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California Votes to Impose 340B Spending Restrictions on Targeted 340B Providers

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California is poised to pass a ballot measure aimed at imposing 340B spending restrictions for certain healthcare entities participating in the 340B Program who have historically engaged in spending that is not directly related to patient care and have also owned or operated multifamily dwellings with significant safety issues.

Proposition 34 targets a limited, specific subset of 340B providers who:

- During any 10 calendar-year period of its existence, spent more than $100M for purposes other than direct patient care; and
- The entity (or its parent or any of its subsidiaries or affiliates) currently is, or has ever been, an owner or operator of one or more multifamily dwellings that have cumulatively received at least 500 “high severity” violations in notices or inspection reports by enforcement agencies; and
- Meet at least one of the following criteria:
    - The entity has, or has ever had, a California license to operate as a health plan, pharmacy, or clinic;
    - The entity has, or has ever, contracted with Medi-Cal as a primary care case management organization; or
    - The entity has, or has ever, contracted with CMS as a Medicare Advantage Special Needs Plan.

Entities that meet the above requirements are identified as “prescription drug price manipulators.” A prescription drug price manipulator would be required to submit annual reports to the State to demonstrate that in the prior calendar year it: 1) spent at least 98% of 340B net revenues on direct patient care; and 2) it did not engage in conduct that was unprofessional, dishonest, or harmful to public health or safety.

If a prescription drug price manipulator is found to be noncompliant with these requirements, all of the following penalties would be imposed, as applicable:

- Any and all California pharmacy licenses would be permanently revoked;
- The entity would be banned for 10 years from applying for, obtaining, or possessing a

California pharmacy, health plan, or clinic license;
- The entity would lose, and be banned for 10 years from obtaining, California tax-exempt status;
- The entity would be ineligible to receive new California governmental grants or contracts for 10 years; and
- Any of the entity's owners, operators, or directors would be prohibited for 10 years from serving as an owner, officer, director, or employee of a California-licensed pharmacy, health plan, or clinic.

While Proposition 34 would only affect a limited number of 340B entities in California, the total impact is currently unknown. Some opponents of the proposition argue that it will likely only impact one organization due to its narrow application—the AIDS Healthcare Foundation—however, this has yet to be conclusively confirmed. Notably, the AIDS Healthcare Foundation has been advocating for stricter rent control in California over the last few election cycles and representatives of the organization speculate the ballot measure is intended as retribution for these efforts. As of November 11, 2024, 50.9% of voters have voted "Yes" to pass the ballot measure. If passed, the new restrictions would go into effect on January 1, 2025.

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