likely to fully utilize primary care when they can obtain 90-day medication supplies without follow-up from their physicians.[17]

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[10] 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.
[11] The term "pharmacy benefit manager" is defined in S. 465.1862(b), F.S.
[12] Academy of Managed Care Pharmacy (AMCP). *Formulary Management*. Available at http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9298 (last accessed December 20, 2017).
[13] Khandelwal, Nikhil, et al. "Community Pharmacy and Mail Order Cost and Utilization for 90-Day Maintenance Medication Prescriptions." *J Manag Care Spec Pharm*, 2012 Apr;18(3):247-255. Available at http://www.jmcp.org/doi/10.18553/jmcp.2012.18.3.247 (last accessed January 6, 2018).
[14] Visante, Inc. "Mail-Service and Specialty Pharmacies to Save $1.8 Billion for California Consumers, Employers, and Other Payers in 2015." Prepared on behalf of the Pharmaceutical Care Management Association (PCMA). June 2014. Available at https://www.pcmanet.org/wp-content/uploads/2016/10/visante-pcma-ca-mail-specialty-savings.pdf (last accessed January 7, 2018).
[15] Sabaté E, editor., ed. *Adherence to Long-Term Therapies: Evidence for Action*. Geneva, Switzerland: World Health Organization; 2003. Available at http://apps.who.int/iris/bitstream/10665/42682/1/9241545992.pdf (last accessed January 7, 2018).
[16] Zhang, Linua, et al. "Mail-order pharmacy use and medication adherence among Medicare Part D beneficiaries with diabetes." *J Med Econ.* 2011;14(5):562-7. Available at https://www.ncbi.nlm.nih.gov/pubmed/21728913 (last accessed January 7, 2018).
[17] Schmittdiel, Julie A., et al. "The Safety and Effectiveness of Mail Order Pharmacy Use in Diabetes Patients." *The American Journal of Managed Care* 19.11 (2013): 882–887. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4278640/ (last accessed January 7. 2018).

The federal Centers of Medicare and Medicaid Services (CMS) documents and periodically releases complaints related to mail order pharmacy made by Medicare Part D members. Among the complaints reported by CMS were the following:

- A patient received the wrong medication and encountered difficulty in returning the medication;
- A patient received a brand-name drug, but had previously utilized a lower-cost generic drug;
- A patient incurred a higher copayment using mail order than he/she previously incurred at a retail pharmacy;
- A patient was dissatisfied with the shipping of a medication by a mail order pharmacy.[18]

Federal Law

Federal regulations implementing PPACA limit the use of mail order pharmacy. For plan years beginning on or after January 1, 2017, a health plan subject to PPACA requirements must allow enrollees to obtain prescription drug benefits at in-network retail pharmacies, unless:

- The drug is subject to restricted distribution by the U.S. Food and Drug Administration; or
- The drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.[19]

The PPACA rule allows plans to encourage mail order use by charging a different cost-sharing amount for drugs obtained at a network retail pharmacy versus those obtained via mail order.[20]

State Law

The Florida Insurance Code contains no provisions regulating the use of mail order pharmacy. However, Florida law does address its use for purposes of the state employee group health insurance program.

The Department of Management Services (DMS), through the Division of State Group Insurance, administers the state group health insurance program pursuant to ss. 110.123-110.1239, F.S.[21] To administer the program, DMS contracts with third party administrators for self-insured health plans, insured health maintenance organizations (HMOs), and a PBM for the self-insured prescription drug program.[22]

Under s. 110.12315, F.S., DMS must allow members to use any licensed pharmacy that accepts the same contractual terms, conditions, and reimbursement as the mail order pharmacy for up to a 90-day supply of all non-specialty maintenance medications. These retail pharmacies may be participating in either the PBM's retail pharmacy network or the State of Florida specific "maintenance 90 at retail" pharmacy network. Copayments and conditions for a 90-day supply at retail are the same as for mail order.[23]

[18] U.S Department of Health and Human Services, Centers for Medicare and Medicaid Services. "Sample of Beneficiary Complaints Relating to Mail Order." 2013. Available at https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/sampleofbeneficiarycomplaintsmailorder.pdf (last accessed January 7, 2018).
[19] Title 45 C.F.R. §156.122 (2016). 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 accessed January 5, 2018).
[20] Title 45 C.F.R. § 156.122(e).
[21] Title 26 U.S.C. § 125.
[22] S. 110.12315, F.S.
[23] Department of Management Services, 2016 Agency Legislative Bill Analysis, HB 583, p. 2.

Effect of Proposed Changes

The bill amends the insurance code to limit the ability of insurers to require the use of mail order pharmacy. Consistent with the PPACA rule, the bill prohibits insurers and HMOs from requiring the exclusive use of mail order pharmacy to obtain prescription drugs. The prohibition does not apply to an "excluded drug", which the bill defines as a drug subject to restricted distribution by the United States Food and Drug Administration or a drug that requires special handling, provider coordination, or patient education *and* cannot be provided by a retail pharmacy. This definition corresponds to one included in PPACA rules, but is not identical. PPACA rule defines "excluded drug" as a drug which is subject to restricted distribution by the U.S. FDA or a drug that requires special handling, provider coordination, or patient education *that* cannot be provided by a retail pharmacy.[24] This distinction is subtle, but meaningful. The definition included in HB 289 refers to drugs that cannot be dispensed by a retail pharmacy, whereas the federal definition refers to drugs requiring handling, provider coordination, or education that cannot be provided by a retail pharmacy.

In addition, the prohibition on mail order mandates only applies to patients with a "chronic illness" when obtaining drugs to treat that illness. The bill defines "chronic illness" as human immunodeficiency virus (HIV) infection.

PPACA rules allow insurers and HMOs to establish preferential patient cost sharing for prescriptions filled via mail order pharmacy.[25] HB 289 prohibits this practice for drugs which treat HIV infection in cases where a retail pharmacy agrees to the same terms, conditions, and payment amounts applicable to a mail order pharmacy. In other words, if a retail pharmacy agrees to the same terms, conditions and payment amounts as the mail order pharmacy, the insurer cannot charge higher copayments or impose different conditions for using the retail pharmacy that may discourage its use.

The bill requires a health insurer or HMO that issues a health insurance policy that provides coverage for prescription drugs through a mail order pharmacy to disclose in the outline of coverage that an insured may obtain prescription drugs for the treatment of these certain chronic illness from a retail pharmacy and that the exclusive use of a mail order pharmacy is not required unless the drug is an excluded drug. This requirement is technically unnecessary, however, as the state outline of coverage requirement was repealed in 2016.[26]

The bill expressly exempts grandfathered health plans and certain non-health care and limited benefit insurance policies from these provisions.

The bill has an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Creates s. 627.6442, F.S., relating to access to prescription drugs.
Section 2: Creates s. 627.6572, F.S., relating to access to prescription drugs.
Section 3: Amends s. 641.31, F.S., relating to health maintenance contracts.
Section 4: Provides an effective date of July 1, 2018.

[24] U.S Department of Health and Human Services. *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016.* 80 Fed. Reg. 39 (February 26, 2015). Available at https://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-03751.pdf (last accessed January 11, 2018).
[25] Id.
[26] Ch. 2016-194, Laws of FL (2016). The outline of coverage requirement was removed, effective July 1, 2016, as it was largely duplicative of documentation requirements established under PPACA.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None. The bill appears to have no impact on drug expenditures incurred by the state employee group health insurance program, as copayments and other conditions for prescription drugs are the same whether obtained through a retail pharmacy or by mail order.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

To the extent that local government employee health plans use differential copayments and other conditions to encourage use of mail order for drugs to chronic illness, as defined by the bill, the bill may reduce savings achieved by those methods.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill could result in an increase in drug expenditures incurred by private health insurers, HMOs and employers. These insurers often benefit from mail order pharmacy discounts arranged by PBMs, and could forego certain discounts if patients transition prescriptions from mail order pharmacy to retail pharmacies. Insurers and employers could shift cost increases to consumers in the form of higher premiums.

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 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.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 10, 2018, the Health Innovation Subcommittee adopted a strike-all amendment that modified the definition of “chronic illness” for purposes of this bill. The amendment limits the scope of the bill by restricting its applicability to drugs that treat human immunodeficiency virus (HIV) infection.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Innovation Subcommittee.