



## AB 2911—The California Discount Prescription Drug Program

On August 31, 2006, the California State Assembly passed AB 2911<sup>1</sup>, a bill that will establish the California Discount Prescription Drug Program (“Program”). Governor Schwarzenegger is expected to sign the bill into law within the next two weeks.

The Program is intended to “make prescription drugs more affordable for qualified California residents, thereby increasing the overall health of California residents, promoting healthy communities, and protecting the public health and welfare.” The Program will provide drugs to qualified California residents at reduced prices that result from rebates agreements between the state and drug manufacturers. Under certain circumstances, the Program will also permit the state to impose a prior authorization requirement for drugs provided under California’s Medicaid program, Medi-Cal, if a drug manufacturer does not enter into a rebate agreement. This client advisory summarizes the key provisions of AB 2911.

### 1. Eligibility

California residents are eligible to participate in the Program if they:

- Have total unreimbursed medical expenses equal to at least 10% of their family income and their family income is equal to or less than the median California family income;
- Are enrolled in Medicare but whose drugs are not covered by Medicare;
- Have a family income of no more than 300% of the federal poverty guidelines and do not have Medi-Cal, private, or state-funded drug coverage<sup>2</sup>; or
- Have a family income of no more than 300% of the federal poverty guidelines and have prescription drug coverage, but have reached an annual limit on drug coverage imposed by the third-party payer.

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*This summary is intended to be a general summary of the law and does not constitute legal advice. You should consult with competent counsel to determine applicable legal requirements in a specific fact situation.*

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<sup>1</sup> The official title of the Bill is “An Act to Add Division 112 (commencing with section 130500) to the Health and Safety Code, Relating to Pharmacy Assistance.” See [http://www.leginfo.ca.gov/pub/bill/asm/ab\\_2901-2950/ab\\_2911\\_bill\\_20060830\\_enrolled.pdf](http://www.leginfo.ca.gov/pub/bill/asm/ab_2901-2950/ab_2911_bill_20060830_enrolled.pdf)

<sup>2</sup> A patient assistance program or prescription drug discount card is not considered insurance or a third-party payer program.

## 2. Negotiated Rebates

The California Department of Health Services (DHS) is authorized to negotiate “the maximum possible” discounts with manufacturers of single-source<sup>3</sup> prescription drugs “at a volume weighted average discount<sup>4</sup> that is equal to or below any one of the following benchmark prices”:

- 85% of the average manufacturer price (AMP, as defined by federal law);
- “The lowest price provided to any nonpublic entity in the state by a manufacturer to the extent that the Medicaid best price exists under federal law”; or
- The Medicaid Best Price (as defined by federal law).

Although the language in AB 2911 is less than clear, the legislature presumably wants California to be able to negotiate discounts off a gross price that will result in a net price at, or below, one of the benchmark amounts.

<sup>3</sup> While the definition of “single-source drug” is unclear, it appears that it would encompass innovator multiple-source drugs. If it does not, manufacturers of innovator multiple-source drugs may not be subject to the same discount and prior authorization requirements as single source drugs.

<sup>4</sup> The volume weighted average discount is essentially the “aggregated average discount for the drugs of a manufacturer, weighted by each drug’s percentage of the total prescription volume of that manufacturer’s drugs.”

DHS will seek discount agreements that provide access to a variety of drugs comparable to the drugs available on the Medi-Cal list of contract drugs or the CalPERS formulary. DHS may limit the number of drugs available through the Program, however, to obtain deeper discounts.

The bill will require that manufacturers “provide information that is reasonably necessary” for DHS to perform its duties under the new Program. All information provided by the manufacturer as part of the rebate negotiations and agreements will be considered confidential and will not be subject to California’s public disclosure law.

## 3. Prior Authorization or the “Medi-Cal Hammer”

Beginning August 10, 2010, DHS will be required to determine: (1) whether manufacturer participation has been sufficient to provide eligible Californians with a formulary comparable to Medi-Cal’s list of contract drugs or CalPERS enrollees’ formulary; and (2) whether the volume weighted average discount of single-source prescription drugs offered pursuant to the program is comparable to or lower than one of the three benchmark prices.

If DHS determines that either formularies or discounts are insufficient under the Program’s guidelines, DHS “may” impose a

Medi-Cal prior authorization requirement “for any drug of a manufacturer if the manufacturer fails to agree to a volume weighted average discount for single-source prescription drugs that is comparable to or lower than any one of the benchmark prices.” No later than five days after imposing a prior authorization requirement, DHS must notify the Speaker of the Assembly and the President pro Tempore of the Senate.

DHS will be permitted to implement the prior authorization provision only to the extent that it does not increase costs to the Medi-Cal program. The bill also states that “[i]f prior authorization is required for a drug pursuant to this section, a Medi-Cal beneficiary shall not be denied the continued use of a drug that is part of a prescribed therapy.” The prior authorization provision will also be implemented only to the extent it is consistent with state and federal law.

## 4. Patient Assistance Programs (PAPs)

The Program requires DHS to develop a system to provide Program participants with the best discounts available to them. To that end, the bill states that DHS “may” require Program applicants to provide information to determine the applicant’s eligibility for PAPs and other discount programs. However, the bill also states that DHS cannot

require applicants to participate in a PAP or to “disclose information that will determine the applicant’s eligibility to participate [in a PAP].”

The bill also imposes new reporting obligations on drug manufacturers with PAPs, including the reporting of the total value of drugs and number of prescriptions provided at no or very low cost to Californians.

## **CONCLUSION**

The California bill is part of a trend by states to increase their ability to negotiate with drug manufacturers for greater discounts. California’s attempt to lower drug prices, by threatening drug manufacturers with prior authorization requirements, will likely face legal challenge in federal or state court. Absent a successful legal challenge, the threat of prior authorization requirements may force most drug manufacturers to the negotiating table.

*If you have questions about this advisory, or other related issues, please feel free to contact your Arnold & Porter attorney or:*

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