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BACKGROUND ON COST SHARING FOR OUTPATIENT PRESCRIPTION DRUGS

CHBRP presents the following background information about concepts important to the analysis of AB 339: cost sharing for outpatient prescription drugs. This information is general in nature and provides context for the consideration of this bill. CHBRP's full analysis of AB 339 will be provided as requested, by May 19, 2015.

Outpatient Prescription Drugs

Prescription drug benefits are a specific type of covered benefit usually subject to cost sharing. Outpatient prescription drug coverage can fall within the medical benefit, for example when a medication is administered by an infusion at a medical setting and/or a designated outpatient prescription drug benefit under a separate pharmacy benefit. The designs are complex and vary widely within and between plans and policies. AB 339 specifies coverage and/or cost sharing requirements for outpatient prescription drugs in regards to the following specific types of drugs which are discussed in more detail below: therapeutically equivalent drugs, single tablet and multiple tablet drug regimens, extended release and nonextended release drugs, drugs placed on the highest cost-sharing tiers, and specialty prescription drugs.

Prescription Drug Types Relevant to AB 339

Therapeutic Equivalents

Therapeutic equivalent has two different meanings depending on the context. In the context of pharmacy benefit design, therapeutic equivalence generally denotes a drug that has essentially the same clinical response as one or more other drugs.¹ In this definition, a drug that is a therapeutic equivalent may or may not be chemically equivalent, bioequivalent, or generically equivalent. In the FDA's *Orange Book*², drug products are considered to be therapeutically equivalent "only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients

¹ An example of this usage can be found at: https://www.pbmplplus.com/docs/Pharmacy_Benefit_Design.pdf.

² The FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* is commonly known as "The Orange Book", found at: <http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm>.

under the conditions specified in the labeling” (FDA, 2015). For therapeutic equivalent prescription drugs, the federal Food and Drug Administration (FDA) definition is used in this analysis.

Single and Multiple Tablet Regimens

Single-tablet regimens typically refer to fixed-dose pills that combine multiple drugs from the same or different drug classes into a single tablet (FDA, 2011). This is in contrast to multiple tablet regimens where prescribed medications to treat a condition are taken as separate tablets (Sax, et.al., 2012). This is primarily seen in chronic conditions requiring multiple pills each day. The advantages of the single-tablet combination drug regimen are that taking one single daily pill simplifies treatment, cuts down on errors, and leads to better adherence with the treatment regimen (Sax, et al., 2012). **Throughout this letter the term single-tablet combination drug will be used to clearly identify that the single tablet is comprised of multiple drugs.**

Extended Release and Nonextended Release Drugs

The typical mechanism for the release of active ingredients in regular medications (i.e., nonextended release medications) is that the effect takes hold within 15 to 30 minutes of when they are ingested (Schoenwald, 2000). Some types of medications are prescribed to be taken three or four times a day. For these types of medications, there also may be an extended release equivalent drug in which medications are released over a much longer period of time and are usually taken only once or twice a day (Schoenwald, 2000). The advantages of extended release medications are a more stable level of medications in the body over the course of a day and a higher adherence rate (Wen & Park, 2011). The main disadvantage of extended release drugs is that missing a single dose means that the patient missed a whole day of medication as opposed to one-third or one-fourth of their daily medications.

Specialty Prescription Drugs

There is no standard industry definition of specialty prescription drugs, but a 2011 national survey of 102 commercial and Medicare/Medicaid plans found that 84% of payers identify cost as this category’s primary characteristic, with an average minimum monthly cost of \$1,154. Other criteria for defining a specialty prescription drug include treating a rare condition, requiring special handling, or having a limited distribution network (EMD Serono, 2012).

Cost Sharing for Outpatient Prescription Drugs in California

Payment for covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Specifically, the *patient* cost-share is the portion that enrollees are responsible for paying out-of-pocket directly to the provider for the health care service or treatment (including prescription drugs) covered by the plan or policy. Noncovered services or treatments are always paid in full by the enrollee, heretofore referred to as “noncovered expenses.” Common cost-sharing mechanisms include copayments, coinsurance, and/or deductibles (but do not include premium payments). CHBRP

refers to these as enrollee out-of-pocket expenses.³ Health plans and insurers use many different combinations of cost-sharing mechanisms to help assure medically necessary treatment and control costs.

Common Cost-Sharing Mechanisms

The following steps describe a common interaction of a set of cost-sharing mechanisms. The steps indicated here correspond to Figure 1 below. CHBRP notes that there are numerous cost-sharing combinations, and this example will not apply to all situations.

- **Step 1: Deductibles**

Deductibles are a fixed dollar amount (lump sum for one or more services) an enrollee is required to pay out-of-pocket within a given time period (e.g., a year) before the health plan or insurer begins to pay, in part or in whole, for covered health care services. A plan or policy can have more than one deductible, for example, a general deductible that applies to a specified set of covered medical benefits and another deductible that applies to prescription drugs or hospital admissions. Deductibles can range from \$200 for an outpatient pharmacy benefit to \$2,500 or more for a family medical benefit. Not all plans and policies have deductibles.

- **Step 2: Copayments and/or coinsurance**

Copayments and coinsurance are activated after the deductible has been met, if a plan/policy has a deductible.

Copayment is a form of cost sharing in which an enrollee pays a predetermined, flat dollar amount out-of-pocket at the time of receiving a health care service or when paying for a prescription, such as a \$5 copayment for a generic prescription drug. Copayments can vary across covered benefits, and a plan or policy may not require any copayments or may only require copayments for some covered benefits.

Coinsurance is the percentage of covered health care costs for which an enrollee is responsible, such as 25% of a hospitalization charge. As with copayments, coinsurance percentages can vary across covered benefits, and a plan or policy may not require any coinsurance or may only require coinsurance for some covered benefits.

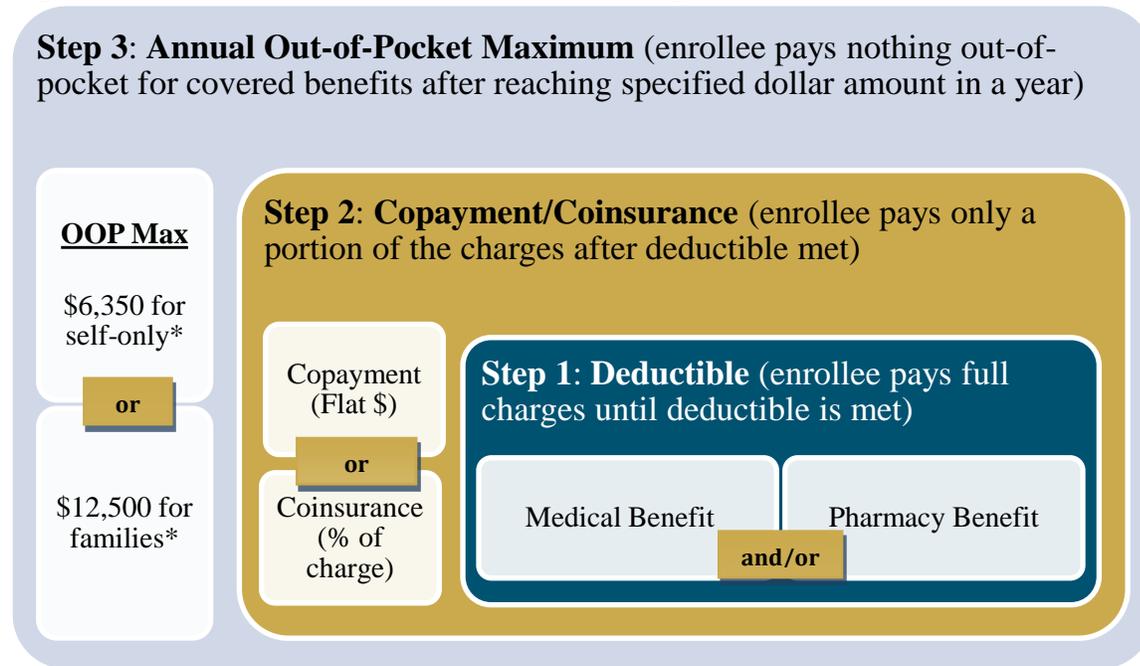
It is not unusual for a prescription drug benefit plan to use copayments and coinsurance. For example, many times, generics are subject to a copayment, whereas specialty drugs are subject to a coinsurance.

- **Step 3: Annual out-of-pocket maximums**

Annual out-of-pocket maximums are limits on the enrollee's cost-sharing (copayments, coinsurance, and deductibles) obligations in a 1-year period. Health care services that are not covered by the health plan or insurer would not be included in the maximum; enrollees are responsible for the full charges associated with noncovered services.

³ See CHBRP's Glossary of Key Terms available at: www.chbrp.org/analysis_methodology/glossary_key_terms.php.

Figure 1. Overview of the Intersection of Cost-Sharing Mechanisms Used in Health Insurance



Source: California Health Benefits Review Program, 2014.

Note: * The annual out-of-pocket amounts in this figure are the maximum amounts allowed in 2014; some plans and policies may have lower annual out-of-pocket maximums. The figure assumes that the enrollee is in a plan with a deductible. If no deductible, then enrollee pays a coinsurance and/or a copayment beginning with the first dollar spent (Step 2).

Key: OOP Max=annual out-of-pocket maximum.

Cost Sharing and Outpatient Prescription Drug Benefits

Prescription drug benefits are a specific type of covered benefit usually subject to cost sharing. Outpatient prescription drug coverage can fall within the medical benefit and/or a designated outpatient prescription drug benefit. The designs are complex and vary widely within and between plans and policies. For example, a drug benefit design may require coinsurance on a prescription drug, but cap the amount paid per 30- or 90-day supply. A health plan or insurer may have lower cost-sharing rates for prescriptions filled at a mail-order pharmacy service instead of a retail pharmacy, or at preferred versus nonpreferred pharmacies. Self-administered injectable drugs may be covered under the medical benefit by some health plans or insurers, and the prescription drug benefit by others. In addition, a health plan or insurer may require copayments for generic or preferred drugs and coinsurance on nonpreferred or specialty drugs (see discussion of prescription drug tiers below).

Outpatient prescription drug tier structures

In general, outpatient prescription drug benefit designs can be characterized by the number of tiers into which the drugs are divided, each tier having a distinct cost-sharing level. The prescription drugs in the lower tiers are less costly to both the enrollee and to the health plan or insurer. Some health plans or insurers use a four-tier system that generally includes life-style drugs (e.g., infertility, erectile

dysfunction, weight loss) 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, thus this discussion is particularly relevant to the analysis of AB 339, which would limit cost sharing to no more than 1/24 of the annual out-of-pocket maximum (\$265).

- One-tier designs have the same cost sharing regardless of drug type.
- Two-tier designs generally have one payment for (1) generic⁴ drugs and another for (2) brand-name drugs.
- Three-tier designs generally have one payment for (1) generics, and two different payments for brand-name drugs, dividing them into (2) preferred,⁵ with lower cost sharing, and (3) nonpreferred,⁶ with higher cost sharing.
- Four-tier designs generally have the three tiers above, plus a fourth and/or fifth cost-sharing level for specific drugs, such as “lifestyle” drugs (e.g., infertility, erectile dysfunction, weight loss), and/or specialty drugs, or others for which a plan may want to impose differential cost sharing (CHCF, 2014; KFF/HRET, 2013).

Average copayment/coinsurance by tier level in California

The California Employer Health Benefits Survey found that the average copayment among California workers in 2013 was \$10.04 for generics, \$25.41 for preferred, and \$41.85 for nonpreferred drugs (CHCF, 2014), meaning that a preferred drug has, on average, 60% of the copayment of a nonpreferred drug for California enrollees with an employer-sponsored plan. A national survey found that fourth-tier drug copayments averaged \$80 in 2013, and the average coinsurance was 32% (KFF/HRET, 2013). The national survey also reported that workers in a four-tier system were divided fairly evenly between cost-sharing type, 48% coinsurance and 39% copayment, regardless of plan type (KFF/HRET, 2013).

Distribution of Prescription Drugs by Tiers in California

As noted previously, a 2011 national survey of commercial and public payers identify high cost as the top defining feature of specialty drugs, and there is no standard industry definition of specialty prescription drugs. Yet, the number and cost of specialty prescription drugs continues to increase and payers are managing these high-cost drugs with different cost-sharing methods. For example, in the aforementioned survey, 49% of plans place specialty drugs in tier 4, and 51% distribute specialty drugs among tiers 2 and 3 depending on their preferred status. About 40% of plans used a coinsurance benefit design rather than copayments. Of the commercial plan respondents, 25% reported an average copayment of \$120, and 72% reported an average coinsurance of 22% for specialty drugs. Specialty drug copayments among all tiers ranged from \$10 to \$250 per prescription, and coinsurance ranged from 10% to 50%. In 2011, 71% of plans with coinsurance had a maximum dollar amount cap on cost sharing for a prescription drug with an average cap of \$218 (EMD Serono, 2012).

⁴ A generic drug is no longer covered by patent protection and thus may be produced and/or distributed by multiple drug companies.

⁵ A preferred drug is one included on a formulary or preferred drug list; for example, a brand-name drug without a generic substitute.

⁶ A nonpreferred drug is one included on a formulary, but not on the preferred drug list; for example, a brand-name drug with a generic substitute.

Payment for covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Common cost-sharing mechanisms include copayments, coinsurance, and/or deductibles (but do not include premium payments). CHBRP refers to these as enrollee out-of-pocket expenses.⁷ Health plans and insurers use many different combinations of cost-sharing mechanisms to help assure medically necessary treatment and control costs.

Overall, it appears that insured Californians have less exposure to the highest levels of cost sharing for prescription drugs than their counterparts in other states. Table 1 shows the prevalence of different prescription drug benefit structures among employer-sponsored health insurance (ESHI) in California and nationally. The proportion of workers in tier 4 cost-sharing structures has increased in California from 2% in 2005 to 7% in 2013. Nationally, there was a statistically significant increase in the percent of workers shifting to a four-tier structure between 2005 and 2013 (7% to 23%, respectively) (CHCF, 2014).

⁷ See CHBRP's Glossary of Key Terms available at: www.chbrp.org/analysis_methodology/glossary_key_terms.php.

Table 1 Distribution of the Types of Prescription Drug Benefit Structures for Health Insurance Products in California and Nationally, 2013

Tiered Prescription Drug Design	California	United States
1 Tier	9%	5%
2 Tier	22%	10%
3 Tier	59%	59%
4 Tier	7%	23%
Other	3%	4%

Source: *CHCF, 2013.*

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