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## Report to California Legislature

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# California Health Benefits Review Program

## Analysis of California Assembly Bill 1860

## Cancer Treatment

A Report to the 2017–2018 California State Legislature April 20, 2018

CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

# Key Findings:

## Analysis of California Assembly Bill 1860 Cancer Treatment

Summary to the 2017–2018 California State Legislature, April 20, 2018

## AT A GLANCE

The version of California Assembly Bill (AB) 1860 analyzed by CHBRP would repeal the sunset date for provisions of the current law that prohibit plans and policies from requiring an enrollee or insured to pay, notwithstanding any deductible, a total amount of copayments and coinsurance that exceeds $200 for an individual prescription of up to a 30-day supply of a prescribed orally administered anticancer medication.

1. CHBRP estimates that, in 2019, of the 23.4 million Californians enrolled in state-regulated health insurance, 15.9 million of them will have insurance subject to AB 1860.
2. **Benefit coverage.** 100% of enrollees have health insurance fully compliant with AB 1860, because the provisions are included in current law. AB 1860 would not exceed the essential health benefits (EHBs).
3. **Utilization.** Utilization is not expected to increase in the first year post implementation due to the passage of AB 1860.
4. **Expenditures.** Expenditures are not expected to increase due to the passage of AB 1860.
5. **Medical effectiveness.** There is a preponderance of evidence that lower cost-sharing is associated with greater likelihood of initiating treatment with oral anticancer medications, adherence to treatment, and persistence with treatment.
6. **Public health.** There is no short-term public health impact.
7. **Long-term impacts.** The $200 out-of-pocket cost-sharing limits are fixed; therefore, as drug costs increase, more drugs and enrollees will get closer to the out-of-pocket cost-sharing limit.

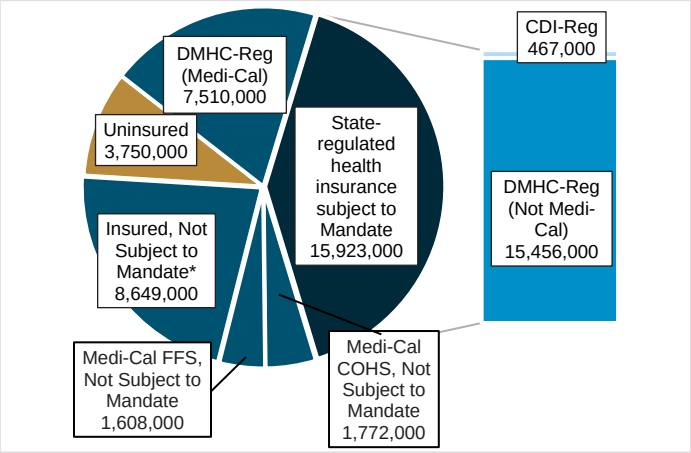
## CONTEXT

To date, the Food and Drug Administration (FDA) has approved 83 oral anticancer medications used to kill or slow the growth of cancerous cells. These medications are used to treat more than 62 different of types of cancers and play a variety of roles in cancer treatment.[1] Oral anticancer medications are used to treat frequently diagnosed cancers, such as breast, lung, prostate, and colorectal cancers. They are also used for rare cancers, such as adrenocortical cancer (cancer of the adrenal gland), dermatofibrosarcoma protuberans (a cancer of the dermis layer of skin), and retinoblastoma (an eye cancer).

## BILL SUMMARY

AB 1860 would repeal the sunset date for provisions of current law that prohibit Department of Managed Health Care (DMHC)-regulated plans and California Department of Insurance (CDI)-regulated policies from requiring an enrollee or insured to pay, notwithstanding any deductible, a total amount of copayments and coinsurance that exceeds $200 for an individual prescription of up to a 30-day supply of a prescribed orally administered anticancer medication. Figure 1 notes how many Californians have health insurance that would be subject to AB 1860.

**Figure 1.** Health Insurance in CA and AB 1860




*Source:* California Health Benefits Review Program, 2018.
*Note:* * Medicare beneficiaries, enrollees in self-insured products, etc.

[1] Refer to CHBRP's full report for full citations and references.

# IMPACTS

## Benefit Coverage, Utilization, and Cost

Current law limits copayments or coinsurance to $250 for *all* individual prescriptions for up to a 30-day supply. If the $200 limit on copayments and coinsurance for oral anticancer prescription drugs sunsets on January 1, 2019, enrollees filling oral anticancer prescriptions would have their copayments and coinsurance limited to $250 per 30-day supply at least through January 1, 2020.

### Benefit Coverage

All enrollees with health insurance that would be subject to AB 1860 have fully compliant coverage due to existing law.

### Utilization

CHBRP estimates that enrollees utilize 33.1 prescriptions of oral anticancer medication per year per 1,000 enrollees and that 0.64%, or 102,000, of enrollees with coverage subject to AB 1860 will use oral anticancer medications in 2019. Overall utilization, the number of users, and the number of units of oral anticancer medications will not change within the first year postmandate due to the passage of AB 1860, because the cost-sharing limitations are included in current law.

### Expenditures

The estimated average cost per prescription for 2019 is $1,362, an increase from $856 in 2014, which may be due to the availability and price of new drugs. The three most frequently prescribed oral anticancer medications represent 62.1% of all oral anticancer medication prescriptions, but account for only 1.5% of total cost. The three most expensive oral anticancer medications represent 0.5% of prescriptions, but account for 6.1% of total cost. The top three oral anticancer medications as a percentage of total cost represent 32.4% of total cost, but account for 3.4% of total prescriptions.

No changes in total premiums would be expected due to the passage of AB 1860 in the short term, because AB 1860 extends current law indefinitely. However, were AB 1860 not to pass, the maximum cost-sharing paid by enrollees using oral anticancer medications may increase by $50 per prescription given the current law that limits cost-sharing to $250 for *all* prescriptions.

### Medi-Cal

Medi-Cal is not subject to the provisions of AB 1860, and therefore, no impact is projected.

### CalPERS

No measureable impact is projected.

### Number of Uninsured in California

No measureable impact is projected.

## Medical Effectiveness

This analysis examines studies of the effects of cost-sharing for oral anticancer mediations on measures of medication use, such as abandonment of prescriptions, initiation of treatment, persistence with treatment, and adherence to treatment for oral anticancer medications. There is a preponderance of evidence that lower cost-sharing is associated with greater likelihood of initiating treatment with oral anticancer medications, adherence to treatment, and persistence with treatment.

## Public Health

CHBRP concludes that passage of AB 1860 would have no short-term[2] public health impact because it would extend current coinsurance/copayment limitations for oral anticancer medications. However, were AB 1860 to fail to pass, CHBRP still does not project a public health impact in 2019 because another existing law limits copayments and coinsurance to no more than $250 per 30-day supply of any prescription medication.

## Long-Term Impacts

Long-term impacts on overall health care costs as a result of the elimination of the sunset that limits cost-sharing for oral anticancer medications to $200 per prescription for up

[2] CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

to a 30-day supply are unknown. However, it is expected that the overall utilization and cost of premiums in the long term will increase due to increased availability of new and expensive oral medications.

The $200 out-of-pocket cost-sharing limit is fixed [assuming plans and policies continue to not increase the cost-sharing limit by the Consumer Price Index (CPI)]; therefore, as drug costs increase, more enrollees will reach the out of pocket cost-sharing limit. CHBRP completed a 3 year projection of the maximum number of enrollees hitting the cost-sharing limit of $200 per prescription for up to a 30-day supply, assuming all else remains constant (i.e., number of approved drugs and utilization).

**Table 1.** Projected Maximum Number and Percentage of Enrollees Who Will Hit the Cost-Sharing Limitation of AB 1860

| Year | Maximum Number of Enrollees | Maximum Percentage of Enrollees |
|---|---|---|
| 2019 | 13,800 | 0.087% |
| 2020 | 14,500 | 0.091% |
| 2021 | 15,100 | 0.095% |

*Source:* California Health Benefits Review Program, 2018.

*Note:* Based on MarketScan claims database sample data. The cost-sharing limit of $200 per individual prescription is for up to a 30-day supply of outpatient oral anticancer medications.

CHBRP estimates that approximately 85% of the 102,000 patients using oral anticancer medications will not reach the $200 cost-sharing limit. On the basis of the evidence that lower cost-sharing for oral anticancer medications is associated with a greater likelihood of medication initiation and adherence, CHBRP assumes medication utilization and health outcomes for these enrollees would remain the same regardless of the presence of the cost-sharing provision(s). However, for some portion of the 15% of enrollees who may reach the $200 cost-sharing limit, especially those in high deductible health plans, there could be significant financial and health benefits associated with the passage of AB 1860.

## Essential Health Benefits and the Affordable Care Act

AB 1860 would not require coverage for a new state benefit mandate, but instead, specifies cost-sharing limits, and therefore appears not to exceed the definition of EHBs in California.

# A Report to the California State Legislature

# Analysis of California Assembly Bill 1860
# Cancer Treatment

April 20, 2018

**California Health Benefits Review Program**
**MC 3116; Berkeley, CA 94720-3116**
**www.chbrp.org**

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.

An analytic staff based at the University of California, Berkeley, supports a task force of faculty and research staff from multiple University of California campuses to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact. Content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP reports and other publications are available at www.chbrp.org.

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# POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)[3] conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 1860, Cancer Treatment.

## Bill-Specific Analysis of AB 1860, Cancer Treatment

### Bill Language

Current law[4] states:

- "Notwithstanding any deductible, the total amount of copayments and coinsurance an enrollee is required to pay shall not exceed $200 for an individual prescription of up to a 30-day supply of prescribed orally administered medications covered by the contract."
- "Anticancer medications" are defined as medications used to kill or slow the growth of cancerous cells.
- Beginning annually on January 1, 2016, plans and policies may adjust the $200 copayment or coinsurance by the Consumer Price Index (CPI) for that year.

These provisions are scheduled to sunset January 1, 2019. AB 1860 would remove the sunset, extending this law indefinitely. The full text of AB 1860 can be found in Appendix A.

### Relevant Populations

If enacted, AB 1860 would affect the health insurance of approximately 15.9 million enrollees (41% of all Californians). This represents 68% of the 23.4 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law — health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). If enacted, the law would affect the health insurance of enrollees in DMHC-regulated plans and CDI-regulated policies, exempting Medi-Cal.

As further discussed in Appendix D , approximately 1.4% of enrollees in DMHC-regulated plans and CDI-regulated policies have no coverage for outpatient prescription drugs (OPDs) and 3.0% have OPD coverage that is not regulated by DMHC or CDI. Such health insurance is considered to be compliant with AB 1860, and so CHBRP has projected no mandate impacts related to enrollees without a DMHC- or CDI-regulated OPD benefit.

## Interaction With Existing Requirements

Health benefit mandates may interact and align with the following state and federal mandates or provisions.

[3] CHBRP's authorizing statute is available at http://chbrp.org/faqs.php.
[4] H&SC 1367.656 and IC 1023.206.

## California Policy Landscape

### *California law and regulations*

Although there is not a California mandate that requires all DMHC-regulated plans and CDI-regulated policies to cover prescription medications, the Affordable Care Act (ACA) requires Qualified Health Plans (QHPs) to cover the ten Essential Health Benefit (EHB) categories, one of which is prescription drugs. California has codified this federal law into state law, and therefore requires nongrandfathered plans and policies in the small-group and individual markets to cover outpatient prescription drugs.[5]

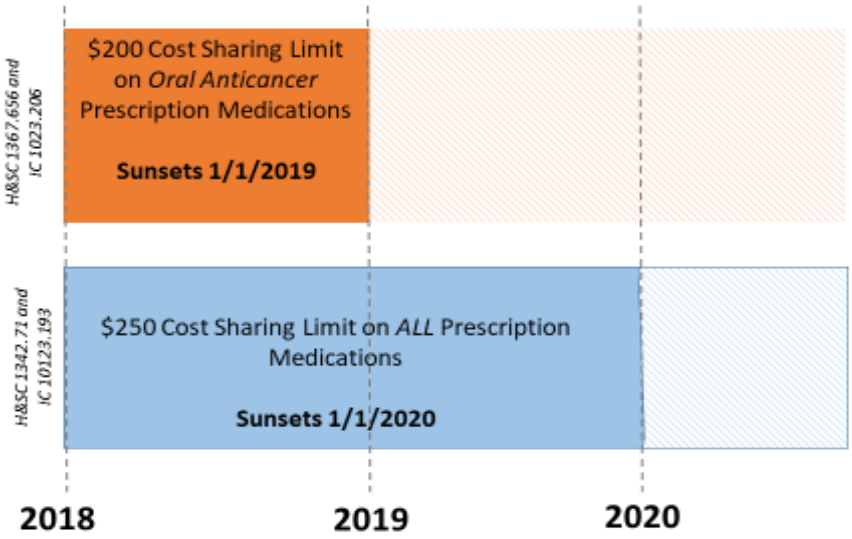
There are a number of requirements that impact coverage of prescription medications.

For DMHC-regulated plans, the department requires that benefits not be subject to "exclusion, exception, reduction, deductible, or copayment that renders the benefit illusory."[6] DMHC-regulated plans and CDI-regulated policies are also subject to specific limitations regarding prescription drug cost-sharing. Cost-sharing (copayments, coinsurance, and deductibles) rules require the following:

- Copayments or coinsurance cannot exceed $250 for an individual prescription for up to a 30-day supply.[7] If the $200 limit on copayments and coinsurance for oral anticancer prescription drugs sunsets on January 1, 2019, enrollees filling oral anticancer prescriptions would have their copayments and coinsurance limited to $250 per 30-day supply in 2019. This related provision will sunset on January 1, 2020, although SB 1021 (Weiner) Prescription Drugs would extend this provision indefinitely if enacted.[8] Figure 1 provides a timeline of these related provisions.

[5] H&SC 1367.005
[6] California Code of Regulations, Section 1300.67.4.
[7] H&SC 1342.71 and IC 10123.193.
[8] SB 1021, California Legislature, 2018.

**Figure 1.** Overlap of Two Current Prescription Drug Cost-Sharing Limitation Provisions in California Law




*Source:* California Health Benefits Review Program, 2018.
*Notes:* This figure assumes current laws limiting cost-sharing for oral anticancer medications (H&SC 1367.656 and IC 1023.206) and all prescription medications (H&SC 1342.71 and IC 10123.193) will sunset on their designated dates. The $250 limit for all prescription drugs sunsets 1 year later (2020) than the $200 limit for oral anticancer prescription drugs (2019). Two active bills (AB 1860 Cancer Treatment and SB 1021 Prescription Drugs) would eliminate the sunset dates and extend these provisions indefinitely.

DMHC-regulated plans are further subject to these limitations regarding prescription drug cost-sharing: [9]

- A copayment cannot exceed the retail price of the drug.[10] Current law applies only to DMHC-regulated plans, but SB 1021 (Weiner) Prescription Drugs would expand this requirement to CDI-regulated policies.[11]
- A copayment or percentage coinsurance shall not exceed 50% of the "cost to the plan."
- If a plan uses coinsurance, it must:
    - Have a maximum dollar amount that the percentage coinsurance that will be charged for an individual prescription cannot exceed;
    - Apply toward an annual out-of-pocket maximum for the product; or
    - Apply toward an annual out-of-pocket maximum for the prescription drug benefit.

Other requirements that might interact with AB 1860 are listed below, with Health and Safety Code (H&SC) and Insurance Code (IC) footnoted where applicable:

[9] California Code of Regulations, Section 1300.67.24.
[10] California Code of Regulations, Section 1300.67.24.
[11] SB 1021, California Legislature, 2018.

**Prescription drugs: Off-label use.**[12] Mandate to cover "off-label" uses of FDA-approved drugs — uses other than the specific FDA-approved use — in life-threatening situations and, in cases of chronic and seriously debilitating conditions, when a set of specified provisions regarding evidence is met.

**Prescription drugs: Coverage of previously covered drugs; medically appropriate alternatives.**[13] Mandate to cover prescription drugs if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition.

**Breast cancer benefits.**[14] Mandate to provide coverage for screening for, diagnosis of, and treatment for breast cancer.[15]

**Authorization for nonformulary prescription drugs.**[16] Mandate to review coverage for nonformulary drugs.

### *Similar requirements in other states*

CHBRP is aware of 42 other states and the District of Columbia that have similar laws in place as of March 2018 (PEAC, 2018). Thirty-one of these state laws create cost-sharing parity between intravenous chemotherapy and oral anticancer medications, whereas 12 states have laws that limit cost-sharing to a specific dollar limit for oral anticancer medications. Cost-sharing limits in other states range from $50 per prescription to $300 per prescription, with the most states limiting cost-sharing per prescription to $100.

## Federal Policy Landscape

### *Affordable Care Act*

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how AB 1860 may interact with requirements of the ACA as presently exists in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).[17]

Any changes at the federal level may impact the analysis or implementation of this bill, were it to pass into law. However, CHBRP analyzes bills in the current environment given current law and regulations.

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[12] H&SC Section 1367.21 and Section IC 10123.195.
[13] H&SC Section 1367.22.
[14] H&SC Section 1367.6 and IC Section 10123.8.
[15] Due to this existing mandate, persons enrolled in policies without pharmacy benefits may still have coverage for prescriptions related to breast cancer treatment, including oral anticancer medications. However, responses to CHBRP's Bill-Specific Survey during the analysis of AB 219 in 2013 indicated no coverage for oral anticancer medications did not specify breast cancer treatment as an exception. Therefore, CHBRP assumes in this analysis that no exception would be made for persons with a breast cancer diagnosis.
[16] H&SC Section 1367.24.
[17] The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to QHPs sold in Covered California — to cover 10 specified categories of EHBs. Resources on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other_publications/index.php.

### Essential Health Benefits

State health insurance marketplaces, such as Covered California, are responsible for certifying and selling qualified health plans (QHPs) in the small-group and individual markets. QHPs are required to meet a minimum standard of benefits as defined by the ACA as essential health benefits (EHBs). In California, EHBs are related to the benefit coverage available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.[18,19]

States may require QHPs to offer benefits that exceed EHBs.[20] State rules related to provider types, cost-sharing, or reimbursement methods would *not meet* the definition of state benefit mandates that could exceed EHBs.[21]

AB 1860 would not require coverage for a new state benefit mandate, but instead specifies cost-sharing limits, and therefore appears not to exceed the definition of EHBs in California.

## Analytic Approach and Key Assumptions

CHBRP conducted an analysis on similar legislation, AB 219, introduced during the 2013 to 2014 Legislative Session. The analysis of AB 1860 builds on the previous report. The key difference between AB 1860 and AB 219 as analyzed is that AB 219 initially including a cost-sharing limitation of $100 for oral anticancer medications for prescriptions for up to a 30-day supply.

- **Definition of oral anticancer medications:** Because current law defines "anticancer medications" as medications used to kill or slow the growth of cancerous cells, this analysis therefore assumes that AB 1860 would not affect cost-sharing for supportive therapies, such as antipain or antinausea drugs, that a cancer patient might use during the course of chemotherapy.

- **Coverage of oral anticancer drugs:** Chemotherapy can be covered under the medical benefit — which provides coverage of hospital and physician/provider services — or outpatient prescription drug pharmacy benefit of a DMHC-regulated plan or CDI-regulated policy. CDI interprets current law and AB 1860 to apply to both the medical and outpatient prescription drug benefit,[22] whereas DMHC interprets current law and AB 1860 to apply only to the outpatient prescription drug benefit.[23] Because the bill explicitly names "prescribed, orally administered" medications, CHBRP assumes that the bill applies to the outpatient pharmacy benefit portion of the plan or policy.

- **Interaction with deductibles**: Current law and AB 1860 state that for high deductible plans and policies, an enrollee's deductible must be satisfied before the $200 cost-sharing limitation for oral anticancer medications applies. However, for other plans and policies, interpretation of whether an enrollee must satisfy their deductible before the $200 cost-sharing limitation applies is

[18] The U.S. Department of Health and Human Services (HHS) has allowed each state to define its own EHBs for 2014 and 2015 by selecting one of a set of specified benchmark plan options. CCIIO, Essential Health Benefits Bulletin. Available at: http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.
[19] H&SC Section 1367.005; IC Section 10112.27.
[20] ACA Section 1311(d)(3).
[21] Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.
[22] Personal communication with CDI on March 8, 2018.
[23] Personal communication with DMHC on March15, 2018.

unclear.[24] CHBRP discusses deductibles as a piece of enrollee cost-sharing throughout the report.

- **No expansions of coverage:** AB 1860 would not require DMHC-regulated plans and CDI-regulated policies that do not already provide coverage for prescription drugs on an outpatient basis to begin covering them, nor would it require DMHC-regulated plans and CDI-regulated policies that cover only generic prescription drugs on an outpatient basis to begin covering nongeneric (brand) drugs.

- **Consumer Price Index:** AB 1860 and existing statute are unclear as to which CPI by which plans are able to adjust the $200 cost-sharing limit. For example, there is the CPI for all goods and services, as well as the medical CPI. However, as of March 2018, DMHC and CDI have not received a request from a plan or policy seeking to increase the cost-sharing limit in excess of $200. CHBRP therefore assumes that the cost-sharing limit remains at $200 for an individual prescription for up to a 30-day supply.

[24] Personal communication with CDI on March 8, 2018 and DMHC on March 15, 2018.

# BACKGROUND ON CANCER, ANTICANCER MEDICATIONS, AND COST-SHARING DEFINITIONS

## Cancer in California

Overall, Californians have experienced a 15% decrease in cancer incidence rates and a 30% decrease in cancer mortality rates between 1988 and 2014 due primarily to improved screening and improved treatment options (ACS, 2017). Nevertheless, cancer remains the second leading cause of mortality in California, accounting for 24% of all deaths (ACS, 2017). The American Cancer Society estimates that 178,130 new cases of cancer will be diagnosed and 60,650 cancer deaths will occur in California in 2018 (excluding *in situ* and basal and squamous cell skin cancers) (ACS, 2018). Data show that fewer than 45% of cancer cases occur in those younger than age 65 (the most relevant population to this report because AB 1860 excludes Medicare) (CCR, 2017). An estimate of the future cancer burden projects that one in two Californians born today will be diagnosed with cancer during their lifetime, and about one in five will die of cancer (ACS, 2018).

Breast cancer is the most prevalent of cancers in California with an estimated 29,360 new cases in 2018, followed by cancer of the lung/bronchus (18,760), prostate (15,190), colon/rectum (14,400), melanoma (9,830), and non-Hodgkin lymphoma (8,190) (ACS, 2018). These top six cancers comprise about 54% of the 178,130 estimated cancers diagnosed in California in 2018.

Early diagnoses through population-based screening, reductions in smoking rates, as well as advances in cancer treatment have greatly improved survival rates of cancer patients. Nationally, the American Cancer Society reported the relative 5-year survival rate from all cancers is 67% with 26% of survivors under age 60 years (ACS, 2016).

## Oral Anticancer Medications

The treatment options for cancer depend on the type of cancer, as well as the stage of diagnosis, and include surgical removal, radiation treatment, and medications, including chemotherapy (which may include oral anticancer medications). Delivery of anticancer medications is shifting from intravenous (IV) fluid or injection in a clinician setting to oral medications self-administered by the patient. Facilitating this shift in administration mode is the increased number of oral anticancer medications approved by the Food and Drug Administration (FDA) as a primary cancer treatment (Sawicki et al., 2016). IMS Health reports that in 2015, 33% of oncology drug costs were attributed to oral anticancer purchases at the retail pharmacy level--an increase from 25% in 2010 (IMS, 2016). Many of the most prevalent cancers in California, such as breast, lung, colorectal, lymphoma, and leukemia cancers, have oral anticancer medication options (NCI, 2015).

Studies estimate that a majority of patients (up to 89%) prefer oral anticancer medications to traditional IV fluid or injection therapies when available (Verbrugghe et al., 2013). Reasons for patient preference of oral administration include less invasive administration methods, time savings, feeling of control over treatment regimen, fewer side effects, and less disruption to daily life (Mekdad and AlSayed, 2017; Mazzaferro et al., 2013). However, challenges associated with oral anticancer medications include complex medication schedules, and proper patient adherence. For example, some patients must monitor drug-food or drug-drug interactions to prevent interference with oral cancer medication absorption, which could dilute the prescribed dosing (Mazzaferro et al., 2013). See the *Medical Effectiveness* section for further description of oral anticancer medications.

## Disparities[25] and Social Determinants of Health[26] in Cancer

Per statute, CHBRP discusses disparities and social determinants of health (SDoH) as they relate to a proposed insurance mandate, in this case cancer prevalence and barriers to oral anticancer treatment. Disparities are differences between groups that are modifiable.

Racial and ethnic disparities in overall cancer incidence and mortality exist in California (NCI, 2016). Whites and blacks have the highest incidence rates (455.6 per 100,000 and 430.7 per 100,000, respectively) followed by Hispanics, American Indian/Alaska Native, and Asian/Pacific Islander (329.2, 165.1, and 291.2 per 100,000, respectively). Blacks also have the highest overall cancer mortality rate in California (188.3 per 100,000) followed by whites (164.8 per 100,000), Hispanics (118.4 per 100,000), Asian/Pacific Islanders (108.5 per 100,000) and American Indian/Alaska Natives (7.5 per 100,000) (NCI, 2018b).

The National Cancer Institute notes that, across the United States, cancer disparities among racial/ethnic groups are closely associated with social determinants of health including income, and built and social environments (i.e., stress and diet) (NCI, 2016). Numerous studies have documented that individuals from lower socioeconomic groups and specific racial and ethnic minorities have greater cancer risk and poorer cancer-related outcomes. This differential burden results in lower overall survival rates, a generally more advanced stage of cancer at time of diagnosis, and a higher eventual risk of death (Albain et al., 2009; Sloane, 2009). Compared with whites, African Americans have poorer survival once cancer is diagnosed. Five-year relative survival is lower in blacks than in whites within every stratum of stage of diagnosis for nearly every cancer site (Ward et al., 2004). As cancer treatments become more sophisticated, the disparity between whites and non-whites is likely to widen (Meropol and Schulman, 2007). This is likely because disparities in socioeconomic status lead to disparities in access to new medical advances and ultimately in health status. Therefore, medical advances (such as oral anticancer medications) can exacerbate disparities in relative racial/ethnic cancer survival rates (Tehranifar et al., 2009).

Furthermore, smoking, obesity, and exposure to environmental hazards (known causal agents for many cancers) are also disproportionately experienced by low-income and minority groups. Other research suggests that cultural differences (mistrust of health care system; geographic barriers or fatalistic view of cancer outcomes) and biological differences, regardless of socioeconomic status, appear to affect minority groups' risk of cancer differently (i.e., more aggressive breast, colorectal, and prostate cancer markers in African Americans than other groups) (NCI, 2016). Although these disparities do not extend to every type of cancer, minorities do experience a disproportionately higher incidence and mortality rates for many cancers.

## Overview of Cost-Sharing and Outpatient Prescription Drug Benefits

AB 1860 limits cost-sharing for oral anticancer medications. This section briefly explains the cost-sharing relationship between an enrollee and a payer (e.g., health plan/insurer or employer). To manage the total

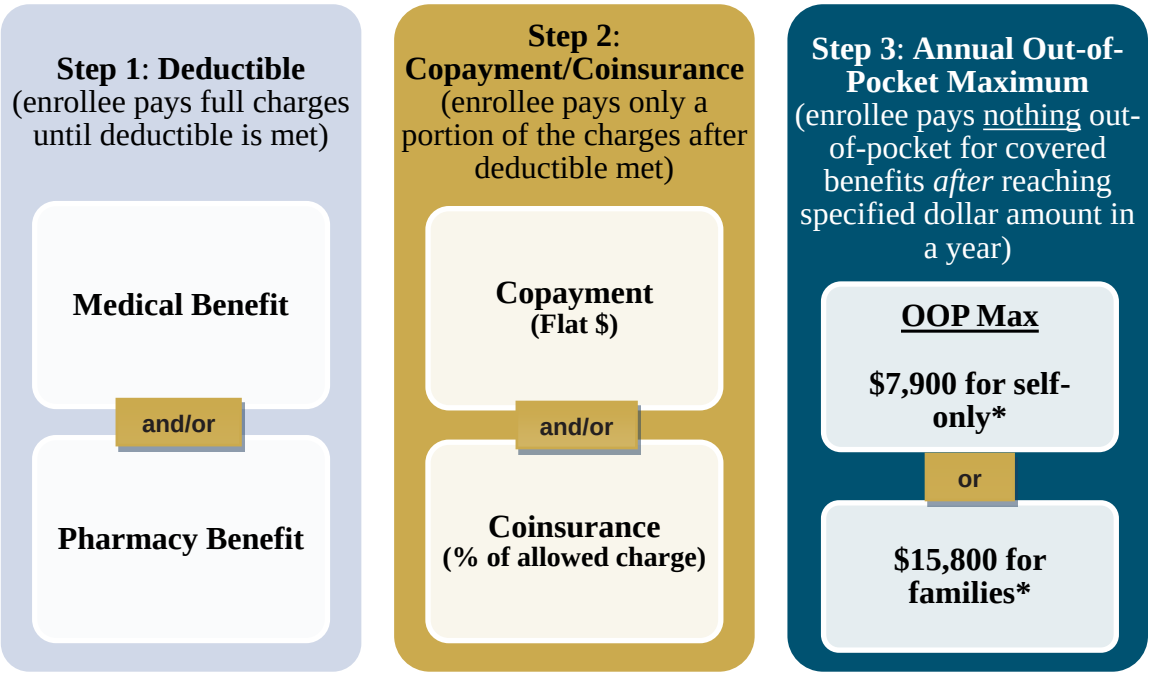
[25] Several competing definitions of "health disparities" exist. CHBRP relies on the following definition:
Health disparity is defined as the differences, whether unjust or not, in health status or outcomes within a population (Wyatt et al., 2016).

[26] CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from Healthy People 2020, 2015; CDC, 2014). See CHBRP's SDoH white paper for further information: www.chbrp.org/analysis_methodology/docs/Incorporating Relevant Social_Determinants of Health in CHBRP Analyses Final to WEBSITE 033016.pdf.

cost of health care, a payer shares many of the costs of covered health insurance benefits with enrollees. Common cost-sharing methods include copayments, coinsurance, and/or deductibles (but do not include premium payments). CHBRP refers to these as enrollee out-of-pocket expenses.[27]

Annual out-of-pocket maximums are limits on the enrollee's cost-sharing (copayments, coinsurance, and deductibles) obligations in a 1-year period. After the amount an enrollee has paid for copayments, coinsurance, and deductibles reaches this limit, insurance pays 100% of the cost of covered care. 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 (Figure 2).

**Figure 2.** Overview of the Intersection of Cost-Sharing Methods Used in Health Insurance




*Source:* California Health Benefits Review Program, 2018.

*Notes:* 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).

*The annual out-of-pocket amounts in this figure are the HHS proposed maximum amounts allowed in 2019 (Klinger, 2017); some plans and policies may have lower annual out-of-pocket maximums.

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

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

# MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, AB 1860 would repeal the sunset date for provisions of current law that prohibit DMHC-regulated plans and CDI-regulated policies from requiring an enrollee or insured to pay, notwithstanding any deductible, a total amount of copayments and coinsurance that exceeds $200 for an individual prescription of up to a 30-day supply of a prescribed orally administered anticancer medication.

To date, the FDA has approved 83 oral anticancer medications used to kill or slow the growth of cancerous cells. These medications are used to treat more than 62 different of types of cancers and play a variety of roles in cancer treatment. This section of the report provides general information about oral anticancer medications. AB 1860 would apply to such a large number of medications that a systematic review of the literature on the effectiveness of all of them was not feasible for this analysis. This section also reviews literature on the impact of cost-sharing on use of orally administered anticancer medications.

Additional information on oral anticancer medications is included in the *Background* section.

## Research Approach and Methods

Studies of oral anticancer medications were identified through searches of PubMed, the Cochrane Library, Web of Science, EMBASE, and the Cumulative Index of Nursing and Allied Health Literature. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the UK National Health Service (NHS) Centre for Reviews and Dissemination, the UK National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network.

The search was limited to studies published in English from 2013 to present because CHBRP had previously conducted thorough literature searches on these topics in 2013 for the analysis of AB 219. Findings are presented for five articles discussed in CHBRP's report on AB 219 plus five additional articles published since CHBRP released its report on AB 219.

CHBRP's review was limited to studies of the impact of differences in cost-sharing for oral anticancer medications that affect all persons enrolled in the health plans regardless of their income because the provisions in current California law that limit cost-sharing for oral anticancer medications apply to all enrollees in DMHC- and CDI-regulated plans and policies that provide a prescription drug benefit regardless of income. Studies of the effects of subsidies provided to low-income persons enrolled in Medicare Part D prescription drug plans were not included.[28]

The conclusions below are based on the best available evidence from peer-reviewed and grey literature. Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

### Key Question

1. What is the impact of cost-sharing on use of oral anticancer medications?

[28] Centers for Medicare & Medicaid Services. Guidance to States on the Low-income Subsidy, 2009. www.cms.gov/Medicare/Eligibility-and-Enrollment/LowIncSubMedicarePresCov/Downloads/StateLISGuidance021009.pdf.

## Methodological Considerations

All of the studies of the effects of cost-sharing for oral anticancer medications are observational studies (i.e., participants are not randomly assigned to any particular level of cost-sharing). The lack of randomization reduces confidence in the studies' ability to conclude that differences in medication use between persons who face different levels of cost-sharing for oral anticancer medications are due to those differences and not to other differences between these persons.

Another important limitation of the literature on cost-sharing for oral anticancer agents is that none of the studies examine limitations on cost-sharing that are similar to those in current California law. All studies looked at variation in cost-sharing due to variation in health plan benefit design and did not examine the impact of statutory limits on cost-sharing. Thus, their findings may not be fully generalizable to AB 1860. For example, some of the studies examined the impact of changes in cost-sharing for older, less expensive oral anticancer medications for which health plans and health insurance policies would be unlikely to require cost-sharing greater than $200 per 30-day supply, regardless of whether AB 1860 is enacted.

In addition, all of the studies CHBRP identified analyzed data from health insurance claims databases. These databases are a rich source of information about the cost and use of prescription drugs and other health care services but contain little information about health outcomes. Thus, they do not provide direct evidence about whether differences in use or medications are associated with differences in health outcomes.

Finally, some studies did not control for the effect of income on use of oral anticancer medications. This is an important limitation. People with lower incomes may be more sensitive to differences in costs associated with prescriptions for oral anticancer medications because they have less discretionary income than people with higher incomes.

## Overview of Oral Anticancer Medications and Their Uses

Anticancer medications may be administered intravenously, by injection, or orally. Although oral anticancer medications have been available for many years (Bedell, 2003; Weingart et al., 2008), the number of oral anticancer medications approved by the FDA has grown substantially over the past decade. The FDA approved 29 new oral anticancer medications between 2013 and early 2018, which increased the total number of oral anticancer medications from 54 to 83 medications. This trend is likely to continue.

### Types of Oral Anticancer Medications

Oral anticancer medications may be divided into three major categories of medications:

- Cytotoxic agents;
- Targeted agents; and
- Endocrine agents

Cytotoxic agents were the first type of anticancer medication developed. They include some of the first oral anticancer medications, such as Myleran (generic name = busulfan), Leukeran (generic name = chlorambucil), Purinethol (generic name = mercaptopurine), and methotrexate sodium (Bedell, 2003; Weingart et al., 2008). One major limitation of both oral and intravenous cytotoxic agents is that they are

associated with a high rate of side effects because they kill healthy cells as well as cancer cells (Mazzaferro et al., 2013).

A number of new cytotoxic agents have been approved by the FDA over the past 20 years. One of the most widely used new cytotoxic agents is Xeloda (generic name = capecitabine). Xeloda is an oral prodrug of 5-fluorouracil (5-FU), an intravenous medication. Other newer cytotoxic agents include Revlimid (generic name = lenalidomide) and Zolinza (generic name = vorinostat) (Aisner, 2007).

Targeted agents, also referred to as biological agents, are drugs that are targeted at specific cancer biologic pathways (Bedell, 2003; Weingart et al., 2008). They tend to have fewer side effects because they kill fewer healthy cells than cytotoxic agents. Most new oral anticancer medications are targeted agents. Most of the new oral anticancer medications that have been approved over the past decade are targeted agents.

Endocrine agents are a third class of oral anticancer medications. Endocrine agents interfere with the activity of hormones in the body that can promote the development, growth, and spread of cancer cells, such as estrogen and androgen. They are used to regulate the production of hormones associated with cancer. Endocrine agents are used to treat cancers in which hormones play a major role, such as certain types of breast cancer, endometrial cancer, ovarian cancer, uterine cancer, and prostate cancer (Mazzaferro et al., 2013). They include tamoxifen, a medication that prevents tumors from using estrogen, which is used primarily to treat or prevent breast cancer. Over the past 15 years, a new class of endocrine agents for treatment of cancers associated with estrogen has been developed. These medications, known collectively as aromatase inhibitors, are most frequently used to treat advanced breast cancer and to prevent the recurrence of early stage breast cancer among postmenopausal women (Gibson et al., 2009; NCCN, 2010; NCI, 2018a).

## Roles of Oral Anticancer Medications in Cancer Treatment

Oral anticancer medications are used to treat frequently diagnosed cancers, such as breast, lung, prostate, and colorectal cancers. They are also used for rare cancers, such as adrenocortical cancer (cancer of the adrenal gland), dermatofibrosarcoma protuberans (a cancer of the dermis layer of skin), and retinoblastoma (an eye cancer).

The roles of oral anticancer medications in cancer treatment vary. Some oral anticancer medications, most notably tamoxifen and aromatase inhibitors, are used to reduce the likelihood of recurrence of cancer in patients with early stage cancers who were previously treated with surgery, radiation, and/or intravenous anticancer medications. Others, such as Gleevec (generic name = imatinib mesylate), are taken on an ongoing basis to prevent the growth of cancer cells. Still others, such as Xeloda (generic name = capecitabine) and Zolinza (generic name = vorinostat), are used to treat metastatic cancers, recurrent cancers, or cancers that cannot be surgically removed.

Oral anticancer medications may be used as “first-line” treatments for persons newly diagnosed with cancer or as “second-line” treatments for persons who do not respond to first-line treatments. Treatment of chronic myeloid leukemia provides an illustration. One oral anticancer medication, Gleevec (generic name = imatinib mesylate), is used as a first-line treatment for chronic myeloid leukemia. Persons with chronic myeloid leukemia who cannot tolerate Gleevec or whose cancers do not respond to it may be prescribed one of four other oral medications, Bosulif (generic name = bosutinib), Iclusig (generic name = ponatinib), Sprycel (generic name = dasatinib), or Tasigna (generic name = nilotinib).

Some oral anticancer medications are used alone, whereas others are used in combination with intravenous medications. Specific uses of oral anticancer medications vary depending on the type of

cancer, or severity or stage of cancer being treated. Many are dispensed following surgery to remove all or part of a cancerous tumor. A few are used to reduce the size of a tumor prior to surgery. Some oral anticancer medications are used concurrently with radiation therapy. An example is Temodar (generic name = temozolomide), which is used concurrently with radiation to treat persons who are newly diagnosed with glioblastoma multiforme, a form of brain cancer (NCCN, 2010; NCI, 2018a).

## Advantages and Disadvantages of Oral Anticancer Medications

When compared to intravenous and injectable anticancer medications, oral anticancer medications have both advantages and disadvantages. Advantages include that oral anticancer medications are easier to administer on a daily basis, may be more convenient for patients, and may reduce the risk of infection or other complications (Mazzaferro et al., 2013). Disadvantages include less certainty about patient adherence to treatment regimens and a reduction in interaction between patients and their health care providers to manage complications of treatment (Mazzaferro et al., 2013). Less frequent interaction may make it more difficult for health care providers to identify dangerous side effects and adjust treatment regimens (Zerillo et al., 2017). There may also be higher risks of drug-food and drug-drug interactions relative to intravenous and injectable anticancer medications (Banna et al., 2010).

A recent systematic review of studies of interventions aimed at improving the safety and quality of treatment with oral anticancer medications found that interventions in which pharmacists or registered nurses provided patients with education about their medications or monitored patients remotely via telephone reduce toxicity and may improve adherence. The systematic review found that sending text messages to patients did not reduce toxicity or improve adherence (Zerillo et al., 2017).

## Availability of Generic Equivalents for Oral Anticancer Medications

Most oral anticancer medications are available only as brand-name (i.e., nongeneric) medications. Generic equivalents are available for 20% of oral anticancer medications approved by the FDA (17 of the 83 medications). Many oral anticancer medications are relatively new medications for which the pharmaceutical company that developed the medication (i.e., the brand-name manufacturer) has exclusive marketing rights and/or for which the patent has not expired. In other cases, manufacturers do not currently market generic equivalents of brand-name drugs.

Although generic equivalents are available for only 20% of oral anticancer medications, they account for a large percentage of prescriptions filled for these medications. As Table 2 (in the *Benefit Coverage, Utilization, and Cost Impacts* section) indicates, CHBRP estimates that in 2019, methotrexate sodium, a generic oral anticancer medication used to treat 10 types of cancer, accounts for the largest percentage of prescriptions among all oral anticancer medications (28.9%). Nolvadex (generic name = tamoxifen), an oral anticancer medication used to treat breast, endometrial, ovarian, and uterine cancers, accounts for 18.1% of prescriptions filled for oral anticancer medications in California in 2019. Anastrozole, another oral medication used to treat breast, endometrial, ovarian, and uterine cancers, accounts for an estimated 15.1% of prescriptions for oral anticancer medications filled in California.

## Substitutability of Oral and Intravenous/Injectable Anticancer Medications

Intravenous or injected equivalents are available for only 11% of oral anticancer medications (9 of the 83 oral anticancer medications). These alternatives may be intravenous or injected versions of the same drug or a very similar drug. They may also be therapeutic equivalents (i.e., different drugs that are equally effective for treating a particular cancer). One of the most widely used oral anticancer medications for which an intravenous or injected alternative is available is Xeloda (generic name = capecitabine). Xeloda is an oral prodrug of 5-fluorouracil (5-FU), an intravenous medication that has been used for a number of

years to treat metastatic breast and colon cancers (Aisner, 2007; Walko and Lindley, 2005). Other oral anticancer medications for which intravenous or injected alternatives are available include Temodar (generic name = temozolomide), Cytoxan (generic name = cyclophosphamide), Vepesid (generic name = etoposide), and Hycamtin (generic name = topotecan hydrochloride). (See Table E-1 for a complete listing of oral anticancer medications for which intravenous or injected substitutes are available.)

## Effectiveness of Anticancer Medications

It is important to recognize that what constitutes an effective oral anticancer medication varies depending on the purpose for which a medication is being used. In the case of medications that are used to treat an early stage cancer or prevent recurrence of an early stage cancer, an effective medication is one that enables a person to live disease-free for multiple years. Where medications are used to treat advanced or metastatic cancers, patients are less likely to attain long periods of disease-free survival. In the context of advanced and metastatic cancer, an effective medication is generally considered one that improves quality of life and/or prolongs survival or prevents disease progression for a period of months rather than years.

## Outcomes Assessed

This analysis examines studies of the effects of cost-sharing for oral anticancer mediations on measures of medication use, such as abandonment of prescriptions, initiation of treatment, persistence with treatment, and adherence to treatment for oral anticancer medications. Abandonment of prescriptions refers to instances in which a patient takes a prescription to a pharmacy to be filled but does not pick it up or pay for it. Persistence is defined as the length of time a person takes a medication. Adherence measures the extent to which people have a sufficient supply of a medication to take it as directed.

## Study Findings

CHBRP identified five studies of the impact of cost-sharing on use of anticancer medications published since CHBRP issued its most recent report on oral anticancer medication in 2013. Findings from these studies are summarized along with the findings from five studies included in CHBRP's 2013 report on AB 219. The preponderance of evidence from all studies included in CHBRP's review suggests that lower cost-sharing for oral anticancer medications is associated with greater likelihood of initiating treatment with oral anticancer medications and with adherence to treatment. There is limited evidence that lower cost-sharing for oral anticancer medications is associated with persistence with treatment over a longer period of time.

### Types of Oral Anticancer Medications Studied

Table 1 lists the studies of oral anticancer medications CHBRP included in its review along with the medications and populations studied. Three studies exclusively focused on targeted oral anticancer medications (Goldman et al., 2010; Hess et al., 2017; Streeter et al., 2011). Four studies exclusively addressed endocrine agents used to treat breast cancer (Farias and Du, 2017; Farias et al., 2016; Neugut et al., 2011; Sedjo and Devine, 2011). One study examined both targeted agents and endocrine agents (Kaisaeng et al., 2014). One study examined targeted agents, cytotoxic agents, and endocrine agents (Kim et al., 2011). One study included 38 oral anticancer medications but did not report the names of the medications studied (Doshi et al., 2018).

**Table 1.** Characteristics of Studies Included in the Medical Effectiveness Review

| Study | Drugs Included | Population Studied |
|---|---|---|
| Goldman et al., 2010 | Erlotinib and imatinib | Persons enrolled in multiple private group health insurance plans |
| Kim et al., 2011 | 8 medications (mix of endocrine agents and targeted agents) | Persons enrolled in a single private group health insurance plan |
| Neugut et al., 2011 | Endocrine agents for breast cancer | Persons enrolled in multiple private group health insurance plans |
| Sedjo and Devine, 2011 | Endocrine agents for breast cancer | Persons enrolled in multiple private group health insurance plans |
| Streeter et al., 2011 | Capecitabine, erlotinib, imatinib, lapatinib, lenalidomide, sorafenib, sunitinib, and temozolomide | Persons enrolled in multiple private group health insurance plans and Medicare managed care plans |
| Kaisaeng et al., 2014 | Anastrozole, erlotinib, imatinib, letrozole and thalidomide | Medicare beneficiaries |
| Farias et al., 2016 | Endocrine agents for breast cancer | Persons enrolled in multiple private group health insurance plans |
| Farias and Du, 2017 | Endocrine agents for breast cancer | Medicare beneficiaries |
| Hess et al., 2017 | Erlotinib | Persons enrolled in multiple private group health insurance plans and Medicare managed care plans |
| Doshi et al., 2018 | 38 medications | Persons enrolled in multiple private group health insurance plans and Medicare beneficiaries |

*Source:* California Health Benefits Review Program, 2018.

## Sources of Data

All ten studies analyzed data from health insurance claims for anticancer medications. As Table 1 indicates, eight studies assessed data obtained from multiple health plans (Doshi et al., 2018; Farias et al., 2016; Goldman et al., 2010; Hess et al., 2017; Neugut et al., 2011; Sedjo and Devine, 2011; Streeter et al., 2011). Kim et al., 2011 analyzed data from a single commercial health plans. Farias and Du (2017) analyzed data from the SEER-Medicare database and Kaisaeng et al. (2014) examined Medicare claims data. Due to the limited availability of literature on the effects of cost-sharing for oral anticancer agents, we included Farias and Du (2017) and Kaisaeng et al. (2014) studies of Medicare beneficiaries even though AB 1860 does not apply to Medicare beneficiaries.

## Research Design

Nine studies were cross-sectional analyses that examined the effects of variation in the generosity of health plan benefits over a single period of time (Doshi et al., 2018; Farias and Du, 2017; Farias et al., 2016; Goldman et al., 2010; Hess et al., 2017; Kaisaeng et al., 2014; Neugut et al., 2011; Sedjo and Devine, 2011; Streeter et al., 2011). One small study compared enrollees whose copayment for a 30-day supply of a specialty medication for cancer and other diseases increased by 25% or more to enrollees whose copayment did not increase (Kim et al., 2011). All of the studies were observational (i.e., patients were not randomly assigned to any particular level of cost-sharing).

## Findings for Specific Outcomes Assessed

The 10 studies examined multiple indicators of the impact of cost-sharing on medication use.

### *Abandonment of prescription*

Two studies assessed the impact of cost-sharing on abandonment of prescriptions for specialty oral anticancer medications (Doshi et al., 2018; Streeter et al., 2011). Abandonment occurs when a patient submits a prescription to a pharmacy but does not pick up or pay for the prescription. Streeter and colleagues (2011) examined abandonment of prescriptions for one of eight specialty oral anticancer medications[29] by persons who did not subsequently fill a prescription for another anticancer medication. The authors compared persons with seven levels of cost-sharing and found that persons who had cost-sharing greater than $200 per prescription were more likely to abandon their prescriptions than persons who had cost-sharing of $100 or less. One study (Doshi et al., 2018) examined the association between out-of-pocket costs of treatment with oral anticancer agents and prescription abandonment for 38 oral anticancer medications. The authors found that only 10% of patients in the lowest out-of-pocket cost category (≤$10 per prescription) abandoned their prescription versus 49% of patients in the highest out-of-pocket cost category (>$2,000 per prescription). An important strength of the studies by Doshi et al. and Streeter et al. is that the authors include variables that control for the effect of income on abandonment of for oral anticancer medications. Streeter et al. included a variable that measures patients' incomes. Doshi et al. included a variable that measures mean household income in the zip code in which a patient resides.[30]

### *Initiation of treatment*

Two studies have examined the impact of cost-sharing on initiation of treatment with oral anticancer medications and have reached opposite conclusions. A study by Goldman et al. (2010) assessed the effect of cost-sharing on initiation of treatment for two orally administered anticancer medications: erlotinib and imatinib (Tarceva and Gleevec). The authors found that initiation of treatment with erlotinib and imatinib was not associated with the average out-of-pocket cost per prescription for these medications. In contrast, another study (Neugut et al., 2011) found that patients who faced cost-sharing greater than $90 for a 30-day supply of an endocrine agent medication had lower odds of initiating treatment with aromatase inhibitors than patients who faced cost-sharing of $0 to $29.99 for these oral anticancer medications. Both of these studies controlled for patients' incomes. One potential explanation for the difference between the findings of these studies is that the authors assessed the impact of cost-sharing on different medications. Goldman et al. (2010) examined two targeted medications that are used to treat patients with metastatic cancers, whereas Neugut et al. (2011) studied endocrine agents that are most frequently prescribed to women who have had breast cancer to prevent recurrence. Persons who are taking an oral anticancer medication to prevent recurrence may be more sensitive to their out-of-pocket cost for the medication than people who have metastatic cancer.

### *Delay in initiation of treatment*

Doshi et al. (2018) assessed whether higher cost-sharing is associated with delayed initiation of one of 38 oral anticancer agents. Delayed initiation occurs when a patient reverses claim, when a patient submits a

[29] Gleevec (generic name = imatinib), Nexavar (generic name = sorafenib), Revlimid (generic name = lenalidomide,), Sutent (generic name = sunitinib), Tarceva (generic name = erlotinib), Temodar (generic name = temozolomide), Tykerb (generic name = lapatinib), Xeloda (generic name = capecitabine).

[30] Mean or median household income at the zip code or Census tract level if often used as a proxy for a person's income if person-level data on income are not available.

prescription to a pharmacy and does not pick up or pay for a prescription drug but subsequently fills the same medication within 90 days. Among patients in the lowest out-of-pocket cost category, only 3% (≤$10 per prescription) delayed initiation of their prescription, compared with 18% of patients in the highest out-of-pocket cost category (>$2,000 per prescription). This study controlled for mean household income at the zip code level.

### *Persistence with treatment*

Four studies examined the effects of cost-sharing on persistence with oral anticancer medications.

Goldman et al. (2010) defined persistence as the number of prescriptions filled for an oral anticancer medication. The authors found that persons who had higher average out-of-pocket costs for erlotinib and imatinib (Tarceva and Gleevec), two expensive targeted oral anticancer medications, filled fewer prescriptions for these medications than people who had lower average out-of-pocket costs and that the difference was statistically significant. The study controlled for median household income in a patient's zip code to separate the effect of cost-sharing on persistence with treatment from the effect of income.

Hess et al. (2017), Kaisaeng et al. (2014), and Kim et al. (2011) measured persistence as the length of time until a patient stops taking an oral anticancer medication. Hess et al. (2017) found that for every $100 increase in erlotinib out-of-pocket costs, the odds of a patient remaining on therapy *increased* by 15.0%.[31] By contrast, Kim et al. (2011) found that increasing cost-sharing was not associated with a statistically significant difference in persistence.

One study found that the effects of cost-sharing on persistence differed across different types of oral anticancer medications. Kaisaeng et al. (2014) found that higher out-of-pocket costs were associated with higher levels of medication discontinuation for patients on expensive drugs (imatinib, erlotinib, and thalidomide), but not for those on less expensive drugs (anastrozole and letrozole). For each $10 increase in out-of-pocket spending per month, the likelihood of discontinuation or delay in initiation of treatment increased 13%, 14%, and 20% for imatinib, erlotinib, and thalidomide users, respectively, but decreased 26% for anastrozole and letrozole users (Kaisaeng et al., 2014). This counterintuitive finding for anastrozole and letrozole users may reflect the unique "coverage gap" aspect of Medicare Part D coverage for prescription drugs. If beneficiaries discontinued one of these medications before they entered the "coverage gap," their out-of-pocket costs would have been lower than persons who continued to take these medications after they entered the coverage gap.

### *Adherence to treatment*

Adherence is an important outcome because it assesses whether patients are taking medication as prescribed.[32] Studies that use health insurance claims to assess adherence to medication typically measure adherence as ratio of days of medication dispensed to total days in a time period, which is usually referred to as a medication possession ratio or a proportion of days covered. Unlike persistence, which is typically measured as the length of time during which a person continuously fills prescriptions for an oral anticancer medication, adherence is typically measured the number of days during a specific time period, often 12 months, on which a person had filled sufficient prescriptions to be able to take an oral

[31] Patients were considered to have discontinued therapy if there was a gap in therapy of at least 60 days.
[32] Neugut and colleagues (2011) and Sedjo and Devine (2011) measured adherence as a categorical variable. Patients were considered adherent if the ratio of the days of medication dispensed to the total number of days in the time period during which adherence was examined was ≥80%. Kim and colleagues (2011) measured adherence as a continuous variable, which consisted of the ratio of the total days of medication supplied to the total number of days in the time period assessed.

anticancer medication as directed. This method enables researchers to account for gaps in refills and to measure all subjects' use of medication over the same period of time.

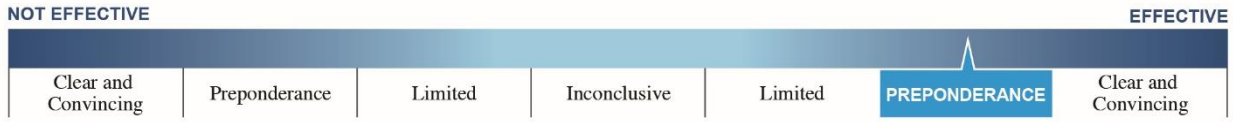
Six studies examined the impact of cost-sharing on adherence to oral anticancer medications. Four studies limited their analyses to aromatase inhibitors, a type of oral anticancer medications used to treat breast cancer (Farias and Du, 2016; Farias et al., 2017; Neugut et al., 2011; Sedjo and Devine, 2011). One study assessed multiple oral anticancer medications (Kim et al., 2011) and one study examined erlotinib (Hess et al., 2017).

All four studies of oral anticancer medications for breast cancer concluded that patients who had higher cost-sharing were less likely to be adherent. Neugut and colleagues' (2011) findings are particularly relevant for AB 1860 because the authors compared three levels of cost-sharing for a 30-day supply of medication ($0 to $29.99, $30 to $89.99, and greater than $90) and found that patients with cost-sharing ≥$90 were significantly less likely to be adherent than patients with cost-sharing of $0 to $29.99. In addition, Neugut and colleagues (2011) controlled for patients' incomes and, thus, were better able to isolate the effect of cost-sharing than authors of other studies of adherence to endocrine agents.

Findings from the studies of adherence to targeted oral anticancer medications reached conflicting conclusions. Kim and colleagues' (2011) study of adherence to multiple oral anticancer medications found that an increase in cost-sharing for multiple oral anticancer medications was not associated with a statistically significant reduction in adherence. Hess et al. (2017) found that higher out-of-pocket cost were associated with lower adherence to erlotinib ($P < 0.0001$). Specifically, with every $100 increase in out-of-pocket costs per erlotinib prescription, the odds of being adherent decreased by 3.0% (Hess et al., 2017).[33]

**Summary of findings regarding the impact of cost-sharing on use of oral anticancer medications:** There is a preponderance of evidence that lower cost-sharing is associated with greater likelihood of initiating treatment with oral anticancer agents and with adherence to treatment. There is limited evidence that lower cost-sharing is associated with persistence with treatment over a longer period of time.

**Figure 3**. Findings Regarding the Effect of Cost-sharing on Use of Oral Anticancer Medications




[33] Nonadherence was defined as patients having a medication possession ratio of 0.80 (80%) or less.

# BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, AB 1860 would repeal the sunset date for provisions of current law that prohibit DMHC-regulated plans and CDI-regulated policies from requiring an enrollee or insured to pay, notwithstanding any deductible, a total amount of copayments and coinsurance that exceeds $200 for an individual prescription of up to a 30-day supply of a prescribed orally administered anticancer medication. In 2013, CHBRP analyzed AB 219, which had similar requirements, but with a cost-sharing limit of $100 per prescription for up to a 30-day supply. AB 219 was amended and signed into law with a cost-sharing limit of $200. The AB 1860 analysis will refer to relevant aspects of that CHBRP AB 219 report to provide context.

This section reports the potential incremental impacts of AB 1860 on estimated benefit coverage, utilization, and overall cost. Anticancer medication can be covered under the medical benefit or outpatient prescription drug pharmacy benefit. Because the bill explicitly names “prescribed, orally administered” medications, CHBRP assumes that the bill applies to the outpatient pharmacy benefit portion of a DMHC-regulated plan or CDI-regulated policy. For further details on the underlying data sources and methods, please see Appendix C.

## Baseline and Postmandate Benefit Coverage

Currently, all enrollees with health insurance that would be subject to AB 1860 have fully compliant coverage due to the existing law, put in place by AB 219. AB 1860 would affect the coverage of approximately 15.9 million enrollees in DMHC-regulated health care service plans and CDI-regulated health insurance policies in California.

As discussed in the *Policy Context*, all plans and policies subject to AB 1860 — even those without an *outpatient* prescription drug/pharmacy benefit — cover some form of prescription drugs under the medical benefit; however, the bill does not require plans or policies that do not provide coverage for oral anticancer medications as part of their prescription drug benefit to begin covering them.

Cost-sharing provisions for anticancer medications provided on an outpatient basis vary widely by plan or policy. Enrollees who have coverage for oral anticancer medications generally access the coverage as an outpatient prescription drug benefit. Copayments for outpatient prescription drugs generally range from $11 to $110 per prescription (Henry J. Kaiser Family Foundation, 2017). However, some prescription medications are subject to coinsurance, which can range from 0% to 38% of the medication cost after any applicable deductible has been met. The deductible amount also varies by plan or policy. CHBRP assumes that these benefit designs would not change under AB 1860.

## Baseline and Postmandate Utilization

Based on PwC’s analysis of 2016 California claims data using the MarketScan database, CHBRP estimates that enrollees with coverage of oral anticancer medications utilize 33.1 prescriptions of oral anticancer medication per year per 1,000 enrollees and that 0.64% of or 102,000 enrollees with coverage subject to the mandate will use oral anticancer medications in 2019, the first year post implementation. The utilization of oral anticancer medications increased slightly from the estimates CHBRP provided when analyzing the potential impacts of AB 219 for 2014, which indicated that enrollees utilized 27.4 prescriptions of oral anticancer medications per 1,000 enrollees and that 0.54% of enrollees used these medications in a year. This may reflect an increased number of oral anticancer drugs available to treat more types of cancers.

Overall utilization rates for oral anticancer medications are not assumed to change because AB 1860 maintains provisions already included under the current law. CHBRP also assumes the number of users of oral anticancer medications will not increase and the number of units of oral anticancer medications among existing users will not change due to the passage of AB 1860.

As indicated in the *Medical Effectiveness* section, there is a preponderance of evidence that lower cost-sharing is associated with greater likelihood of initiating treatment with oral anticancer agents and with adherence to treatment. Additionally, enrollees may prefer to have an oral anticancer medication due to its convenience if there is an intravenous medication substitute (Schott et al., 2011) and when patient out-of-pocket costs are lower. Intravenous or injected equivalents are available for 11% of oral anticancer medications (9 of the 83 oral anticancer medications), though clinical considerations may further limit substitutability. This dynamic cannot be quantified due to the complex clinical factors that are involved when considering potential substitutions and uncertainty in the availability of new oral anticancer medication in the future.

## Baseline and Postmandate Per-Unit Cost

The average annual cost per oral anticancer medication prescription for 2019 was estimated using MarketScan commercial claims and enrollment data for California in 2016 (Table 2). The estimated average cost per prescription for 2019 is $1,362, an increase from $856 in 2014, which may be due to the availability and price of new drugs. The percentage distribution of prescriptions, the average cost (health plan cost plus enrollee cost-sharing), and the distribution of total cost are presented in Table 2.

The three most frequently prescribed oral anticancer medications are all generic medications. They represented 62.1% of the prescriptions, but only 1.5% of the total cost.

- Methotrexate — 28.9% of prescriptions;
- Tamoxifen citrate — 18.8% of prescriptions; and
- Anastrozole — 15.1% of prescriptions.

The three most expensive oral anticancer medications on an average cost per prescription basis were all new medications released after 2014. They represented 0.5% of the prescriptions but 6.1% of the total cost.

- Tagrisso — $19,449 per prescription;
- Pomalyst — $17,451 per prescription; and
- Lenvima — $17,350 per prescription.

The top three oral anticancer medications as a percentage of total costs of all medications represented 32.4% of the total cost, but 3.4% of the total prescriptions.

- Ibrance — 13.4% of total costs;
- Sprycel — 9.6% of total costs; and
- Gleevec — 9.4% of total costs.

**Table 2.** Outpatient Oral Anticancer Medication (OAM) Prescriptions, 2019

| Drug name | Drug Type | Percentage of OAM Prescriptions | Average Cost of OAM Prescriptions | Percentage of Total Cost of OAM Prescriptions |
|---|---|---|---|---|
| Methotrexate | Generic | 28.9% | $49 | 1.0% |
| Tamoxifen citrate | Generic | 18.1% | $25 | 0.3% |
| Anastrozole | Generic | 15.1% | $14 | 0.2% |
| Letrozole | Generic | 9.3% | $14 | 0.1% |
| Mercaptopurine | Generic | 6.5% | $114 | 0.5% |
| Exemestane | Generic | 3.4% | $352 | 0.9% |
| Hydroxyurea | Generic | 2.3% | $33 | 0.1% |
| Capecitabine | Generic | 1.9% | $2,557 | 3.6% |
| Megestrol acetate | Generic | 1.3% | $74 | 0.1% |
| Ibrance | Brand | 1.3% | $14,178 | 13.4% |
| Temozolomide | Generic | 1.3% | $2,615 | 2.5% |
| Gleevec | Brand | 1.1% | $12,164 | 9.4% |
| Sprycel | Brand | 1.0% | $13,215 | 9.6% |
| Bicalutamide | Generic | 0.7% | $26 | 0.0% |
| Tarceva | Brand | 0.5% | $8,933 | 3.1% |
| Afinitor | Brand | 0.5% | $13,743 | 4.8% |
| Imatinib mesylate | Generic | 0.5% | $12,245 | 4.2% |
| Imbruvica | Brand | 0.5% | $13,758 | 4.6% |
| Zortress | Brand | 0.4% | $3,012 | 0.9% |
| Tasigna | Brand | 0.4% | $12,210 | 3.3% |
| Cyclophosphamide | Generic | 0.3% | $782 | 0.2% |
| Votrient | Brand | 0.3% | $9,367 | 2.0% |
| Jakafi | Brand | 0.3% | $13,962 | 2.7% |
| Sutent | Brand | 0.2% | $11,965 | 1.9% |
| Zytiga | Brand | 0.2% | $10,507 | 1.6% |
| Pomalyst | Brand | 0.2% | $17,451 | 2.6% |
| Trexall | Brand | 0.2% | $237 | 0.0% |
| Xtandi | Brand | 0.2% | $11,351 | 1.7% |
| Tykerb | Brand | 0.2% | $7,321 | 1.0% |
| Tagrisso | Brand | 0.2% | $19,449 | 2.4% |
| Lynparza | Brand | 0.2% | $14,269 | 1.7% |

| Drug name | Drug Type | Percentage of OAM Prescriptions | Average Cost of OAM Prescriptions | Percentage of Total Cost of OAM Prescriptions |
|---|---|---|---|---|
| Arimidex | Generic | 0.2% | $582 | 0.1% |
| Gleostine | Brand | 0.2% | $448 | 0.1% |
| Fareston | Brand | 0.2% | $1,529 | 0.2% |
| Purixan | Brand | 0.1% | $1,356 | 0.1% |
| Tafinlar | Brand | 0.1% | $11,560 | 1.0% |
| Xeloda | Generic | 0.1% | $4,128 | 0.4% |
| Xalkori | Brand | 0.1% | $16,982 | 1.4% |
| Gilotrif | Brand | 0.1% | $9,624 | 0.8% |
| Mekinist | Brand | 0.1% | $13,519 | 1.1% |
| Nexavar | Brand | 0.1% | $15,629 | 1.2% |
| Lenvima | Brand | 0.1% | $17,350 | 1.1% |
| Stivarga | Brand | 0.1% | $16,743 | 1.1% |
| Zykadia | Brand | 0.1% | $17,151 | 1.0% |
| Other brand | Brand | 1.0% | $12,279 | 9.14% |
| Other generic | Generic | 0.3% | $6,628 | 1.19% |
| **Total/average** | | **100.0%** | **$1,362** | **100.00%** |

*Source:* PwC Analysis of Truven MarketScan data for 2016.

*Notes:* Costs per prescription were trended by 10% per year to 2019. "Average Cost" here represents the total of amounts paid by the health plan/insurer plus amounts paid by the patient, out of pocket, due to cost-sharing provisions of his/her plan contract or policy (cost-sharing may take the form of copays or coinsurance, and either may have applicable deductibles or annual/lifetime caps).

## Baseline and Postmandate Expenditures

No changes in total premiums would be expected due to the passage of AB 1860 in the short term, since AB 1860 extends current law indefinitely. However, were AB 1860 not to pass, the maximum cost-sharing paid by enrollees using oral anticancer medications may increase by $50 per prescription given the current law that limits cost-sharing to $250 for all prescriptions.[34] Nevertheless, premiums may increase due to factors not impacted by the passage of AB 1860, such as rising drug costs and increased availability of oral anticancer medications (Kircher et al., 2016). As estimated during the analysis of AB 219, any premium increases due to the limitation of cost-sharing for oral anticancer medications was expected to be minimal since CHBRP estimated that total net expenditures (premiums and out-of-pocket expenditures) for oral anticancer medications and services would increase by $454,000, or 0.0003%, in 2014 as a result of AB 219.

[34] Current law limits copayments or coinsurance to $250 for an individual prescription for up to a 30-day supply. If the $200 limit on copayments and coinsurance for oral anticancer prescription drugs sunsets on January 1, 2019, enrollees filling oral anticancer prescriptions would have their copayments and coinsurance limited to $250 per 30-day supply at least through January 1, 2020.

### Premiums

No change in premiums is expected as a result of AB 1860, due to the existing law. There may be concerns that the reduction in enrollee expenses for oral anticancer medications due to cost-sharing limitations would lead to health plans and insurers increasing premiums. However, CHBRP estimated minimal changes in premiums due to the enactment of AB 219, which found premiums would increase by $0.01 per member per month in 2014 at most.

### Enrollee Expenses

No change in related enrollee expenses for covered benefits (deductibles, etc.) is expected as a result of AB 1860. The major impact of the passage of AB 219 was the shift of some of the costs from individual patients who use high-cost oral anticancer medications to the purchasers of health plans and policies. The CHBRP analysis of AB 219 estimated that such a shift could range from $0 to $58,744, averaging $25.63 per user per year in 2014. The wide variations in cost-sharing shifts are related to the price of a particular oral anticancer medication, as well as the benefit structure of a particular health plan or policy. These changes are expected to continue should AB 1860 pass, but additional shifts are not expected. CHBRP does not project any cost offsets or savings in health care that would result from the enactment of provisions in AB 1860.

### Postmandate Administrative Expenses and Other Expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies will remain proportional to the increase in premiums. Because 100% of plans and policies are fully compliant with existing law, CHBRP assumes that there would not be an increase in administrative cost to continue compliance. However, compliance with AB 1860 would require that plans and insurers notify members and applicants of the repeal of the sunset for oral anticancer medication. These administrative changes are reflected in the standard administrative cost load associated with premiums.

## Other Considerations for Policymakers

In addition to the impacts a bill may have on benefit coverage, utilization, and cost, related considerations for policymakers are discussed below.

### Postmandate Changes in the Number of Uninsured Persons[35]

Because the change in average premiums does not exceed 1% for any market segment, CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 1860.

### Changes in Public Program Enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of AB 1860.

[35] See also CHBRP's *Criteria and Methods for Estimating the Impact of Mandates on the Number of Uninsured*, available at www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

## How Lack of Benefit Coverage Results in Cost Shifts to Other Payers

Because AB 1860 would not expand coverage for oral anticancer medications, the costs that would shift to other payers postmandate would be those for *covered* benefits. CHBRP recognizes that if AB 1860 were to not pass, some portion of out-of-pocket expenses by enrollees utilizing oral anticancer medications may be shifted to public programs, or to drug-assistance or charitable programs, but the extent of such a potential shift is unknown.

# PUBLIC HEALTH IMPACTS

## Estimated Public Health Outcomes

CHBRP concludes that passage of AB 1860 would have no short-term[36] public health impact because it would extend current coinsurance/copayment limitations for oral anticancer medications. For these reasons, CHBRP also concludes that AB 1860 would have no short-term impact on premature death; societal economic losses; or existing disparities in health outcomes by gender, race/ethnicity, sexual orientation/gender identity, or other social determinants.

However, were AB 1860 fail to pass, CHBRP still does not project a public health impact in 2019 because another existing law limits copayments and coinsurance to no more than $250 per 30-day supply of *any* prescription medication.[37]

See the *Long-Term Impacts* section for a more general discussion about effects of increased cost-sharing.

[36] CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.
[37] H&SC 1342.71 and IC 10123.193

# LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact[38] of AB 1860, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. As described in the *Policy Context* section, if the $200 limit on copayments and coinsurance for oral cancer prescription drugs sunsets on January 1, 2019, enrollees filling oral anticancer prescriptions would have their copayments and coinsurance limited to $250 per 30-day supply under another law[39] that sunsets in 2020. The following discussion is informed by peer-reviewed literature and primary data analysis, and projects to 2020 and beyond.

## Long-Term Utilization and Cost Impacts

CHBRP is unaware of an empirical study measuring the long-term effects of a decrease in out-of-pocket expenses on the utilization and cost of oral anticancer medications. Thus, long-term impacts on overall health care costs as a result of the elimination of the sunset that limits cost-sharing for oral anticancer medications to $200 per prescription for up to a 30-day supply are unknown. However, it is expected that the overall utilization and cost of premiums in the long term will increase due to increased availability of new and expensive oral medications (Kircher et al. 2016). There are currently more than 80 FDA approved oral anticancer medications, with many more in the clinical trial stage (Kircher et al. 2016). According to a recent pharmaceutical industry report on cancer medication development, oral medicines now represent 38% of U.S. oncology costs, up from 23% 10 years ago (IMS, 2016). As a result, health plans' and insurers' costs for oncology medications, especially the more targeted and long-term oral anticancer medications, will continue to grow over the next several years. There are several other factors that may be influential. For example, there is an increase in the number of patients receiving long-term treatment with more targeted oral anticancer medications. Oral forms of targeted oncologic therapies represent 39% of the $27.8 billion spent on targeted therapy in the United States in 2015, up from 26% in 2010 (IMS, 2016). In addition, continued growth in the use of combination treatment for various types of cancers is likely, and there is a trend of expanding indications for off-label use of existing drugs for the treatment of various cancers.

Some intravenous cancer treatments may be substituted with the use of oral therapy, as discussed in the *Medical Effectiveness* section. Several studies in Europe and in U.S. have demonstrated cost savings from replacing intravenous cancer therapy with oral therapy, mainly due to the savings of costs related to the visits for IV drug administration, hospital use, and transportation costs (Cassidy et al., 2006; Findlay et al., 2008; Twelves, 2006). Should more oral anticancer medications serve as substitutes in the future, there is a potential reduction in expenditures for cancer treatment.

### Projections Of Impact of Rising Drug Costs on the Number of Enrollees Hitting Cost-Sharing Limits

To assess the potential impact of rising drug prices on the number of enrollees who hit the cost-sharing limits due to the elimination of the sunset included in current law outlined in AB 1860, CHBRP provides a long-term projection of how many enrollees may hit the cost-sharing limitation in future years, based on drug price growth (assumed to be 10% annual growth based on published trends from the 2017 Drug Trends Report from Express Scripts®). For the projection, CHBRP used 2016 MarketScan commercial claims data to compile a list of oral anticancer outpatient prescription drugs that are likely to be subject to the cost-sharing limit. These include drugs in 2016 that were at least $500 per 30-day prescription, which

[38] See also CHBRP's *Criteria and Guidelines for the Analysis of Long-Term Impacts on Healthcare Costs and Public Health*, available at www.chbrp.org/analysis_methodology/cost_impact_analysis.php.
[39] H&SC 1342.71 and IC 10123.193.

is based on an assumption of maximum cost share of 40%, meaning an enrollee would exceed the $200 per 30-day supply prescription out-of-pocket cost-sharing limitation (note, Table 2 above includes the list of the most costly oral anticancer medications). The $200 out-of-pocket cost-sharing limit is fixed (assuming plans and policies continue to not increase the cost-sharing limit by CPI); therefore, as drug costs increase, more enrollees will reach the out of pocket cost-sharing limit. Because of the uncertainty around the approval of new drugs, stagnant or decreased drug costs due to competition, and the inability to predict new users, CHBRP limits the projection of impact of rising costs to the drugs in the 2016 market only.

Table 3 summarizes the findings of the projection analysis. In 2019, it is estimated there will be a maximum of 13,800 enrollees hitting the cost-sharing limit of $200 per individual prescription for up to a 30-day supply; these enrollees represent 0.087% of all enrollees with health insurance in California subject to AB 1860. The number of enrollees hitting the cost-sharing limit grows each year as drug prices trend upwards by the 10% annual increase in costs that was applied in this analysis (published trends from the 2017 Drug Trends Report from Express Scripts®). By 2021, the maximum number of enrollees hitting the cost-sharing limit is estimated to be about 15,100 enrollees.

**Table 3.** Projected Maximum Number and Percentage of Enrollees Who Will Hit the Cost-Sharing Limit of AB 1860

| Year | Maximum Number of Enrollees | Maximum Percentage of Enrollees |
|---|---|---|
| 2019 | 13,800 | 0.087% |
| 2020 | 14,500 | 0.091% |
| 2021 | 15,100 | 0.095% |

*Source:* California Health Benefits Review Program, 2018.

*Note:* Based on MarketScan 2016 claims database sample data; the percentage of those who hit the limit is compared to enrollees subject to AB 1860 based on 2019 enrollment (15.9 million enrollees). The cost-sharing limit of $200 per month for a 30-day supply of oral anticancer medications, as originally mandated by AB 219, would be extended without a sunset by AB 1860.

## Impact on Access and Health Service Availability

CHBRP expects that there will be impacts on the access to and availability of oral anticancer medications as a result of AB 1860 in the long run. To the extent that cost-sharing will continue to be limited because of AB 1860 mandated cost-sharing limits, access to expensive oral medications would be expected to increase for the small number of enrollees who are prescribed expensive oral anticancer medications. Nonetheless, possible implementation of prior authorization requirements and formulary structure is expected to mediate the response by the health plans and insurers to this increase in demand. CHBRP is unable to estimate these effects quantitatively.

## Interaction Between Rising Drug Costs and Policies on Cost-Sharing Limits

There are current policy debates on how best to protect consumers from rising drug costs — policy solutions include:

- Outpatient drug cost-sharing limits (such as those examined here) to relieve patient out-of-pocket expenses (Robinson et al., 2016)

- Limits and transparency around drug pricing practices of drug manufacturers (Sarpatwari et al., 2016)
- Regulation around how pharmacy benefit managers (PBMs) that contract with health plans to administer coverage of drugs negotiate drug placement on formularies; current pricing practices may limit access to less expensive versions of drugs, for example biosimilar drugs that are less expensive versions of expensive biologic drugs (Riley, 2018)
- Restrictions on how PBMs obtain and distribute rebates or discounts to plans and to consumers (Egilman et al., 2018; Falit et al., 2015)
- Use of value-based insurance design, including value-based formularies, such that cost-sharing corresponds/aligns with the cost-effectiveness of the intervention or medication covered by insurance, (Chernew, 2010, 2016; Yeung et al., 2017).

Because of this heightened interest at the state and federal level in finding policy solutions to shield consumers from rising drug costs, it is possible there will be major shifts in the near future that change the current system of pricing and cost-sharing.

## Long-Term Public Health Impacts

CHBRP estimates that approximately 85% of the 102,000 patients using oral anticancer medications will not reach the $200 cost-sharing limit. Based on the evidence that lower cost-sharing for oral anticancer medications is associated with a greater likelihood of medication initiation and adherence, CHBRP assumes medication utilization and health outcomes for these enrollees would remain the same regardless of the presence of the cost-sharing provision(s). This conclusion is based on CHBRP's analysis showing that more than 80% of oral anticancer medications cost less than $114 per prescription (Table 2), and thus, would not subject to the patient cost-sharing protection in AB 1860. The most expensive medications were prescribed infrequently (Tagrisso, Pomalyst, and Lenvima representing 0.5% of the prescriptions and 6.1% of the total cost). And the three most frequently prescribed medications as a percent of total costs of all medications (Ibrance, Sprycel, and Gleevec) represented 32.4% of the total cost, but 3.4% of the total prescriptions (see Table 2 in the *Cost* section for details).

In addition to cost-sharing limits, there are at least two other financial mechanisms that may assist patients with limiting their out-of-pocket expenses for oral anticancer medications. There are patient assistance programs (i.e., pharmaceutical company-sponsored rebates and coupons, foundation payments) that can help income-qualified patients pay for the more expensive oral anticancer drugs. IMS Institute for Healthcare Informatics (2016) reported that, nationally, about 25% of patients received pharmaceutical manufacturer coupons or rebates for retail anticancer drugs in 2015, up from 7% in 2011. These patient assistance programs averaged patient savings of about $750 per prescription. Additionally, were both cost-sharing limit laws to sunset, there still remains a higher limitation on patient out-of-pocket expenses. The ACA limits annual out-of-pocket expenses for most enrollees to $7,900 (single) or $15,800 (family) (proposed for 2019) (Klinger, 2017) (see *Background* section). Most patients reach the annual out-of-pocket maximum to pay for their cancer treatment within the first three months of diagnosis. Treatment costs may include diagnostic tests, radiation, surgery, hospital stays, and/or prescription drugs (including anticancer medications) (ACS-CAN, 2017),

Although enrollees with cancer are likely receiving other treatments in addition to oral anticancer medications that would lead them to meet their deductible, a small portion of enrollees taking oral anticancer medications may still face out of pocket costs that reach the $200 cost-sharing limit per prescription. For some portion of the 15% of enrollees who may reach the $200 cost-sharing limit,

especially those in high deductible health plans, there could be financial and health benefits associated with the passage of AB 1860. As explained in the *Medical Effectiveness* section, some enrollees are price sensitive to high(er) cost-sharing, wherein they forgo medication due to the cost, which results in negative health outcomes. Stump et al. (2013) surveyed cancer patients, 99% of whom were insured, and found that 30% were concerned about paying for their treatment, 22% of their families made financial sacrifices to pay for care, and 8% reported that insurance adequately covered their cancer treatment (which included anticancer medications). Extension of the $200 limit on cost-sharing for oral anticancer medications could improve certain individual's medication adherence and health outcomes.

# APPENDIX A TEXT OF BILL ANALYZED

On February 22, 2018, the California Assembly Committee on Health requested that CHBRP analyze AB 1860.

**ASSEMBLY BILL** **No. 1860**

**Introduced by Assembly Members Limón and Cervantes**

January 10, 2018

An act to amend Section 1367.656 of the Health and Safety Code, and to amend Section 10123.206 of the Insurance Code, relating to health care coverage.

## LEGISLATIVE COUNSEL'S DIGEST

AB 1860, as introduced, Limón. Health care coverage: cancer treatment.
Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law prohibits, until January 1, 2019, an individual or group health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2015, that provides coverage for prescribed, orally administered anticancer medications used to kill or slow the growth of cancerous cells from requiring an enrollee or insured to pay, notwithstanding any deductible, a total amount of copayments and coinsurance that exceeds $200 for an individual prescription of up to a 30-day supply of a prescribed orally administered anticancer medication, as specified. Under existing law, a willful violation of this prohibition by a health care service plan is a crime.
This bill would extend the duration of this prohibition indefinitely. Because the bill would expand the scope of a crime, the bill would impose a state-mandated local program.
The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement. This bill would provide that no reimbursement is required by this act for a specified reason.

## Digest Key

Vote: MAJORITY Appropriation: NO Fiscal Committee: YES Local Program: YES

## Bill Text

### THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

## SECTION 1.

Section 1367.656 of the Health and Safety Code is amended to read:

**1367.656.**

~~(a)~~Notwithstanding any other law, an individual or group health care service plan contract issued, amended, or renewed on or after January 1, 2015, that provides coverage for prescribed, orally administered anticancer medications used to kill or slow the growth of cancerous cells shall comply with all of the following:

~~(1)~~

*(a)* Notwithstanding any deductible, the total amount of copayments and coinsurance an enrollee is required to pay shall not exceed two hundred dollars ($200) for an individual prescription of up to a 30-day supply of a prescribed orally administered anticancer medication covered by the contract.

~~(2)~~

*(b)* For a health care service plan contract that meets the definition of a “high deductible health plan” set forth in Section 223(c)(2) of Title 26 of the United States Code, ~~paragraph (1)~~ *subdivision (a)* shall only apply once an enrollee’s deductible has been satisfied for the year.

~~(3) Paragraph (1)~~

*(c) Subdivision (a)* shall not apply to any coverage under a health care service plan contract for the Medicare Program pursuant to Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

~~(4)~~

*(d)* On January 1, 2016, and on January 1 of each year thereafter, health care service plans may adjust the two hundred dollar ($200) limit described in ~~paragraph (1).~~ *subdivision (a).* The adjustment shall not exceed the percentage increase in the Consumer Price Index for that year.

~~(5)~~

*(e)* A prescription for an orally administered anticancer medication shall be provided consistent with the appropriate standard of care for that medication.

~~(b)This section shall remain in effect only until January 1, 2019, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2019, deletes or extends that date.~~

## SEC. 2.

Section 10123.206 of the Insurance Code is amended to read:

**10123.206.**

~~(a)~~Notwithstanding any other law, an individual or group health insurance policy issued, amended, or renewed on or after January 1, 2015, that provides coverage for prescribed, orally administered anticancer medications used to kill or slow the growth of cancerous cells shall comply with all of the following:

~~(1)~~

*(a)* Notwithstanding any deductible, the total amount of copayments and coinsurance an insured is required to pay shall not exceed two hundred dollars ($200) for an individual prescription of up to a 30-day supply of a prescribed orally administered anticancer medication covered by the policy.

~~(2)~~

*(b)* For a health insurance policy that meets the definition of a “high deductible health plan” set forth in Section 223(c)(2) of Title 26 of the United States Code, ~~paragraph (1)~~ *subdivision (a)* shall only apply once an insured’s deductible has been satisfied for the year.

~~(3)Paragraph (1)~~

*(c) Subdivision (a)* shall not apply to any coverage under a health insurance policy for the Medicare Program pursuant to Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

~~(4)~~

*(d)* On January 1, 2016, and on January 1 of each year thereafter, health insurers may adjust the two hundred dollar ($200) limit described in ~~paragraph (1).~~ *subdivision (a)* The adjustment shall not exceed the percentage increase in the Consumer Price Index for that year.

~~(5)~~

*(e)* A prescription for an orally administered anticancer medication shall be provided consistent with the appropriate standard of care for that medication.

~~(b)This section shall remain in effect only until January 1, 2019, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2019, deletes or extends that date.~~

## SEC. 3.

No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

# APPENDIX B LITERATURE REVIEW METHODS

This appendix describes methods used in the medical effectiveness literature review conducted for this report. A discussion of CHBRP's system for grading evidence, as well as lists of MeSH Terms, publication types, and keywords, follows.

Studies of the effects of cost-sharing on use of oral anticancer medications were identified through searches of (PubMed, the Cochrane Library, Web of Science, and Scopus, and Embase. Websites maintained by the following organizations were also searched: Agency for Healthcare Research and Quality; National Guideline Clearinghouse; National Institute for Clinical Excellence; National Institutes of Health; Scottish Intercollegiate Guideline Network; and World Health Organization, the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE); Substance Abuse and Mental Health Services Administration (SAMHSA); US Preventive Services Task Force (USPSTF).

The search was limited to abstracts of studies published in English. The medical effectiveness search was limited to studies published from 2013 to present, because CHBRP had previously reviewed this literature using the same search terms in 2014 for the AB 219 analysis.

Reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria.

The literature review returned abstracts for 313 articles, of which 10 were reviewed for inclusion in this report. A total of 5 studies were included in the medical effectiveness review from AB 219: A total of 5 new studies since 2013 were included in the medical effectiveness review for AB 1860.

## Evidence Grading System

In making a "call" for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's *Medical Effectiveness Analysis Research Approach.*[40] To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Statistical significance;
- Direction of effect;
- Size of effect; and
- Generalizability of findings.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

[40] Available at: www.chbrp.org/analysis_methodology/docs/medeffect_methods_detail.pdf.

- *Clear and convincing evidence;*
- *Preponderance of evidence;*
- *Limited evidence*
- *Inconclusive evidence; and*
- *Insufficient evidence.*

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

A grade of *inconclusive evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *insufficient* evidence indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

## Search Terms

- Abiraterone
- Abiraterone acetate
- adherence
- Administration, Intravenous
- Administration, Oral
- Afinitor
- Age Factors
- Alkeran
- Altretamine
- Anastrozole
- anticancer
- anti-neoplastic
- Antineoplastic Agents
- Antineoplastic Agents/administration and dosage
- Antineoplastic Agents/therapeutic use
- anti-tumor
- Arimidex
- Aromasin
- Axitinib
- Bexarotene
- Bicalutamide
- Bosulif
- Bosutinib
- burden
- Busulfan
- Cabozantinib
- California
- cancer
- Capecitabine
- Caprelsa
- Casodex
- CeeNU
- chemotherapeutics
- chemotherapy
- Chlorambucil
- Coinsurance
- Cometriq
- compliance
- Copayment
- cost
- cost analysis
- cost effective
- cost effectiveness
- Cost of Illness
- cost saving
- cost sharing
- cost shifting
- cost utility
- cost-benefit
- Cost-Benefit Analysis
- Crizotinib
- Cyclophosphamide
- cytotoxic
- Cytotoxic agent
- Cytotoxic antitumor
- Cytoxan
- Dasatinib
- Deductible*
- Droxia
- Drug Costs
- Drug Prescriptions
- drug
- economic

- economic loss(es)
- Emcyt
- endocrine
- Endocrine agent
- Enzalutamide
- erlotinib
- Estramustine
- ethnic
- Ethnic Groups
- ethnicities
- ethnicity
- ethnology
- Etoposide
- Eulexin
- Everolimus
- Exemestane
- expenditure
- expensive
- Fareston
- Femara
- Flutamide
- Gefitinib
- gender
- geographic access
- Gleevec
- Global Burden of Disease
- Health Services Accessibility
- Health Social Determinants
- Hexalen
- Hycamtin
- Hydrea
- Hydroxyurea
- Iclusig
- Imatinib
- Imatinib mesylate
- Incidence
- Inlyta
- Iressa
- Jakafi
- Lapatinib
- Lenalidomide
- Letrozole
- Leukeran
- Lomustine
- long term impact(s)
- Los Angeles
- low income
- Lysodren
- Matulane
- medication adherence
- medication compliance
- medication
- Megace
- Megestrol
- Megestrol acetate
- Melphalan
- Mercaptopurine
- Methotrexate
- Methotrexate sodium
- Minority Health
- Mitotane
- Morbidity
- mortality
- Myleran
- neoplasms
- Neoplasms/drug therapy
- Nexavar
- nilandron
- Nilotinib
- Nilotinib hydrochloride monohydrate
- Nilutamide
- Nolvadex
- Oakland
- oral chemotherapy
- oral
- out of pocket
- patient
- patient compliance
- Pazopanib
- Pomalidomide
- Pomalyst
- Ponatinib
- Poverty
- premature death
- premature mortality
- prescribing
- prescription
- prevalence
- price(s)
- Procarbazine
- productivity
- Purinethol
- quality of life
- racial
- Regorafenib
- Revlimid
- Rheumatrex
- Ruxolitinib
- sacramento
- San Diego
- San Francisco
- SDOH
- sex differences
- Sexism
- social determinants of health
- societal
- societal burden
- societal impact
- Sorafenib
- Sorafenib tosylate
- Sprycel
- Stivarga
- Sunitinib
- Sunitinib malate
- Sutent
- Tabloid
- Tamoxifen
- Tamoxifen citrate
- Tarceva
- targeted
- Targeted agent
- Targeted anticancer
- Targeted anti-neoplastic
- targeted therapy
- Targretin
- Tasigna
- Temodar
- Temozolomide
- Thalidomide
- Thalomid
- therapy
- Thioguanine
- Topotecan
- Topotecan hydrochloride
- Toremifene
- treatment
- treatment adherence
- treatment compliance
- Tretinoin
- Trexall
- Tykerb
- unit cost
- utilization
- Vandetanib

- Vemurafenib
- Vepesid
- Vesanoid
- Visnodegib
- Vorinostat
- Votrient
- worker productivity
- Xalkori
- Xeloda
- Xtandi
- Zelboraf
- Zolinza
- Zytiga

# APPENDIX C COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors primarily from the University of California, Los Angeles, and the University of California, Davis, as well as the contracted actuarial firm, PricewaterhouseCoopers (PwC).[41]

Information on the generally used data sources and estimation methods, as well as caveats and assumptions generally applicable to CHBRP's cost impacts analyses are available at CHBRP's website.[42]

This appendix describes analysis-specific data sources, estimation methods, caveats and assumptions used in preparing this cost impact analysis.

## Analysis-Specific Caveats and Assumptions

This subsection discusses the caveats and assumptions relevant to specifically to an analysis of AB 1860.

### *Identification of oral anticancer medications*

Baseline oral anticancer drug treatment costs and associated utilization were based on 2016 MarketScan® commercial claims and enrollment data for the state of California. Indicators for therapeutic class (Antineoplastic Agents) and route of administration (oral) were used to identify National Drug Codes (NDCs) for oral anticancer drugs based on the Truven Health Analytics Red Book.™

### *Oral anticancer medication projection and cost-sharing limits*

This subsection discusses the caveats and assumptions relevant to the projection analysis of AB 1860's provision regarding the cost-sharing limits.

**Allowed Cost:** For the 2016 base year, CHBRP normalized the allowed cost (per line) to a 30-day supply. That is, for lines with more than 30-day supply, CHBRP adjusted the allowed cost to represent the cost for a 30-day prescription supply. Allowed cost for a supply of less than 30 days were left unchanged.

**Unit Cost Trend:** CHBRP calculated projected allowed cost from 2017 to 2021, respectively, by applying a 10.0% annual unit cost trend to the normalized allowed cost described above. The trend assumption is based on the "2017 Drug Trend Report" by Express Scripts, reflecting oncology drug trends for the commercial population represented within the report, with some dampening based on actuarial judgment and observations from the MarketScan® data between 2014 and 2016.

**Cost-Sharing:** Cost-sharing was calculated by multiplying the normalized (and, if applicable, trended) allowed cost by an actuarial value assumption of 40%.

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[41] CHBRP's authorizing statute, available at www.chbrp.org/docs/authorizing_statute.pdf, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
[42] See *2017 Cost Impact Analyses: Data Sources, Caveats, and Assumptions*, available at www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

**Enrollees Hitting the Cost-Sharing Limit:** In estimating the upper bound of the impacted population, the analysis assumed a bronze plan with actuarial value of 60% and cost-sharing of 40%. Therefore, enrollees were determined to hit the limit in years 2016 to 2021 if their cost-sharing (i.e., 30- day normalized hypothetical maximum cost-sharing amount for the projected year) was at least $200 per prescription line. The range of distinct enrollees count determined to hit the limit is as follows: 1,440 in 2016 to 1,770 in 2021. Total 2016 California enrollment in the MarketScan data is 1,862,814. Extrapolating to the California population impacted by the mandate: 12,309 in 2016 to 15,130 in 2021.

CHBRP found that for the majority of high-cost oral anticancer drugs identified for year 2016, the associated actual copayments and/or coinsurance amounts in the MarketScan data are relatively low, and it is unclear how comparable OAC cost-sharing for the MarketScan population is to OAC cost-sharing in the population impacted by the mandate. Therefore, the hypothetical bronze-level cost-sharing should be considered an upper bound, and the projected enrollee impact is likely a high estimate. Based on the data, the number of enrollees who have actual drug copay costs above the $200 out of pocket cost-sharing limit is smaller than the upper bound because 1) many enrollees have prescription coverage that is more generous than a bronze actuarial value and 2) health plans may put expensive drugs on a formulary tier that has flat co-pay amounts that are significantly below the $200/30-day supply limit.

## Determining Public Demand for the Proposed Mandate

This subsection discusses public demand for the benefits AB 1860 would mandate. Considering the criteria specified by CHBRP's authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

- Considers the bargaining history of organized labor; and
- Compares the benefits provided by self-insured health plans or policies (which are not regulated by the DMHC or CDI and therefore not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include cost-sharing arrangements for description treatment or service. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS currently have the largest number of enrollees. The CalPERS PPOs currently provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask carriers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

# APPENDIX D OUTPATIENT PRESCRIPTION DRUG BENEFITS AND STATE-LEVEL MANDATES

As noted in Table 4, for 2019, CHBRP estimates that approximately 1.4% of enrollees in plans regulated by the California Department of Managed Health Care (DMHC) or policies regulated by the California Department of Insurance (CDI) have no coverage for outpatient prescription drugs (OPDs) and 3.0% of these enrollees have OPD coverage that is not regulated by DMHC or CDI.

**Table 4.** 2019 Outpatient Prescription Drug Coverage

| | Enrollees in DMHC-Regulated Plans and in CDI-Regulated Policies |
|---|---|
| | *Total* |
| **Enrollee Counts** | |
| Total enrollees in plans/policies subject to state Mandates (a) | 23,433,000 |
| **Outpatient Prescription Drug (OPD) Coverage** | |
| DMHC- or CDI-regulated brand name and generic OPD coverage | 95.5% |
| DMHC- or CDI-regulated generic-only coverage | 0.1% |
| No OPD coverage | 1.4% |
| Other OPD coverage | 3.0% |

*Source*: California Health Benefits Review Program, 2018.

*Notes:* (a) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

*Key:* CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; HMO = Health Maintenance Organization; OPD = outpatient prescription drug.

Additional detail about the presence and absence of OPD coverage in various market segments is presented below, in Table 5, Table 6, and Table 7.

## Relevant State and Federal Law

- A number of overlapping state and federal laws require broad OPD coverage or coverage for particular drugs, but the requirements are not applicable to all forms of health insurance.
- Some (but not all) small-group and individual market health care service plans and health insurance policies are required to provide coverage for OPDs as part of coverage for Essential Health Benefits (EHBs).[43]
- Some (but not all) large-group, small-group, and individual market health care service plans and health insurance policies are required to provide coverage for particular drugs as part of preventive services, but not for all OPDs.[44]
- Some state-level mandates, applicable to some or all plans and policies regulated by DMHC or CDI, require coverage for particular drugs. For example, there is a mandate that requires coverage for insulin and prescription drugs for the treatment of diabetes but does not require coverage for drugs that treat diabetes-related conditions.[45]

However, this mix of laws does not require that all enrollees in plans and policies regulated by DMHC or CDI have an OPD benefit.

## Presence or Absence of Coverage for Outpatient Prescription Drugs and Related Regulation

Coverage of OPDs was estimated through surveys and queries. For enrollees in the privately funded markets regulated by DMHC and CDI, coverage was determined by responses to a survey of the largest providers of health insurance in California. Responses to this survey represent 95% of enrollees in these markets. The California Public Employees' Retirement System (CalPERS) was queried regarding coverage among DMHC-regulated plan enrollees associated with CalPERS. The California Department of Health Care Services (DHCS) was queried about coverage among Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

From this information, CHBRP concluded that most enrollees have coverage for OPDs through their DMHC-regulated plan or CDI-regulated policy. These enrollee's OPD coverage is generally accessed through the enrollee's "pharmacy benefit," and generally used when acquiring drugs at an outpatient pharmacy or mail order service. When OPD coverage is handled through a subcontracting pharmacy benefit management (PBM) organization, the plan or policy, licensed by DMHC or CDI, requires the subcontracting PBM to comply with relevant state-level health insurance benefit mandates.

As coverage for OPDs is not universally required, some enrollees in DMHC-regulated plans and CDI-regulated policies have no OPD coverage. Although these enrollee's health insurance cover prescription drugs delivered during a hospital (or other facility) admission and some prescription drugs that are dispensed through a clinician's office, these enrollees' health insurance would not generally help them acquire drugs intended for outpatient use. As noted above, there are some drug specific exceptions, such as insulin, but coverage would be limited to those specific outpatient drugs.

[43] California Health & Safety Code: 1367.005, 1367.006, 1367.0065; California Insurance Code: 10112.27, 10112.28, 10112.285; Federal Affordable Care Act of 2010: Section 1301, 1302, and Section 1201 modifying Section 2707 of the PHSA.
[44] California Health & Safety Code: 1367.002; California Insurance Code: 10112.2; Federal Affordable Care Act of 2010: Section 1001 modifying Section 2713 of the PHSA.
[45] California Health & Safety Code: 1367.51 and California Insurance Code: 10176.61.

In terms of alternate regulation, some enrollees who have no OPD benefit through their DMHC-regulated plan or CDI-regulated policy still do have an OPD benefit — but have it through another source, one that is not regulated by DMHC or CDI. Such a circumstance can occur if, for example, an employer arranges for a large-group plan to exclude coverage for OPDs and then contracts separately with a PBM to administer an OPD benefit. In this example, the PBM is not a subcontractor to a plan or insurer; it is directly contracting with the employer. If the contracting PBM is not licensed by either DMHC or CDI, it is not subject to state-level health insurance benefit mandates.

**Table 5.** 2019 Outpatient Prescription Drug Coverage in the Large Group and Publicly Funded Markets

| | DMHC-Regulated Plans | | | | | CDI-Regulated Policies | |
|---|---|---|---|---|---|---|---|
| | Privately Funded Large Group | | Publicly Funded Plans | | | Privately Funded Large Group | |
| | *Grand-fathered* | *Non-Grand-fathered* | *CalPERS HMOs (a)* | *MCMC (Under 65) (b)* | *MCMC (65+) (b)* | *Grandfathered* | *Non-Grand-fathered* |
| **Enrollee counts** | | | | | | | |
| Total enrollees in plans/policies subject to state mandates (c) | 1,860,000 | 7,511,000 | 887,000 | 6,832,000 | 678,000 | 5,000 | 209,000 |
| **Outpatient prescription drug (OPD) coverage** | | | | | | | |
| DMHC- or CDI-regulated brand name and generic OPD coverage | 95.9% | 90.5% | 79.5% | 100.0% | 100.0% | 80.3% | 86.8% |
| DMHC- or CDI-regulated generic only coverage | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| No OPD coverage | 3.8% | 3.0% | 0.0% | 0.0% | 0.0% | 14.9% | 2.2% |
| Other OPD coverage | 0.3% | 6.5% | 20.5% | 0.0% | 0.0% | 4.8% | 11.0% |

*Source:* California Health Benefits Review Program, 2018.

*Notes:* (a) As of September 2017, 56% of CalPERS HMO members were state retirees under age 65, state employees or their dependents. CHBRP assumes the same ratio for 2019.

(b) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(c) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

*Key:* CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Operated Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care; OPD = outpatient prescription drug.

**Table 6.** 2019 Outpatient Prescription Drug Coverage in the DMHC-Regulated Small-Group and Individual Markets

| | Privately Funded Small Group | | | | Privately Funded Individual | | | |
|---|---|---|---|---|---|---|---|---|
| | *Grand-fathered* | *Non-Grand-fathered Covered California (a)* | *Non-Grand-fathered Mirror Plans (b)* | *Other Non-Grand-fathered* | *Grand-fathered* | *Non-Grand-fathered Covered California (a)* | *Non-Grand-fathered Mirror Plans (b)* | *Other Non-Grand-fathered* |
| **Enrollee counts** | | | | | | | | |
| Total enrollees in plans/policies subject to state mandates (c) | 355,000 | 49,000 | 687,000 | 2,026,000 | 103,000 | 1,157,000 | 611,000 | 210,000 |
| **Outpatient prescription drug (OPD) coverage** | | | | | | | | |
| DMHC-regulated brand name and generic OPD coverage | 99.9% | 100.0% | 100.0% | 100.0% | 90.7% | 100.0% | 100.0% | 100.0% |
| DMHC-regulated generic only coverage | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| No OPD coverage | 0.0% | 0.0% | 0.0% | 0.0% | 9.3% | 0.0% | 0.0% | 0.0% |
| Other OPD coverage | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |

*Source:* California Health Benefits Review Program, 2018.

*Notes:* (a) The Affordable Care Act (ACA) requires the establishment of health insurance exchanges in every state, now referred to as health insurance marketplaces. In California, the marketplace is called "Covered California."

(b) "Mirror Plans" are qualified health plans (QHPs) available outside of Covered California.

(c) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

*Key:* CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Operated Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care; OPD = outpatient prescription drug.

**Table 7.** 2019 Outpatient Prescription Drug Coverage in CDI-Regulated Small-Group and Individual Markets

| | Privately Funded Small Group | | | | Privately Funded Individual | | | |
|---|---|---|---|---|---|---|---|---|
| | *Grand-fathered* | *Non-Grand-fathered Covered California (a)* | *Non-Grand-fathered Mirror Plans (b)* | *Other Non-Grand-fathered* | *Grand-fathered* | *Non-Grand-fathered Covered California (a)* | *Non-Grand-fathered Mirror Plans (b)* | *Other Non-Grand-fathered* |
| **Enrollee counts** | | | | | | | | |
| Total enrollees in plans/policies subject to state mandates (c) | 1,000 | 3,000 | 23,000 | 106,000 | 186,000 | 3,000 | 22,000 | 26,000 |
| **Outpatient prescription drug (OPD) coverage** | | | | | | | | |
| CDI-regulated brand name and generic OPD coverage | 96.5% | 100.0% | 100.0% | 100.0% | 50.9% | 100.0% | 100.0% | 100.0% |
| CDI-regulated generic only coverage | 0.0% | 0.0% | 0.0% | 0.0% | 39.1% | 0.0% | 0.0% | 0.0% |
| No OPD coverage | 0.0% | 0.0% | 0.0% | 0.0% | 10.0% | 0.0% | 0.0% | 0.0% |
| Other OPD coverage | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |

*Source:* California Health Benefits Review Program, 2018.

*Notes:* (a) The Affordable Care Act (ACA) requires the establishment of health insurance exchanges in every state, now referred to as health insurance marketplaces. In California, the marketplace is called "Covered California."

(b) "Mirror Plans" are qualified health plans (QHPs) available outside of Covered California.

(c) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

*Key:* CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Operated Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care; OPD = outpatient prescription drug.

# APPENDIX E ORAL ANTICANCER MEDICATIONS APPROVED BY THE FDA SINCE 2013

**Table 8.** Oral Anticancer Medications Approved by the FDA Since CHBRP Issued Its Report on AB 219 in 2013

| Brand Name | Generic Name (Agent) | Year FDA Approved | Type of Oral Anticancer Drug | Cancers Used to Treat | Generic Equivalent Available | IV/Injectable Alternative Available |
|---|---|---|---|---|---|---|
| Alecensa | Alectinib | 2015 | Kinase inhibitor that targets ALK and RET | ALK-positive, metastatic non-small cell lung cancer | No | No |
| Alunbrig | Brigatinib | 2017 | Multikinase inhibitor | ALK-positive metastatic non-small cell lung cancer | No | No |
| Cabometyx | Cabozantinib | 2016 | Kinase inhibitor | Advanced renal cell carcinoma | No | No |
| Calquence | Acalabrutinib | 2017 | Tyrosine kinase Inhibitor | Mantle cell lymphoma | No | No |
| Cotellic | Cobimetinib | 2015 | Kinase inhibitor | BRAF V600E or V600K melanoma | No | No |
| Erleada | Apalutamide | 2018 | Androgen receptor inhibitor | Non-metastatic castration-resistant prostate cancer | No | No |
| Farydak | Panobinostat | 2015 | Histone deacetylase inhibitor | Multiple myeloma | No | No |
| Gilotrif | Afatinib | 2013 | Tyrosine kinase inhibitor | Metastatic non-small cell lung cancer with EGFR mutations | No | No |
| Ibrance | Palbociclib | 2015 | Pyridopyrimidine-derived cyclin-dependent kinase (CDK) inhibitor with antineoplastic activity. | Estrogen-positive, HER2-negative breast cancer | No | No |
| IDHIFA | Enasidenib | 2017 | IDH2 Inhibitor | Relapsed or refractory acute myeloid leukemia with IDH2 mutation | No | No |
| Imbruvica | Ibrutinib | 2013 | Selective inhibitor of Bruton's tyrosine kinase (Btk), | Chronic lymphocytic leukemia, mantle cell or marginal zone lymphoma, | No | No |

| Brand Name | Generic Name (Agent) | Year FDA Approved | Type of Oral Anticancer Drug | Cancers Used to Treat | Generic Equivalent Available | IV/Injectable Alternative Available |
|---|---|---|---|---|---|---|
| | | | | Waldenstrom macroglobulinemia | | |
| Kisqali | Ribociclib | 2017 | Cyclin-dependent Kinase Inhibitor | Hormone receptor positive, HER2- advanced for metastatic breast cancer | No | No |
| Lenvima | Lenvatinib | 2015 | Receptor tyrosine kinase (RTK) inhibitor that inhibits the kinase activities of vascular endothelial growth factor (VEGF) receptors VEGFR1, as well as other RTKs that have been implicated in pathogenic angiogenesis, tumor growth, and cancer progression | Thyroid cancer, advanced renal cell carcinoma | No | No |
| Lonsurf | Trifluridine/tipiracil | 2015 | Combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor. | Metastatic colorectal cancer | No | No |
| Lynparza | Olaparib | 2014 | Poly (ADP-ribose) polymerase (PARP) inhibitor | Previously treated BRCA mutated advanced ovarian cancer | No | No |
| Mekinist | Trametinib | 2013 | Inhibitor of mitogen-activated protein kinase kinase (MEK) with potential antineoplastic activity. | Unresectable or metastatic melanoma with BRAF V600E or V600K mutations | No | No |
| Nerlynx | Neratinib | 2017 | Tyrosine Kinase Inhibitor | HER2 breast cancer | No | No |
| Ninlaro | Ixazomib | 2015 | Proteasome inhibitor | Multiple myeloma | No | No |
| Odomzo | Sonidegib | 2015 | Hedgehog pathway inhibitor | Locally advanced basal cell carcinoma | No | No |

| Brand Name | Generic Name (Agent) | Year FDA Approved | Type of Oral Anticancer Drug | Cancers Used to Treat | Generic Equivalent Available | IV/Injectable Alternative Available |
|---|---|---|---|---|---|---|
| Rubraca | Rucaparib | 2016 | Poly (ADP-ribose) polymerase (PARP) inhibitor | Advanced ovarian cancer and deleterious germline or somatic BRCA mutation | No | No |
| Rydapt | Midostaurin | 2017 | Multikinase Inhibitor | FLT3 positive acute myeloid leukemia and mastocytosis | No | No |
| Tafinlar | Dabrafenib | 2013 | Inhibitor of some mutated forms of BRAF kinases, as well as wild-type BRAF and CRAF kinases | Unresectable or metastatic melanoma with BRAF V600E mutation | No | No |
| Tagrisso | Osimertinib | 2015 | Targeted cancer therapy, designed to inhibit both the activating, sensitizing mutations (EGFRm), and T790M, a genetic mutation responsible to EGFR-TKI treatment resistance | EGFR T790M mutation positive non-small cell lung cancer | No | No |
| Venclextra | Ventoclax | 2016 | BCL-2 inhibitor, an antiapoptotic protein | Chronic lymphocytic leukemia with 17p deletion | No | No |
| Verzenio | Abemaciclib | 2017 | Cyclin-dependent Kinase Inhibitor | Hormone receptor positive, HER2- breast cancer | No | No |
| Zejula | Niraparib | 2017 | Poly(ADP-ribose) polymerase (PARP) inhibitor | Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer | No | No |
| Xermelo | Telotristat ethyl | 2017 | Tryptophan hydroxylase inhibitor | Carcinoid syndrome diarrhea | No | No |
| Zydelig | Idelalisib | 2014 | Inhibitor of phosphoinositide-3 kinase (PI3K) delta | Relapsed CLL, follicular B-cell NHL and small lymphocytic lymphoma | No | No |
| Zykadia | Ceritinib | 2014 | Anaplastic lymphoma kinase (ALK). | ALK positive metastatic non-small cell lung cancer | No | No |

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# CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM COMMITTEES AND STAFF

A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing researchers and analysts who are **Task Force Contributors** to CHBRP from UC that conduct much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, **PricewaterhouseCoopers**, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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Janet Coffman, MA, MPP, PhD, and Margaret Fix, MPH, both of the University of California, San Francisco, prepared the medical effectiveness analysis. Stephen L. Clancy, MLS, AHIP, of the University of California, Irvine conducted the literature search. Joy Melnikow, MD, MPH, and Dominique Ritley, MPH, both of the University of California, Davis, prepared the public health impact analysis. Ying-Ying Meng, DrPH, University of California, Los Angeles, prepared the cost impact analysis. Peter Davidson, FSA, MAAA, of PricewaterhouseCoopers, and supporting actuarial staff, provided actuarial analysis. Robert Mowers, PharmD, BCPS, of the University of California, Davis, provided technical assistance with the literature review and expert input on the analytic approach. Adara Citron, MPH, of CHBRP staff prepared the Policy Context and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Brent Fulton, PhD, of the University of California, Berkeley, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request. CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

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