

Issue Brief Outpatient Prescription Drug Cost Sharing

January 2021

Prepared by California Health Benefits Review Program

www.chbrp.org

Suggested Citation: California Health Benefits Review Program (CHBRP). (2021). Issue Brief: Outpatient Prescription Drug Cost Sharing. Berkeley, CA



OUTPATIENT PRESCRIPTION DRUG COST SHARING

This issue brief discusses cost sharing laws and limits that are applicable to outpatient prescription drug benefits regulated by the Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI). A brief discussion of pharmacy benefits, cost sharing, and the laws that are relevant to them follows. Definitions for terms commonly used in discussions of pharmacy benefits are included in the appendix.

Pharmacy Benefits in Health Insurance Plans and Policies

Pharmacy benefits cover self-administered drugs prescribed by a healthcare professional (i.e. outpatient prescription drugs). A pharmacy benefit is independent from a medical benefit, which covers office visits and hospitalizations, and can include drugs administered by a healthcare professional. Pharmacy benefits are often administered through a third-party, called Pharmacy Benefit Managers (PBMs), who work on behalf of payers to provide coverage for outpatient prescription drugs for enrollees.

For DMHC-regulated plans and CDI-regulated policies, almost all commercial enrollees have coverage for outpatient prescription drugs through a pharmacy benefit that is part of the plan or policy.³ In this arrangement, the health insurer may use an in-house PBM of their own, or sub-contract with a PBM. A small percentage of enrollees in state-regulated health insurance (about 1.9% in 2021) access pharmacy benefits directly through a PBM.⁴

Drugs included in the pharmacy benefit are typically accessed through a pharmacy. This brief focuses on cost sharing related aspects of pharmacy benefit design, which include cost sharing mechanisms, drug classifications, formularies, and formulary tiers (see details below).⁵

Cost Sharing and Outpatient Prescription Drugs

Prescription drugs are generally covered through an enrollee/beneficiary's pharmacy benefit, and cost sharing may apply to their coverage. Cost sharing is the amount an enrollee/beneficiary pays towards the cost of covered benefits (e.g. outpatient prescription drugs).⁶ For enrollees in non-grandfathered DMHC-regulated plans or CDI-regulated policies, cost sharing for outpatient prescription drugs related to certain preventive services is not allowed.⁷

The vast majority of Medi-Cal beneficiaries in DMHC-regulated plans (Medi-Cal managed care plans) do not have cost sharing for their outpatient prescription drug coverage. More information about regulations and laws governing cost sharing for Medi-Cal beneficiaries is below. However, cost sharing is common for commercial enrollees and enrollees associated with the California Public Employees' Retirement System (CalPERS), so cost sharing mechanisms and cost sharing related to pharmacy benefits are described in this section.

¹ Pharmacy benefits in some cases may also cover vaccines administered by a pharmacist.

² This includes in-person or virtual office visits.

³ A small number of enrollees either do not have a pharmacy benefit in their plan/policy or have a pharmacy benefit that is separate from their plan/policy that is not subject to regulation by DMHC or CDI. See CHBRP's resource, *Estimates of Pharmacy Benefit Coverage in California*, available at: https://chbrp.org/other-publications/index.php.

⁴ See CHBRP's resource, *Estimates of Pharmacy Benefit Coverage in California*, available at: https://chbrp.org/other-publications/index.php.

⁵ Other aspects of pharmacy benefit design include but are not limited to usage of pharmacy benefit managers (PBMs) and utilization management protocols (such as prior authorization, step therapy, quantity limits, etc.).

⁶ For more general background on cost sharing, see CHBRP's resource, *What is Cost Sharing in Health Insurance?*, available at: https://chbrp.com/other_publications/index.php.

⁷ For more information on preventive services, see CHBRP's resource, *Federal Preventive Services Mandate and California Mandates*, available at: https://chbrp.org/other-publications/index.php.



Cost Sharing Mechanisms

The following three steps describe a common interaction of a set of cost sharing mechanisms (when cost sharing is applicable).

• Step 1: Deductible

Some health plans and policies have plan designs that include one or more deductibles.⁸ A deductible is an amount an enrollee pays before the health plan or insurer begins to pay (in part or in whole) for covered benefits. Not all enrollees – and no Medi-Cal beneficiaries – are in a plan/policy with a deductible. When applicable, the deductible usually has to be met on an annual basis. An enrollee/beneficiary may be in a plan/policy with more than one deductible; for example, there may be one deductible applicable to medical benefits and another deductible applicable to pharmacy benefits. A deductible may also be integrated, applying to both medical and pharmacy benefits. An enrollee/beneficiary's deductible may vary depending on whether or not their plan/policy is for self-only or family coverage.⁹ For example, in 2020, bronze level plans/policies associated with Covered California have a \$500 pharmacy benefit deductible for self-only coverage and a \$1,000 pharmacy benefit deductible for family coverage (Covered CA, 2019).

Not all enrollees – and no Medi-Cal beneficiaries – are in a plan/policy with a deductible.

• Step 2: Copays and Coinsurance

<u>Copayments</u> (copays) refer to flat dollar payments an enrollee/beneficiary pays for covered benefits, such as a \$5 copayment for a 30-day supply of a prescription drug.

<u>Coinsurance</u> is a percentage of costs that an enrollee/beneficiary pays for covered benefits, such as 20% of a prescription drug's cost for a 30-day supply.

When applicable, copays and coinsurance can vary across covered benefits. An enrollee's pharmacy benefits can include both, specifying copayments as applicable to the coverage of certain prescription drugs and coinsurance as applicable to the coverage of others.

As previously noted, neither copays nor coinsurance can be applicable to the coverage of some prescription drugs. Neither copays nor coinsurance are commonly applicable for prescription drug coverage for Medi-Cal beneficiaries.

Step 3: Annual cost sharing limit¹⁰

An annual cost sharing limit caps the amount an enrollee/beneficiary pays each year for covered benefits (medical and pharmacy benefits), which includes spending on deductibles, copays, and coinsurance for covered benefits and does not include spending on premiums and non-covered benefits. After an enrollee/beneficiary has reached the spending limit ("cap") for cost sharing, the enrollee/beneficiary pays no cost sharing for the remainder of the year for covered benefits. The annual cost sharing limit for an enrollee/beneficiary may vary depending on whether or not their plan/policy is for self-only or family coverage. In 2021, the annual cost sharing limit for enrollees with a silver level plan/policy associated with Covered California is \$8,200 for self-only coverage and \$16,400 for family coverage (Covered CA, 2021).

The steps discussed above are displayed below in Figure 1.

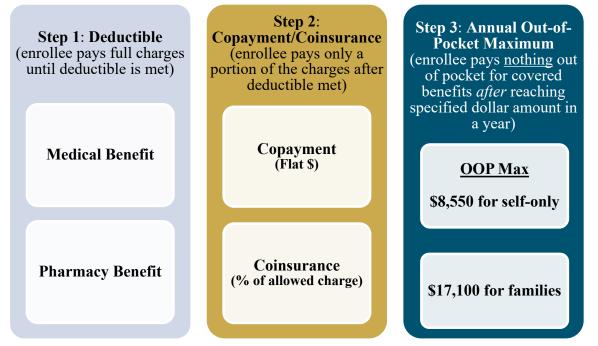
⁸ Medi-Cal beneficiaries do not have plans containing deductibles.

⁹ Family coverage includes coverage for the enrollee and a spouse, child, and/or dependent(s).

¹⁰ Also referred to as the annual out-of-pocket maximum.



Figure 1. Overview of the Interaction of Cost-Sharing Methods Used in Health Insurance



Source: California Health Benefits Review Program, 2021.

Note: Steps 1 and 2 are not mutually exclusive. Under certain circumstances (i.e., preventive screenings or therapies), enrollees may pay coinsurance or copayments prior to their deductible being met; also copayments and coinsurance may be applied against the deductible in some circumstances. 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 Pharmacy Benefits

The pharmacy benefit design for a plan/policy may have different cost sharing amounts for different drug classifications (e.g. specialty vs. non-specialty drugs) and may have other differences by plan/policy, such as differences in their formularies or formulary tiers.

A pharmacy benefit generally includes coverage for three different drug classifications: generic drugs, brand name drugs, and specialty drugs. "Generic" drugs refer to drugs that are not covered by patent protection and may be produced and/or distributed by multiple drug manufacturers. "Brand name" drugs refer to drugs marketed under a proprietary, trademark-protected name. "Specialty" drugs refer to drugs that are generally more expensive or require special administration and handling. It is common for generic drugs to be subject to a copay and specialty drugs to be subject to coinsurance. Generic drugs are typically cheaper than and have lower cost sharing than brand name drugs, which are typically cheaper than and have lower cost sharing than specialty drugs. For example, in 2021, enrollees with a silver level plan/policy associated with Covered California would pay (per prescription) a \$16 copay for their generic drugs, a \$60 copay for preferred brand name drugs (those included on a formulary or preferred drug list, such as a brand-name drug without a generic substitute), a \$90 copay for non-preferred generic drugs (also included on a formulary or non-preferred drug list, such as a brand-name drug with a generic substitute), , and 20% coinsurance up to \$250 per prescription for specialty drugs (KFF/HRET, 2014; Covered CA, 2019).

A "formulary" refers to a list of covered drugs. Formulary drugs included in the pharmacy benefit usually have some form of cost sharing. If a drug is not a covered benefit (i.e. off-formulary), an



enrollee/beneficiary would either have to apply for an exception for coverage or pay the full cost of the drug. ¹¹ Exactly which drugs are on-formulary or off-formulary can vary by plan/policy.

Formularies generally include formulary tiers with different levels of cost sharing. ¹² Drugs on lower tiers generally have lower cost sharing than drugs on higher tiers. Some plans/policies use four-tier formularies in which generic drugs are on the first tier and have lower cost sharing than brand name drugs on tiers two (preferred brands) or three (non-preferred brands), which generally have lower cost sharing than specialty drugs on tier four. Other plans/policies may have pharmacy benefits with more or fewer formulary tiers. Exactly which drugs are at which tier and are subject to what cost sharing level can vary by plan/policy. A plan/policy may have set copays or coinsurance for drugs at each tier. For example, in 2020, enrollees with a silver level plan/policy associated with Covered California – after meeting their pharmacy benefit deductible – have a \$16 copay per prescription for tier one generic drugs and 20% coinsurance up to \$250 per prescription for tier four specialty drugs (Covered CA, 2019).

Cost Sharing Laws and Pharmacy Benefit Design

As discussed in the preceding section, cost sharing can vary by plan/policy and drug classification (generic, brand, specialty) due to different pharmacy benefit designs (formularies, formulary tiers, etc.). Cost sharing also varies due to differences in enrollee utilization of outpatient prescription drugs and any relevant statutory limits on cost sharing. In combination, these variations can result in varied prescription drug cost sharing experiences among enrollees/beneficiaries.

This section describes variations in cost sharing related to pharmacy benefits for Medi-Cal beneficiaries enrolled in DMHC regulated plans, and statutory cost sharing limits related to pharmacy benefits for commercial/CalPERS enrollees in grandfathered and non-grandfathered DMHC-regulated plans and CDI-regulated policies.

Medi-Cal beneficiaries in DMHC regulated plans

For the vast majority of Medi-Cal beneficiaries in DMHC-regulated plans there is no cost sharing for covered outpatient prescription drugs (LAO, 2019). The same is true for covered OTC drugs. When prescribed by the beneficiary's provider, OTC drugs are regularly covered for Medi-Cal beneficiaries, but OTC drugs are not typically covered for commercial/CalPERS enrollees. There are federal rules that limit Medicaid-related cost sharing for outpatient prescription drugs, but these are not relevant to the vast majority of Medi-Cal beneficiaries because there is generally no cost sharing for them.

With the limited number of Medi-Cal beneficiaries attached to the Medically Needy Program or who are also Medicare beneficiaries (dual-eligible), cost sharing for outpatient prescription drugs and OTC drugs

¹¹ A plan/policy may cover a drug that is off-formulary due to medical necessity, or a regulator may require coverage due to medical necessity.

¹² Formulary tiers are generally applicable to commercial/CalPERS enrollees.

¹³ No cost sharing for outpatient prescription drugs and OTC drugs also applies to the vast majority of beneficiaries enrolled in Medi-Cal FFS and Medi-Cal COHS plans, which are not regulated by DMHC or CDI (LAO, 2019).

¹⁴ Although there is a near absence of cost sharing for outpatient prescription drugs and OTC drugs for Medi-Cal beneficiaries, beneficiaries may be in plans that have various forms of utilization management, including formularies, prior authorization, quantity limits, and pharmacy networks. Some or all of these forms of utilization management may also be applicable to pharmacy benefits for enrollees in commercial/CalPERS plans/policies.

¹⁵ Federal rules limit copays for preferred drugs to \$4 and non-preferred drugs to \$8 for Medi-Cal beneficiaries with income at or below 150% FPL, and limits cost sharing to 20% of the cost of the drug for beneficiaries with income above 150% FPL. It is up to each state to determine what is a preferred vs. non-preferred drug, so a preferred drug list could include OTC drugs. If a state does not differentiate between preferred vs. non-preferred drugs on their list of covered drugs, all drugs are preferred. For more on the federal rules, see Federal Register, Vol. 78, No. 135, Monday, July 15, 2013, Rules and Regulations, 78 FR 42159, available at:

https://www.federalregister.gov/documents/2013/07/15/2013-16271/medicaid-and-childrens-health-insurance-programs-essential-health-benefits-in-alternative-benefit.



may be applied. Medi-Cal beneficiaries attached to the Medically Needy Program have a 'share of cost' that has to be met each month, after which, the beneficiary pays nothing for covered benefits (CHCF, 2019). Dually-eligible beneficiaries may have to pay nominal copays for drugs covered through their Part D benefit or Medicare Advantage plan (MedPAC, 2018). 17

Commercial/CalPERS enrollees in grandfathered plans/policies

For the limited number of commercial/CalPERS enrollees in grandfathered plans/policies regulated by DMHC or CDI¹⁸, outpatient prescription drug cost sharing varies by plan/policy and drug classification due to different pharmacy benefit designs. Cost sharing can also vary due to differences in enrollee utilization of outpatient prescription drugs. There are no caps on annual cost sharing limits for commercial/CalPERS enrollees in grandfathered plans/policies, but there is one statutory limit on cost sharing per prescription. An enrollee would, at most, pay the lesser of the retail price for a drug, or the cost sharing amount (copays, coinsurance) according to their plan/policy.¹⁹ For example, if the retail price for a week supply of the specialty drug etanercept used for treatment of autoimmune diseases (Enbrel) was \$1,400²⁰, and the cost sharing according an enrollee's plan/policy was a 25% coinsurance²¹, the enrollee's cost sharing would be \$350.

Commercial/CalPERS enrollees in non-grandfathered plans/policies

For the vast majority of commercial/CalPERS enrollees – those who are enrolled in non-grandfathered plans/policies regulated by DMHC or CDI – cost sharing varies by plan/policy and drug classification due to different pharmacy benefit designs. For the limited number of enrollees with a non-grandfathered plan/policy associated with Covered California, pharmacy benefit designs are standardized (set copay/coinsurance structures and deductibles within metal tiers).²² Cost sharing among enrollees in non-grandfathered plans/policies can also vary due to differences in enrollee utilization of outpatient prescription drugs.

However, there are multiple statutory limits on cost sharing for commercial/CalPERS enrollees in non-grandfathered plans/policies. Some statutory limits on cost sharing may only be relevant to certain market segments (individual market, small group, and/or large group). The cost sharing laws relevant to each market segment are summarized below.²³

¹⁶ The 'share of cost' is similar to a deductible, but it has to be met each month and beneficiaries have no cost sharing after the deductible is met. The 'share of cost' is calculated based on monthly family income less a Maintenance Need Allowance based on family size (CHCF, 2019).

¹⁷ Dually-eligible beneficiaries pay copays up to the catastrophic coverage limit. Copays vary from plan to plan, but there are federal rules that limit copays for dually-eligible beneficiaries (MedPAC, 2018).

¹⁸ A large majority of enrollees in grandfathered plans and policies have a plan/policy in the large group market segment. For more information on the enrollees in each market segment, see CHBRP's resource, *Estimates of Sources of Health Insurance in California*, available at: https://chbrp.org/other_publications/index.php.

¹⁹ H&SC 1342.71, 1367.47; IC 10123.193, 10123.65. This law also applies to non-grandfathered plans/policies regulated by DMHC or CDI.

²⁰ In 2018, Enbrel was one of the top 25 most frequently prescribed specialty drugs and of the top 25 most costly specialty drugs by total annual spending (DMHC, 2018). The list price of Enbrel for a week supply (as of September 10, 2020) was approximately \$1,400 for a 50 mg dose (Amgen, n.d.).

²¹ 25% was the average coinsurance for tier 4 specialty drugs in 2018 for group market plans and policies in California (CHCF/NORC, 2019).

²² Plans/policies available through Covered California are presented in four "metal" tier categories: bronze, silver, gold, and platinum. Enrollees pay on average 40%, 30%, 20%, and 10% of annual healthcare costs for bronze, silver, gold, and platinum metal tier plans/policies, respectively. Plans/policies in each metal tier generally have set deductibles, copay and coinsurance structures, and annual cost sharing limits (HealthCare.gov Glossary, n.d.). These conditions do not apply to catastrophic health plans/policies that generally have low monthly premiums and very high deductibles (HealthCare.gov Glossary, n.d.). A significant portion of enrollees in California's individual market are associated with Covered California and some enrollees in the small group market are as well.

²³ There are additional cost sharing laws not listed here and/or are only relevant for specific drugs, such as limits on cost sharing for oral anti-cancer drugs (H&SC 1367.656; IC 10123.206), and prorated cost sharing for partial fills of Schedule II substances (H&SC 1367.43; IC 10123.203; Business and Professions Code 4052.10).



Cost Sharing Laws

Enrollees in non-grandfathered plans/policies in all market segments (individual market, small group, large group) that include a pharmacy benefit have health insurance subject to the cost sharing laws below.

- Annual cost sharing limits for a plan/policy (in 2021) may not exceed \$8,550 for self-only coverage and \$17,100 for a family (CCIIO, 2016; CCIIO, 2019).²⁴
- Cost sharing (e.g. copays, coinsurance, deductibles) is prohibited for outpatient prescription drugs and prescribed OTC drugs related to certain preventive services recommended by the following sources:²⁵
 - United States Preventive Services Task Force's (USPSTF) A and B recommendations (e.g. no cost sharing for preventive medications for Breast Cancer or Cardiovascular Disease),²⁶
 - Health Resources and Services Administration (HRSA)-supported coverage guidelines for women and infants, children, and adolescents (e.g. no cost sharing for FDA-approved contraceptive methods, including oral contraceptives),²⁷ and
 - Advisory Committee on Immunization Practices (ACIP) recommendations adopted by the Director of the Center for Disease Control and Prevention (CDC) (e.g. no cost sharing for vaccines).²⁸
- Cost sharing per prescription for outpatient prescription drugs is limited to the lesser of the retail
 price for a drug, or the cost sharing amount (copays, coinsurance) according to a plan/policy.²⁹
- Cost sharing per prescription for covered outpatient prescription drugs for a supply of up to 30 days shall not exceed \$250 (copays, coinsurance after any applicable deductible).³⁰ However, this statute has different terms for enrollees in plans/policies with an actuarial value at or equivalent to bronze level and high deductible health plans/policies (HDHPs).³¹

²⁴ 42 U.S.C. §18022; H&SC 1367.006; IC 10112.28. These amounts are federally set and updated annually. According to clarification from the Department of Health and Human Services (HHS), "the self-only maximum annual limitation on cost sharing applies to each individual, regardless of whether the individual is enrolled in self-only coverage or in coverage other than self-only" (CCIIO, 2015). This means that if an individual exceeds the annual cost sharing limit for self-only coverage, they will pay nothing for covered benefits after spending more than \$8,-550 (in 2020) on covered benefits, regardless of whether or not they have family coverage.

²⁵ 42 U.S.C. §300gg-13; H&SC 1367.002; IC 10112.2. For more information on each mandate and related benefit mandates in California state law, see CHBRP's resource, *The Federal Preventive Services Health Insurance Benefit Mandate and California's Health Insurance Benefit Mandates*, available at: https://chbrp.com/other_publications/index.php.

²⁶ For example, there is no cost sharing for Breast Cancer preventive medication (tamoxifen, raloxifene, aromatase inhibitors) for women at increased risk for developing Breast Cancer and have lower risk of side effects (CCIIO, 2014). There is also no cost sharing for prescribed low-dose aspirin for those at high risk of developing Cardiovascular Disease. According to CMS, "aspirin and other OTC recommended items and services must be covered without cost-sharing only when prescribed by a health care provider" (CCIIO, 2013).

²⁷ Insurers or health plans must cover without cost sharing at least one of each of the 18 different contraceptive methods for women (e.g. oral contraceptives), as outlined in the FDA's Birth Control Guide. Employers with religious or moral objections can receive exemptions or accommodations from covering contraceptives. (HRSA, 2019).

²⁸ Depending on the plan/policy and vaccine, vaccines can be covered under the medical and/or pharmacy benefit. ²⁹ H&SC 1342.71, 1367.47; IC 10123.193, 10123.65. This cost sharing law also applies to enrollees in grandfathered plans/policies regulated by DMHC or CDI.

³⁰ H&SC 1342.73; IC 10123.1932. These laws have a scheduled expiration date of January 1, 2024. The cost sharing limit is relevant to non-grandfathered plans/policies issued, amended, or renewed on or after January 1, 2015.
³¹ HDHPs are defined in 26 U.S.C. §223. In 2020, the IRS defines a HDHP as a plan/policy with a deductible of at least \$1,400 for self-only coverage or \$2,800 for a family. The annual cost sharing limit for a HDHP cannot exceed \$6,900 for self-only coverage and \$13,800 for a family (HealthCare.gov Glossary, n.d.). These deductible and annual cost sharing limit amounts are updated annually by the IRS.



- For plans/policies with an actuarial value at or equivalent to bronze level, cost sharing for covered outpatient prescription drugs for a supply of up to 30 days shall not exceed \$500 (copays, coinsurance after any applicable deductible).
- For HDHPs, until the deductible is met, the full cost of outpatient prescription drugs is applied. After the deductible is met, one of the above cost sharing limits per prescription is applicable depending on the plan/policy (up to the annual cost sharing limit).

Deductible Laws

Deductibles can also vary by plan/policy plans/policies regulated by DMHC or CDI.

Enrollees in non-grandfathered plans/policies in the individual and small-group markets that include a pharmacy benefit have health insurance subject to the deductible laws below.

- The annual deductible for outpatient prescription drugs (i.e. pharmacy benefit deductible), if any, shall not exceed \$500.³² However, this statute has different terms for enrollees in plans/policies with an actuarial value at or equivalent to bronze level.
 - For plans/policies with an actuarial value at or equivalent to bronze level, the pharmacy benefit deductible shall not exceed \$1000.

The outpatient prescription drug coverage of enrollees in non-grandfathered small group plans is also subject to deductible limits that are indexed to federal law and guidance.³³ In 2020, the following limits applied:

- \$2,550 for a small employer health insurance policy covering a single individual, and;
- \$5,100 for any other policy.

Conclusion

Cost sharing for outpatient prescription drugs for enrollees/beneficiaries in plans and policies regulated by DMHC or CDI can vary due to different pharmacy benefit designs, differences in enrollee/beneficiary drug utilization, and any relevant statutory limits on cost sharing. For the vast majority of Medi-Cal beneficiaries in DMHC-regulated plans, there is no cost sharing for outpatient prescription drugs and OTC drugs. For the limited number of commercial/CalPERS enrollees in grandfathered plans and policies, cost sharing can vary by plan and policy and there are few statutory limits on cost sharing. For commercial/CalPERS enrollees in non-grandfathered plans and policies, cost sharing can also vary by plan and policy, but there are multiple statutory limits on cost sharing (such as per-prescription limits on cost sharing and annual limits).

³² H&SC 1342.73; IC 10123.1932. These laws have a scheduled expiration date of January 1, 2024. The cost sharing limit is relevant to non-grandfathered plans/policies issued, amended, or renewed on or after January 1, 2015.

³³ H&SC 1367.007.



Summary

For the 55.1% of Californians enrolled in plans or policies regulated by DMHC or CDI in 2020³⁴, cost sharing varies for three subgroups. The subgroups are:

- 8.4 million Medi-Cal beneficiaries enrolled in DMHC regulated plans (over 70% of Medi-Cal beneficiaries)³⁵,
- 13.1 million commercial enrollees and enrollees associated with the California Public Employees' Retirement Systems (CalPERS)³⁶ in plans/policies regulated by DMHC or CDI, including:
 - o 1.9 million enrollees in grandfathered³⁷ plans/policies; and
 - o 11.2 million enrollees in non-grandfathered plans/policies.

For the vast majority of Medi-Cal beneficiaries in DMHC-regulated plans³⁸ (the first group listed above), cost sharing is not relevant for outpatient prescription drug coverage or for prescribed over-the-counter (OTC) drugs.

For commercial/CalPERS enrollees (the second group listed above), cost sharing is generally applicable for covered outpatient prescription drugs. Cost sharing can vary by plan/policy due to different pharmacy benefit designs (such as different copay/coinsurance structures for specialty drugs versus non-specialty drugs). Additionally, OTC drugs are not typically covered for enrollees in commercial/CalPERS plans/policies.

- For enrollees in grandfathered plans/policies, there is one state law that limits cost sharing to the lesser of the retail price for a drug, or the cost sharing according to the enrollee's plan or policy, but there are no restrictions on annual cost sharing limits.
- For enrollees in non-grandfathered plan/policies, there are multiple state and federal laws that limit cost sharing, such as laws stating that:
 - the annual cost sharing limit for a plan/policy in 2021 (inclusive of cost sharing related to medical and pharmacy benefits) cannot exceed \$8,550 for self-only coverage and \$17,100 for a family³⁹:
 - cost sharing is prohibited for outpatient prescription drugs and prescribed OTC drugs related to certain preventive services⁴⁰; and

³⁴ Other Californians have either no insurance (the uninsured) or have insurance that is subject only to federal law, such as the majority of Medicare beneficiaries and enrollees in self-insured products. For further detail, see CHBRP's resource, *Estimates of Sources of Health Insurance in California*, available at: https://chbrp.org/other-publications/index.php.

³⁵ Other Medi-Cal beneficiaries are enrolled in a Medi-Cal County Organized Health System (COHS) or are principally attached to the Medi-Cal Fee For Service (FFS) program. See CHBRP's resource, *Estimates of Sources of Health Insurance in California*, available at: https://chbrp.org/other_publications/index.php.

³⁶ This includes the 522,000 Californians associated with CalPERS who are enrolled in a DMHC regulated plan (it does not include those enrolled in CalPERS self-insured plans, which are subject only to federal law).

³⁷ The Affordable Care Act (ACA), defines as grandfathered a group/individual plan/policy created/purchased on or before March 23, 2010; the cutoff date for grandfathered plans/policies in state law may vary depending on the statute. Plans/policies may lose grandfathered status if they make significant changes that reduce benefits or increase costs to consumers (HealthCare.gov Glossary, n.d.). Non-grandfathered plans/policies are subject to more ACA requirements than are grandfathered plans/policies.

³⁸ For the limited number of Medi-Cal beneficiaries also attached to the Medically Needy Program or who are also Medicare beneficiaries, they may have cost sharing applicable to outpatient prescription drugs (CHCF 2010; CHCF 2019; MedPAC 2018).

³⁹ 42 U.S.C. §18022; H&SC 1367.006; IC 10112.28. These amounts are for 2020, are federally set, and are updated annually (CCIIO, 2016; CCIIO, 2019).

⁴⁰ 42 U.S.C. §300gg-13; California Health and Safety Code (H&SC) 1367.002; California Insurance Code (IC) 10112.2. H&SC 1367.002 and IC 10112.2 are relevant to non-grandfathered plans/policies issued, amended, or renewed on or after September 23, 2010. For more on preventive services, see CHBRP's resource *Federal Preventive Services and California Mandates*, available at: https://chbrp.org/other-publications/index.php.



per prescription cost sharing (e.g. copays, coinsurance) generally cannot exceed \$250 for up to a 30-day supply.

⁴¹ H&SC 1342.73; IC 10123.1932. Enrollees excluded from this rule include those in Covered California bronze level or equivalent plans/policies, high deductible health plans/policies, and specialized health plans/policies. The cost sharing limit per prescription only applies after any applicable deductible. The cost sharing limit is relevant to non-grandfathered plans/policies issued, amended, or renewed on or after January 1, 2015.



APPENDIX DEFINITIONS OF COMMON TERMS

<u>Brand-name drug:</u> A brand name drug is a drug marketed under a proprietary, trademark-protected name (FDA, 2017).

Generic drug: A generic drug is no longer covered by patent protection and thus may be produced and/or distributed by multiple drug companies. On essential aspects, such as drug dosage, safety, and strength, the U.S. Food and Drug Administration (FDA) considers a generic drug to be the same as a brand name drug, but generic drugs are generally cheaper (FDA, 2017).

<u>Specialty drug:</u> There is no standard industry definition_of specialty prescription drugs, but many payers identify cost as this category's primary characteristic. Other criteria for defining a specialty prescription drug include treating a rare disease, requiring special handling, or having a limited distribution network (AMCP, 2019).

<u>Prescription drug formulary:</u> A formulary, or a drug list, is a list of the prescription drugs covered by a health insurance plan or policy, or a prescription drug plan or policy (HealthCare.gov, 2020).

<u>Preferred drug:</u> A preferred drug is one included on a formulary or preferred drug list, such as a brandname drug without a generic substitute (KFF/HRET, 2014).

Non-preferred drug: A nonpreferred drug is one not included on a formulary or preferred drug list, such as a brand-name drug with a generic substitute (KFF/HRET, 2014).

<u>Prescription drug tiers:</u> Health plans may design their outpatient prescription drug benefits as a "tiered" benefit, 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.



REFERENCES

- AMCP. Specialty Pharmaceuticals. July, 2019. Available at https://www.amcp.org/about/managed-care-pharmacy/specialty-pharmaceuticals. Accessed on January 7, 2021.
- Amgen. *Paying for Enbrel*. Available at: https://www.enbrel.com/support/financial-support. Accessed on September 10, 2020.
- California Health Care Foundation (CHCF). Share of Cost Medi-Cal. September 2010. Available at: https://www.chcf.org/wp-content/uploads/2017/12/PDF-ShareOfCostMediCal2010.pdf. Accessed on September 10, 2020.
- California Health Care Foundation (CHCF). California Health Care Almanac, Medi-Cal Facts and Figures: Crucial Coverage for Low-Income Californians. February 2019. Available at: https://www.chcf.org/wp-content/uploads/2019/02/MediCalFactsFiguresAlmanac2019.pdf. Accessed on September 10, 2020.
- California Health Care Foundation, NORC at the University of Chicago (CHCF/NORC). 2019 Edition California Employer Health Benefits. August 29, 2019. Available at: https://www.chcf.org/publication/2019-edition-california-employer-health-benefits/. Accessed on September 10, 2020.
- Covered California (Covered CA). Covered CA Plan Benefit Changes for 2021. 2021. Available at: https://www.healthforcalifornia.com/blog/covered-ca-plan-benefit-changes-for-2021. Accessed on January 15, 2021.
- California Department of Managed Health Care (DMHC). Prescription Drug Cost Transparency Report Measurement Year 2018. 2018. Available at: https://www.dmhc.ca.gov/Portals/0/Docs/DO/2018SB17PrescriptionDrugTransparencyReport.pdf. Accessed on September 10, 2020.
- Food and Drug Administration. *Drugs@FDA Glossary of Terms*. November 2017. Available at: https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms. Accessed on January 7, 2021.
- HealthCare.Gov. *Glossary*. Available at: https://www.healthcare.gov/glossary. Accessed on September 10, 2020.
- Health Resources & Services Administration (HRSA). *HRSA-supported Women's Preventive Services Guidelines*. December 2019. Available at: https://www.hrsa.gov/womens-guidelines-2019. Accessed on September 10, 2020.
- Kaiser Family Foundation, Health Research & Educational Trust (KFF/HRET). 2014 Employer Health Benefits Survey, 2014. Available at: http://kff.org/healthcosts/report/2014-employer-health-benefits-survey/. Accessed December 17, 2014.
- Legislative Analyst's Office (LAO). *Analysis of the Carve Out of Medi-Cal Pharmacy Services From Managed Care*. April 5, 2019. Available at: https://lao.ca.gov/Publications/Report/3997. Accessed on September 10, 2020.
- Medicare Payment Advisory Commission (MedPAC). Beneficiaries Dually Eligible for Medicare and Medicaid. January 2018. Available at: http://medpac.gov/docs/default-source/data-book/jan18 medpac macpac dualsdatabook sec.pdf?sfvrsn=0. Accessed on September 10, 2020.



- Shefali, L. & Gorman, A. Rising Cost Of PrEP To Prevent HIV Infection Pushes It Out Of Reach For Many. June 30, 2018. Available at: https://www.npr.org/sections/health-shots/2018/06/30/624045995/rising-cost-of-prep-a-pill-that-prevents-hiv-pushes-it-out-of-reach-for-many. Accessed on September 10, 2020.
- The Center for Consumer Information & Insurance Oversight (CCIIO). Affordable Care Act Implementation FAQs Set 12. February 20, 2013. Available at: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12. Accessed on September 10, 2020.
- The Center for Consumer Information & Insurance Oversight (CCIIO). Affordable Care Act Implementation FAQs Set 18. January 9, 2014. Available at: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18. Accessed on September 10, 2020.
- The Center for Consumer Information & Insurance Oversight (CCIIO). Affordable Care Act Implementation FAQs Set 27. May 26, 2015. Available at: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part-XXVII-MOOP-2706-FINAL.pdf. Accessed on September 10, 2020.
- The Center for Consumer Information & Insurance Oversight (CCIIO). Affordable Care Act Implementation FAQs Set 31, "Limitations on Cost-Sharing under the Affordable Care Act". April 20, 2016. Available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31 Final-4-20-16.pdf. Accessed on September 10, 2020.
- The Center for Consumer Information & Insurance Oversight (CCIIO). Affordable Care Act Implementation FAQs Set 40. August 26, 2019. Available at: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-40.pdf. Accessed on September 10, 2020.



ABOUT CHBRP

The California Health Benefits Review Program (CHBRP) was established in 2002. As per its authorizing statute, CHBRP provides the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit-related legislation. The state funds CHBRP through an annual assessment on health plans and insurers in California.

Detailed information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP analyses and other publications are available at http://www.chbrp.org/.

CHBRP Staff

Garen Corbett, MS, Director John Lewis, MPA, Associate Director Adara Citron, MPH, Principal Policy Analyst Sabrina Woll, Policy Associate Karen Shore, PhD, Contractor* An-Chi Tsou, PhD, Contractor* California Health Benefits Review Program MC 3116
Berkeley, CA 94720-3116
info@chbrp.org

*Karen Shore, PhD, and An-Chi Tsou, PhD, are Independent Contractors who work with CHBRP to support legislative analyses and other special projects on a contractual basis.

CHBRP is an independent program administered and housed by the University of California, Berkeley, in the Office of the Vice Chancellor for Research.

CHBRP assumes full responsibility for the issue brief and the accuracy of its contents.