

Key Findings:

Analysis of California Assembly Bill AB 623 Abuse Deterrent Opioid Analgesics

Summary to the 2015-2016 California State Legislature, May 2015



AT A GLANCE

Assembly Bill AB 623 as amended March 2015, would require compliant utilization management protocols for coverage of opioid analgesics and opioid analgesics labeled by the Food and Drug Administration as abuse-deterrent (FDA-ADOAs).

- **Enrollees covered.** In 2016, approximately 24.6 million Californians will have state-regulated health insurance subject to AB 623.
- **EHBs.** AB 623 would not exceed essential health benefits, because the mandate is applicable to terms and conditions but does not require new benefit coverage.
- **Background.** National recommendations regarding abuse prevention focus on broad policy interventions, including education; tracking and monitoring; enforcement, regulation, and oversight. Oral (including swallowing unaltered pills) is the most common form of abuse.
- **Medical effectiveness.** The impact of ADOAs on abuse is *ambiguous*. Some studies suggest abuse-deterrent formulations reduce some forms of abuse (particularly those related to inhaling or injecting) of the reformulated drug, but other studies suggest ADOAs shift abuse to other opioid analgesics and/or to illicit drugs (such as heroin).
- **Utilization and expenditures.** Total utilization of opioid analgesics would not change, but use of FDA-ADOAs may increase as much as 38%, resulting in a 13% average unit cost increase (FDA-ADOAs cost more) and a 0.0058% total expenditures increase. These estimates are an “upper bound”, as not all patients associated with changing protocols may shift to FDA-ADOAs.
- **Public health.** As the impact of ADOAs on abuse is ambiguous and it is unclear how many patients would shift to FDA-ADOAs, it is unlikely that AB 623 would affect overdoses, associated use of emergency rooms and/or hospitals, or deaths.
- **Long-term impacts.** Long-term reduction in abuse may be more associated with broad policy intervention and with prescriber behavior than with changes in health plan and health insurer utilization management protocols.

BACKGROUND

Opioid analgesics are drugs prescribed to alleviate pain. Prescribed opioid analgesics are increasingly abused. Oral (including swallowing of unaltered pills) is the most common form of abuse. Methods of abuse include crushing, cutting, or dissolving pills (for inhalation or injection) to achieve a more intense and immediate effect. Many opioids are available as extended-release (ER) formulations, which deliver the drug steadily over a long period of time. Altering ER opioids for inhalation or injection effectively increases the dose, which increases the euphoric effect. Nearly half of young users report abusing prescription opioid analgesics before starting heroin. In order to combat the increase in abuse, the White House Administration’s *National Drug Control Strategy* and the Centers for Disease Control and Prevention (CDC) recommend implementation of state-level policies addressing three broad areas – education; tracking and monitoring; and enforcement, regulation, and oversight activities. Actions recommended within these broad areas focus on influencing prescriber and patient behavior.

MEDICAL EFFECTIVENESS

Abuse-deterrent opioid analgesics (ADOAs) are intended to deter some forms of abuse (especially abuse related to inhalation or injection) by establishing physical or chemical barriers to the more intense or immediate highs achieved by altering the drug (through crushing, chewing, cutting, or dissolving). However, abuse-deterrent formulations do not reduce or eliminate the addictive properties of opioids or prevent abuse related to swallowing pills. The FDA reviews inclusion of physical and/or chemical deterrents in drug formulation and labels drugs as FDA-ADOAs, but notes that the technologies have not yet proven successful at deterring the most common form of abuse – swallowing intact pills. As of May 2015, CHBRP is aware of three available FDA-ADOAs on the market: Embeda, Hysingla ER, and OxyContin.

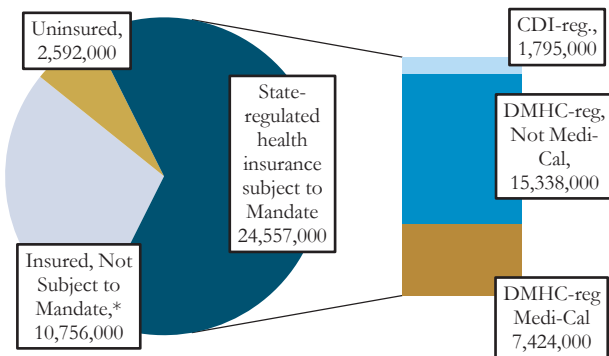
CHBRP reviewed the literature and determined that the impact of ADOAs on abuse is *ambiguous*. Although some studies suggest that abuse-deterrent formulations can

reduce some forms of abuse (particularly those related to inhalation or injection) of a reformulated drug, other studies suggest the presence of ADOAs shifts abuse to other opioid analgesics and/or to illicit drugs (such as heroin).

BILL SUMMARY

In 2016, as noted in Figure 1, AB 623 would apply to the health insurance of 24.6 million Californians (all enrollees with health insurance potentially subject to state-level benefit mandates).

Figure 1. Health Insurance in CA and AB 623



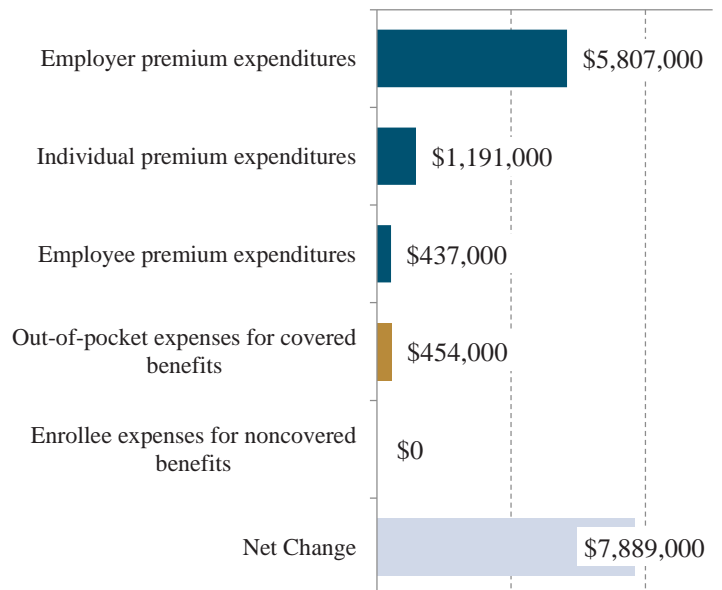
*Federally regulated health insurance, such as Medicare, veterans, or self-insured plans.
 Source: California Health Benefit Review Program, 2015.

AB 623 would place requirements on the terms and conditions of outpatient prescription drug (OPD) benefits covered by health plans regulated by the Department of Managed Health Care (DMHC) and by health insurers regulated by the California Department of Insurance (CDI). AB 623 would: (1) prohibit utilization management protocols requiring use of other opioid analgesics before covering opioid analgesics labeled by the Food and Drug Administration as abuse-deterrent (FDA-ADOAs); (2) require that prior authorization protocols for a drug be the same whether the drug is in regular formulation or abuse-deterrent formulation; and (3) require coverage for less than 30-day prescriptions of opioid analgesics.

UTILIZATION AND COST IMPACTS

AB 623 would not alter benefit coverage, but it would require changes in utilization management protocols for approximately 58% of enrollees in DMHC-regulated plans and CDI-regulated policies. The changed protocols would not impact the total number of filled opioid analgesic prescriptions, but would increase the portion of filled prescriptions represented by FDA-ADOAs. AB 623 could increase utilization of FDA-ADOAs by 38%. Such an increase would raise the average unit cost by 13% because FDA-ADOAs cost more (on average) than other opioid analgesics. The increased unit cost would impact total expenditures (premiums and cost sharing), resulting in an increase of 0.0058% across all market segments. Details of the expenditure impacts are presented in Figure 2. These impacts represent a likely upper bound, because CHBRP modeled the replacement of other opioid analgesics with some abuse-deterrent properties, most of which are extended release (ER) drugs, with FDA-ADOAs for all enrollees with utilization management protocols that would change to be compliant with AB 623. The estimate is an upper bound, because not all providers are aware of or interested in prescribing FDA-ADOAs, and not all enrollees would want FDA-ADOAs to be prescribed for them.

Figure 2. Expenditure Impacts of AB 623



PUBLIC HEALTH IMPACTS

In the first postmandate year, AB 623 would have an unknown public health impact due to both the ambiguous evidence of effectiveness of ADOAs in deterring overall abuse and the unknown magnitude of changes in prescriber and patient behavior in response to changing utilization management protocols. However, CHBRP posits that it is unlikely AB 623 would have a measurable impact on abuse, overdose, or premature death for the following reasons:

- Addictive properties are still present in FDA-ADOAs.
- Initial abuse frequently begins with oral abuse (swallowing pills), which is not affected by abuse-deterrent formulation.
- Many continuing abusers prefer to orally abuse.
- Continuing abusers are also able to choose oral abuse when faced with abuse-deterrent formulations.
- Only three FDA-ADOAs are available in the marketplace as of April 2015, so substitution with non-abuse-deterrent formulation opioid analgesics will still occur for some portion of the population.
- Substitution with heroin, which is reportedly cheaper and easier to obtain, will occur for some abusers.

For these reasons, AB 623 is unlikely to materially affect the number of opioid analgesic overdoses and associated emergency department use, hospitalizations, or deaths in the first year after passage.

LONG-TERM IMPACTS

AB 623 would have an unknown long-term public health impact because ADOAs are only one of many population-based, primary and secondary abuse prevention strategies; changes to insurers' utilization management protocols associated with ADOAs would be a small subset of those prevention strategies. Furthermore, to date ADOAs have yet to demonstrate a statistically significant reduction in *overall* prescription opioid abuse and overdose. ADOAs are a relatively new addition to the collection of strategies and, as more ADOAs are FDA-approved, further epidemiologic surveillance and study is required to ascertain its effectiveness.