Date of Hearing: April 29, 2014

ASSEMBLY COMMITTEE ON HEALTH
Richard Pan, Chair
AB 2418 (Bonilla and Skinner) – As Amended: April 23, 2014

SUBJECT: Health care coverage: prescription drugs: refills.

SUMMARY: Requires health plan contracts and health insurance policies issued amended or renewed on or after January 1, 2016, which cover prescription drugs, to allow enrollees/insureds to opt out of any mandatory mail order program, allow for the synchronization of prescription refills, and permit refill of topical ophthalmic medications at 70% of the predicted days of use, if specified conditions are met. Specifically, this bill:

1) Requires health plan contracts and health insurance policies which cover prescription drugs to comply with the following requirements:

   a) *Mail order opt out*. Establish a process for enrollees/insureds to opt out of any mandatory mail order program imposed by the contract or policy providing:

      i) The opt out process does not impose conditions or restrictions, including but not limited to, prescriber approval or submission of documentation by the enrollee/insured;
      ii) Enrollees/insureds are allowed to opt out and to revoke the opt out at any time;
      iii) Enrollee/insured opt out choices are valid for the duration of the plan year or until the enrollee revokes the opt out, whichever occurs first, if the enrollee is in the same product with the same subscriber or plan sponsor;
      iv) The issuing health plan or insurer provides notice to the enrollee/insured that they are subject to the mandatory mail order program, at the time of first fill of an affected drug, informing them of the right to opt out, as specified; and,
      v) The opt out process does not apply to any drug which is not available at a network pharmacy due to any of the following: an industry shortage as determined by the federal Food and Drug Administration (FDA); a manufacturer's instructions or restrictions; any risk evaluation and management strategy approved by FDA; or, a special shortage affecting the plan's pharmacy network.

   b) *Synchronization of refills*. Permit and apply a prorated daily cost-sharing rate to the refills of prescriptions dispensed at a network pharmacy for less than the standard amount in order to synchronize an enrollee/insured's medications providing:

      i) The prescriber or pharmacist indicates the refill could be in the enrollee/insured's best interest for the purpose of synchronizing medications;
      ii) The prescription is not subject to quantity limits or other utilization controls inconsistent with synchronization, including but not limited to, prescribing and dispensing guidelines for controlled substances;
      iii) The prescription is dispensed by a single network pharmacy;
      iv) The patient has completed at least 90 consecutive days on the medication and the prescription can be effectively split, as specified;

v) The prescriber has not indicated orally or in writing "no change in quantity," or words of similar meaning, as specified; and
vi) Synchronization does not apply to any drug which is not available at a network pharmacy due to any of the following: an industry shortage as determined by the federal FDA; a manufacturer's instructions or restrictions; any risk evaluation and management strategy approved by FDA; or, a special shortage affecting the plan's pharmacy network.

c) *Topical ophthalmics*. Allow for refills of covered ophthalmic products at 70% of the predicted days of use.

2) Specifies that this bill does not establish a new or mandated benefit or prevent the application of deductibles, copayments and coinsurance provisions in the contract or policy.

EXISTING LAW:

1) Establishes the Department of Managed Health Care (DMHC) to regulate health plans and the California Department of Insurance to regulate health insurers.

2) Establishes the California State Board of Pharmacy (Board) which regulates and licenses pharmacists and issues pharmacy permits in multiple settings.

3) Imposes requirements on pharmacists and on the dispensing of prescription medicines, including, but not limited to, specific notice and labeling requirements related to the dispensing of prescription drugs and the requirement for a pharmacist to provide oral consultation to a patient or patient's agent in all care settings, for new or revised prescriptions, as specified, unless the patient/agent refuses consultation. If the patient/agent is not present, the pharmacist must provide a written notice, as specified, which must include a telephone number from which the patient can obtain consultation.

4) Requires health plans and insurers providing health coverage in the individual and small group markets to cover, at a minimum, essential health benefits (EHBs), including the ten EHB benefit categories in the Patient Protection and Affordable Care Act (ACA), (one of which is prescription drugs), and consistent with California's EHB benchmark plan, the Kaiser Foundation Health Plan Small Group HMO 30 plan (Kaiser benchmark), as specified in state law.

5) Requires EHB prescription drug coverage offered, sold and renewed by health plans and insurers after January 1, 2014 to comply with specified California statutory and regulatory standards which predated the ACA and applied to health plans under the jurisdiction of DMHC, including the Kaiser benchmark.

6) Requires health and insurers that cover prescription drug benefits to provide notice in the evidence of coverage and disclosure form to enrollees/insureds regarding whether the plan uses a formulary.

7) Establishes in federal law the ACA which, among other provisions:

a) Requires issuers of individual and small group coverage to, at a minimum, cover EHBs in the following ten categories: Ambulatory patient services, emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, including behavioral health treatment, prescription drugs, rehabilitative and habilitative services and devices, laboratory services, preventive and wellness services and chronic disease management, and pediatric services, including oral and vision care.

b) Requires states to select a "benchmark plan" to serve as the minimum coverage standard for EHBs, choosing from among specified employer plans offered in the state.

FISCAL EFFECT: This bill has not been analyzed by a fiscal committee.

COMMENTS:

1) PURPOSE OF THIS BILL. According to information provided by the author, this bill is aimed at improving patient medication adherence and health outcomes through streamlining the medication refill process using the three strategies mandated. The author states that by creating processes that support and improve patient access to medications; patients experience better health outcomes and improved quality of life. Patients who pick up their medications at their local pharmacy have the opportunity to talk with the pharmacist about how to properly take their medications and to understand the positive benefits of taking their medication. The author points to research that shows approximately 50% of patients with chronic health conditions such as heart disease and diabetes do not take their medications as prescribed and 20-30% of medications are never filled. Patients that do not take their medications regularly are at a greater risk of poor health outcomes and hospitalization.

2) BACKGROUND.

a) *California Health Benefits Review Program*. The California Health Benefits Review Program (CHBRP) reviewed this bill at the request of this committee. CHBRP analyzed the introduced version of this bill but subsequently notified the committee that the April 22, 2014 amendments do not change the substantive findings of their analysis. The key findings of the CHBRP report are:

CHBRP estimates that in 2015, 23.4 million Californians will be enrolled in state-regulated health insurance and that 23.1 million of these enrollees will have coverage for outpatient prescription drugs affected by this bill. These figures include Medi-Cal beneficiaries and CalPERS enrollees with coverage in health plan contracts and health insurance policies subject to this bill.

i) *Impact on expenditures*. Total expenditures are estimated to increase by $3.3 million (0.003%), due to this bill;
ii) *EHBs*. This bill affects terms of benefit coverage and would not exceed California's definition of EHBs;
iii) *Medical effectiveness*. CHBRP evaluated the literature relating to the effect on adherence of the three provisions in this bill (mandatory mail opt-out requirement; synchronization; early topical ophthalmic product refill). CHBRP found insufficient evidence to determine the effect these provisions may have on adherence. CHBRP noted that the absence of evidence does not mean there is no effect. CHBRP did find

some evidence in the literature that pharmacist-based interventions may increase medication adherence, but noted that this bill does not mandate such interactions.

iv) *Benefit coverage*. Post mandate, CHBRP estimates the following changes: 1.07 million enrollees (who have mandatory mail order requirements) would gain an opt-out process for mandatory mail order; 10.28 million enrollees would gain coverage for synchronization refills; 10.43 enrollees (who had coverage for topical ophthalmic product refills at 75-85%) would have coverage for topical ophthalmic product refills at 70% of expected days of use;

v) *Utilization*. Post mandate, CHBRP estimates the following changes: retail pharmacy refills would increase by 0.26% (with a commensurate decrease in mandatory mail refills due to switching from mail to retail refills); topical ophthalmic product refills would increase by 0.12%; and,

vi) *Public health*. Although this bill would result in a limited increase in filled prescriptions, CHBRP found insufficient evidence to estimate any impact on medication adherence, so the impact on the public's health from this bill is unknown.

b) *Specialty drugs*. New developments in medication therapy have resulted in break-through treatments for complex diseases. These advances have created a relatively new class of prescription medications that is commonly referred to as biopharmaceuticals - also known as specialty medications or specialty drugs. According to CHBRP, prescription drug benefits are a specific type of covered benefit usually subject to cost-sharing as part of the medical benefit or a separate outpatient prescription drug benefit. Some payers use a four-tier system which includes life-style drugs and specialty drugs in the fourth tier; typically these are the most costly drugs. The four-tier design frequently results in greater enrollee out-of-pocket expenses. CHBRP notes that there is no standard industry definition of specialty prescription drugs, but it is generally recognized by many payers as prescription drugs with an average minimum monthly cost of $1,150. Specialty medications can cost as much as $200,000 per year and are costly to ship, store, and administer. Other criteria may include prescription drugs that treat a rare disease, require special handling, or have a limited distribution network. Most of the conditions targeted by specialty drugs tend to be chronic and progressive in nature and can impact quality of life, along with morbidity and mortality, such as growth hormone disorders, rheumatoid arthritis, asthma, multiple sclerosis, hepatitis C, hemophilia, cancer, and lupus.

c) *Medicare Part D prescription drug program*. Medicare Part D, the Medicare prescription drug benefit, is the federal program which subsidizes the cost of prescription drugs for Medicare beneficiaries, enacted as part of the Medicare Modernization Act of 2003 and effective on January 1, 2006. According to CHBRP, all three of the strategies required under this bill are in effect for Medicare beneficiaries. Regulations implementing Medicare Part D require that Part D sponsors have an accessible network of retail pharmacies (specifically, within two miles in urban areas, within five miles in suburban areas, and 15 miles in rural areas). The contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail-order and institutional pharmacies, provided certain requirements are met. The regulations also include "level playing field between mail-order and network pharmacies" provisions which require a sponsor to permit its plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A sponsor may require an enrollee obtaining a covered drug at a network retail pharmacy to pay higher cost-sharing applicable for that setting than

would otherwise apply at a mail-order pharmacy.

d) *Patient consultation*. California pharmacy regulations require pharmacies to maintain patient medication profiles and counsel patients regarding their prescription medication before dispensing. According to information on the Website of the Board, consultation provides the pharmacist with the opportunity to educate patients who present new prescriptions and protect them from potential problems associated with a new medication by discussing possible side effects, contraindications and the importance of following directions. The Board also states consultation provides the pharmacist one more opportunity to prevent dispensing errors by inspecting the medication container's contents to assure that the proper drug is dispensed.

e) *Pharmacist Dispensing of 90-Day Supply of Drugs*. SB 1301 (Ed Hernandez), Chapter 455, Statutes of 2012, authorizes a pharmacist to dispense no more than a 90-day supply of a dangerous drug other than a controlled substance, pursuant to a valid prescription that specifies an initial quantity of less than a 90-day supply followed by periodic refills of the same amount if the following requirements are satisfied:

   i) The patient has completed an initial 30-day supply of the dangerous drug;
   ii) The total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills;
   iii) The prescriber has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary; and,
   iv) The pharmacist is exercising his or her professional judgment.

f) *Pharmacy Benefit Managers (PBMs)***.** According to the Federal Trade Commission (FTC), many health plan sponsors offer their members prescription drug insurance and hire PBMs to manage these pharmacy benefits. As part of the management of these benefits, PBMs assemble networks of retail and mail-order pharmacies so that the plan sponsors' members can fill prescriptions easily and in multiple locations. PBMs contract with employers, labor unions, insurance companies, the state, Medicaid (Medi-Cal in California) and Medicare managed care plans, and managed care companies (collectively, "plan sponsors") to manage pharmacy benefits. There are large PBMs (Express Scripts/Medco, and Caremark), small and insurer-owned PBMs (Aetna, Cigna Corporation, Wellpoint Health Networks), retailer-owned (Eckerd Health Systems, PharmaCare Management Services [a subsidiary of CVS Corp]), Walgreens Health Initiative or stand-alone retail pharmacies (CVS Corp, Rite Aid Corporation, Walgreen and Wal-Mart Stores, Inc.).

   FTC reports that PBMs engage in many activities to manage their clients' prescription drug insurance coverage. In addition to assembling pharmacy networks, PBMs consult with plan sponsors to decide for which drugs a plan sponsor will provide insurance coverage to treat each medical condition (e.g., hypertension, high cholesterol, etc.). The PBM manages this list of preferred drug products (the "formulary") for each of its plan sponsor clients. Consumers with insurance coverage are then provided incentives, such as low copayments, to use formulary drugs. Because formulary listing will affect a drug's sales, pharmaceutical manufacturers compete to ensure that their products are included on these formularies. They do so by paying PBMs "formulary payments" to

obtain formulary status, and/or "market-share payments" to encourage PBMs to dispense their drugs. These payments are based on the quantity of drugs dispensed under the plans administered by the PBM. PBMs also often use mail-order pharmacies to manage prescription drug costs. Many plan sponsors encourage patients with chronic conditions who require repeated refills to seek the discounts that 90-day prescriptions and high-volume mail-order pharmacies can offer. Many PBMs own their own mail-order pharmacies. PBMs have suggested that they have greater control over the drugs dispensed through mail-order pharmacies and, therefore, can provide greater formulary compliance.

a) *Anthem mandatory mail opt out settlement*. In 2013, Anthem Blue Cross (Anthem) required policyholders to fill any prescriptions on an Anthem-developed specialty drug list via mail order through CuraScript, a specialty pharmaceutical distribution company wholly owned by Express Scripts. Anthem notified members with conditions such as HIV/AIDs and cancer that, for any drug on the list, failure to get the prescription filled through CuraScript would be considered an out-of-network service and patients would have to pay full price at any retail drugstore. Other Anthem members, including those with chronic conditions such as diabetes, faced no such requirement. In *Los Angeles Times* articles at the time, Anthem stated it was imposing the new requirement to help keep costs down for patients and businesses. Subsequently, Consumer Watchdog filed a class action lawsuit alleging that the Anthem program illegally targeted members with HIV/AIDS, delaying the program. In May 2013, parties to the lawsuit reached a settlement in which Anthem agreed to send a notice to existing members allowing them to permanently opt out of the mail order program by calling CuraScript before August 1, 2013, and stating that members who chose initially to receive their drugs through CuraScript could subsequently opt out at any time in the same way.

2) SUPPORT. California Pharmacists Association and California Healthcare Institute, co-sponsors of this bill, write in support that lack of medication adherence results in lost opportunities to treat patients and improving adherence requires a multi-faceted approach, including the strategies outlined in this bill. The sponsors state that poor medication adherence accounts for as much as $290 billion per year in avoidable medical spending. The sponsors argue that pharmacists play a key role in helping improve medication adherence, educating patients about their medications, including how and when to take them, what side effects to watch out for, what to expect when taking medication, foods and other drugs to avoid, and more. Sponsors contend that hundreds of clinical studies show improvement in medication adherence and benefits to patient health outcomes when pharmacists work with other members of the care team on medication therapy. California Optometric Association (COA) supports this bill and points out that the provision allowing early refill of eye drops due to inadvertent spillage in patient use is especially important for glaucoma patients who are often elderly and may have difficulty dispensing the proper amount. COA points out that glaucoma is a preventable cause of blindness if timely and successful treatment is provided. Patient and consumer advocacy groups support this bill because it promotes strategies to improve medication adherence, including synchronization to make it more convenient for patients to obtain all of their medications in one visit to the pharmacy. Advocates maintain that allowing patients to choose between in-person pickup and mail delivery of medications ensures that patients can obtain important therapies in the way that best suits their medical needs. California Pan-Ethnic Health Network argues that requiring patients to receive their prescriptions by mail could create confusion, especially among limited English-proficient

populations. The California Hepatitis C (Hep C) Task Force points out that this bill would help patients avoid the catastrophic interventions needed to treat liver cancer or costly liver transplantation which can result from the Hep C virus by implementing strategies leading health organizations recommend to increase medication adherence.

3) OPPOSE UNLESS AMENDED. Several organizations write in opposition to this bill as introduced, unless amended. The April 22, 2014 amendments appear to be responsive to the concerns but it is not known if the amendments address some or all of the concerns. Express Scripts and America's Health Insurance Plans (AHIP) suggest any alternative process to mail order pharmacy be available for limited circumstances, such as for maintenance medications an individual has been taking for three months, only if the patient is stabilized on a treatment plan, the patient has privacy concerns or the enrollee's condition does not permit effective use of mail order. Express Scripts specifically requests that the alternative process exclude specialty medications and that the provision allowing refills at 70% estimated days of use be changed to five days prior to the next scheduled refill. California Society of Health System Pharmacists seeks amendments to allow synchronization only if the prescriber or pharmacist finds it in the best interest of the patient, the medication can be effectively split and the medication is not an opioid, stimulant, sedative or hypnotic medication subject to abuse.

4) OPPOSITION. CSAC Excess Insurance Authority, a joint powers authority representing public agencies, opposes this bill as not prudent in controlling health care costs since mail order pharmacies and associated cost containment measures help to control costs and educate consumers about alternatives. Health plans, insurers and pharmacy benefit managers oppose this bill concerned about the costs and administrative complexity of the proposed changes. Health plans and insurers view this bill as micromanaging the prescription refile process. Blue Shield of California (BSC) argues that this bill will eviscerate the benefits members realize from mandatory mail order programs and states that most specialty medications are currently provided through such programs. According to BSC, specialty drug mail order programs provide unique patient monitoring and utilization services which result in higher adherence rates and allow many members to receive a 2 or 3 month supply for one single 30-day copayment. Association of California Life and Health Insurance Companies (ACLHIC) states the synchronization provisions could actually decrease medication adherence if required for patients that are not on a comparatively long term, steady and stable treatment schedule. ACLHIC cites the example of an individual on blood thinners which the provider wants them to stop or decrease prior to surgery in which case synchronization would not be appropriate. Pharmaceutical Care Management Association (PCMA) is concerned that the synchronization proposal in this bill over-simplifies what can be potentially dangerous strategies depending on the underlying health conditions and the nature of the medicines being prescribed. PCMA also views the refill requirement for ophthalmic medicines as an intrusion in the commercial health insurance market imposing a Medicare standard that will not mesh with existing commercial drug benefit designs. California Association of Health Plans (CAHP) opposes this bill because it will do nothing to control the underlying costs of high-priced drugs and points out that the increases in costs for specialty drugs stems from the release of newer, more sophisticated therapies with extremely high price tags being brought to market. CAHP specifically mentions the new Hep C treatment, Sovaldi, which costs $1,000 per pill and approximately $84,000 per treatment cycle making it unsustainable to cover the medicine in the commercial and Medi-Cal markets.

5) PREVIOUS LEGISLATION.

a) AB 299 (Holden) of 2013 would have prohibited a health plan or insurer that provides prescription drug benefits from requiring an enrollee to utilize in-network mail order pharmacy services for covered prescription drugs available at an in-network retail pharmacy. AB 299 was held on the Assembly Appropriations suspense file.

b) SB 1301 authorizes a pharmacist to dispense not more than a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription, except for psychotropic medication or drugs or controlled substances, as specified.

c) SB 1195 (Price), Chapter 706, Statutes of 2012, requires a contract that is issued, amended, or renewed on or after January 1, 2013, between a pharmacy and a carrier or a PBM to provide pharmacy services to beneficiaries of a health benefit plan to comply with standards and audit requirements.

6) POLICY COMMENTS.

a) *Interaction with Anthem settlement*. The 2013 Anthem settlement resulted in Anthem members being able to permanently opt out of the mandatory mail order drug program with no stated timeline on the opt out. This bill establishes an opt out program "for the plan year" which would presumably require enrollees to repeat the request for the opt out on an annual basis. The author may wish to ensure that this bill does not enact a lesser standard than the terms of the Anthem settlement;
b) *Consumer cost sharing*. This bill states that nothing shall be construed to prevent the application of copayments, deductibles and coinsurance, but at the same time, prohibits the imposition of any conditions or restrictions on the opt out, including *but not limited to*, prescriber approval or enrollee documentation. The author may wish to clarify whether differential copayments, in the form of financial incentives, where the enrollee's cost sharing is reduced when they use mail order versus retail pharmacy, could be employed by health plans and insurers under the provisions of this bill; and,
c) *Suggested clarifying amendments*. This bill allows for synchronization if the prescriber or pharmacists finds it "could be" in the best interest of the enrollee. Since this requirement is based on professional judgment, wouldn't the condition be stated more directly; synchronization "is in the best interests of the enrollee?" This bill does not specifically state that the purpose of synchronization is to coordinate refill *dates*. This bill also includes terminology used in federal but not California law. for example, a group "plan sponsor" would instead be a "subscriber" in the Health and Safety Code and a "policyholder" in the Insurance Code. Also, use of the term "network" pharmacy is more often referenced in California law as a "contracting" or "participating" provider.

REGISTERED SUPPORT / OPPOSITION:

Support

California Healthcare Institute (cosponsor)
California Pharmacists Association (cosponsor)
ALS Association
American Cancer Society Action Network

American Federation of State, County and Municipal Employees, AFL-CIO
Association of Northern California Oncologists
BayBio
BioCom
Biotechnology Industry Organization
California Association of Area Agencies on Aging
California Chronic Care Coalition
California Grocers Association
California Health Collaborative
California Hepatitis C Task Force
California IA Urological Association
California Optometric Association
California Pan-Ethnic Health Network
California Senior Advocates League
Herndon Pharmacy
Huntington's Disease Society of America
International Foundation for Autoimmune Arthritis
Latina Breast Cancer Agency
Latinas Contra Cancer
Mental Health Systems
National Association for the Advancement of Colored People, California State Conference
National Association of Chain Drug Stores
Patterson Family Pharmacy
Pharmaceutical Research and Manufacturers of America
Rite Aid
Sacramento Latino Medical Society
Safeway
Spondylitis Association of America
The Wall Las Memorias
TMJ Society of America
United Nurses Association of California/Union of Health Care Professionals
Walgreens

Oppose unless amended (prior version)

America's Health Insurance Plans
California Society of Health System Pharmacists
Express Scripts

Opposition

CSAC Excess Insurance Authority
Association of California Life and Health Insurance Companies
Blue Shield of California
California Association of Health Plans
Pharmaceutical Care Management Association

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