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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SACRAMENTO

ASHOKE TALUKDAR, Petitioner, v. SHIRLEY N. WEBER, Ph.D., in her official capacity as California Secretary of State; and DOES 1-50, Respondent.	Case No. 24VVM000118 **VERIFIED PETITION FOR PEREMPTORY WRIT OF MANDATE** (Elec. Code, § 9092; Gov. Code, § 88006) **ELECTION MATTER – PROPOSITION 34 CALENDAR PREFERENCE REQUIRED BY STATUTE [Elec. Code, § 13314(a)(3)]**
PAUL G. DIXON, in his official capacity as State Printer for the State of California; EVAN LOW; KELLY GOSS; NILZA SERRANO; BRIAN K. RICE; STUART FONG; DWIGHT WILLIAMS; and ROES 1-50, Real Parties in Interest.	

Petitioner ASHOKE TALUKDAR ("Petitioner") hereby petitions this Court for a peremptory writ of mandate directed to Respondent Secretary of State SHIRLEY N. WEBER, Ph.D., commanding her to delete or amend the false and misleading statements contained in the proposed ballot arguments in favor of Proposition 34, and alleges as follows:

INTRODUCTION

1. Dueling initiative campaigns in which competing interests sponsor rival ballot measures are familiar and often messy, but never before has one side sponsored a measure explicitly intending to destroy its adversary by stripping it of business and professional licenses, revoking its tax-exempt status, rendering it ineligible to receive federal or state funds, and banning its executives from engaging in their professions — all on the basis of the adversary's activities that were wholly legal when undertaken but that the initiative purports to retroactively outlaw. This is the case this year with Proposition 34 and its proponents.

2. In service of their manipulation of the initiative process to attack a political opponent, the proponents of Proposition 34 have obfuscated and misrepresented their initiative's true purpose to the electorate. One way they have attempted to do this is by presenting false and misleading arguments in support of the initiative within the Voter Information Guide for the upcoming November 5, 2024 General Election.

3. The arguments submitted by the proponents of Proposition 34 misrepresent the federal 340B Drug Discount Program, which lies at the heart of Proposition 34, including the program's basic functions and its purpose, in order to heighten the appearance of supposed abuse. The arguments also claim the initiative will punish and correct a litany of "financial abuses" committed by healthcare providers, among which are "paying for naming rights on sports stadiums" and "giving their executives multimillion dollar salaries."

4. These arguments constitute a fraud on the electorate. They are calculatingly designed to mislead voters into believing this sham measure is a comprehensive reform with a broad reach. In reality, Proposition 34 targets a single entity, the AIDS Healthcare Foundation — an organization that has never acquired stadium naming rights, nor has it ever paid any of its executives multi-million dollar salaries. Even if Proposition 34's proponents identify different organizations that it contends did name a stadium

or pay executives multi-million dollar salaries, the reality is that Proposition 34 would not prevent those organizations from continuing to do so, because the class it regulates is so narrowly drawn that every other healthcare provider in California could continue to carry on its spending exactly as it did before Proposition 34 was enacted. Voters are entitled to an argument that does not mislead the public about the scope of the measure and the activities that the measure would regulate.

5. Petitioner urges this Court to strike from the Voter Information Guide the falsehoods and misrepresentations described herein.

PARTIES

6. Petitioner ASHOKE TALUKDAR is a citizen, taxpayer, elector, and registered voter of the State of California. He is also the proponent of Proposition 33 and a Deputy General Counsel for the AIDS Healthcare Foundation.

7. Respondent SHIRLEY N. WEBER, Ph.D., is the Secretary of State for the State of California and is sued in her official capacity. Among other duties, Respondent Weber is responsible for the preparation of the ballot pamphlet for the November 5, 2024 general election (hereinafter, the "Ballot Pamphlet").

8. Real Party in Interest PAUL G. DIXON is the Printer of the State of California and is responsible for the printing of the Ballot Pamphlet. On information and belief, the copy deadline established by the Secretary of State and the State Printer for materials to be included in the ballot pamphlet is August 12, 2024.

9. Real Parties in Interest EVAN LOW, KELLY GOSS, and NILZA SERRANO are the authors of the Argument in Favor of Proposition 34 proposed for inclusion in the Ballot Pamphlet. A true and correct copy of this argument, as posted on the Secretary of State's website, is attached hereto as **Exhibit A**.

10. Real Parties in Interest BRIAN K. RICE, STUART FONG, and DWIGHT WILLIAMS are the authors of the Rebuttal to Argument Against Proposition 34 proposed for inclusion in the Ballot Pamphlet. A true and correct copy of this argument, as posted on the Secretary of State's website, is attached hereto as **Exhibit B**.

//

JURISDICTION AND VENUE

11. This action is brought pursuant to Elections Code section 9092 and Government Code section 88006, which provide that any elector may seek a writ of mandate requiring the deletion or amendment of any copy from the ballot pamphlet that is false, misleading, or inconsistent with the requirements of the pertinent provisions of the Elections and Government Codes.

12. This action is brought in the Superior Court for the County of Sacramento in accordance with Elections Code section 9092 and Government Code section 88006, which provide that venue for any proceeding under those sections shall be exclusively in Sacramento County.

GENERAL ALLEGATIONS

The AIDS Healthcare Foundation & Ballot Measure Advocacy

13. Founded at the height of the AIDS epidemic, when there were no effective treatments and AIDS patients were shunned and isolated, the AIDS Healthcare Foundation ("AHF") erected three hospices and helped thousands of people spend their final days in peace, support, love, and dignity during the darkest days of the epidemic.

14. Today, AHF provides prevention, testing, and treatment services, and operates medical clinics, specialty pharmacies, and managed-care insurance plans. It is the largest HIV/AIDS organization in the United States, operating a network of healthcare centers and co-located specialty pharmacies where it serves many indigent, uninsured, and underinsured Californians, regardless of ability to pay.

15. AHF operates 15 HIV/AIDS outpatient medical clinics in California, serving approximately 10,500 patients annually, providing over 10 percent of all HIV/AIDS medical care for people living with the disease. Nationally, it operates 69 clinics and 62 pharmacies in 17 states plus Washington, D.C., and Puerto Rico — providing about 10 percent of all HIV/AIDS medical care in the United States. Today, effective medication treatments for AIDS allow patients to manage their disease and live a normal lifespan. People who are adherent to their medication and thereby achieve "viral suppression" are non-infectious. Treatment not only saves lives, it prevents new infections. AHF has one of the highest rates of patients with an undetectable viral load in the State.

16. AHF's success is due, at least in part, to AHF's integrated approach to HIV/AIDS care, which involves providing not only direct medical services but retaining patients in care by giving them

access to specialists, managing their comorbid conditions, and helping them to adhere to their medication regimen.

17. It has been well documented that the loss of housing contributes to HIV/AIDS patients having greater difficulty adhering to their prescription regimen and greater risks of complications, and housing insecurity is also closely correlated with poor health outcomes in general. Hence, AHF advocates for housing affordability because secure and stable housing is vital to positive health outcomes.

18. One example of this work is the AHF-sponsored measure on the November 2024 ballot known as the Justice for Renters Act, which is designed to eliminate anti-rent control provisions in state law. By empowering cities and counties to impose rent control on apartments and single-family homes, the measure would give local governments another tool to fight the affordability crisis in California's housing market, and keep more tenants in their homes. AHF had proposed similar statewide initiatives in 2018 and 2020.

19. AHF participates in the federal 340B Discount Drug Program (42 U.S.C., § 256b), in which drug manufacturers voluntarily sell discounted outpatient drugs to eligible nonprofit healthcare providers like AHF as a condition of Medicaid covering their drugs. The 340B program is discussed *infra*, paragraphs 27-31.

The California Apartment Association & Proposition 34

20. The California Apartment Association ("CAA"), the largest trade association in the country for apartment professionals and owners, opposed AHF's previous efforts to modify California's rent control laws and actively opposes the rent control initiative on the November 2024 ballot.

21. The CAA has responded to these efforts by sponsoring its own ballot measure — Proposition 34 — for the November 2024 ballot with the express intent of destroying AHF.[1]

22. Proposition 34[2] uses carefully circumscribed definitions designed to apply to AHF, and

[1] CAA admitted in a September 1, 2023 news announcement that Proposition 34's aim is to "defeat [AHF CEO Michael] Weinstein's current rent control measure and prevent him from . . . fund[ing] rent control campaigns in the future." A true and correct copy of this announcement is attached hereto as pages 61-63 of **Exhibit C**.

[2] A true and correct copy of Proposition 34 is attached hereto as **Exhibit D**. All citations beginning with "section" or "§," when not otherwise specified, refer to Proposition 34.

AHF alone, that would strip it of business and professional licenses to operate 15 HIV/AIDS California outpatient clinics serving some 10,500 Californians annually, as well as providing sexually transmitted disease testing and treatment, and prevention centers accommodating over 40,000 patient visits per year.

23. CAA has called Proposition 34 part of its "dual approach" to defeating rent control, and its purpose is to prevent AHF from spending "on future rent control campaigns or other political ventures." (See Exhibit C, p. 62.) Indeed, "CAA's dual campaigns aim to defeat both Weinstein's current rent control measure and prevent him from . . . fund[ing] rent control campaigns in the future." (*Id.*, p. 63.)

24. Proposition 34 seeks to regulate expenditures by a single California healthcare provider — AHF. It imposes a punitive spending rule on revenues AHF receives from dispensing drugs to its patients.

25. Proposition 34 creates a term, "prescription drug price manipulator," and defines it so that it could apply only to AHF, out of over 800 California entities participating in the 340B program. It does this through the following targeted criteria:

a. The entity participates in the 340B program;

b. During *any* 10-year period in the entity's existence, it spent "more than one hundred million dollars" on "purposes that do not qualify as direct patient care;"

c. The entity is or was at one time, an owner or operator of "highly dangerous properties," which are defined as multi-family dwellings that have been inspected and received notices or reports identifying violations "affecting the health and safety of occupants," and there must be a combined total of "at least five hundred (500) violations which were categorized in violation severity level 'high;'" and

d. The entity must also have, or have had, either a license to operate as a health care service plan, as a pharmacy, or as a clinic; contract as a primary care case management organization; or contract as a Medicare special needs plan. (§ 14124.48(l) & (h).)

26. This highly specific and unrelated list of requirements is tailored and intended to capture a class of one: AHF. There is no other entity in California that comes close to satisfying this combination of criteria.

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The 340B Drug Discount Program

27. Proposition 34 seeks to regulate non-profit healthcare providers (specifically, one such provider — AHF) who participate in what is known as the 340B Drug Discount Program. The program was created by federal law, 42 U.S.C. section 256b, entitled "Limitation on Prices of Drugs Purchased by Covered Entities."

28. The 340B program puts conditions on private drug makers who wish to participate in the Medicaid program and have access to that market. As a voluntary condition of participating in the Medicaid program and having the Medicaid program pay for their drugs, the 340B program requires that private drug makers allow certain non-profit safety net health providers — "covered entities," as defined by federal law — to purchase drugs from them at a discount for all purposes, not just for the Medicaid program:

> The Secretary [of HHS] shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act . . . . Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

42 U.S.C. section 256b(a)(1). "Covered entities" are defined at 42 U.S.C. section 256b(a)(4).

29. Federal case law and government reports confirm that this is how the 340B program operates. For instance, a United States Government Accountability Office — Congress's watchdog — describes the program as follows:

> The program, created in 1992 and named for the statutory provision authorizing it in the Public Health Service Act (PHSA), requires drug manufacturers to give 340B discounts to entities covered under the law—known as covered entities—in order to have their drugs covered by Medicaid.
>
> Participation in the 340B program is voluntary for both covered entities and drug manufacturers . . . . Covered entities can realize substantial savings through 340B price discounts . . . . In addition, covered entities can generate 340B revenue. For example, covered entities can purchase drugs at the 340B price for all patients eligible under the program regardless of their income or insurance status, and generate revenue, such as through a patients' insurance reimbursement, that may exceed the 340B price paid for the

drugs.

Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (GAO-11-836, Sept. 2011), at pp. 1-2. A true and correct copy of this report is attached hereto as **Exhibit E**.

30. In *Genesis Health Care, Inc. v. Becerra* (D.S.C., Nov. 3, 2023, No. 4:19-CV-01531-RBH) 2023 WL 7549156, a federal district court described the 340B program as such:

> The 340B program . . . was enacted in response to the increase in drug prices that flowed from the . . . creat[ion of] the Medicaid Drug Rebate Program. . . . The drug manufacturer's price increases in outpatient prescription drugs 'reduced the level of services and the number of individuals that these hospitals and clinics [were] able to provide with the same level of resources.' . . . By providing "covered entities" access to price reductions, the 340B program would "enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Put simply, the purpose of the 340B program was to provide a means to make 340B entities profitable in order for those 340B entities to "stretch scarce Federal resources as far as possible." 340B entities are able to stretch these scarce Federal resources because they receive their drugs at a discount and are reimbursed by insurers at the non-discounted price of the drug, thereby increasing the 340B entity's profit margin. This allows 340B entities to provide more services to a larger population of under-served patients.

31. And the United States Court of Appeals for the District of Columbia Circuit, in *Novartis Pharmaceuticals Corporation v. Johnson* (D.C. Cir. 2024) 102 F.4th 452, 455, described the 340B program in this manner:

> As a condition of participating in Medicare Part B and Medicaid, section 340B requires drug manufacturers to sell certain drugs to covered entities at bargain prices. Covered entities—such as healthcare providers serving low-income patients—benefit through insurance reimbursements that exceed the marked-down cost of the drugs.

The Campaign for Proposition 34 and Associated Media Coverage

32. The CAA has been clear from the beginning that the purpose of Proposition 34 is to "defeat [AHF CEO Michael] Weinstein's current rent control measure and prevent him from . . . fund[ing] rent control campaigns in the future." (Exhibit C, p. 63.) Explaining the purpose and effect of Proposition 34, CAA has declared: "CAA is sponsoring a separate ballot measure aimed at preventing Weinstein from misusing taxpayer dollars on future rent control campaigns or other political ventures." (*Id.*, p. 62.)

33. Until late November 2023, when AHF challenged the legality of Proposition 34 in pre-election review litigation, nearly every public statement made on the social media accounts and website

of the campaign in support of Proposition 34 identified, depicted, or otherwise explicitly referred to AHF or Mr. Weinstein, revealing the unambiguous intent to target and cripple AHF. The accounts and website abruptly halted posting material naming AHF and Mr. Weinstein thereafter. True and correct copies of scores of these statements are attached hereto as part of Exhibit C.

34. Numerous media outlets that have studied Proposition 34 have all concluded that the initiative applies only to AHF. *Politico* reported it could find no entity other than AHF that satisfies Proposition 34's criteria, labeled the measure as the "anti-Weinstein initiative," and described it as "aimed squarely at the AIDS Healthcare Foundation and Weinstein." The *San Francisco Chronicle* concluded that Proposition 34 "targets" AHF and that "[t]he only organization that fits [Proposition 34's criteria] is the AIDS Healthcare Foundation." The Editorial Board of the *Los Angeles Times* characterized Proposition 34 as a "new low" in the state's history of "self-serving ballot initiatives" and a "misuse" of the initiative process; and described its "sole purpose" as being "stopping one guy [(Mr. Weinstein)] from putting his own measures on future ballots," whose language is "tailored specifically to target the AIDS Healthcare Foundation." These news reports and editorials are attached hereto as **Exhibit F**.

FIRST CAUSE OF ACTION
(Argument in Favor of Proposition 34)

35. Petitioner incorporates as though fully set forth herein each and every allegation in paragraphs 1 through 34 above.

36. The Argument in Favor of Proposition 34 contains false or misleading statements in violation of Elections Code § 9092 and Government Code § 88006, which require deletions and amendments to avoid misleading the voters.

37. The Argument in Favor of Proposition 34 contains the following false or misleading statement in a section under the heading "Stop Healthcare Corporation Financial Abuse in California":

> "However, healthcare corporations across the country have used a legal loophole to game the system and divert money from the drug discount program to pet projects that have done nothing to benefit patients: wasting money on renting out football stadiums to put on private concerts, ***giving their executives multimillion dollar salaries, paying for naming rights on sports stadiums,*** spending millions on lobbying and dumping millions more into political campaigns." (Emphasis added.)

38. The above statement is false and misleading because it contains multiple objectively verifiable factual inaccuracies. As detailed above, Proposition 34 targets a single California healthcare provider: AHF. AHF has never paid for the naming rights of a stadium. It also has never paid any of its executives multi-million dollar salaries. To be sure, the Argument in Favor of Proposition 34 does not hide that the purpose of the initiative is to target AHF. The very next paragraph after the one containing the false and misleading statement noted above discusses *Los Angeles Times* articles concerning low-income housing owned and operated by AHF. This section of the argument concludes by declaring, "Prop. 34 will prevent this abuse from occurring in California . . . ." The clear and false implication of the statement is that all of the aforementioned "abuses" were committed by AHF — Proposition 34's sole target.

39. Moreover, the Argument in Favor of Proposition 34 misleads voters by implying that the initiative will eliminate a wide range of abuses when it will only affect a single entity — AHF. Other healthcare entities — that do not own or operate certain categories of housing — could continue to pay its CEO millions or name a stadium.

40. The above statement must be amended, as reflected in ~~strikethrough~~ here:

> "However, healthcare corporations across the country have used a legal loophole to game the system and divert money from the drug discount program to pet projects that have done nothing to benefit patients: wasting money on renting out football stadiums to put on private concerts, ~~giving their executives multimillion dollar salaries, paying for naming rights on sports stadiums,~~ spending millions on lobbying and dumping millions more into political campaigns."

41. The Argument in Favor of Proposition 34 also contains the following false or misleading statement:

> "Over 30 years ago, the federal government began offering discounted prescription drugs and other treatments to uninsured and low-income patients."

42. As explained above, this statement is an objectively and demonstrably false and misleading description of the 340B program that Proposition 34 purports to address. The 340B program is not a program whereby drugs purchased by the federal government, using tax dollars, are offered for sale at a discount directly to individual low income and uninsured people. Proponents present this misrepresentation to falsely claim that covered entities like AHF are abusing the 340B program by taking the discount offered by the federal government to individuals for themselves, thus misusing tax dollars

and depriving poor and uninsured people of federal benefits.

43. Under the 340B program, the federal government does not purchase drugs. It does not offer drugs for sale at a discount. And the discount is not offered by the federal government to individuals, but by participating private drug makers to specific "covered entities."

44. Under the 340B program, the federal government does not sell the drugs — private drug makers do. The federal government does not offer the drugs at a discount — private drug makers do. The program is not mandatory — drug makers voluntarily participate in it. The drug discounts, given by participating drug makers, are not offered to individual patients — they are offered only to non-profit safety net healthcare providers ("covered entities" under the law).

45. This false statement misleads and confuses voters about a program at the heart of Proposition 34 and how it operates. Voters will have false impressions about the conduct and supposed harms the initiative seeks to regulate; the entities targeted for regulation; whether the stated penalties for noncompliance are proportionate and effective deterrence; and thus, ultimately, whether such regulation deserves voter support.

46. The above statement must be amended, as reflected in underline and ~~strikethrough~~ here:

> "Over 30 years ago, the federal government ~~began offering~~created a program through which certain non-profit healthcare providers could purchase discounted prescription drugs ~~and other treatments to uninsured and low-income patients~~from participating private drug makers."

47. Respondent Secretary of State SHIRLEY N. WEBER, Ph.D., and Real Party in Interest State Printer PAUL G. DIXON have a clear, present, and ministerial duty not to include any of the above statements in the Ballot Pamphlet. Unless ordered by this Court to delete or amend the false and misleading statements in the Argument in Favor of Proposition 34 as set forth above, Respondent WEBER and Real Party in Interest DIXON will violate their duties under the law and will print the Ballot Pamphlet containing the false and misleading statements as set forth above.

48. Issuance of the writ of mandate prayed for herein will not substantially interfere with the printing or distribution of the Ballot Pamphlet or with the conduct of the November 5, 2024 general election.

49. Petitioner TALUKDAR has a direct and beneficial interest in the action herein and brings

this action as a private attorney general pursuant to Code of Civil Procedure section 1021.5 in order to vindicate his interest and those of all the taxpayers and citizens of the State of California in the distribution of fair and accurate ballot arguments regarding Proposition 34 and in the proper implementation of the election laws.

SECOND CAUSE OF ACTION
(Rebuttal to Argument Against Proposition 34)

50. Petitioner incorporates as though fully set forth herein each and every allegation in paragraphs 1 through 49 above.

51. The Rebuttal to Argument Against Proposition 34 contains the following false or misleading statement:

> "Buy stadium naming rights: https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html
>
> And pay corporate CEOs millions: https://lowninstitute.org/projects/2023-shkreli-awards/"

52. The above statement is false and misleading for the same reasons noted above with respect to the Argument in Favor of Proposition 34. AHF has not paid for stadium naming rights, nor does it pay its executives millions. As with the Argument in Favor of Proposition 34, this argument clearly identifies AHF as the entity that engaged in supposed "abuses" of the 340B program, and includes URLs identifying AHF by name. The reference to stadium naming rights contains a URL identifying a non-California health care provider, misleadingly implying that this provider would be subject to regulation by Proposition 34. The reference to paying corporate CEOs millions does not even disclose who is identified, so any reader would have to manually type the URL to determine that it refers to Common Spirit, which does not meet the qualifications for regulation under Proposition 34 because they are targeted to only capture AHF. For the same reasons discussed in the First Cause of Action, this is a misleading list because of the narrow application of Proposition 34.

53. The above statement must be stricken entirely, as reflected in ~~strikethrough~~ here:

> "~~Buy stadium naming rights: https://www.nytimes.com/2022/09/24/health/bonsecours-mercy-health-profit-poor-neighborhood.html~~

~~And pay corporate CEOs millions: https://lowninstitute.org/projects/2023-shkreli-awards/~~"

54. Respondent Secretary of State SHIRLEY N. WEBER, Ph.D., and Real Party in Interest State Printer PAUL G. DIXON have a clear, present, and ministerial duty not to include any of the above statements in the Ballot Pamphlet. Unless ordered by this Court to delete or amend the false and misleading statements in the Rebuttal to Argument Against Proposition 34 as set forth above, Respondent WEBER and Real Party in Interest DIXON will violate their duties under the law and will print the Ballot Pamphlet containing the false and misleading statements as set forth above.

55. Issuance of the writ of mandate prayed for herein will not substantially interfere with the printing or distribution of the Ballot Pamphlet or with the conduct of the November 5, 2024 general election.

56. Petitioner TALUKDAR has a direct and beneficial interest in the action herein and brings this action as a private attorney general pursuant to Code of Civil Procedure section 1021.5 in order to vindicate his interest and those of all the taxpayers and citizens of the State of California in the distribution of fair and accurate ballot arguments regarding Proposition 34 and in the proper implementation of the election laws.

PRAYER FOR RELIEF

Wherefore, Petitioner prays for relief as follows:

1. On the First Cause of Action, that this Court issue its peremptory writ of mandate commanding Respondent Secretary of State SHIRLEY N. WEBER, Ph.D., and Real Party in Interest State Printer PAUL G. DIXON, and all of their agents, employees, and other persons acting in concert with them, to delete or amend the false, misleading, or inconsistent statements from Real Parties in Interest's proposed Argument in Favor of Proposition 34 as set forth above so that the Argument in Favor of Proposition 34 that appears in the Ballot Pamphlet for the November 5, 2024 general election contains only statements that are true, not misleading, and consistent with the requirements of the Elections Code and the Government Code.

2. On the Second Cause of Action, that this Court issue its peremptory writ of mandate commanding Respondent Secretary of State SHIRLEY N. WEBER, Ph.D., and Real Party in Interest State Printer PAUL G. DIXON, and all of their agents, employees, and other persons acting in concert

with them, to delete or amend the false, misleading, or inconsistent statements from Real Parties in Interest's proposed Rebuttal to Argument Against Proposition 34 as set forth above so that the Rebuttal to Argument Against Proposition 34 that appears in the Ballot Pamphlet for the November 5, 2024 general election contains only statements that are true, not misleading, and consistent with the requirements of the Elections Code and the Government Code.

3. That this Court grant Petitioner his costs of suit herein, including out-of-pocket expenses and reasonable attorneys' fees; and

4. That this Court grant Petitioner such other, different, or further relief as the Court deems just and proper.

Dated: August 5, 2024

Respectfully submitted,

STRUMWASSER & WOOCHER LLP

BY: _____

Beverly Grossman Palmer

Attorneys for Petitioner Ashoke Talukdar

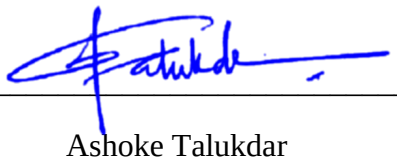
VERIFICATION

I, Ashoke Talukdar, declare:

I am the Petitioner in this action. I have read the foregoing Verified Petition for Peremptory Writ of Mandate and know the contents thereof to be true, except as to those matters that are stated on information and belief, and as to those matters, I believe them to be true.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 5th day of August, 2024 at Los Angeles, California.



Ashoke Talukdar

EXHIBIT A

ARGUMENT IN FAVOR OF PROPOSITION 34

Rising healthcare costs are squeezing millions of Californians. Prop. 34 will give California patients and taxpayers much needed relief, and lowers state drug costs, while saving California taxpayers billions.

CUT PRESCRIPTION DRUG PRICES

Prop. 34 will drastically cut the cost of prescription drugs for Medi-Cal patients by permanently authorizing the State of California to negotiate lower Medi-Cal prescription drug costs.

PROTECT PATIENTS AND TAXPAYERS

Prop. 34 stands to save taxpayers millions of dollars more every year by requiring the greediest healthcare corporations to spend at least 98% of the taxpayer funds they receive through the drug discount program in California on directly treating patients.

STOP HEALTHCARE CORPORATION FINANCIAL ABUSE IN CALIFORNIA

Prop. 34 stops egregious financial abuse of the taxpayer-funded drug discount program in California.

Over 30 years ago, the federal government began offering discounted prescription drugs and other treatments to uninsured and low-income patients. However, healthcare corporations across the country have used a legal loophole to game the system and divert money from the drug discount program to pet projects that have done nothing to benefit patients: wasting money on renting out football stadiums to put on private concerts, giving their executives multimillion

dollar salaries, paying for naming rights on sports stadiums, spending millions on lobbying and dumping millions more into political campaigns.

Worse yet, these same corporations that get billions in taxpayer dollars have spent hundreds of millions of dollars on housing projects that are often run like slums. An LA Times investigation found that residents at several of these housing projects were forced to live in squalid conditions, exposed to roach and bed bug infestations, putting the health and safety of tenants at risk.

Prop. 34 will prevent this abuse from occurring in California and requires drug discount program dollars generated in California to be used for their intended purpose: helping patients.

HOLD ABUSERS ACCOUNTABLE

Prop. 34 holds violators accountable. Healthcare organizations that break the rules and misuse these taxpayer dollars must either recommit to spending on direct patient care, or risk losing their California tax-exempt status and professional licenses.

Prop. 34 is targeted at those bad actors who have continually abused the system to pocket billions of taxpayer dollars for their own use. That's why it is supported by a wide coalition, including organizations that advocate to help patients, and leaders in the LGBTQ community. Those supporting Prop. 34 include the California Chronic Care Coalition, the ALS Association, the Defeating Epilepsy Foundation, California Senior Alliance, AiArthritis, Support Fibromyalgia Network, Lupus and Allied Diseases Association, Inc., and the Community Access National Network.

ARGUMENT IN FAVOR OF PROPOSITION 34

It's time to close the corporate loophole that allows wealthy pharmacy corporations to divert money meant to help patients. Protect Patients Now. Vote Yes on Prop. 34

Learn more at YesOnProp34.com

Assemblymember Evan Low

Former Chair, Legislative LGBT Caucus

Kelly Goss

Managing Director, The ALS Association

Nilza Serrano

Founder, Latino Heritage Los Angeles

EXHIBIT B

REBUTTAL TO ARGUMENT AGAINST PROPOSITION 34

(Rebuttal to the Argument Against Prop. 34; submitted by Supporters of Prop. 34)

When we have bad corporate actors that profit off public programs, the services our families rely upon take the hit, including schools, public safety, and emergency responders. The current system is being abused by corporations that are wasting billions of dollars intended for patient care every year and making our communities less safe, endangering the public's health and safety.

Instead of helping patients, those funds are being used to:

Finance slums that are unsafe and violate health codes: https://www.latimes.com/homeless-housing/story/2023-11-16/aids-healthcare-foundation-low-income-housing-landlords

Sue low-income tenants and throw them out on the street: https://www.poz.com/article/aids-healthcare-foundation-reportedly-houses-tenants-squalid-conditions

Buy stadium naming rights: https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html

And pay corporate CEOs millions: https://lowninstitute.org/projects/2023-shkreli-awards/

Prop. 34 would stop the worst corporate abuses of the federal low-cost prescription drug program, and ensure that money meant for patients is not wasted on corporations' pet projects,

political crusades, or misused in ways that risks the public's health and safety. Prop. 34 will ensure corporations that are misusing public funds are held accountable. It's time to stop the rip-off. We must make sure that money meant for patients is spent on taking care of those who need help, not risking public safety. Vote Yes on 34.

Brian K. Rice,
President, California Professional Firefighters

Stuart Wong
Chair, San Francisco Hep B Free

Rev. Dwight Williams
Chair, California Senior Alliance

EXHIBIT C

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https://www.hivplusmag.com/.../op-ed-10-worst-offenses...

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The Protect Patients Now Act will force the worst abusers of the drug discount program, like Weinstein's AHF, back to the program's original mission to provide healthcare to low-income patients.

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"Mr. Weinstein's vociferous opposition to PrEP has made him perhaps **the most hated man in the AIDS business."**

The New York Times
November 16, 2014

"I consider him a **menace to H.I.V. prevention,**" said Peter Staley, a veteran activist"

"James Loduca, the vice president for public affairs at the San Francisco AIDS Foundation, compared him to a **"climate-change denialist."**

#ProtectPatientsNow

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September 26 ·

How has Michael Weinstein been misusing our tax dollars? Let's shed light on the truth with non-profits like AHF. It's time to #ProtectPatientsNow! Learn more: http://protectcapatientsnow.com

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LGBTQ Community Calls for Removal of Michael Weinstein, Entire Board of AIDS Healthcare Foundation

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Why is Weinstein spending lavishly on political campaigns and putting disgraced politicians on his payroll? To fuel his political agenda instead of patient care. Support the #ProtectPatientsNow to put an end to the drug pricing scam by non-profits like AHF!

LATIMES.COM

Inside the financial ties between a controversial housing nonprofit and Kevin de León

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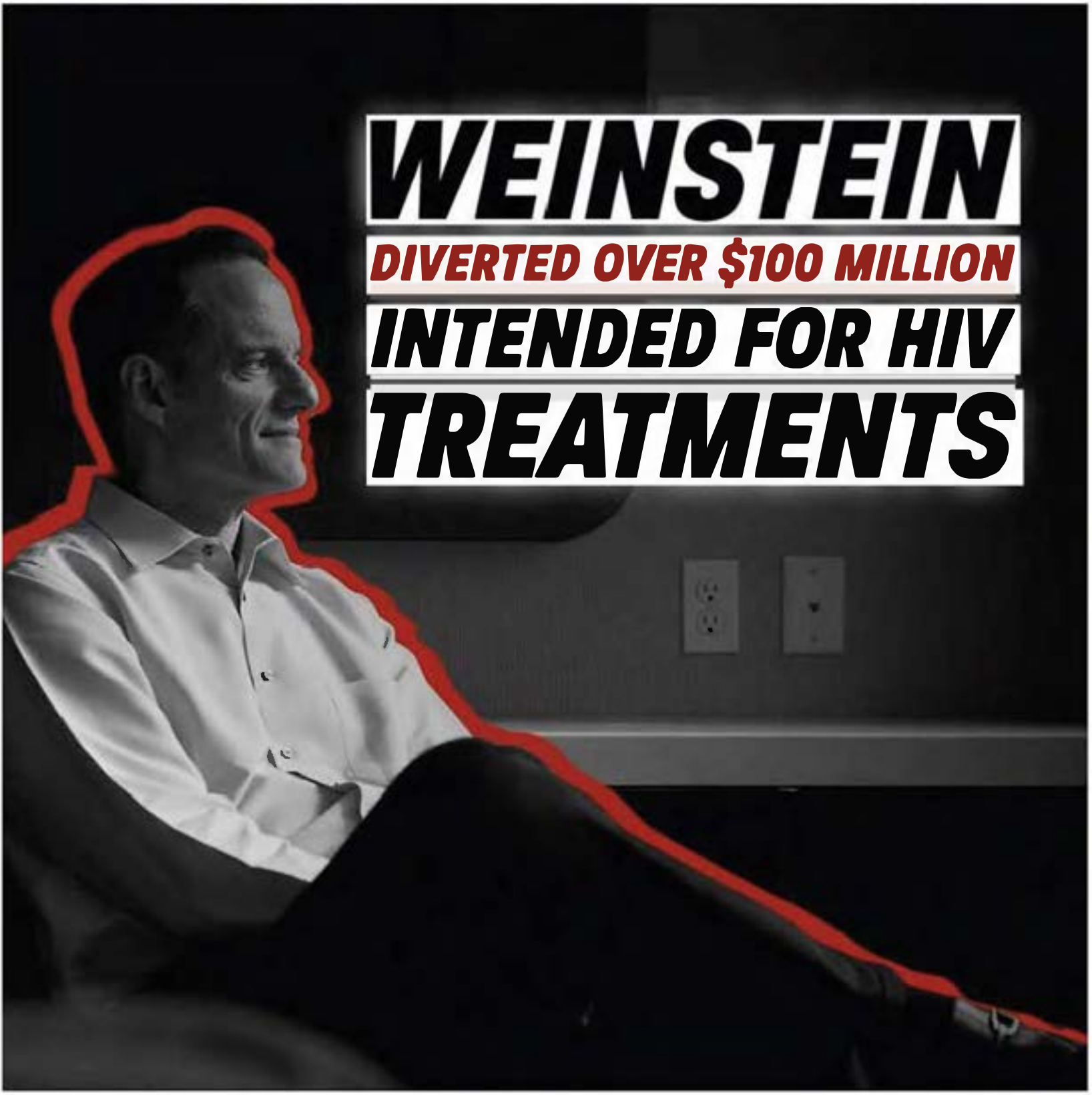

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Misusing taxpayer money meant for patients is not just unethical – it's immoral. Join #ProtectPatientsNow to stop the drug pricing scam.

Read more: https://www.politico.com/.../powerhouse-aids-organization...

POLITICO

Powerhouse AIDS organization faces scrutiny for use of federal money

Under the leadership of Weinstein, AHF has morphed over more than three decades into not only a massive health care enterprise but a controversial political player that has raised eyebrows with its unusual "social enterprise" model. | Joe Raedle/Getty Images

By CARLA MARINUCCI and VICTORIA COLLIVER

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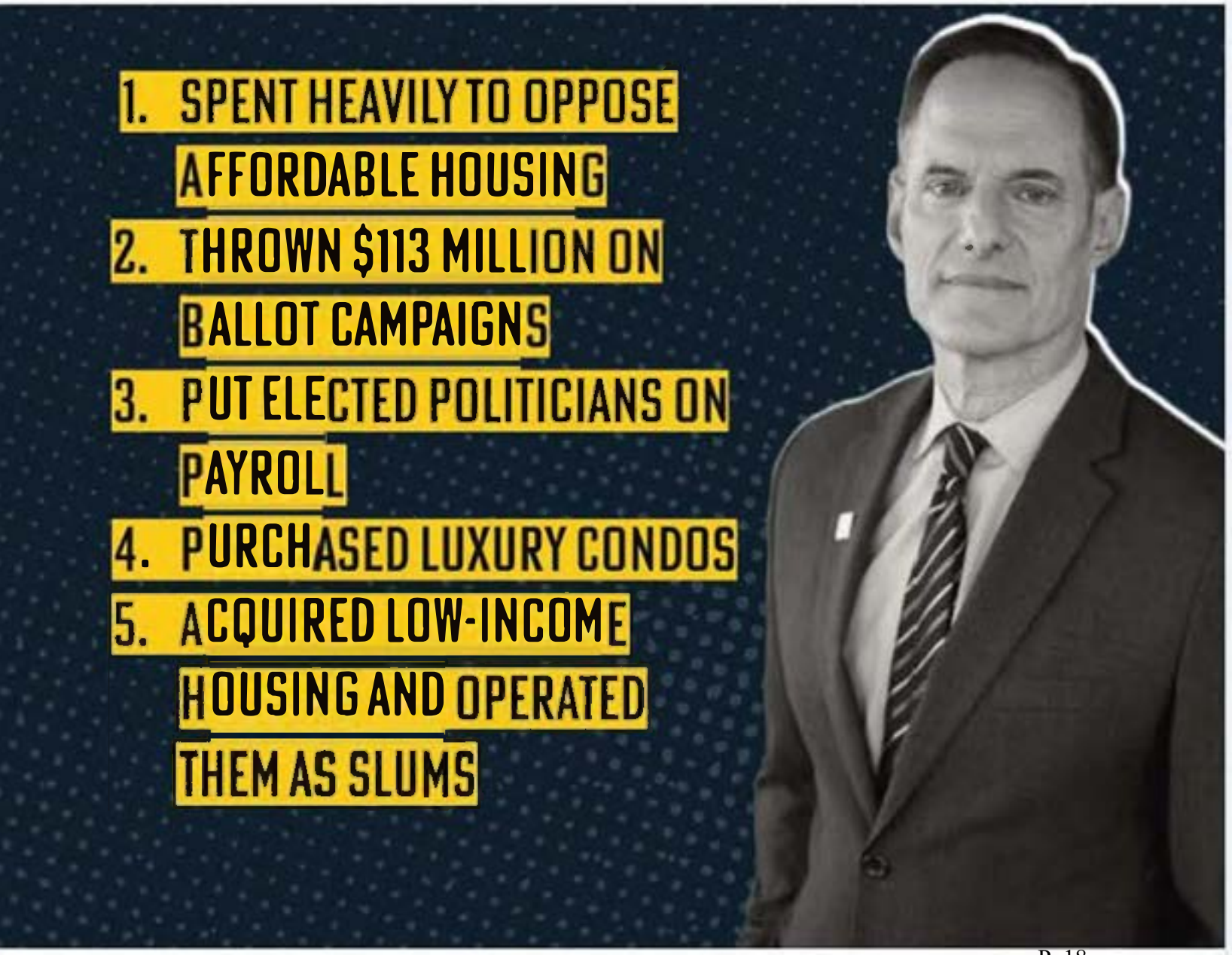

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ICYMI: The Protect Patients Now Act would stop the drug pricing scam and require non-profits like "AHF to spend 98 percent of its taxpayer-generated revenues on direct patient care. It also would seek to prevent the group from overcharging government agencies for prescription drugs." 👏👏👏

POLITICO.COM

California proposal would sideline a prolific ballot measure player

The ballot initiative would block one man from using his nonprofit to fund his political agen...

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Los Angeles Times

A powerful nonprofit owns apartments for poor tenants. Why are some tenants trapped in their rooms?

Kenneth Owens, 70, stands at the steps with his walker inside the Madison Hotel, which is owned by the AIDS Healthcare Foundation. Owens is one of 18 tenants who sued the foundation over a chronically broken elevator. (Francine Orr / Los Angeles Times)

BY LIAM DILLON, BENJAMIN ORESKES, DOUG SMITH

JAN. 20, 2023 5 AM PT

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The New York Times
November 16, 2014

"I consider him **a menace to H.I.V. prevention**," said Peter Staley, a veteran activist"

"James Loduca, the vice president for public affairs at the San Francisco AIDS Foundation, compared him to a "**climate-change denialist.**"

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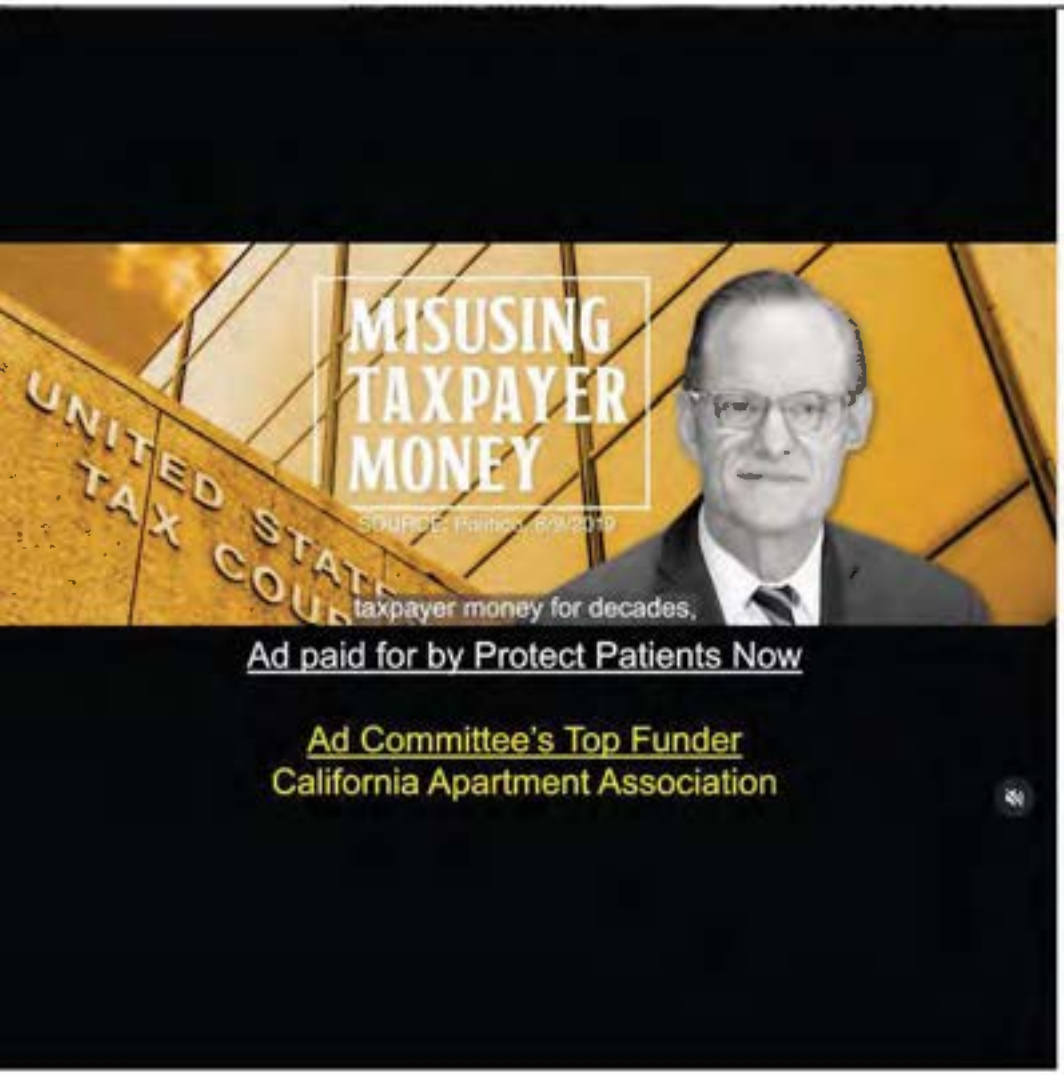

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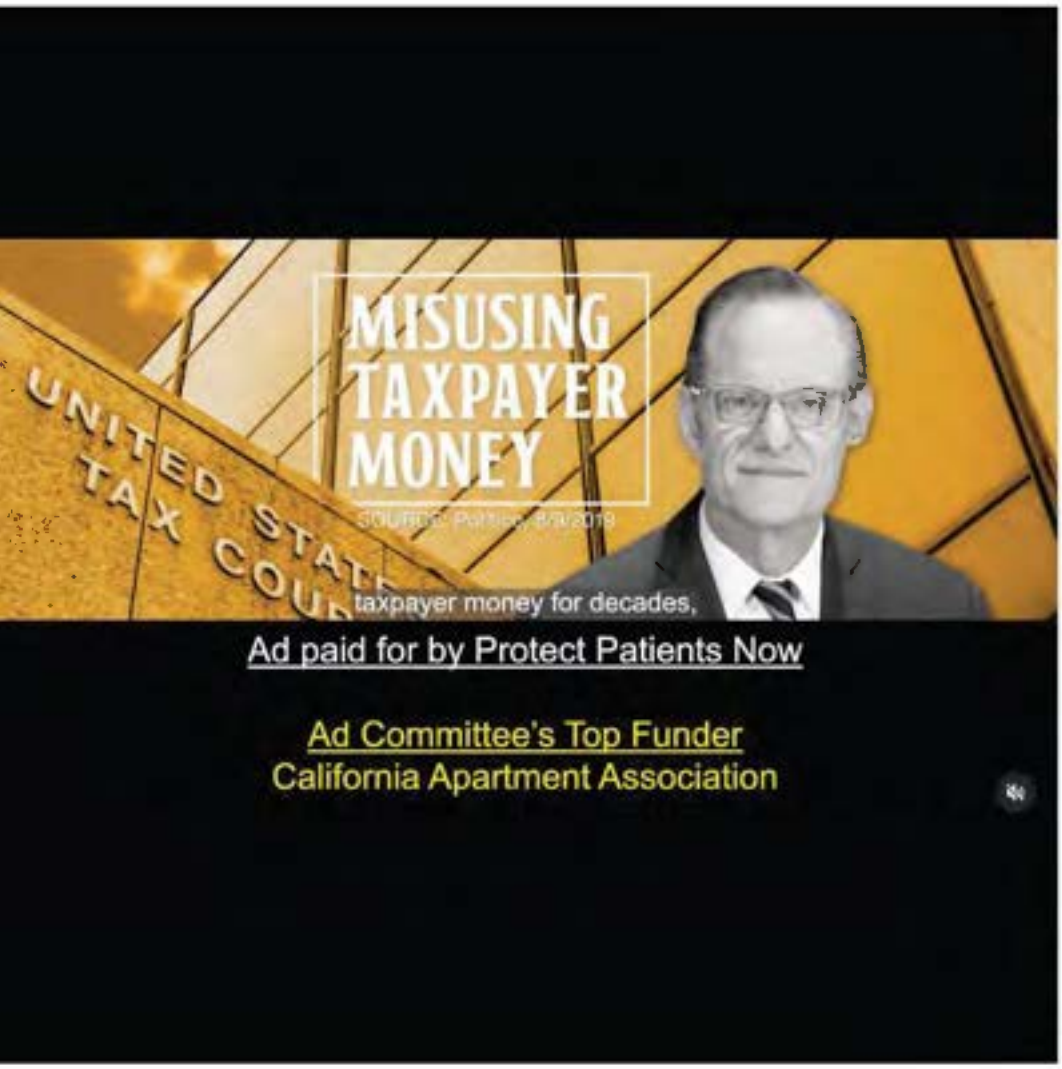

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LGBTQ Community Calls for Removal of Michael Weinstein, Entire Board of AIDS Healthcare Foundation

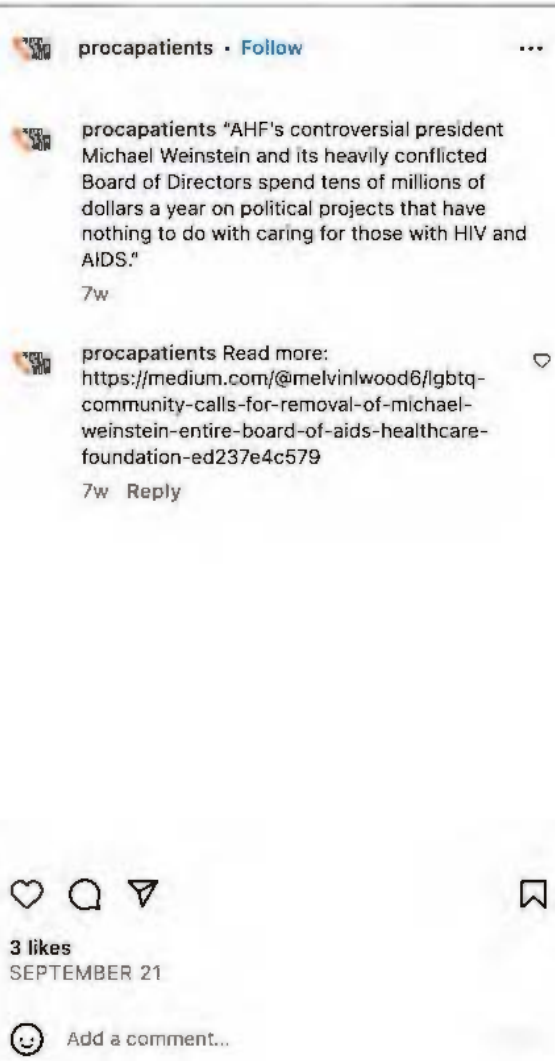
*Change.org Petition Launched As AHF Faces Multiple Investigations, Lawsuits, Conflicts of Interest

Melvin Wood · Follow
3 min read · Aug 3, 2020

Sixth in a series

Facing multiple regulatory investigations, litigation and conflicts of interest, the AIDS Healthcare Foundation is in desperate need of new leadership.

That's why the LGBTQ community is backing a change.org petition calling for AHF President Michael Weinstein and the entire Board of Directors of AHF to be replaced. You can sign the petition here.



Los Angeles Times

HOUSING & HOMELESSNESS

Inside the financial ties between a controversial housing nonprofit and Kevin de León

Los Angeles City Councilmember Kevin de León speaks at a groundbreaking ceremony on skid row in January 2022 for an affordable housing project developed by the AIDS Healthcare Foundation. (Michael Owen Baker / For The Times)

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Powerhouse AIDS organization faces scrutiny for use of federal money

Under the leadership of Weinstein, AHF has morphed over more than three decades into not only a massive health care enterprise but a controversial political player that has raised eyebrows with its unusual "social enterprise" model. | Joe Raedle/Getty Images

By CARLA MARINUCCI and VICTORIA COLLIVER

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Los Angeles Times

CALIFORNIA

California to end AIDS Healthcare contract, alleging improper negotiation tactics

Michael Weinstein, founder and president of the AIDS Healthcare Foundation, in 2016. (Barbara Davidson / Los Angeles Times)

BY MELODY GUTIERREZ | STAFF WRITER

JUNE 30, 2022 UPDATED 5:30 PM PT

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https://www.latimes.com/california/story/2022-06-30/california-aids-healthcare-foundation-state-contract

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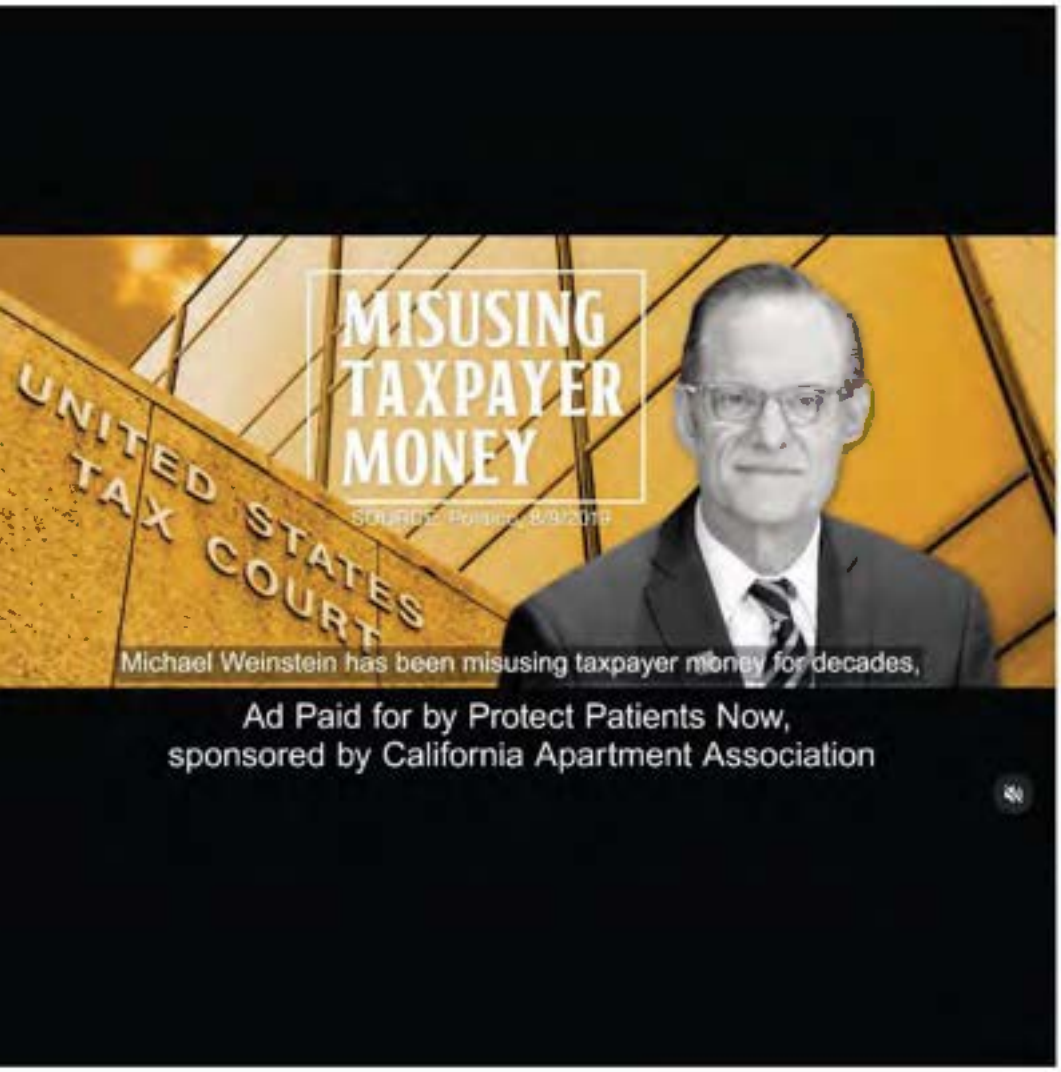

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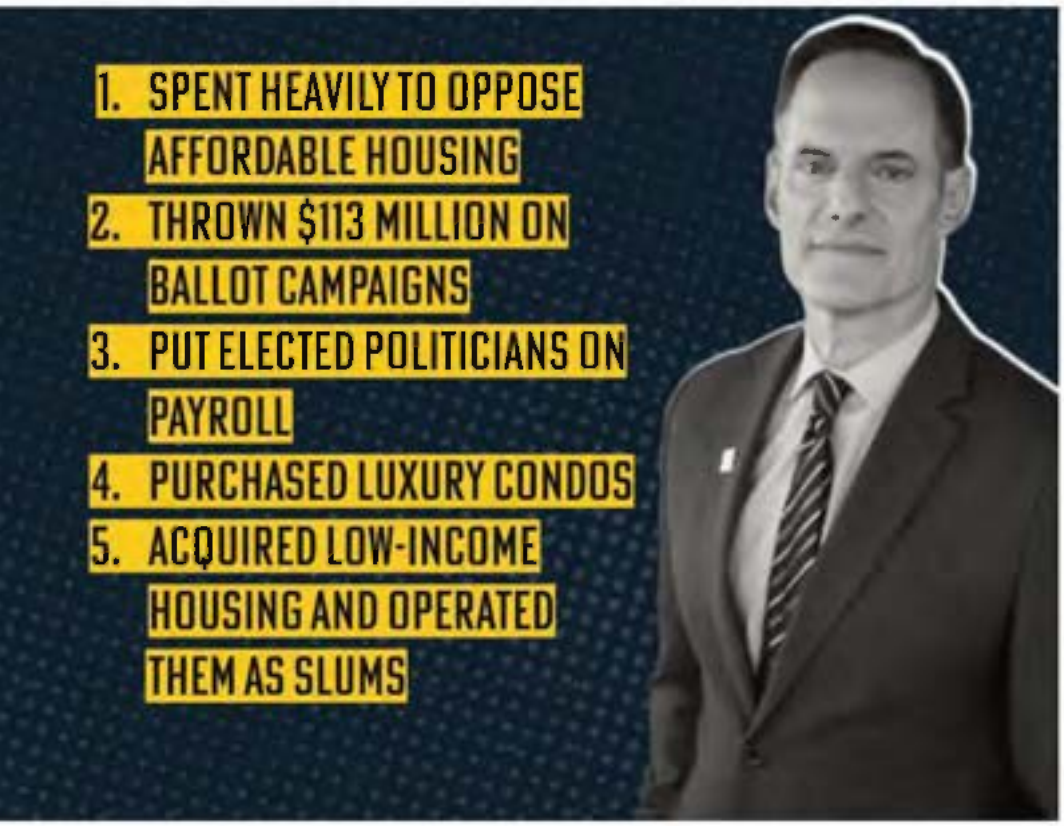

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hivplusmag.com/opinion/2015/0...

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nytimes.com/2014/11/17/ups...

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POLITICO

Powerhouse AIDS organization faces scrutiny for use of federal money

Under the leadership of Weinstein, AHF has morphed over more than three decades into not only a massive health care enterprise but a controversial political player that has raised eyebrows with its unusual "social enterprise" model. | Joe Raedle/Getty Images

By CARLA MARINUCCI and VICTORIA COLLIVER

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How has Michael Weinstein misused our tax dollars?

1. Spent heavily to oppose affordable housing
2. Thrown $113 million on ballot campaigns
3. Put elected politicians on payroll
4. Purchased luxury condos
5. Acquired low-income housing and operated them as slums

12:35 PM · Sep 5, 2023 · **160** Views

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"It's common sense: tax dollars meant for patients should be spent on patients. Next November, Californians can pass the Protect Patients Now Act to stop Weinstein's scam and prevent others from following in his footsteps." Asm @Evan_Low

Learn more 👉 protectcapatientsnow.com

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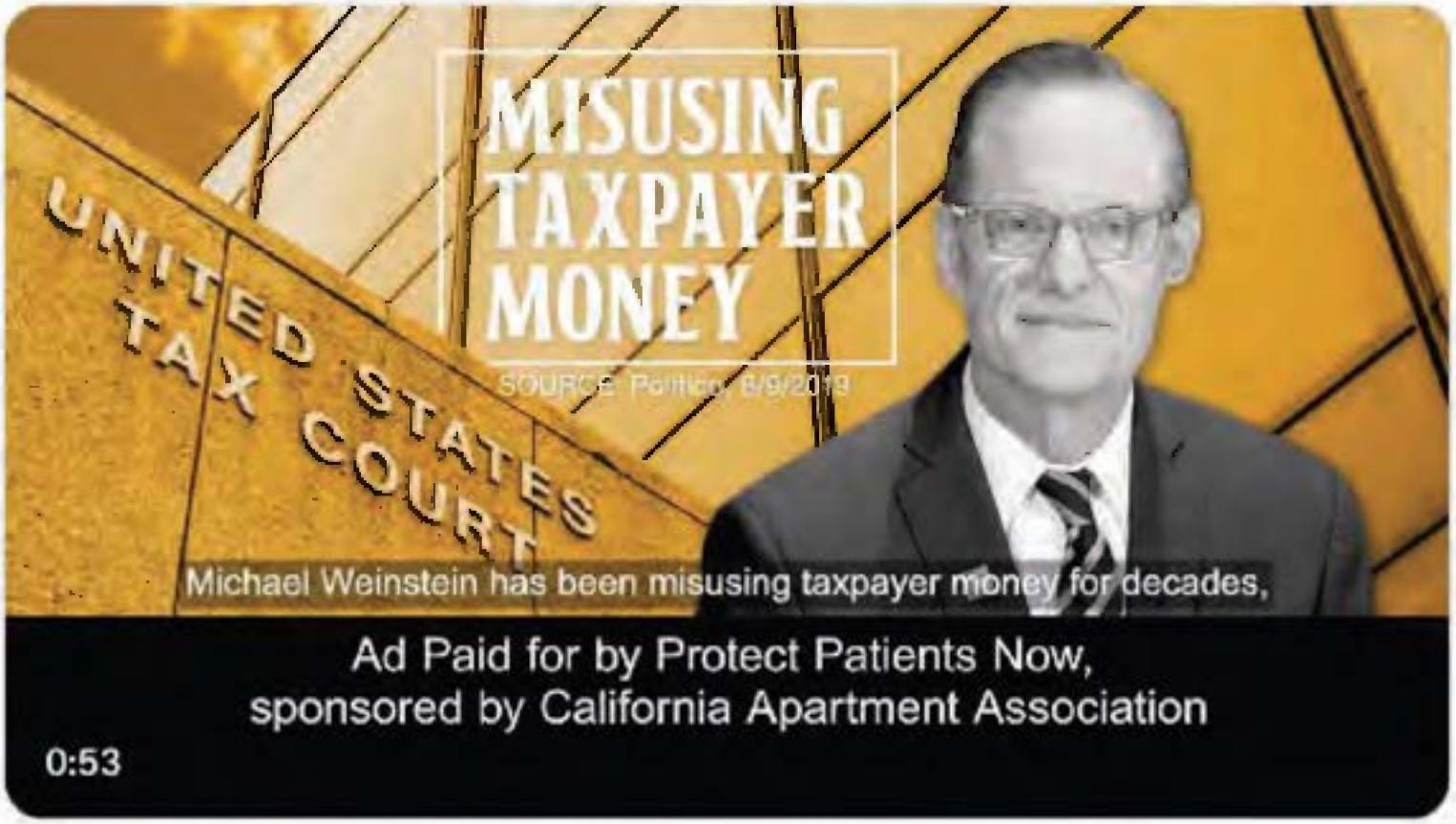

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STOP THE DRUG PRICING SCAMS

Pass the Protect Patients Now Act to Help Patients and Protect Our Tax Dollars

EXPOSING THE WORST DRUG PRICING SCAMS

Almost 30 years ago, lawmakers designed a federal drug discount program that aimed to help health care nonprofits treat more low-income patients. The program allows these nonprofits to buy prescription drugs at a steep discount and then be reimbursed by health plans at a much higher price. Under existing law, these nonprofits are supposed to use this taxpayer-generated excess revenue to offer more health care benefits and serve more patients.

But some organizations such as AHF, led by safety net scammer Michael Weinstein, have abused the program, amassing hundreds of millions meant to help patients and instead spent it to further his own personal and political agenda.

Under Weinstein's direction, AHF has used these taxpayer funds to purchase luxury condominiums, fund ballot measure campaigns to block housing construction, put an elected politician on its payroll, and acquire low-income multi-tenant housing complexes and operate them as slums.

These types of blatant abuse of taxpayer money violates the intent of the law, but because of loopholes in the drug discount program, bad actors can abuse their non-profit status to waste millions of dollars and avoid accountability.

And even in the face of widespread criticism from patients and health experts, Weinstein arrogantly says he will continue spending these taxpayer dollars inappropriately for as long as he is allowed to do so.

Californians can stop the worst drug pricing scams and close this loophole in the drug discount program.

PASS THE PATIENT PROTECTION NOW ACT TO PROTECT OUR CARE

The Protect Patients Now Act will force the worst abusers of the drug discount program like Weinstein's AHF back to the program's original mission to provide healthcare to low-income patients. This measure focuses only on the program's worst offenders, putting in place new accountability measures to ensure they are appropriately using taxpayer dollars.

The Act requires the program's worst offenders like Weinstein to spend 98% of their taxpayer-generated revenues on direct patient care.

So long as these worst offenders meet these requirements, they can continue their health care operations.

But if these offenders continue to misuse taxpayer funds, the Protect Patients Now Act requires the state to take away their non-profit status and make them ineligible to keep getting paid using taxpayer dollars.

Stop the scams and vote yes on the Patient Protection Act.

Rather than helping patients, the worst offenders have amassed hundreds of millions of dollars to further their own political and personal interests.

HOW HAVE YOUR TAX DOLLARS BEEN MISUSED?

For example, here are just some of the ways one of the worst drug price manipulators misspent money meant to help patients:

Opposing affordable housing

Under **Weinstein** leadership, AHF has spent heavily to oppose affordable housing, including funding a local ballot measure that would have blocked construction of housing so **Weinstein** could preserve the view from his office. **Weinstein** sued the state in hopes of blocking laws that promote affordable housing. Leaders of the NAACP and housing advocates have strongly condemned **Weinstein**'s tactics that harm communities of color.

Stopping housing construction

Under **Weinstein**, AHF has spent $113 million on ballot measure campaigns to stop housing construction, to repeal state laws that make it easier to build housing, to put price controls on all residential rental properties and other

initiatives. Although voters have repeatedly rejected **Weinstein**'s initiatives, **Weinstein** recently vowed he will continue to dump millions every year on these campaigns. "We'll do it again if we have to – and again and again and again," he told reporters in 2023.

Receiving "Slumlord" violations

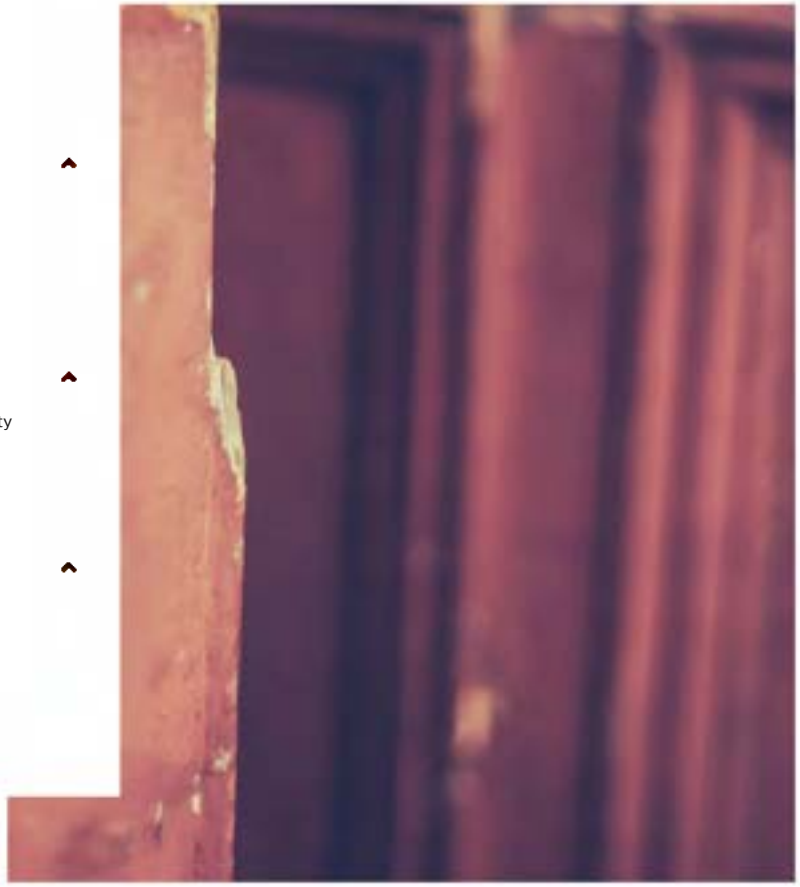
According to Los Angeles Times reporting, tenants have described **Weinstein**'s AHF as a multi-billion dollar "slumlord," and under his leadership, his organization has amassed hundreds of serious health and safety citations for failing to provide adequate housing for their low-income tenants.

Supporting disgraced Councilman

A recent Los Angeles Times report showed that AHF paid disgraced L.A. City Councilmember-elect Kevin de León more than $100,000 as a consultant without public disclosure. During this time, de León met with city officials advocating on behalf of the AHF without divulging his employment status.

Purchasing luxury condos

Weinstein's AHF has used taxpayer money to purchase luxury condominiums and townhomes in California and Florida. When AHF bought their luxury Hollywood condominium in 2007, the listing described the 2 bedroom unit as "an entertainer's dream" while Redfin currently estimated the unit's value at $1 million dollars. Between 2018 and 2022, AHF also purchased and then sold at a profit 10 luxury townhomes in South Florida.



Sept. 1, 2023 Annoucement

CAA takes dual approach to fight Weinstein's crusade for radical rent control

September 1, 2023

Mike Nemeth
CAA Marketing and Communications Director

The California Apartment Association is ramping up its campaign to fight another anti-housing rent control measure headed for the statewide ballot.

The measure, bankrolled by the AHF and its president, Michael Weinstein, recently qualified for the Nov. 5, 2024, general election ballot and seeks to repeal the Costa-Hawkins Rental Housing Act of 1995, California's most important rental housing protection law.

In response, CAA has reactivated Californians for Responsible Housing, the same campaign committee that successfully defeated Weinstein's previous two radical rent control measures, Propositions 10 and 21. To support the committee, CAA has hired a cadre of seasoned pollsters, campaign consultants, legal advisors, and media relations specialists.

Concurrently, CAA is sponsoring a separate ballot measure aimed at preventing Weinstein from misusing taxpayer dollars on future rent control campaigns or other political ventures unrelated to the core mission of the AHF. It would mark a substantial shift for Weinstein, who's funneled upward of $100 million to political ventures in recent years, reports Politico. He's also vowed to continue bankrolling statewide rent control measures until one passes.

By repealing Costa-Hawkins, Weinstein's so-called "Justice for Renters Act" not only would empower cities and counties to impose strict rent control on all apartments and single-family homes, but it would abolish the state's existing ban on vacancy control. Vacancy control prohibits rental housing providers from adjusting rents to market rates when a tenant moves out. Such a policy

leads to property deterioration and stifled investment in housing.

CAA's statewide initiative, the Protect Patients Now Act, would impose safeguards to prevent the AHF from misspending taxpayer dollars that should be spent on patient healthcare. The Protect Patient Now Act provides that, should the law be violated, the offending organizations could face severe repercussions, including potential investigations and loss of federal funding.

CAA's dual campaigns aim to defeat both Weinstein's current rent control measure and prevent him from misusing taxpayer dollars to fund rent control campaigns in the future.

In the coming weeks, CAA will provide details on how rental housing providers can help defeat Weinstein's latest attack on housing and support CAA's Protect Patients Now Act.

Topics

Costa-Hawkins Act

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EXHIBIT D

TEXT OF PROPOSITION 34

SUBJECT TO COURT ORDERED CHANGES

This initiative measure is submitted to the people in accordance with the provisions of Section 8 of Article II of the California Constitution.

This initiative measure adds sections to the Welfare and Institutions Code; therefore, new provisions proposed to be added are printed in *italic type* to indicate that they are new.

PROPOSED LAW

SUBJECT TO COURT
ORDERED CHANGES

[No bold text.]
[Printer: unless directed otherwise, all text should be in ital.]

SECTION 1. ***Article 3.3 (commencing with Section 14124.39) is added to Chapter 7 of Part 3 of Division 9 of the Welfare and Institutions Code, to read:*** — Roman

~~ARTICLE~~ 3.3. Protect Patients Now Act of 2024

Section 14124.39. Title.

This article shall be known and may be cited as the Protect Patients Now Act of 2024.

Section 14124.40. Findings and declarations.

(a) In 1992, the federal government established a program giving safety net health care providers access to discounted prescription drugs. The intent of the law was for safety net health care providers to use the discounted drugs to treat patients who are "medically uninsured, on marginal incomes and have no other sources to turn to for preventive and primary care services" and to "reach[] more eligible patients and provide[] more comprehensive services" to "low-income and most vulnerable patients." (H.R. Rep. No. 102-384 (Part 2), at 12 (1992)(Conf. Rep.).) The program was NOT intended to be used by safety net health care providers to accumulate massive fortunes running into the hundreds of millions of dollars or more. — not

(b) Unfortunately, some safety net health care providers have manipulated the program to receive enormous markups on the discounted prescription drugs they receive and then stick taxpayers with the added cost. Instead of using this massive windfall to help patients, the worst offenders have used their fortunes to purchase luxury coastal condominiums, wasted hundreds of millions of dollars on failed political campaigns, put elected politicians on their payrolls, and acquired low-income multifamily housing complexes that are operated as slums. Abusing net revenues generated through the discount prescription drug program in this manner does not result in better health care for low-income patients. Instead, it cheats low-income patients out of the care they deserve and scams taxpayers who end up footing the bill.

(c) Governor Newsom has already ended this type of prescription drug scamming in the Medi-Cal program through Executive Order N-01-19, which requires the Department of Health Care Services to transition Medi-Cal pharmacy services away from arrangements that are susceptible to price scams. Known as the Medi-Cal Rx program, it achieves cost-savings for prescription drug purchases made by the State, standardizes the pharmacy benefit statewide for — Cost savings

all Medi-Cal patients, increases overall access, and eliminates the ability of prescription drug price manipulators to game the system through Medi-Cal. However, other vulnerabilities in taxpayer-funded drug programs that price manipulators still exploit have not yet been addressed.

(d) California needs to make the cost-savings achieved through the Medi-Cal Rx program permanent. Furthermore, additional reforms are necessary to protect taxpayer dollars and help the neediest patients by ensuring that prescription drug price manipulators are required to end other scams in order to continue operating in our State.

Section 14124.41. Statement of intent.

In enacting this article, the purpose and intent of the People of the State of California is to do all of the following:

(a) To permanently authorize the Medi-Cal Rx program so that its expanded patient access and cost-savings can be continued in perpetuity.

(b) To protect patients and taxpayers by putting an end to other prescription drug pricing scams that are still being perpetrated in our State through the discount prescription drug program.

(c) To impose strict accountability on prescription drug price manipulators by requiring them to spend at least ninety-eight percent (98%) of their net revenues generated in this State through the discount prescription drug program on direct patient care.

(d) To ensure that health care providers that have a track record of scamming the discount prescription drug program refocus on providing direct patient care or lose their state-provided privileges and benefits, including suspension and revocation of licenses, loss of state and local grant funding, and elimination of California tax-exempt status.

Section 14124.42. Permanent authorization for the Medi-Cal Rx program.

The Department of Health Care Services is authorized to provide and administer Medi-Cal pharmacy services under a single statewide fee-for-service delivery system.

SUBJECT TO COURT
ORDERED CHANGES

Section 14124.43. Limitation on pharmacy sales agreements involving prescription drug price manipulators.

(a) On and after January 1, 2025, a prescription drug price manipulator shall not enter into, or participate in, a pharmacy sales agreement that applies to, operates in, or intends or proposes to operate in or apply to, this State unless the prescription drug price manipulator is in compliance with Section 14124.44.

(b) Any pharmacy sales agreement which involves a prescription drug price manipulator not in compliance with Section 14124.44 is, as of January 1, 2025, contrary to public policy and is void and unenforceable to the extent that the pharmacy sales agreement applies to, operates in, or intends or proposes to operate in or apply to, this State.

Section 14124.44. Patient protection requirements imposed on prescription drug price manipulators.

Notwithstanding any other provision of law, on and after January 1, 2025, a prescription drug price manipulator shall only be eligible for tax-exempt status in this State or to be licensed to operate as a pharmacy, a health care service plan, or a clinic in this State if it complies with all of the following requirements:

(a) In the prior calendar year, the prescription drug price manipulator spent at least ninety-eight percent (98%) of the net revenues it generated in California from participation in the discount prescription drug program on direct patient care.

(b) In the prior calendar year, the prescription drug price manipulator was not engaged in any unprofessional conduct, dishonest dealing, or conduct inimical to the public health, welfare, or safety of the People of the State of California.

Section 14124.45. Oversight of prescription drug price manipulators.

(a)(1) In order to determine compliance with Section 14124.44, on and after January 1, 2025:

(A) A prescription drug price manipulator that holds tax-exempt status in this State shall annually submit to the Attorney General a detailed accounting for the prior calendar year of both its California statewide and nationwide gross and net revenues generated from participation in the discount prescription drug program as well as how those net revenues were spent.

SUBJECT TO COURT ORDERED CHANGES

(B) A prescription drug price manipulator that holds a pharmacy license in this State shall annually submit to the Board of Pharmacy a detailed accounting for the prior calendar year of both its California statewide and nationwide gross and net revenues generated from participation in the discount prescription drug program as well as how those net revenues were spent.

(C) A prescription drug price manipulator that holds a health care service plan license in this State shall annually submit to the Department of Managed Health Care a detailed accounting for the prior calendar year of both its California statewide and nationwide gross and net revenues generated from participation in the discount prescription drug program as well as how those net revenues were spent.

(D) A prescription drug price manipulator that holds a clinic license in this State shall annually submit to the Department of Public Health a detailed accounting for the prior calendar year of both its California statewide and nationwide gross and net revenues generated from participation in the discount prescription drug program as well as how those net revenues were spent.

(2) The People of California hereby find and declare that, similar to the need for out-of-state information under Chapter 17 of Part 11 of Division 2 of the Revenue and Taxation Code, it is necessary for prescription drug price manipulators to provide information on both California statewide and nationwide gross and net revenues in order to ensure proper allocation of in-state and out-of-state revenues.

(b) In addition to any other authority granted by this article, the Attorney General, the Board of Pharmacy, the Department of Managed Health Care, or the Department of Public Health may do either of the following:

(1) Standardize the necessary contents of the detailed accounting(s) required to be submitted pursuant to this section.

(2) Request from a prescription drug price manipulator any other information deemed necessary or convenient to determine compliance with the requirements set forth in Section 14124.44.

(c) All information submitted pursuant to this section shall be submitted under penalty of perjury.

(d)(1) All financial information submitted to the Attorney General, Board of Pharmacy, Department of Managed Health Care, or Department of Public Health pertaining to either of the

following shall be treated as confidential and sensitive business information exempt from public disclosure:

(A) Specific prices or amounts paid by, or charged to, a prescription drug price manipulator for specific prescription drugs acquired by the prescription drug price manipulator through the discount prescription drug program.

(B) Specific prices or amounts charged by, or paid to, a prescription drug price manipulator for specific prescription drugs it obtained through the discount prescription drug program.

(2)(A) Total aggregated gross and net revenues generated by a prescription drug price manipulator through the discount prescription drug program are not covered by this subdivision so long as the figures do not reveal the specific information described in subparagraphs (A) or (B) of paragraph (1).

(B) After removing or anonymizing the specific information described in subparagraphs (A) and (B) of paragraph (1), the Attorney General, Board of Pharmacy, Department of Managed Health Care, and Department of Public Health shall make total aggregated statewide and nationwide gross and net revenues figures publicly available upon request.

(e)(1) The Attorney General, Board of Pharmacy, Department of Managed Health Care, and Department of Public Health shall cooperatively establish the deadline each year for a prescription drug price manipulator to submit the information required by this section.

(2) For calendar year 2025, the deadline shall not be later than December 31, 2025.

(3) A prescription drug price manipulator that fails to submit required information by the deadline established pursuant to this subdivision shall be deemed to be out of compliance with the requirements of Section 14124.44 for the applicable calendar year, according to the procedures set forth in subdivision (b) of Section 14124.46.

(f) The Attorney General, Board of Pharmacy, Department of Managed Health Care, and Department of Public Health may each impose a fee on a prescription drug price manipulator for the costs associated with concluding whether the prescription drug price manipulator was in compliance with the requirements of Section 14124.44 during the prior calendar year. The charges shall not exceed the reasonable regulatory costs to the respective agency incident to performing the investigations, inspections, and audits required by this article, including any administrative enforcement and adjudication thereof.

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(g)(1) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the Attorney General, Board of Pharmacy, Department of Managed Health Care, and Department of Public Health may implement this article by means of bulletins, notices, or other similar instructions, without taking further regulatory action.

(2) Actions taken pursuant to an interagency agreement entered into pursuant to subdivision (c) of section 14124.46 shall be covered by paragraph (1).

Section 14124.46. Conclusions regarding compliance.

(a)(1) Within 60 calendar days of the deadline established pursuant to subdivision (e) of Section 14124.45, the Attorney General, Board of Pharmacy, Department of Managed Health Care, and Department of Public Health shall each separately issue an independent written conclusion regarding whether or not the prescription drug price manipulator is in compliance with the requirements of Section 14124.44. Failure to reach a conclusion within 60 calendar days shall not excuse noncompliance with Section 14124.44.

(2) The Attorney General, Board of Pharmacy, Department of Managed Health Care, or Department of Public Health shall only be required to issue an independent written conclusion pursuant to this subdivision if the prescription drug price manipulator was required to submit information to the relevant official, board, or department pursuant to subdivision (a) of Section 14124.45.

(b)(1) If, within the 60-calendar day period set forth in paragraph (1) of subdivision (a), the information submitted by a prescription drug price manipulator is found to be incomplete or insufficient by the Attorney General, Board of Pharmacy, Department of Managed Health Care, or Department of Public Health for issuance of a written conclusion required by this section, then the relevant official, board, or department shall issue to the prescription drug price manipulator a written notice to correct. The notice to correct shall contain a description of the additional information required.

(2) The prescription drug price manipulator shall have 10 calendar days from the date of the notice to correct to provide complete and/or sufficient information. If the prescription drug price manipulator fails to remedy the incompleteness and/or insufficiency within 10 calendar days, then the prescription drug price manipulator shall be deemed to be out of compliance with

the requirements of Section 14124.44 for the applicable calendar year and the relevant official, board, or department shall issue a written conclusion to that effect immediately upon the expiration of the 10-calendar day period.

(c) The Attorney General, Board of Pharmacy, Department of Managed Health Care, or Department of Public Health may, either collectively or separately, enter into an inter-agency agreement with the California State Auditor's Office for assistance in reaching a conclusion about a prescription drug price manipulator's compliance with the requirements of Section 14124.44. Costs incurred pursuant to an inter-agency agreement under this subdivision may be recovered pursuant to subdivision (f) of Section 14124.45.

(d)(1) If the Attorney General, Board of Pharmacy, Department of Managed Health Care, or Department of Public Health concludes a prescription drug price manipulator is not in compliance with the requirements of Section 14124.44, then a written notice of noncompliance shall be provided to the prescription drug price manipulator notifying it of that conclusion. The written notice of noncompliance shall provide instructions on requesting a hearing pursuant to subdivision (e).

(2) If a hearing is not requested pursuant to subdivision (e), then a conclusion issued pursuant to this section shall become a final determination.

(e)(1)(A) A prescription drug price manipulator may request a hearing in response to a written notice of noncompliance issued pursuant to paragraph (1) of subdivision (d).

(B) The request shall be submitted in writing and must made be within 30 calendar days of the date of the written notice of noncompliance.

(2)(A) Except as otherwise provided in this article, hearings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(B) The Attorney General, Board of Pharmacy, Department of Managed Health Care, and Department of Public Health may consolidate hearings on written notices of noncompliance pertaining to the same prescription drug price manipulator for the same calendar year and may mutually appoint a single hearing officer therefor. The hearing may be conducted by a hearing officer appointed by an official, board, or department that issued a written notice of noncompliance.

SUBJECT TO COURT ORDERED CHANGES

(C) The prescription drug price manipulator may, but need not, be represented by counsel at any of the stages of the proceedings.

(3)(A) If judicial review is not sought pursuant to subdivision (f), then the decision of the hearing officer shall become a final determination.

(B) If the hearing officer's decision is that the prescription drug price manipulator is not in compliance with the requirements of Section 14124.44, then any exemption from California state taxation and any licenses described in subdivision (a) of Section 14124.45 held by the prescription drug price manipulator shall be immediately suspended. If judicial review is thereafter sought pursuant to subdivision (f), the state tax exemption and license(s) shall remain suspended pending judicial review pursuant to subdivision (f).

(f)(1) Any party aggrieved by the decision of the hearing officer may seek review pursuant to Section 1094.5 of the Code of Civil Procedure within 30 calendar days of issuance of the hearing officer's decision.

(2) If review is sought pursuant to Section 1094.5 of the Code of Civil Procedure, the final determination shall be based upon the outcome of that review.

Section 14124.47. Final determinations.

Notwithstanding any other provision of law, if a prescription drug price manipulator is finally determined pursuant to the procedures set forth in this article to have violated the requirements of Section 14124.44, then all of the following shall apply:

(a) Any and all California pharmacy licenses, health care service plan licenses, or clinic licenses held by the prescription drug price manipulator shall be permanently revoked.

(b) The prescription drug price manipulator shall be prohibited from applying for, or obtaining or possessing, a California pharmacy license, health care service plan license, or clinic license for a period of 10 years.

(c) Any person serving as an owner, chief executive officer, chief financial officer, chief administrative officer, chief operating officer, president, or any other similar position exercising significant influence or control over the prescription drug price manipulator at the time the violation of Section 14124.44 occurred shall be prohibited from serving as an owner, officer, director, or employee of a California licensed pharmacy, health care service plan, or clinic for a period of 10 years.

SUBJECT TO COURT ORDERED CHANGES

(d) The prescription drug price manipulator shall lose, and no longer be eligible for, tax-exempt status in the State of California, including under Chapter 4 (commencing with Section 23701) of Part 11 of Division 2 of the Revenue and Taxation Code, and shall instead be subject to the Revenue and Taxation Code and other state laws as a taxable organization. The prescription drug price manipulator shall be prohibited from reapplying for, or again being granted, tax-exempt status in this State for a period of 10 years.

(e) The prescription drug price manipulator shall be ineligible to receive any new or renewed California state or local grants or contracts for a period of 10 years.

Section 14124.48. Definitions.

For purposes of this article, as used in both the singular and plural form, the following definitions shall apply:

(a) "Clinic" means an entity operating as one or more of the clinics described in Section 1204 of the Health and Safety Code.

(b) "Direct patient care" means the provision of medical services, dental services, pharmaceutical services, or behavioral health services directly administered to individual patients being treated for, or suspected of having, medical or behavioral health conditions. Direct patient care includes preventive care that is directly administered to patients. Further, in order to qualify as "direct patient care," the services must be health care services that are regularly provided by other health care providers in the community or nonprofit community-based organizations that are also receiving reimbursements or payments from the Medi-Cal, Medicaid, or Medicare programs.

(c) "Discount prescription drug program" means the program established by the Veterans Health Care Act of 1992, P.L. 102-585 § 602, within section 340B of the Public Health Service Act (§ 340B; 42 U.S.C § 256b) that is administered by the Office of Pharmacy Affairs in the Health Resources and Services Administration within the United States Department of Health and Human Services.

Sec. = Section 602 of

(d) "Enforcement agency" means any department of a state, county, or city agency within California that has the authority to inspect a multifamily dwelling and enforce health, safety, or building codes including, but not limited to, a building department or building division,

SUBJECT TO COURT
ORDERED CHANGES

a housing department, a housing and community investment department, a fire department or fire district, and a health department.

(e) "Entity" means a natural person, corporation, or other legal or corporate organization of any kind, whether non-profit or for-profit, and includes any parent, subsidiary, or affiliate of the entity.

(f) "Health care service plan" means an entity operating as a health care service plan under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(g) "Medi-Cal Rx Program" means the program initially established pursuant to Paragraph (1) of Executive Order N-01-19 and permanently authorized by Section 14124.42.

(h) "Multifamily dwelling" means any structure located in this state designed or used for human habitation or occupancy that has been divided into two or more independent living quarters.

(i) "Owner-operator of highly dangerous properties" means an entity, including any parent, subsidiary, or affiliate of that entity, that, either currently or previously, owns, operates, or is the responsible party for one or more multifamily dwellings that meet or met the following conditions during the time of the entity's ownership, operation, or responsibility:

(1) One or more of the multifamily dwellings was inspected on one or more occasions by an enforcement agency or officer thereof.

(2) The enforcement agencies or officers issued one or more notices or inspection reports identifying violations affecting the health and safety of occupants of the multifamily dwelling(s).

(3) Cumulatively across all of the multifamily dwellings, the notices and/or inspection reports described in paragraph (2) identified a combined total of at least five hundred (500) violations which were categorized in violation severity level "high."

(j) "Pharmacy" means an entity operating pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code.

(k)(1) "Pharmacy sales agreement" means any agreement involving a pharmacy and another entity that purchases, authorizes, or obtains prescription drugs through the discount prescription drug program where both of the following conditions exist:

(A) The pharmacy dispenses drugs negotiated by the other entity through or pursuant to the discount prescription drug program.

SUBJECT TO COURT ORDERED CHANGES

(B) The price charged by the pharmacy for the drugs described in subparagraph (A), excluding dispensing fees, exceeds the purchase price negotiated and/or paid by the other entity pursuant to or through the discount prescription drug program.

(2) A pharmacy sales agreement can exist between unrelated entities, or between related entities that are parents, subsidiaries, or affiliates of one another or otherwise under common ownership or control.

(l) "Prescription drug price manipulator" means an entity, including any parent, subsidiary, or affiliate of that entity, that individually or collectively with one or more of its parents, subsidiaries, or affiliates meets all of the following requirements:

(1) The entity purchases, negotiates, authorizes, or obtains prescription drugs through the discount prescription drug program.

(2) During any ten calendar year period of its existence, the entity spent more than one hundred million dollars ($100,000,000) on purposes that do not qualify as direct patient care.

(3) The entity currently is, or has previously been, an owner-operator of highly dangerous properties.

(4) The entity meets at least one of the following conditions:

(A) The entity currently has, or previously had, one or more licenses to operate as a health care service plan.

(B) The entity currently contracts, or has previously contracted, with the Department of Health Care Services as a primary care case management organization pursuant to Article 2.9 (commencing with Section 14088) of Chapter 7 of Part 3 of Division 9.

(C) The entity currently contracts, or has previously contracted, with the federal Centers for Medicare and Medicaid Services to provide services in the Medicare Program as a Medicare special needs plan.

(D) The entity currently has, or previously had, one or more licenses to operate as a pharmacy.

(E) The entity currently has, or previously had, one or more licenses to operate as a clinic.

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14124.49. Unprofessional conduct, dishonest dealing, and conduct inimical to public health, welfare, or safety.

(a) In addition to any other conduct, standard, or requirement described in Article 7 (commencing with Section 1386) of Chapter 2.2 of Division 2 of the Health and Safety Code or any other statute or regulation, it shall constitute dishonest dealing for a health care service plan that qualifies as a prescription drug price manipulator to fail to submit timely, accurate information required or requested pursuant to Section 14124.45.

(b) In addition to any other conduct, standard, or requirement described in Article 19 (commencing with Section 4300) of Chapter 9 of Division 2 of the Business and Professions Code, Section 1762 of Title 16 of the California Code of Regulations, or any other statute or regulation, it shall constitute unprofessional conduct for a pharmacy that qualifies as a prescription drug price manipulator to fail to submit timely, accurate information required or requested pursuant to Section 14124.45.

(c) In addition to any other conduct, standard, or requirement described Article 5 (commencing with Section 1240) of Chapter 1 of Division 2 of the Health and Safety Code or any other statute or regulation, it shall constitute conduct inimical to the public health, welfare, or safety of the people of the State of California for a clinic that qualifies as a prescription drug price manipulator to fail to submit timely, accurate information required or requested pursuant to Section 14124.45.

Section 14124.50. California state and local grants and contracts eligibility.

(a)(1) The People of California hereby find and declare that their state and local tax dollars should not be awarded to prescription drug price manipulators that violate the discount prescription drug program's intent to treat patients who are "medically uninsured, on marginal incomes and have no other sources to turn to for preventive and primary care services" and to "reach [] more eligible patients and provide [] more comprehensive services" to "low-income and most vulnerable patients."

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(2) The People of California further find and declare that protecting their state and local tax dollars in this manner is a matter of statewide concern.

(b) Therefore, in addition to the requirements of subdivision (e) of Section 14124.47, a prescription drug price manipulator shall only be eligible to receive any new or renewed

California state or local grants or contracts if, in the prior calendar year, the prescription drug price manipulator spent at least ninety-eight percent (98%) of the net revenues it generated nationwide from participation in the discount prescription drug program on direct patient care.

Section 14124.51. Public input.

The Attorney General, Board of Pharmacy, Department of Managed Health Care, and Department of Public Health shall invite, and provide a process for submission of, public comments and information relating to entities that qualify as a prescription drug price manipulator and/or an owner-operator of highly dangerous properties. Information that can be submitted pursuant to this section includes, but is not limited to, records of expenditures and written notices or inspection reports identifying violations affecting the health and safety of occupants at multifamily dwelling(s).

Section 14124.52. Effective date and severability.

(a) This article shall take effect on the next January 1 following its adoption by the voters.

(b) The provisions of this article are severable. If any portion, section, subdivision, paragraph, subparagraph, clause, subclause, sentence, phrase, word, or application of this article is for any reason held to be invalid by a decision of any court of competent jurisdiction, that decision shall not affect the validity of the remaining portions of this article. The People of the State of California hereby declare that they would have adopted this article and each and every portion, section, subdivision, paragraph, subparagraph, clause, subclause, sentence, phrase, word, and application not declared invalid or unconstitutional without regard to whether any part of this article or application thereof would be subsequently declared invalid.

(c) To the extent a court of competent jurisdiction determines it is legally impossible to comply with any date or deadline set forth in this article during the first calendar year after this article takes effect, the People of the State of California hereby declare their intent for this article to be implemented and applied at the earliest possible date consistent with state and federal law.

SUBJECT TO COURT
ORDERED CHANGES

[Printer: All text in SECs. 2, 3, and 4 should be in Roman.]

SEC.

SECTION 2. ***Conflicting Measures.*** Roman

(a) In the event that this initiative measure and another initiative measure or measures dealing with pharmacy sales agreements or prescription drug price manipulators, as defined in this initiative, shall appear on the same statewide election ballot, the other initiative measure or measures shall be deemed to be in conflict with this measure. In the event that this initiative measure receives a greater number of affirmative votes, the provisions of this measure shall prevail in their entirety, and the provisions of the other initiative measure or measures shall be null and void.

Roman

(b) Notwithstanding subdivision (a), the People hereby find and declare that this initiative measure does *not* conflict with the Protect Access to Healthcare Act of 2024 (Atty. Gen. # 23-0024) or any other initiative measure that provides additional or extended funding for the Medi-Cal program.

Delete and Replace with (23-0024)

SEC.

SECTION 3. ***Liberal Construction.*** Roman

This Act shall be liberally construed to give effect to its intent and purposes, which are as expressed in Sections 14124.40 and 14124.41.

SEC.

SECTION 4. ***Legal Defense.*** Roman

The purpose of this section is to ensure that the people's precious right of initiative cannot be improperly annulled by state politicians who refuse to defend the will of the voters. Therefore, if this Act is approved by the voters of the State of California and thereafter subjected to a legal challenge which attempts to limit the scope or application of this Act in any way, or alleges this Act violates any state or federal law in whole or in part, and both the Governor and the Attorney General refuse to defend this Act to the fullest extent possible on behalf of the State of California, then the following actions shall be taken:

that

(a) Notwithstanding anything to the contrary contained in Chapter 6 (commencing with Section 12500) of Part 2 of Division 3 of Title 2 of the Government Code or any other law, the Attorney General shall appoint independent counsel to faithfully and vigorously defend this Act to the fullest extent possible on behalf of the State of California.

SUBJECT TO COURT ORDERED CHANGES

(b) Before appointing or thereafter substituting independent counsel, the Attorney General shall exercise due diligence in determining the qualifications of independent counsel and shall obtain written affirmation from independent counsel that independent counsel will faithfully and vigorously defend this Act to the fullest extent possible. The written affirmation shall be made publicly available upon request.

(c) In order to support the defense of this Act in instances where the Governor and the Attorney General fail to do so despite the will of the voters, a continuous appropriation is hereby made from the General Fund to the Controller, without regard to fiscal years, in an amount necessary to cover the costs of retaining independent counsel to faithfully and vigorously defend this Act on behalf of the State of California to the fullest extent possible.

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EXHIBIT E

United States Government Accountability Office

GAO

Report to Congressional Committees

September 2011

DRUG PRICING

Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement

September 2011

GAO Highlights

Accountability * Integrity * Reliability

Highlights of GAO-11-836, a report to congressional committees

DRUG PRICING

Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement

Why GAO Did This Study

The Health Resources and Services Administration (HRSA), within in the Department of Health and Human Services (HHS), oversees the 340B Drug Pricing Program, through which participating drug manufacturers give certain entities within the health care safety net—known as covered entities—access to discounted prices on outpatient drugs. Covered entities include specified federal grantees and hospitals. The number of covered entity sites has nearly doubled in the past 10 years to over 16,500.

The Patient Protection and Affordable Care Act (PPACA) mandated that GAO address questions related to the 340B program. GAO examined: (1) the extent to which covered entities generate 340B revenue, factors that affect revenue generation, and how they use the program; (2) how manufacturers' distribution of drugs at 340B prices affects covered entities' or non-340B providers' access to drugs; and (3) HRSA's oversight of the 340B program. GAO reviewed key laws and guidance, analyzed relevant data, and conducted interviews with 61 340B program stakeholders selected to represent a range of perspectives, including HRSA, 29 covered entities, 10 manufacturers and representatives, and 21 others. Selection of stakeholders was judgmental and thus, responses are not generalizable.

What GAO Recommends

To ensure appropriate use of the 340B program, GAO recommends that HRSA take steps to strengthen oversight regarding program participation and compliance with program requirements. HHS agreed with our recommendations.

View GAO-11-836. For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

What GAO Found

Thirteen of the 29 covered entities we interviewed reported that they generated 340B program revenue that exceeded drug-related costs, which includes the costs of purchasing and dispensing drugs. Of those remaining, 10 did not generate enough revenue to exceed drug-related costs, and 6 did not report enough information for us to determine the extent to which revenue was generated. Several factors affected 340B revenue generation, including drug reimbursement rates. Regardless of the amount of revenue generated, all covered entities reported using the program in ways consistent with its purpose. For example, all covered entities reported that program participation allowed them to maintain services and lower medication costs for patients. Entities generating 340B program revenue that exceeded drug-related costs were also able to serve more patients and to provide additional services.

According to the 61 340B program stakeholders we interviewed, manufacturers' distribution of drugs at 340B prices generally did not affect providers' access to drugs. Specifically, 36 stakeholders, including those representing manufacturers, covered entities, and non-340B providers, did not report any effect on covered entities' or non-340B providers' access. The remaining 25, also representing a wide range of perspectives on the 340B program, reported that it affected access primarily in two situations: (1) for intravenous immune globulin (IVIG), a lifesaving drug in inherently limited supply; and (2) when there was a significant drop in the 340B price for a drug resulting in increased 340B demand. In both situations, manufacturers may restrict distribution of drugs at 340B prices because of actual or anticipated shortages. Stakeholders reported that restricted distribution of IVIG resulted in 340B hospitals having to purchase some IVIG at higher, non-340B prices. They also reported that restricted distribution when the 340B price of a drug dropped significantly helped maintain equitable access for all providers.

HRSA's oversight of the 340B program is inadequate to provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements—such as, entities' transfer of drugs purchased at 340B prices only to eligible patients, and manufacturers' sale of drugs to covered entities at or below the 340B price. HRSA primarily relies on participant self-policing to ensure program compliance. However, its guidance on program requirements often lacks the necessary level of specificity to provide clear direction, making participants' ability to self-police difficult and raising concerns that the guidance may be interpreted in ways inconsistent with the agency's intent. Other than relying on self-policing, HRSA engages in few activities to oversee the 340B program. For example, the agency does not periodically confirm eligibility for all covered entity types, and has never conducted an audit to determine whether program violations have occurred. Moreover, the 340B program has increasingly been used in settings, such as hospitals, where the risk of improper purchase of 340B drugs is greater, in part because they serve both 340B and non-340B eligible patients. This further heightens concerns about HRSA's current approach to oversight. With the number of hospitals in the 340B program increasing significantly in recent years—from 591 in 2005 to 1,673 in 2011—and nearly a third of all hospitals in the U.S. currently participating, some stakeholders, such as drug manufacturers, have questioned whether all of these hospitals are in need of a discount drug program.

Contents

Abbreviations

ADAP	AIDS Drug Assistance Program
CMS	Centers for Medicare & Medicaid Services
DSH	disproportionate share hospital
FQHC	federally qualified health center
GPO	group purchasing organization
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IVIG	intravenous immune globulin
PHSA	Public Health Service Act
PPACA	Patient Protection and Affordable Care Act
PSSC	Pharmacy Services Support Center
PVP	Prime Vendor Program

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

September 23, 2011

The Honorable Tom Harkin
Chairman
The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

Our nation's health care safety net provides services to low-income, uninsured, underinsured, and other individuals who experience barriers accessing care, regardless of their ability to pay. Certain types of providers within the safety net have access to discounted prices on outpatient drugs through the 340B Drug Pricing Program.[1] The program, created in 1992 and named for the statutory provision authorizing it in the Public Health Service Act (PHSA),[2] requires drug manufacturers to give 340B discounts to entities covered under the law—known as covered entities—in order to have their drugs covered by Medicaid.[3]

Covered entities include clinics and hospitals that provide general health care services, as well as those that serve patients with specific conditions or diseases, and are typically eligible for the program because they receive some type of federal support, such as a federal grant. According

[1]Outpatient drugs covered under the 340B program may include: prescription drugs approved by the Food and Drug Administration; certain over-the-counter drugs provided as prescriptions; biological products, other than vaccines, that can be dispensed only by a prescription; and insulin approved by the Food and Drug Administration. 42 U.S.C. §§ 256b(b)(2), 1396r-8(k)(2). When payment for an outpatient drug is bundled with payment for other services, the drug is not covered by the 340B program.

[2]42 U.S.C. § 256b.

[3]Medicaid is a joint federal-state program that finances health care for certain categories of low-income individuals. Medicaid programs vary from state to state.

to the Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services (HHS) responsible for administering and overseeing the 340B program, the purpose of the program is to enable covered entities to stretch scarce federal resources to reach more eligible patients, and provide more comprehensive services.[4] Covered entities' current spending on 340B drug purchases is estimated to be about $6 billion annually.

Participation in the 340B program is voluntary for both covered entities and drug manufacturers, but there are strong incentives to participate. Covered entities can realize substantial savings through 340B price discounts—an estimated 20 to 50 percent off the cost of drugs, according to HRSA. In addition, covered entities can generate 340B revenue.[5] For example, covered entities can purchase drugs at the 340B price for all patients eligible under the program regardless of their income or insurance status, and generate revenue, such as through a patients' insurance reimbursement, that may exceed the 340B price paid for the drugs.[6] As of July 2011, there were more than 16,500 covered entity sites

[4]HRSA bases this view on language in a House Energy and Commerce Committee Report pertaining to language similar to what eventually became section 340B of the PHSA. *See* H. Rep. No. 102-384, Pt. 2, at 12 (1992) (discussing bill to amend the Social Security Act); *See also* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the PHSA).

[5]For this report, we define 340B revenue as all monies received by covered entities for drugs they purchase at the 340B price, whether or not the revenue meets or exceeds the costs paid for the drugs.

[6]In 1996, HRSA issued a definition of a 340B patient that defines the situations under which covered entities can use drugs purchased at 340B prices for their patients. While income and insurance status do not dictate whether a patient is eligible under the program, certain patients, such as those who do not receive health care services consistent with the scope of a grant that made an entity eligible for the program or those whose only service from the covered entity is the dispensing of drugs, are prohibited from receiving drugs purchased at the 340B price. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

enrolled in the program—about double the number reported in 2001.[7] Because they must participate in the 340B program to receive Medicaid reimbursement for their drugs, incentives for participation by drug manufacturers also are strong. According to HRSA, most manufacturers that produce outpatient drugs have participated in the program since its inception.

HRSA requires program participants to meet certain conditions set forth both in law and agency guidance. For example, under the PHSA, covered entities are prohibited from transferring 340B drugs to individuals who are not eligible patients of the entities.[8] Similarly, to help ensure covered entities receive the discounts they are entitled to, HRSA has issued nondiscrimination guidance prohibiting drug manufacturers from distributing drugs in ways that would discriminate against covered entities compared to other, non-340B healthcare providers.[9] This includes not conditioning the sale of drugs to covered entities on restrictive conditions, such as requiring them to commit to minimum purchase amounts, which would discourage entities from participating in the program. However, stakeholders, including both covered entities and drug manufacturers, have raised questions about the extent to which 340B program requirements are followed and the extent to which HRSA ensures compliance. Further, because the 340B program has no requirements on how 340B revenue can be used,[10] stakeholders, such as drug manufacturers, have raised questions about covered entities' generation of revenue and whether they are using it in ways consistent with the purpose of the program. Additionally, due to continued growth in the

[7]Data are the most recent available from HRSA's covered entity database and represent both unique covered entities and all their eligible sites, such as satellite clinics. According to HRSA, there are about 3,200 unique organizations currently participating in the program—the agency was unable to provide historical data on unique organizations for all entity types. Additionally, because a covered entity may enroll under any and all eligible grant types it receives, it is possible that certain unique organizations and eligible sites are reflected in the database more than once. However, HRSA estimates that this overlap represents less than 5 percent of all listings in the database.

[8]42 U.S.C. § 256b(a)(5)(B).

[9]Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 58 Fed. Reg. 68922 (Dec. 29, 1993).

[10]According to HRSA, while there are no 340B-specifc requirements, all covered entities eligible for the program based on their grantee status may be required to use 340B revenue in accordance with their grant requirements.

number of covered entities participating in the program, some stakeholders have raised questions about whether increased use of 340B discounts shifts a larger share of drug costs to others in the health care system.

The Patient Protection and Affordable Care Act (PPACA) amended the 340B program by expanding entity eligibility for the program to include additional types of hospitals.[11] PPACA also contained provisions to improve 340B program integrity, and included a provision explicitly prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, consistent with HRSA's nondiscrimination guidance.[12] The passage of PPACA has raised some questions for 340B stakeholders about the program. For example, although proponents of the explicit prohibition on manufacturers contend that it is necessary to prevent discrimination against covered entities, critics are concerned about how it could affect non-340B providers' access to drugs.[13] Additionally, PPACA extends health insurance coverage to more Americans, and some stakeholders, such as drug manufacturers, have questioned whether covered entities will need the discounts provided through the 340B program given this increased coverage.

PPACA directed us to address several questions related to the 340B program. In response to the mandate, we examined: (1) the extent to which covered entities generate 340B revenue, factors that affect their revenue generation, and how entities use the program; (2) how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers; and (3) HRSA's oversight of the 340B program.

[11]Entities that became eligible for the 340B program through PPACA include certain critical access hospitals, sole community hospitals, rural referral centers, and freestanding cancer hospitals. See Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 (2010) as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302, 124 Stat. 1029, 1082.

[12]Pub. L. No, 111-148, § 7102(b).

[13]For this report, we consider providers as having access to a drug if they are able to obtain the amount necessary to meet the needs of their patients—for covered entities this includes being able to obtain the drug at the 340B price.

To examine the extent to which covered entities generate revenue through their participation in the 340B program, factors that affect their revenue generation, and how entities use the program, we conducted interviews with a judgmental sample of 29 covered entity organizations primarily selected to represent five covered entity types located in five states. We selected entity types based on factors, including high levels of participation in the 340B program and variation in organizational structure and the types of services provided. We selected states based on factors, including geographic variation and the percentage of uninsured in the state. Specifically, we interviewed 7 federally qualified health centers (FQHC),[14] 5 family planning clinics, 5 AIDS Drug Assistance Programs (ADAP), 5 hemophilia treatment centers, and 5 general acute care hospitals with a Medicare disproportionate share hospital (DSH) adjustment percentage of greater than 11.75 percent[15]—in this report we refer to these hospitals as DSH hospitals.[16] These entities were located in Illinois, Massachusetts, Tennessee, Texas, and Utah. We specifically selected Massachusetts to gain a better understanding of the potential effect of PPACA's health insurance reforms on the 340B program.[17] In addition to interviewing covered entities located in the five states, we conducted interviews with 2 additional DSH hospitals located in other states, because of questions raised in stakeholder interviews about how these hospitals were using the program. When possible, we collected

[14]FQHCs are urban or rural health centers that provide comprehensive community-based primary and preventive care services to medically underserved populations and have received a "Federally Qualified Health Center" designation from the Centers for Medicare & Medicaid Services (CMS).

[15]General acute care hospitals are eligible for the 340B program when they have a Medicare DSH adjustment percentage of greater than 11.75 percent and meet certain other requirements. Medicare is the federally financed health insurance program for persons aged 65 or over, certain individuals with disabilities, and individuals with end-stage renal disease. The Medicare DSH adjustment percentage is an additional Medicare payment to acute care hospitals paid under the inpatient prospective payment system—a Medicare reimbursement method based on a predetermined, fixed amount. A hospital's DSH adjustment percentage is generally based on its DSH patient percentage, which is a statutory formula created to identify hospitals that treat a significantly disproportionate number of low-income Medicare and Medicaid patients.

[16]While additional types of hospitals are eligible for the 340B program, we only interviewed DSH hospitals because the remaining hospital types had only recently started participating in the program.

[17]In 2006, Massachusetts implemented comprehensive state-level health insurance reform that was similar to PPACA's national-level reform.

relevant documentation from covered entities. Although we selected covered entities to interview that represented a variety of entity types, not all covered entity types are represented. Further, our selection of covered entities was judgmental, and our sample is not generalizable. (See appendix I for more details on how we selected covered entities and appendix II for more information about the entity types eligible to participate in the 340B program.)

To examine how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers, we conducted interviews with 61 340B program stakeholders, including our judgmental sample of 29 covered entities, as well as 32 other program stakeholders representing a wide range of perspectives on the program.[18] Included were interviews with 6 drug manufacturers, selected based on factors such as having a large market share and producing drugs with reported challenges related to their distribution at 340B prices, and 6 organizations representing drug manufacturers and others involved in distributing drugs from manufacturers to providers. We also interviewed stakeholders representing providers, including 9 organizations representing covered entities, 2 organizations representing non-340B providers, and 5 organizations representing both covered entities and non-340B providers. Finally, we interviewed HRSA and the Centers for Medicare & Medicaid Services (CMS), as well as HRSA's 2 340B program contractors. (See appendix I for more details on interviewees and how we selected them.) Similar to our selection of covered entities, our selection of other program stakeholders was judgmental and, as such, responses are not generalizable. In addition, we reviewed relevant documentation from interviewees, and analyzed industry data as well as data from HRSA's covered entity database to determine the number of hospitals in the U.S. currently participating in the 340B program. We reviewed data-related documentation and interviewed agency officials, and determined these data were sufficiently reliable for our purposes.

To examine HRSA's oversight of the 340B program, we conducted interviews with the 61 program stakeholders discussed above and reviewed relevant documentation. We reviewed information from HRSA and other HHS agencies, including those that administer the grants that

[18]We conducted multiple interviews with certain organizations for a total of 65 interviews.

make entities eligible for the 340B program.[19] We also reviewed key laws, guidance, and relevant literature related to the program and to safety net providers. We analyzed data from HRSA's covered entity database to determine changes in 340B program participation among covered entity types since 2001. We reviewed data-related documentation and interviewed agency officials, and determined these data were sufficiently reliable for our purposes.

We conducted our performance audit from September 2010 through September 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The 340B program was created in 1992 following the enactment of the Medicaid Drug Rebate Program and gives certain safety net providers discounts on outpatient drugs comparable to those made available to state Medicaid agencies.[20] HRSA, through its Office of Pharmacy Affairs, is responsible for administering and overseeing the 340B program,[21] which according to federal standards, includes designing and implementing necessary policies and procedures to enforce agency objectives and assess program risk. These policies and procedures include internal controls that provide reasonable assurance that an

[19]HHS agencies that administer the grants that make entities eligible for the 340B program include HRSA, Indian Health Services, Office of Population Affairs, and the Centers for Disease Control and Prevention. CMS calculates Medicare DSH adjustment percentages for hospitals.

[20]The Medicaid Drug Rebate Program was established through the Omnibus Budget Reconciliation Act of 1990 and requires drug manufacturers to pay rebates to states as a condition of having their drugs covered by Medicaid. Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (adding 42 U.S.C. § 1396r-8).

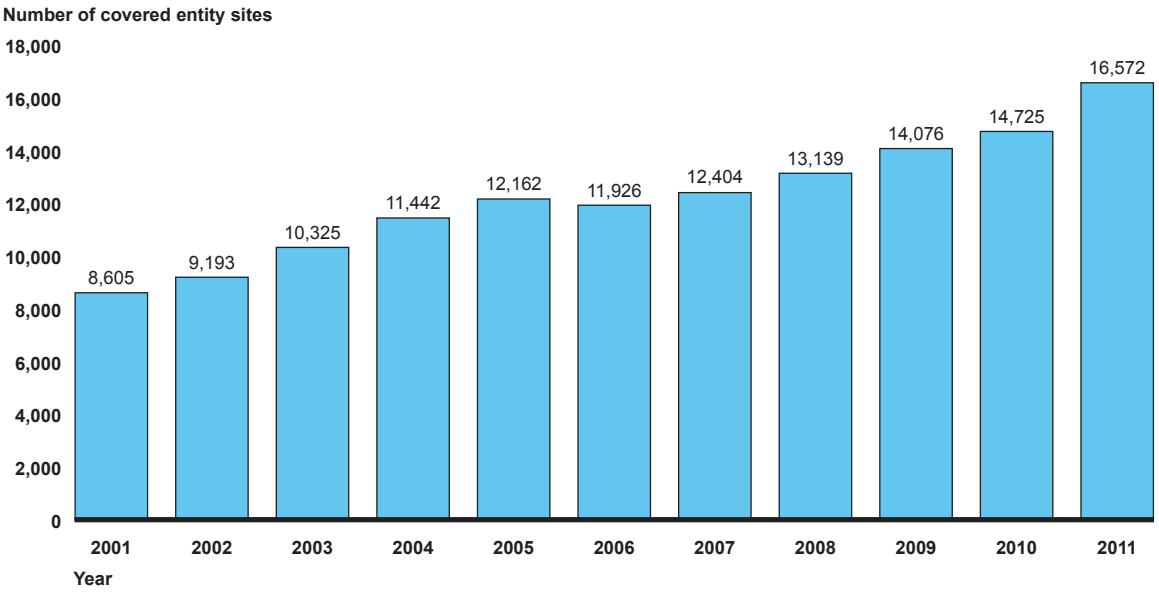
[21]The Pharmacy Services Support Center (PSSC) and the Prime Vendor Program (PVP) assist HRSA with the administration of the 340B program and are managed by contractors. The PSSC provides guidance and free technical assistance to covered entities and helps ensure that patients of covered entities receive comprehensive pharmacy services. The PVP establishes a distribution network for pharmaceuticals to covered entities and negotiates prices for a portfolio of drugs below the 340B price. Participation in the PVP is free and voluntary for covered entities.

agency has effective and efficient operations and that program participants are in compliance with applicable laws and regulations.[22]

Program Participants

Eligibility for the 340B program is defined in the PHSA. Entities generally become eligible by receiving one of 10 federal grants or by being one of six hospital types. (See appendix II for a complete list of covered entity types and their eligibility requirements.) To participate in the 340B program, eligible entities must register with HRSA and be approved. Entity participation in the 340B program has grown over time to include over 16,500 covered entity sites (see fig. 1).

Figure 1: Growth in Covered Entity Sites, 2001 to 2011



Source: GAO analysis of HRSA data.

[22]See GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

Federal grantees are eligible for the 340B program by virtue of receiving certain federal grants administered by different agencies within HHS. Eligible grantees include clinics that offer primary and preventive care services, such as FQHCs,[23] family planning clinics, and clinics that target specific conditions or diseases that raise public health concerns or are expensive to treat, such as hemophilia treatment centers. Participating clinics may offer eligible services at one or multiple sites. They also include state-operated ADAPs, which serve as a "payer of last resort" to cover the cost of providing HIV-related medications to certain low-income individuals.

Hospitals eligible for the 340B program include certain DSH hospitals, children's hospitals, freestanding cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals. While DSH hospitals have been eligible for the program since its inception, children's hospitals became eligible in 2006, and the remaining hospital types became eligible through PPACA.[24]

Hospital eligibility for the 340B program has more elements than that of federal grantees, because unlike federal grantees, hospitals do not qualify for the program based on receipt of a federal grant. Rather, they must meet certain requirements intended to ensure that they perform a government function to provide care to the medically underserved. First, hospitals generally must meet specified DSH adjustment percentages to qualify; however, critical access hospitals are exempt from this requirement.[25] Additionally, all hospitals must be (1) owned or operated

[23]Not all FQHCs receive federal grants. Providers that meet all of the requirements for the FQHC program but do not receive federal grants are referred to as FQHC look-alikes and are eligible to participate in the 340B program.

[24]See Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302, 124 Stat. 1029, 1082. While PPACA explicitly added children's hospitals to the list of covered entities under the 340B program in the PHSA, they were originally made eligible under the Social Security Act through the Deficit Reduction Act of 2005. Pub. L. No. 109-171, § 6004, 120 Stat. 4, 61 (2006) (amending 42 U.S.C. § 1396r-8(a)(5)(B)).

[25]To be eligible for the 340B program, rural referral centers and sole community hospitals must have a DSH adjustment percentage that is equal to or greater than 8 percent, and DSH, children's, and free-standing cancer hospitals must have a DSH adjustment percentage that is greater than 11.75 percent. Although children's and free-standing cancer hospitals do not receive payments under the Medicare inpatient prospective payment system, they must have a payer mix that would result in a DSH adjustment percentage of greater than 11.75 percent.

by a state or local government, (2) a public or private, nonprofit corporation that is formally delegated governmental powers by a unit of state or local government,[26] or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low income individuals who are not eligible for Medicaid or Medicare. Clinics and other sites affiliated with a hospital, but not located in the main hospital building, are eligible to participate in the 340B program if they are an integral part of the hospital, which HRSA has defined as reimbursable sites on the hospital's most recently filed Medicare cost report.[27]

All drug manufacturers that supply outpatient drugs are eligible to participate in the 340B program and must participate if they want their drugs covered by Medicaid. To participate, manufacturers are required to sign a pharmaceutical pricing agreement with HHS in which both parties agree to certain terms and conditions and submit this agreement to HRSA.

Program Structure and Operation

Covered entities typically purchase and dispense 340B drugs through pharmacies and can structure their programs in different ways. Entities can have (1) an in-house pharmacy model, in which the pharmacy is housed within the covered entity, (2) a contract pharmacy model, in which the entity contracts with an outside pharmacy to dispense drugs on their behalf, or (3) both. Historically, only covered entities that did not have an in-house pharmacy were allowed to contract with a single outside pharmacy to provide services. In March 2010, however, HRSA issued guidance allowing all covered entities—including those that have an in-house pharmacy—to contract with multiple outside pharmacies.[28] Some covered entities use HRSA's Pharmacy Services Support Center (PSSC) or private companies that provide technical assistance, information

[26]According to HRSA, a hospital is said to be "formally granted governmental powers" when the state formally delegates to the hospital a type of power(s) usually exercised by the state, for the purpose of providing health care services to the medically indigent population of the state.

[27]Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities, 59 Fed. Reg. 180, 47884 (Sept. 19, 1994).

[28]Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010).

technology, and other services to help develop, implement, and manage their 340B pharmacy program.

The 340B price for a drug—often referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a drug manufacturer may charge covered entities;[29] however, the provision establishing the 340B pricing formula indicates that manufacturers may sell a drug at a price that is lower than the ceiling price.[30] As such, covered entities may negotiate prices below the ceiling price. Manufacturers are responsible for calculating the 340B price on a quarterly basis. Occasionally the formula results in a negative price for a 340B drug.[31] In these cases, HRSA has instructed manufacturers to set the price for that drug at a penny for that quarter—referred to as HRSA's penny pricing policy.

Key Program Requirements

Covered entities must follow certain program requirements as a condition of participating in the 340B program. For example, covered entities are prohibited from diverting any drug purchased at a 340B price to an individual who does not meet HRSA's current definition of a patient. This definition was issued in 1996 and outlines three criteria which generally state that diversion occurs when 340B discounted drugs are given to individuals who are not receiving health care services from covered entities or are only receiving non-covered services, such as inpatient hospital services, from covered entities. (See table 1 for more information on HRSA's definition of a 340B patient.) Covered entities are permitted to use drugs purchased at the 340B price for all individuals who meet the definition of a patient, whether or not they are low income, uninsured, or underinsured.

[29]In general, the 340B price for a drug is calculated quarterly by subtracting the unit rebate amount used in the Medicaid Drug Rebate Program from the drug's average manufacturer price. See 42 U.S.C. § 256b (a)(1). Average manufacturer price is the average price paid to a manufacturer for drugs distributed to retail community pharmacies. It includes direct manufacturer sales to retail community pharmacies, as well as sales by wholesalers. 42 U.S.C. §§ 256b(b), 1396r-8(k).

[30]42 U.S.C.§ 256b(a)(10).

[31]When a drug's average manufacturer price increases more quickly than the rate of inflation, the government requires the manufacturer to pay an additional rebate amount. This may cause the drug's unit rebate amount to be greater than the drug's average manufacturer price, which would result in a negative 340B price.

Table 1: HRSA's Definition of a Patient Eligible for Discounted Drugs under the 340B Program

	Criteria for patient eligibility[a]
1.	The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care.
2.	The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity.[b]
3.	The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or FQHC look-alike status has been provided.[c]

Source: GAO analysis of HRSA guidance.

Notes: HRSA guidance on the definition of a patient eligible for discounted drugs under the 340B program was issued in 1996. See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 207, 55156 (Oct. 24, 1996).

[a]These criteria do not apply to ADAPs; rather, an individual will be considered a patient of an ADAP if enrolled in the ADAP program.

[b]An individual is not considered a patient if the only health care service received from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

[c]DSH hospitals are exempt from this requirement.

Covered entities also are prohibited from subjecting manufacturers to duplicate discounts whereby drugs prescribed to Medicaid patients are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program. To avoid duplicate discounts, covered entities can either purchase drugs for Medicaid patients outside the 340B program, in which case the state Medicaid agency may claim the rebate, or they can use drugs purchased at 340B prices, in which case the agency may not claim the rebate. Covered entities that decide to use 340B drugs for Medicaid patients must notify HRSA so that it can coordinate with state Medicaid agencies for billing purposes. Further, certain covered entities—DSH hospitals, children's hospitals, and freestanding cancer hospitals—are prohibited from purchasing outpatient drugs through any group purchasing organization (GPO).[32] However, they may purchase drugs through the specified HRSA contractor, the Prime Vendor Program (PVP). Rural referral centers, sole community hospitals, and critical

[32]GPOs contract with providers, such as hospitals, and, on behalf of their members, aggregate purchasing volume to negotiate discounts on drugs from drug manufacturers or distributors.

access hospitals participating in the 340B program are allowed to purchase outpatient drugs through any GPO.

Drug manufacturers also must follow certain 340B program requirements. Specifically, they must sell outpatient drugs to covered entities at or below the statutorily determined price. In addition, HRSA's nondiscrimination guidance prohibits manufacturers from distributing drugs in ways that discriminate against covered entities compared to other providers. This includes ensuring that drugs are made available to covered entities through the same avenue that they are made available to non-340B providers, and not conditioning the sale of drugs to covered entities on restrictive conditions, which would have the effect of discouraging participation in the 340B program.

340B Revenue Generated by Covered Entities Varied, but All Entities Reported That the Program Was Used to Support or Expand Access to Services

About half of the covered entities we interviewed reported that they generated 340B program revenue that exceeded drug-related costs—the costs of purchasing and dispensing a drug—and revenue generation depended on several factors. Regardless of the amount of 340B revenue generated or the savings realized through 340B discounts, covered entities generally reported using the 340B program to support or expand access to services.

About Half of Covered Entities Reported Generating 340B Revenue That Exceeded Drug-Related Costs, and Revenue Generated Depended on Several Factors

Thirteen of the 29 covered entities we interviewed reported that they generated revenue through the 340B program that exceeded drug-related costs.[33] Of the 16 remaining, 10 did not generate enough 340B revenue to cover all drug-related costs, and 6 covered entities were unable or did not report enough information for us to determine the extent to which they generated 340B revenue due, in part, to their inability to track 340B-specific financial information.

In general, 340B revenue—whether exceeding drug related costs or not—was generated through reimbursement received for drugs dispensed by 340B in-house or contract pharmacies, though several factors affected the extent to which the covered entities we interviewed generated revenue through the program:[34]

- **Third-party reimbursement rates**: Eighteen of the 29 covered entities we interviewed generated 340B revenue by receiving reimbursement from third-party payers and tracked revenue by payer source. Of the 18, most reported that they generated more 340B revenue from patients with private insurance and Medicare compared to other payers.[35] However, a few of these covered entities reported that their ability to generate 340B revenue from private insurers, including Medicare Part D plans, was decreasing because some insurers were reducing contracted reimbursement rates for drugs based on the entity's status as a 340B provider. Of the 18 covered entities, most of those that used 340B drugs for Medicaid patients reported that state-determined Medicaid reimbursement rates for these drugs were generally lower, compared to private insurers and Medicare. For example, most reported that Medicaid reimbursement for a 340B drug was set at the price paid for the drug—the 340B price

[33]For this report, we define 340B revenue as all monies received by covered entities for drugs they purchase at the 340B price, whether or not the revenue meets or exceeds the costs paid for the drugs. When data provided by covered entities was used to determine revenue generation, the most recent year of reported data was used.

[34]Even though 6 covered entities were unable to report the amount of revenue they generated through the program, they were able to report what factors affected overall revenue generation.

[35]Medicare reimburses outpatient prescription drugs either through Medicare Part B or Part D. Part B covers drugs administered by physicians, such as chemotherapy drugs, and payment for those drugs is set by a fee schedule established quarterly by CMS. Part D sponsors are typically private insurers that contract with CMS to cover outpatient prescription drugs and negotiate reimbursement rates directly with health care providers.

or any lower price—plus a dispensing fee, the latter of which generally did not cover the costs of dispensing the drug.[36] This is typically referred to as reimbursement at actual acquisition cost, which reduces a covered entity's ability to generate revenue because the state, rather than the entity, benefits from any savings from purchasing drugs at the 340B price.[37] However, a few covered entities generated more 340B revenue through Medicaid than others because they had contractual agreements with their states to share 340B-related savings.[38] Covered entities in two of the five states included in our selection had such agreements. Finally, a majority of the 18 covered entities reported that revenue generated from uninsured patients was lower than that from all other payers.

- **ADAP status**: Factors that affected 340B revenue generation for the five ADAPs we interviewed were different than for other entity types, because unlike other covered entity types, ADAPs do not receive third-party reimbursement for drugs. Rather, ADAPs serve as a "payer of last resort" to cover the cost of providing HIV-related medications to certain low-income individuals who, for example, are uninsured and cannot afford to pay for drugs or who cannot afford their health insurance coverage for drugs. ADAPs can choose to cover costs of drugs by either paying for the drugs directly or by assisting patients with the costs associated with health insurance, including payments for premiums and co-payments or deductibles. When ADAPs purchase drugs directly, they realize 340B savings on drugs—either at the point of purchase or after the fact through manufacturer rebates—but do not generate revenue through the program. When ADAPs assist with patients' health insurance by paying for co-payments or

[36]A dispensing fee is typically a set dollar amount per prescription that covers the overhead costs of dispensing a drug, such as pharmacy staff time.

[37]State Medicaid agencies may reimburse entities at actual acquisition cost, because when entities decide to use drugs purchased at 340B prices for Medicaid patients, the state can no longer claim Medicaid rebates for those drugs.

[38]These contractual agreements are commonly referred to as shared savings agreements. Shared savings agreements provide covered entities reimbursement above actual acquisition cost, for example, by paying a higher dispensing fee to covered entities than the fee paid to other providers. According to the HHS Office of Inspector General, states may be interested in shared savings agreements with covered entities because 340B prices can be considerably lower than states' standard Medicaid reimbursement rates and entering into such agreements could encourage entities to use 340B drugs for Medicaid patients while still saving money for states.

deductibles on a drug, they sometimes generate revenue by collecting the rebates representing the full 340B discount on a drug for which they may have only paid a portion of the price. Three of the five ADAPs we interviewed reported generating revenue this way.

- **Ability to leverage resources to access the lowest drug prices**: Some of the 29 covered entities we interviewed reported leveraging resources, such as through their larger parent organizations or the PVP, to access drugs at prices below the 340B ceiling price, potentially increasing the difference between the price paid for the drug and the reimbursement received. In addition, some covered entities said they had access to sophisticated information technology—for example by contracting with private companies—or had more staff to help ensure that they were obtaining the lowest priced drugs.

As more people gain insurance coverage under PPACA, covered entities may serve more patients with private insurance and Medicaid,[39] which may affect the extent to which they generate 340B revenue. One covered entity located in Massachusetts reported that after the state implemented universal health care, while they received more revenue from reimbursement for low-income patients that gained private insurance, these patients often could not afford associated co-payments or deductibles, and the entity covered these costs.[40] In addition, according to one ADAP we interviewed, as more individuals gain private insurance, the ADAP may increasingly choose to pay for health insurance for patients rather than paying for patients' drugs directly. This may enable it to generate revenue through the 340B program if it can claim more rebates for drugs for the newly insured patients. According to some covered entities, the impact of serving more Medicaid patients may depend on the Medicaid reimbursement rate that entities receive. For example, patients that gain Medicaid coverage may begin to seek services from covered entities, and for those entities that lose money on Medicaid patients, this may decrease their ability to generate 340B revenue. Conversely, for covered entities that have contractual agreements to share 340B-related

[39]PPACA contains provisions to expand private health insurance and Medicaid coverage to more Americans. See, e.g., Pub. L. No. 111-148, § 2001, 124 Stat. 119, 271.

[40]HRSA officials told us that this statement is consistent with their belief that low-income patients will continue to require assistance with health care costs after gaining insurance.

savings with their states, the increased Medicaid population may increase their ability to generate 340B revenue.

Covered Entities Reported Using the 340B Program to Support or Expand Access to Services

Regardless of the amount of revenue generated through the program, all of the 29 covered entities we interviewed reported that the 340B program, including the up-front savings they realized on the cost of drugs, allowed them to support their missions by maintaining services and lowering medication costs for patients, which is consistent with the purpose of the program. For example, some covered entities reported that they used the 340B revenue generated by certain patients to offset losses incurred from other patients, which helped support the financial stability of the organization and allowed them to maintain services. Further, one covered entity reported that without 340B revenue or the savings on drugs through its participation in the program, it would be unable to offer all the services it provides—both pharmaceutical and clinical—and another reported that it would have to close its outpatient pharmacy without the program. In addition to maintaining services, some covered entities passed 340B savings on to patients by providing lower-cost drugs to uninsured patients. For example, many covered entities determined the amount that a patient is required to pay based on the lower cost of 340B-priced drugs.

In addition, the 13 covered entities that generated 340B revenue that exceeded drug-related costs were able to use this revenue to serve more patients and to provide services that they might not have otherwise provided, including additional service locations, patient education programs, and case management, which is also consistent with the purpose of program. One covered entity, for example, reported that it used the revenue generated through the 340B program to provide additional service delivery sites in other parts of the state, which eliminated the need for some patients to travel more than 60 miles to receive services. A few covered entities reported using 340B revenue to support patient and family education programs, such as those where pharmacists provide education on drug interactions. Additionally, one covered entity reported using 340B program revenue to fund a case management program that did not generate any revenue on its own;[41] some services provided through this program included arranging

[41]Case management services facilitate access to appropriate health care, and are not typically reimbursed by payers.

transportation for patients to receive clinical services, coordinating necessary specialty care, and providing translation services.

Even though the uses of revenue generated through the 340B program were for similar purposes, some covered entities relied on the program more than others. For example, one FQHC reported that 340B revenue accounted for approximately 5 percent of its total budget, and was used to provide additional services within the organization. However, one hemophilia treatment center reported that 340B revenue accounted for about 97 percent of its total budget and was used to support all of its program operations.[42]

Manufacturers' Distribution of Drugs at 340B Prices Generally Did Not Affect Providers' Access to Drugs Except in Two Situations

According to stakeholders we interviewed, manufacturers' distribution of drugs at 340B prices generally did not affect providers' access to drugs. For example, 36 of the 61 program stakeholders we interviewed did not report any effect on covered entities' or non-340B providers' access to drugs related to manufacturers' distribution of drugs at 340B prices. These stakeholders represented a wide range of perspectives on the 340B program, including those representing manufacturers, covered entities, and non-340B providers.

The remaining 25 program stakeholders—also representing a wide range of perspectives on the 340B program—reported that manufacturers' distribution of drugs at 340B prices affected providers' access to drugs primarily in two situations.[43] The two situations were: (1) for intravenous immune globulin (IVIG), a lifesaving immune deficiency drug, the supply

[42]The organizational structure of hemophilia treatment centers we interviewed varied, and those that operated stand-alone programs were more dependent on 340B revenue than those that were integrated into hospitals.

[43]While stakeholders consistently reported two situations in which manufacturers' distribution of drugs at 340B prices affected providers' access to these drugs, some, such as covered entities, reported other situations that had effects on access, but it was not clear that the other situations were related to manufacturers' distribution of drugs at 340B prices.

of which is inherently limited;[44] and (2) when there was a significant drop in the 340B price of a drug, which may result in increased demand for the drug by covered entities. Both situations relate to the restricted distribution of drugs, which may occur during shortages or when shortages are anticipated.

Stakeholders reported that manufacturers' restricted distribution of IVIG at 340B prices resulted in 340B hospitals having to purchase some IVIG at higher, non-340B prices in order to meet their demand for the drug.[45] Manufacturers restrict the distribution of IVIG on an ongoing basis, because it is susceptible to shortages. Stakeholders, including five of the seven DSH hospitals we interviewed, reported that because of the restricted distribution of IVIG at 340B prices, 340B hospitals often must purchase some IVIG at higher, non-340B prices to meet their patients' needs. For example, DSH hospitals reported that when they were unable to access IVIG at 340B prices, additional IVIG was available for purchase at higher, non-340B prices directly from manufacturers, from specialty pharmacies,[46] or from GPOs.[47] Moreover, one DSH hospital reported that it had to purchase about one-third of the IVIG it needed at non-340B

[44]IVIG is primarily used to treat patients with immune deficiency diseases, a group of disorders in which the immune system fails to produce enough antibodies, thereby predisposing individuals to increased risk of infection. Factors inherent to the development and distribution of IVIG limit its supply making it susceptible to shortages, including that IVIG is made from human plasma, which is an inherently scarce resource, and that IVIG takes between seven and 12 months to manufacture. Additionally, only a few manufacturers develop and distribute these drugs in the United States.

[45]Hospitals are the primary purchaser of IVIG in the United States.

[46]Specialty pharmacies handle and distribute drugs that, among other things, have a high acquisition cost and require special handling practices.

[47]In general, 340B hospitals are prohibited from purchasing outpatient drugs through GPOs. While no DSH hospital we interviewed reported purchasing IVIG through GPOs, GPOs we interviewed told us that 340B hospitals have purchased IVIG through this avenue when they are unable to access it at the 340B price. During a December 2005 congressional hearing on the 340B program, an organization representing 340B hospitals argued that in situations when hospitals are unable to purchase IVIG at 340B prices, they are faced with either violating federal law by purchasing IVIG through GPOs, buying IVIG at cost-prohibitive retail prices, or denying their patients access to these drugs. See "Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency," Hearing before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, December 15, 2005. While 340B hospitals can receive the benefits of group purchasing through the PVP, the PVP does not have any contracts for IVIG.

prices—paying about $20,000 to $25,000 more per month than what it would have paid if it could have purchased it at 340B prices.

Although manufacturers' distribution of IVIG at 340B prices may not meet 340B hospitals' demand, some stakeholders, such as drug manufacturers, reported that changes in the amount of IVIG allocated for sale at 340B prices could negatively affect non-340B providers' access to these drugs. For example, one IVIG manufacturer reported that it restricted its distribution of IVIG by allocating its supply based on the amount of the drug purchased by providers in 2004—allocating 95 percent of its projected monthly sales to non-340B providers and the remaining 5 percent to covered entities at the 340B price.[48] This manufacturer stated that its distribution was fair, and that changing distribution plans to increase the amount of IVIG drugs available at 340B prices could negatively affect non-340B providers' access to the drugs. However, HRSA officials told us that the allocation of IVIG in this way is not sufficient or fair. Nearly a third of the nation's hospitals currently participate in the 340B program, and one large GPO we interviewed reported that 340B hospitals tended to be the bigger hospitals in the company's membership base.[49] Thus, if other manufacturers similarly restrict the distribution of IVIG at 340B prices, it is unlikely that covered entities' demands will be met at the 340B price.[50]

Stakeholders reported that manufacturers' distribution of drugs at 340B prices also affected providers' access to drugs when the 340B prices dropped significantly. In certain cases, when the 340B price of a drug dropped, some covered entities stockpiled the drug, which resulted in shortages in the supply for other providers, including other covered entities. For example, two covered entities we interviewed reported challenges accessing drugs when their 340B prices dropped, because other entities purchased large amounts of these drugs. In other cases

[48]This manufacturer reported that it based its allocation of IVIG on 2004 purchasing patterns, because this was the last period before demand exceeded supply for the product and an allocation system became necessary. While data on the number of hospitals participating in the 340B program in 2004 are not available, the number of 340B hospitals has grown from 591 in 2005 to 1,673 in 2011.

[49]While certain 340B hospitals are prohibited from purchasing outpatient drugs through GPOs, all 340B hospitals can purchase inpatient drugs through GPOs.

[50]The Department of Justice is examining the IVIG market in the United States, in part, due to concerns about the distribution of these drugs at 340B prices.

when the 340B prices dropped, manufacturers restricted the distribution of those drugs at 340B prices to ensure that all providers had equitable access. For example, one manufacturer reported that after the price of an oral contraceptive dropped to a penny as a result of HRSA's penny pricing policy, it received an order from a covered entity that exceeded the manufacturer's current national supply by 50 percent. In response, this manufacturer consulted with HRSA to ensure compliance with the agency's nondiscrimination guidance and restricted the distribution of drugs at 340B prices by allocating its supply based on the projected demand in the market and providers' past purchasing patterns.

HRSA's Oversight of the 340B Program Is Inadequate

HRSA's oversight of the 340B program is inadequate because it primarily relies on participants' self-policing to ensure compliance. Changes in the settings where the program is used may heighten concerns about the inadequacy of HRSA's oversight, and HRSA's plans for improving oversight are uncertain.

HRSA's Oversight Is Inadequate to Ensure Participants' Compliance with 340B Program Requirements

HRSA's oversight of the 340B program is inadequate because it primarily relies on covered entities' and manufacturers' self-policing—that is, participants ensuring their own compliance with program requirements. Upon enrollment, HRSA requires both covered entities and manufacturers to certify that they will comply with applicable 340B program requirements and any accompanying agency guidance. As part of this certification, agency officials told us that they expect participants to develop the procedures necessary to ensure compliance, maintain auditable records that demonstrate compliance, and inform HRSA if violations occur. For example, covered entities must develop adequate safeguards to prevent drugs purchased at 340B prices from being diverted to non-eligible patients, such as inventory tracking systems that separately purchase and dispense 340B drugs, and manufacturers must ensure that they properly calculate the 340B price of their drugs. In both cases, program participants must keep auditable records that can show that they have complied with program requirements and produce that documentation if requested by HRSA.

HRSA officials told us that covered entities and manufacturers can also monitor each other's compliance with program requirements, but in practice, participants may face limitations to doing so. For example, two covered entities we interviewed reported that it is difficult to determine whether they have been charged correctly for drugs because manufacturers' calculations of 340B prices are not transparent—namely,

there is no centralized list of 340B prices.[51] An organization representing covered entities also told us that its members had reported this difficulty. Similarly, three drug manufacturers we interviewed reported that, although they sometimes have suspected covered entities of diverting 340B drugs, it is difficult to prove diversion took place. An organization representing some manufacturers explained that, although manufacturers have the authority to audit covered entities, they have only conducted them in egregious circumstances, because agency requirements for these audits—such as a requirement to hire an independent third party to conduct the audits—are costly and administratively burdensome.

HRSA's guidance on key program requirements often lacks the necessary level of specificity to provide clear direction, making it difficult for participants to self-police or monitor others' compliance and raising concerns that the guidance may be interpreted in ways that are inconsistent with its intent.[52] For example, HRSA's current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for the purposes of 340B and thus, covered entities could interpret it either too broadly or too narrowly. Stakeholders we interviewed, including those representing covered entities and drug manufacturers, raised concerns that the guidance will be interpreted too broadly leading to cases of unintended diversion—that is, using 340B drugs for individuals who HRSA did not intend as eligible patients, but who may not be clearly prohibited in the guidance. However, one of these stakeholders representing covered entities also noted that, in order to ensure compliance, some entities may adhere to a narrow interpretation of the guidance and thus, limit the benefit of the program for their organization. The agency itself has recognized the need to further specify the definition of a 340B patient to ensure that it is interpreted correctly.

[51]Prior to PPACA, covered entities did not have access to 340B pricing data in order to monitor manufacturers because the Social Security Act prohibited the disclosure of the data by HRSA and state Medicaid agencies. 42 U.S.C. § 1396r-8(b)(3)(D). PPACA added a provision to Section 340B requiring that covered entities be allowed access to 340B pricing data. Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 824 (adding 42 U.S.C. § 256b(d)(1)(iii)).

[52]In May 2011, HRSA published its first proposed regulation on the 340B program, Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program, 76 Fed. Reg. 29, 183 (proposed May 20, 2011). Until this point the agency had provided program guidance through notices published in the Federal Register, which were typically finalized after a notice and comment period, as well as more informal guidance on its web site.

For example, HRSA officials told us that the definition currently includes individuals receiving health care services from providers affiliated with covered entities through "other arrangements," as long as the responsibility for care provided remains with the entity. However, HRSA does not define "other arrangements," and officials told us that what is meant by responsibility for care also needs to be clarified. As a result of the lack of specificity in the guidance, the agency has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity is serving an administrative function and does not actually have the responsibility for care.

In addition, HRSA has not issued guidance specifying the criteria under which hospitals that are not publicly owned or operated can qualify for the 340B program.[53] Rather, the agency bases eligibility for these hospitals on the application of broad statutory requirements that they are either formally delegated governmental powers by a unit of a state or local government or have a contract with a state or local government to provide services to low-income individuals who are not eligible for Medicaid or Medicare. HRSA has stated that the determination of whether hospitals meet the first requirement is evaluated by the agency on a case-by-case basis. For the second requirement, HRSA requires a state or local government official and a hospital executive to certify that a contract exists to meet the requirement, but does not require hospitals to submit their contracts for review or outline any criteria that must be included in the contracts, including the amount of care a hospital must provide to these low-income individuals.[54] Therefore, hospitals with contracts that provide a small amount of care to low-income individuals not eligible for Medicaid or Medicare could claim 340B discounts, which may not be what the agency intended.

[53]We use the term hospitals that are not publicly owned or operated to refer to public and private, nonprofit corporations as well as private, nonprofit hospitals that may be eligible for the 340B program. The term does not include private, for-profit hospitals as these hospitals are not eligible for the 340B program.

[54]HRSA officials told us that contracts are selectively reviewed if further clarification is necessary.

Moreover, HRSA's nondiscrimination guidance is not specific in the practices that manufacturers should follow to ensure that drugs are equitably distributed to covered entities and non-340B providers when distribution is restricted. Some stakeholders we interviewed, such as covered entities, have raised concerns about the way IVIG manufacturers have interpreted and complied with the guidance in these cases, because covered entities have sometimes had to purchase IVIG at higher, non-340B prices. Additionally, given current guidance, one stakeholder reported that manufacturers can offer a certain amount of drugs at 340B prices, and while the distribution may not be equitable, still contend that they are complying with the guidance. Although PPACA included a provision prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, officials told us they do not have plans to provide any additional specificity to the nondiscrimination guidance.

Finally, in the case of HRSA's penny pricing policy, agency officials told us that it is well understood by 340B stakeholders and manufacturers we interviewed were generally aware of the policy. However, the agency has never formalized guidance in writing and there have been documented cases of manufacturers charging covered entities more than a penny for drugs when the policy should have been in effect.[55]

Beyond relying on participants' self-policing, HRSA engages in few activities to oversee the 340B program and ensure its integrity, which agency officials said was primarily due to funding constraints. For example, HRSA officials told us that the agency verifies eligibility for the 340B program at enrollment, but does not periodically recertify eligibility

[55]In a 2006 report, the HHS Office of Inspector General found that manufacturers did not always follow HRSA's penny pricing policy. Both in this report and in a 2005 report, the Office of Inspector General recommended that HRSA formalize its penny pricing policy in writing. See HHS Office of Inspector General, *Review of 340B Prices*, OEI-05-02 -00073 (Washington, D.C.: 2006); and HHS Office of Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072 (Washington, D.C.: 2005).

for all covered entity types.[56] As a result, there is the potential for ineligible entities to remain enrolled in the program. In addition, HRSA officials told us that they do not require a review of the procedures participants put in place to ensure compliance, and, although the agency has the authority to conduct audits of program participants to determine whether violations have occurred, it has never done so.[57] For example, officials said that they do not verify whether covered entities have systems in place to prevent diversion. Also, while HRSA encourages manufacturers to work with the agency to develop processes for restricting the distribution of drugs that are equitable to covered entities and non-340B providers, the agency only reviews manufacturers' plans to restrict access to drugs at 340B prices if a manufacturer contacts HRSA or concerns with a plan are brought to the agency's attention. Similarly, although HRSA calculates 340B prices separately from manufacturers, officials told us that, at this time, the agency does not use these calculations to verify the price that manufacturers charge covered entities, unless an entity reports a specific pricing concern.[58]

HRSA's oversight activities are further limited because the agency lacks effective mechanisms to resolve suspected violations and enforce program requirements when situations of non-compliance occur. If covered entities and manufacturers are not able to resolve conflicts on their own, HRSA has had an informal dispute resolution process in place since 1996 through which program participants can request that HRSA

[56]HRSA currently recertifies eligibility for sexually transmitted diseases, tuberculosis, and Ryan White grantees, consistent with requirements under the PHSA. In addition, HRSA verifies the grantee status of FQHCs as well as hospitals' DSH percentages on a quarterly basis. As resources allowed, HRSA has also periodically recertified 340B eligibility for other entity types. For example, HRSA recertified eligibility for family planning clinics in 2010. PPACA added a provision requiring HRSA to conduct annual recertification of eligibility for all covered entity types. HRSA officials told us that the Office of Pharmacy Affairs' fiscal year 2011 budget allowed for the planning of a phased approach to recertification of all entity types, which is scheduled to begin in the fall of 2011. As of August 2011, officials were not able to tell us which entity types would be phased in first.

[57]HRSA officials told us that while they do not conduct audits, if a potential violation of program requirements is brought to their attention, they will refer the matter to the HHS Office of Inspector General. Officials said that they have made two such referrals in the past year related to the diversion of 340B drugs.

[58]HRSA previously operated a voluntary pilot program with manufacturers to improve the integrity of 340B pricing calculations. Twelve manufacturers participated in the program, which was discontinued in March 2008 due to concerns regarding the confidentiality of drug pricing data and a lack of funding to run the program.

review evidence of a suspected violation and the agency then decides whether to initiate the process. However, despite reports by program participants about suspected violations they were unable to resolve on their own, HRSA officials told us that they have only initiated the dispute resolution process twice since its inception.[59] Additionally, HRSA has not issued regulations implementing monetary penalties for non-compliance established by PPACA, and HRSA has rarely utilized the sanctions that existed prior to PPACA. For example, participants found to be in violation of 340B program requirements face termination from the program. Yet according to HRSA officials, since the program's inception, only two covered entities have been terminated from the program due to findings of program violations and no manufacturer has ever been terminated for this reason.[60] Covered entities also are expected to pay back manufacturers for discounts received while out of compliance, and manufacturers are expected to pay back covered entities for overcharges. However, HRSA has not enforced these expectations and officials were unable to tell us the extent to which repayments have occurred.

Because of HRSA's reliance on self-policing to oversee the 340B program as well as its nonspecific guidance, the agency cannot provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements and is not able to adequately assess program risk. As a result, covered entities may be inappropriately

[59]For example, a covered entity we interviewed said that it suspected certain drug manufacturers of implementing strategies to avoid offering drugs at correct 340B prices, but because of the lack of transparency in how 340B prices are calculated, could not determine this on its own. According to the entity, when it contacted HRSA about these strategies, agency officials said that they did not have the resources to help. However, HRSA officials told us that they were unaware of any instances where the agency has not helped a covered entity under these circumstances. Officials from one manufacturer reported that it provided HRSA with evidence that a covered entity had engaged in multiple instances of diversion, and after attempting to resolve the instances with the entity on its own, requested a hearing through the dispute resolution process in January of 2010. HRSA officials told us that the agency dismissed the manufacturer's request to initiate the process, because the covered entity disputed the manufacturer's claim that it had attempted to resolve the issue on its own, and that the agency is currently considering the manufacturer's appeal of this dismissal.

[60]In a 2005 report on the 340B program, the HHS Office of Inspector General noted that terminating a manufacturer from the 340B program also means that the manufacturer would be terminated from the Medicaid program, making it a difficult sanction to put into practice, given the effects on access to medications for Medicaid beneficiaries. See HHS Office of Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072 (Washington, D.C.: 2005).

claiming 340B discounts from drug manufacturers or qualifying for the program when they should not be, potentially increasing the likelihood that manufacturers will offset providing lower prices to covered entities with higher prices for others in the health care system. Additionally, manufacturers may be charging covered entities more than the 340B price for drugs, which would limit the benefit of the program for these entities.

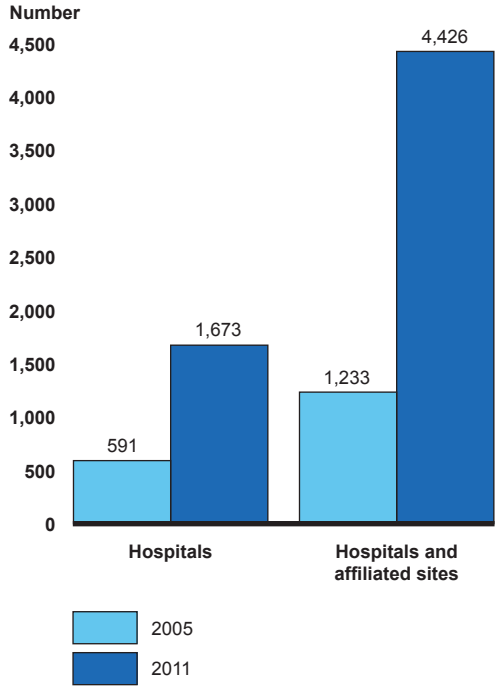
Changes in the Settings Where the 340B Program Is Used May Heighten Concerns about HRSA's Inadequate Oversight

Over time, the settings where the 340B program is used have shifted to more contract pharmacies and hospitals than in the past. According to HRSA officials, the number of covered entities using contract pharmacies has grown rapidly since its new multiple contract pharmacy guidance was issued in March 2010—as of July 2011, there were over 7,000 contract pharmacy arrangements in the program.[61] Hospitals' participation in the 340B program has also grown markedly in recent years. In 2011, the number of hospitals participating in the program was nearly three times what it was in 2005, and the number of these organizations, including their affiliated sites, was close to four times what it was in 2005 (see fig. 2).[62] Further, although participation in the 340B program has increased among other covered entity types over time, hospitals' participation in the 340B program has grown faster than that of federal grantees. In 2005, hospitals represented 10 percent of program participants, and as of July 2011, they represented 27 percent.

[61]HRSA was unable to provide the precise rate of growth of contract pharmacies within the 340B program due to data limitations. Specifically, HRSA currently only tracks contract pharmacy arrangements and is working to develop the ability to capture individual contract pharmacies. Data on the number of contract pharmacy arrangements are the most recent available from HRSA's covered entity database.

[62]One reason for hospital growth could be that more hospitals may have become eligible as a result of state-level Medicaid expansions in recent years. The number of Medicaid patients served by a hospital affects its DSH adjustment percentage, which helps determine hospital eligibility for the 340B program.

Figure 2: 340B Program Participation among Hospitals and Their Affiliated Sites, 2005 and 2011



Source: GAO analysis of HRSA data.

Note: 2005 was the earliest year data were reliable for hospitals without their affiliated sites.

Increased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program. Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies. For example, contract pharmacies are more likely to serve both patients of covered entities and others in the community; in these cases more sophisticated inventory tracking systems must be in place to ensure that 340B drugs are not diverted—intentionally or unintentionally—to non-340B patients.[63]

[63]Some covered entities have in-house pharmacies that also serve as retail pharmacies for the broader community. However, among the covered entities we interviewed, we found that this was not often the case.

Also, for a number of reasons, operating the 340B program in the hospital environment creates more opportunities for drug diversion compared to other covered entity types. First, hospitals operate 340B pharmacies in settings where both inpatient and outpatient drugs are dispensed and must ensure that inpatients do not get 340B drugs. Second, hospitals tend to have more complex contracting arrangements and organizational structures than other entity types—340B drugs can be dispensed in multiple locations, including emergency rooms, on-site clinics, and off-site clinics. In light of this and given HRSA's nonspecific guidance on the definition of a 340B patient, broad interpretations of the guidance may be more likely in the hospital setting and diversion harder to detect. Third, hospitals dispense a comparatively larger volume of drugs than other entity types—while representing 27 percent of participating covered entities, according to HRSA, DSH hospitals alone represent about 75 percent of all 340B drug purchases.

The increasing number of hospitals participating in the 340B program has raised other concerns for some stakeholders we interviewed, such as drug manufacturers, including whether all of these hospitals are in need of a discount drug program. Nearly a third of all hospitals in the U.S. currently participate in the 340B program, and HRSA estimates that more may be eligible.[64] The number of hospitals eligible to participate may increase due to PPACA's Medicaid expansion, because the number of Medicaid patients served by a hospital affects its DSH adjustment percentage—one factor that determines hospital eligibility. Further, one organization we interviewed questioned whether the DSH adjustment percentage is the best measure to determine hospitals' eligibility for the 340B program, because of research indicating that it may not be an adequate proxy for the amount of uncompensated care a hospital provides.[65] The DSH hospitals we interviewed reported a wide range of payer mixes—with the percentage of Medicaid and uninsured patients ranging from about 15 percent of total patient volume for one hospital to about 85 percent for another. However, payer mix may not be the only factor to consider when identifying hospitals that provide care to the

[64]According to HRSA, over 400 additional DSH hospitals may be eligible for the 340B program based on their DSH adjustment percentage. This estimate does not include the additional hospital types made eligible for the program through PPACA.

[65]See MedPAC, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: 2007), pp.78-79.

medically underserved and are part of the health care safety net. There is no established definition of a safety net hospital, and some researchers have argued that it should include factors other than payer mix, for example the disproportionate provision of critical services, that are either too expensive or unprofitable for other hospitals to provide, such as emergency room or trauma care.[66]

HRSA's Plans to Improve Oversight of the 340B Program Are Uncertain and May Not Address All Areas of Concern

While PPACA's 340B program integrity provisions address many of the deficiencies in HRSA's current approach to oversight, the agency has taken few steps to implement these provisions. PPACA requires HRSA to increase oversight of both covered entities and manufacturers, and outlines specific steps for HRSA to take in accomplishing this goal. (See table 2 for the 340B program integrity provisions included in PPACA.) However, according to officials, the agency does not have adequate funding to implement the integrity provisions. Officials also noted that once funding is secured, it could take several years to develop the systems and regulatory structure necessary to implement them.

[66]See for example, Barbara Wynn, et. al., "Analysis of the Joint Distribution of Disproportionate Share Hospital Payments," *PM-1387-ASPE* (Washington, D.C.: 2002); and Megan McHugh, Raymond Kang, and Romana Hasnain-Wynia, "Understanding the Safety Net: Inpatient Quality of Care Varies Based on How One Defines Safety-Net Hospitals," *Med Care Research and Review*, published online April 27, 2009.

Table 2: Key 340B Program Integrity Provisions Included in PPACA

Program participant	Requirements for HRSA	Required start date	Implementation status as of August 2011
Covered entities	Conduct annual recertification of eligibility for all covered entity types.	Not specified[a]	Developing implementation plan[b]
	Develop more detailed guidance on the procedures covered entities can follow to avoid the Medicaid duplicate discount.	Not specified[a]	Not started
	Establish a standard identification system for all covered entities by which each covered entity site can be identified for the purposes of ordering, purchasing, and delivery of 340B drugs.	Not specified[a]	Not started
	Impose certain sanctions on covered entities that knowingly and intentionally divert 340B drugs, by one or more of the following: • requiring a covered entity to pay manufacturers interest on the discounts they received for those drugs; • if the violation was also systematic and egregious, terminating the covered entity from the program and prohibiting re-enrollment for a period of time; and • referral to federal authorities.	Not specified[a]	Not started
Manufacturers	Improve mechanisms to ensure manufacturers charge the correct 340B prices on drugs, including: • making a centralized list of HRSA-verified 340B prices available to covered entities, • conducting selective audits of manufacturers, and • establishing procedures by which manufacturers repay covered entities for overcharges.	Not specified[a]	Not started
	Impose civil monetary penalties on manufacturers that knowingly and intentionally charge covered entities more than the 340B price.	Must issue regulations 180 days after enactment	Issued advanced notice of proposed rulemaking
Both	Develop a formal dispute resolution process, including: • establishing procedures for covered entities to obtain information from manufacturers,[c] and • requiring manufactures to audit covered entities prior to submitting a request to initiate the dispute resolution process.	Must issue regulations 180 days after enactment	Issued advanced notice of proposed rulemaking

Source: GAO analysis of Pub. L. No. 111-148, § 7102, 124 Stat. 119, 823 and interviews with HRSA officials.

[a]PPACA provides that these activities are to be conducted from amounts appropriated under a new authorization of appropriations. As of August 2011, no such appropriations have occurred.

[b]HRSA officials told us that the Office of Pharmacy Affairs' fiscal year 2011 budget allowed for the planning of a phased approach to recertification of all entity types, which is scheduled to begin in the fall of 2011. As of August 2011, officials were not able to tell us which entity types would be phased in first.

[c]Prior to PPACA, covered entities did not have access to 340B pricing data in order to monitor manufacturers because the Social Security Act prohibited the disclosure of the data by HRSA and state Medicaid agencies. 42 U.S.C. § 1396r-8(b)(3)(D). PPACA added a provision to Section 340B requiring that covered entities be allowed access to 340B pricing data. Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 824 (adding 42 U.S.C. § 256b(d)(1)(iii)).

Independent of the provisions in PPACA, HRSA also has recently developed guidance to further specify the definition of a 340B patient. While the Office of Management and Budget completed its review of this definition in April 2011, as of August 2011, HRSA had not yet released it for stakeholder comment. In 2007, HRSA also proposed updating this guidance, but it was never finalized.[67]

Even if HRSA implements PPACA's provisions and updates its definition of a patient, these steps may not be sufficient to address all areas of concern. For example, PPACA specifically requires HRSA to conduct selective audits of manufacturers, but it did not establish the same requirement for audits of covered entities. As such, the effectiveness of HRSA's oversight of covered entities will, in part, be dependent on what additional steps the agency takes to ensure program integrity. Similarly, if in implementing PPACA's provision prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, HRSA does not add specificity to the existing nondiscrimination guidance, it may be inadequate to ensure that all providers are able to equitably access drugs, particularly when manufacturers restrict the distribution of drugs at 340B prices. Also, as part of its 2007 proposed guidance on the definition of a patient, HRSA requested stakeholder comment on the elements that should be required in private, nonprofit hospitals' contracts with state or local governments as well as the different situations in which hospitals that are not publicly owned or operated should be formally granted government powers. However, HRSA officials told us that they have not issued additional guidance on these issues, and that they are not addressed in the clarifying guidance on the definition of a patient currently awaiting agency approval.

Conclusions

The 340B program allows certain providers within the U.S. health care safety net to stretch federal resources to reach more eligible patients and provide more comprehensive services, and we found that the covered entities we interviewed reported using it for these purposes. However, HRSA's current approach to oversight does not ensure 340B program integrity, and raises concerns that may be exacerbated by changes within the program. According to HRSA, the agency largely relies on

[67]Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of a "Patient," 72 Fed. Reg. 1543 (Jan. 12, 2007).

participants' self-policing to ensure compliance with program requirements, and has never conducted an audit of covered entities or drug manufacturers. As a result, HRSA may not know when participants are engaging in practices that are not in compliance. Furthermore, we found that HRSA has not always provided covered entities and drug manufacturers with guidance that includes the necessary specificity on how to comply with program requirements. There also is evidence to suggest that participants may be interpreting guidance in ways that are inconsistent with the agency's intent. Finally, participants have little incentive to comply with program requirements, because few have faced sanctions for non-compliance. With the program's expansion, program integrity issues may take on even greater significance unless effective mechanisms to monitor and address program violations, as well as more specific guidance are put in place. For covered entities, this may be particularly true in settings where there is heightened concern about the opportunities for the diversion of 340B drugs.

PPACA outlined a number of provisions that, if implemented, will help improve many of the 340B program integrity issues we identified. For example, PPACA requires HRSA to recertify eligibility for all covered entity types on an annual basis, which would help ensure entities that lose eligibility for the program do not remain enrolled. Additionally, PPACA requires HRSA to develop a formal dispute resolution process, including procedures for covered entities to obtain information from manufacturers, and maintain a centralized list of 340B prices—provisions that would help ensure covered entities and manufacturers are better able to identify and resolve suspected violations. PPACA also requires HRSA to institute monetary penalties for covered entities and manufacturers, which gives program participants more incentive to comply with program requirements. Finally, PPACA requires HRSA to conduct more direct oversight of manufacturers, including conducting selective audits to ensure that they are charging covered entities the correct 340B price.

However, we identified other program integrity issues that HRSA should also address. For example, the law does not require HRSA to audit covered entities or further specify the agency's definition of a 340B patient. While HRSA has developed new proposed guidance on this definition, it is uncertain when, or if, the guidance will be finalized. Because the discounts on 340B drugs can be substantial, it is important for HRSA to ensure that covered entities only purchase them for eligible patients both by issuing more specific guidance and by conducting audits of covered entities to prevent diversion. Additionally, while PPACA included a provision prohibiting manufacturers from discriminating against

covered entities in the sale of 340B drugs, HRSA does not plan to make any changes to or further specify its related nondiscrimination guidance. Absent additional oversight by the agency, including more specific guidance, access challenges covered entities have faced when manufacturers' have restricted distribution of IVIG at 340B prices may continue and similar challenges could arise for other drugs in the future.

Also, current HRSA guidance may allow some entities to be eligible for the program that should not be. Hospitals qualify for the 340B program in part based on their DSH adjustment percentage. Even though the PHSA establishes additional eligibility requirements for hospitals that are not publicly owned or operated, these requirements are broad, and HRSA has not issued more specific guidance to implement them. We found that nearly a third of all hospitals in the U.S. are participating in the 340B program, more are currently eligible and not participating, and more may become eligible as Medicaid is expanded through PPACA. As the number of covered entities enrolled in the 340B program increases and more drugs are purchased at 340B prices, there is the potential for unintended consequences, such as cost-shifting to other parts of the health care system. As such, it is important that HRSA take additional action to ensure that eligibility for the 340B program is appropriately targeted. While HRSA officials reported that the agency does not have the resources to implement the PPACA provisions or otherwise increase oversight of the 340B program, limited resources could be prioritized to address areas of greatest risk to the program.

Recommendations for Executive Action

PPACA contained several important program integrity provisions for the 340B program, and additional steps can also ensure appropriate use of the program. Therefore, we recommend that the Secretary of HHS instruct the administrator of HRSA to take the following four actions to strengthen oversight:

- conduct selective audits of 340B covered entities to deter potential diversion;
- finalize new, more specific guidance on the definition of a 340B patient;
- further specify its 340B nondiscrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices; and

- issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B program.

Agency Comments and Our Evaluation

In commenting on a draft of this report, HHS stated that it agreed with our recommendations. HHS also had additional comments on several content areas of the report, and we made changes as appropriate to address these comments. (HHS' comments are reprinted in appendix III.) Finally, HHS provided technical comments, which we incorporated as appropriate.

HHS stated that HRSA would continue to work on 340B program integrity efforts and prioritize these efforts based on available funding. HHS also outlined steps that HRSA plans to take in response to each of our recommendations. While we appreciate HHS' commitment to improving oversight of the 340B program, we are concerned that the steps are not sufficient to ensure adequate oversight.

With regard to our first recommendation that HRSA conduct selective audits of covered entities to deter potential diversion, HHS stated that HRSA will continue working with manufacturers to identify and address potential diversion and implement a plan to better educate covered entities about diversion. However, HHS did not state that HRSA will conduct its own audits of covered entities and we reiterate the importance of the agency doing so as part of its ongoing oversight responsibilities.

With regard to our second recommendation that HRSA finalize new, more specific guidance on the definition of a 340B patient, HHS stated that HRSA will review the draft of proposed guidance to update the definition and revise this guidance in light of changes in PPACA. While we agree that it may be important for HRSA to consider the impact of PPACA on the definition, given that PPACA became law more than a year ago, and the potential for broad interpretations of current guidance, we encourage HRSA to complete its review in a timely fashion.

With regard to our third recommendation, that HRSA further specify its non-discrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices, HHS stated that HRSA will: implement a plan to specify existing policy regarding 340B non-discrimination and drug distribution; provide clearer guidance to manufacturers for working with HRSA and develop specific allocation

plans where needed; and continue to work with the Department of Justice when fair, voluntary allocation plans are not developed. However, we are concerned that these steps do not require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices. Without taking this step, HRSA may not know when manufacturers are inequitably distributing drugs to covered entities and non-340B providers.

With regard to our fourth recommendation that HRSA issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B program, HHS stated that HRSA will implement a plan to better educate covered entities on existing criteria for hospital participation in the program and initiate a phased approach to recertifying eligibility for all participating covered entities. Here, we are concerned that these steps do not include further specification of eligibility criteria for hospitals that are not publicly owned or operated, because we determined that additional specification of statutory requirements was needed to ensure that the 340B program is appropriately targeted.

We are sending copies of this report to the Secretary of HHS and appropriate congressional committees. In addition, the report is available at no charge on the GAO web site at http://www.gao.gov.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or at draperd@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

Debra A. Draper
Director, Health Care

Appendix I: Selection of Interviews with Program Stakeholders

Type of stakeholder	Number of stakeholders interviewed	Interview details

Covered entities	29	27 were selected to take into account certain criteria:
		• Entity Type:
		  • We selected five types of covered entities and specifically interviewed: 7 federally qualified health centers (FQHC), 5 disproportionate share hospital (DSH) hospitals, 5 hemophilia treatment centers, 5 family planning clinics, and 5 AIDS Drug Assistance Programs (ADAP). (See appendix II for a list of all entities eligible to participate in the program.)
		  • We picked these types based on:
		  • variation in operational structure,
		  • variation in services and drugs provided,
		  • high levels of 340B participation,
		  • experience with the program, and
		  • potential difficulty accessing drugs at 340B prices.
		• Location:
		  • We selected entities in five states: Illinois, Massachusetts, Tennessee, Texas, and Utah.
		  • States were selected based on variation in a number of factors, including: geography, percent of uninsured individuals, and Medicaid reimbursement policies.[a]
		  • We included Massachusetts to gain a better understanding of the potential effect of the Patient Protection and Affordable Care Act (PPACA) health insurance reforms on the 340B program.[b]
		• We used information provided by trade organizations representing covered entities to help select individual covered entities to interview.
		2 additional DSH hospitals were selected based on concerns raised in stakeholder interviews about how these entities were using the program.

Drug manufacturers	6	Selected based on market share and those that produce drugs with reported challenges related to their distribution at 340B prices.
Organizations representing drug manufacturers and others involved in drug distribution	6	Includes 4 manufacturer trade organizations, 1 distributor, and 1 pharmacy benefits manager.[c]

Type of stakeholder	Number of stakeholders interviewed	Interview details
Organizations representing providers	16	Includes organizations representing providers, including covered entities and non-340B providers: • 9 organizations that represent covered entities, including 6 trade organizations and 3 private companies that provide services and information technology to help covered entities establish and manage their 340B programs. • 2 organizations representing non-340B providers, including 1 trade organization and 1 non-340B provider. • 5 organizations that represent both covered entities and non-340B providers, including 3 trade organizations and 2 group purchasing organizations (GPO).[d]
Federal agencies and contractors	4	HRSA, the contractors that help administer the 340B program, and the Centers for Medicare & Medicaid Services.
Total	**61**	

Source: GAO.

[a]Medicaid is a joint federal-state program that finances health care for certain categories of low-income individuals.

[b]In 2006, Massachusetts implemented comprehensive state-level health insurance reform that was similar to PPACA's national-level reform.

[c]Distributors manage the sale of drugs to purchasers on behalf of manufacturers. Pharmacy benefit managers administer the prescription drug benefits of health insurance plans on behalf of plan sponsors.

[d]GPOs contract with providers, such as hospitals, and, on behalf of their members, aggregate purchasing volume to negotiate discounts on drugs from drug manufacturers or distributors.

Appendix II: Select Information on Entities Eligible to Participate in the 340B Program

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011)[a]	Administering agency within the Department of Health Human Services (HHS)
Federal Grantees					
Federally-qualified health center (FQHC)[b,c]	Receives a section 330 grant under the Public Health Service Act (PHSA) (42 U.S.C. § 254b); meets the requirements to receive such a grant; or is an outpatient health program or facility operated by certain tribal or urban Indian organizations	Urban or rural health centers that provide comprehensive community-based primary and preventive care services to medically underserved populations.	1992[d]	4,826	Health Resources and Services Administration (HRSA)
Urban Indian organizations[e]	Receives funds under title V of the Indian Health Care Improvement Act (25 U.S.C. §§1651 et seq.)	Provide a variety of health programs to eligible individuals.	1992[d]	26	Indian Health Service
Family planning clinics (Title X)	Receives a grant or contract under Section 1001 PHSA (42 U.S.C. § 300)	Provide comprehensive family planning services.	1992[d]	3,868	Office of Population Affairs
Sexually transmitted diseases grantee	Receives funds under Section 318 of the PHSA (42 U.S.C. § 247c) and is certified by the Secretary of HHS	Provide screening and treatment for sexually transmitted diseases.	1992[d]	1,472	Centers for Disease Control and Prevention
Tuberculosis grantee	Receives funds under Section 317E of the PHSA (42 U.S.C. § 247b-6) and is certified by the Secretary of HHS	Provide treatment for tuberculosis.	1992[d]	1,221	Centers for Disease Control and Prevention
Native Hawaiian Health Centers	Receives funds under the Native Hawaiian Health Care Act of 1988 (42 U.S.C. §§ 11701 et seq.)	Provide comprehensive health promotion and disease prevention services to Native Hawaiians.	1992[d]	11	HRSA
State-operated Ryan White AIDS Drug Assistance Program (ADAP)	Receives financial assistance under title XXVI of the PHSA (42 U.S.C. §§ 300ff-11 et seq.)	Serve as a "payer of last resort" to cover the cost of providing HIV-related medications to low-income individuals who are uninsured or underinsured and cannot afford to pay for drugs or who cannot afford their health insurance coverage for drugs.	1992[d]	90[f]	HRSA

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011)[a]	Administering agency within the Department of Health Human Services (HHS)
Other Ryan White grantees	Receives a grant under Part C of title XXVI of the PHSA or non-governmental grantees that receive any financial assistance under title XXVI of the PHSA if certified by the Secretary of HHS	Provide primary care and support services to individuals with HIV or AIDS.	1992[d]	520	HRSA
Hemophilia treatment centers	Receives a grant under section 501(a)(2) of the Social Security Act (42 U.S.C § 701(a)(2))	Provide medical care to individuals with hemophilia.	1992[d]	99	HRSA
Black lung clinics	Receives funds under Section 427(a) of the Black Lung Benefits Act (30 U.S.C. § 937(a))	Provide medical treatment to individuals disabled from pneumoconiosis (black lung) as a result of their employment at U.S. coal mines.	1992[d]	13	HRSA
Hospitals					
Disproportionate share hospitals (DSH)	DSH as defined under Section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. § 1395ww(d)(1)(B)) with a DSH adjustment percentage greater than 11.75[g]	General acute care hospitals paid under the Medicare inpatient prospective payment system.	1992[d]	3,061	Centers for Medicare & Medicaid Services (CMS)
Children's hospitals	Children's hospital as described under Section 1886 (d)(1)(B)(iii) of the Social Security Act with a DSH adjustment percentage greater than 11.75[g]	Primarily provide services to individuals under 18 years of age.	2006[h]	147	CMS
Critical access hospitals	Critical access hospital as determined under Section 1820(c)(2) of the Social Security Act (42 U.S.C. § 1395i-4(c)(2)) (no DSH requirement)[g]	Located in rural areas, provide 24-hour emergency care services, and have no more than 25 inpatient beds.	2010[i]	941	CMS and HRSA
Sole Community Hospitals	Sole community hospital as defined under Section 1886(d)(5)(D)(iii) of the Social Security Act (42 U.S.C. § 1395ww(d)(5)(D)(iii))with a DSH adjustment percentage equal to or greater than 8[g]	Isolated from other hospitals by distance, weather, or travel conditions.	2010[i]	200	CMS and HRSA

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011)[a]	Administering agency within the Department of Health Human Services (HHS)
Rural Referral Centers	Rural referral center as defined under Section 1886(d)(5)(C)(i) of the Social Security Act (42 U.S.C. §1395ww(d)(5)(C)(i)) with a DSH adjustment percentage equal to or greater than 8[g]	Large rural hospitals that provide services for patients from a wide geographic area.	2010[i]	72	CMS and HRSA
Free-standing cancer hospitals	Free-standing cancer hospital as described under Section 1886 (d)(1)(B)(v) of the Social Security Act (42 U.S.C. § 1395ww(d)(1)(B(v))with a DSH adjustment percentage greater than 11.75[g]	Not a unit of another hospital, has a primary purpose of treating or conducting research on cancer.	2010[i]	5	CMS
Total				**16,572**	

Source: GAO analysis of federal laws and regulations.

[a]Data are the most recent available from HRSA's covered entity database and represent both covered entities and their associated sites. Because a covered entity may enroll under any and all eligible grant types it receives, it is possible that a site is reflected in the database more than once. However, HRSA estimates that this overlap represents less than 5 percent of all listings in the database.

[b]Not all FQHCs receive federal grants. Providers that meet all of the requirements for the FQHC program but do not receive federal grants are referred to as FQHC look-alikes and are eligible to participate in the 340B program.

[c]This category includes: FQHC look-alikes; Consolidated Health Centers; Migrant Health Centers; Health Care for the Homeless; Healthy Schools/Healthy Communities; Health Centers for Residents of Public Housing; and Tribal Organizations created under the Indian Self Determination Act (Pub. L.. No. 93-638) and administered by the Indian Health Service.

[d]Eligible to participate in the 340B program from its inception. See Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967.

[e]Section 1905(l)(2)(B) of the Social Security Act includes outpatient health programs or facilities operated by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services in the definition of FQHCs.

[f]According to HRSA, some states have both direct purchase and rebate programs, which are counted separately in the 340B covered entity database, which is the reason for the difference in the number of ADAPs in the database versus the number of states that have ADAP programs overall.

[g]Facility must also be (1) owned or operated by a state or local government, (2) a public or private, nonprofit corporation that is formally delegated governmental powers by a unit of state or local government, or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low income individuals who are not eligible for Medicaid or Medicare. Medicaid is the joint federal-state program that finances health care for certain low-income people, and Medicare is the federal health care program for the elderly and disabled. Children's hospitals and free-standing cancer hospitals do not receive payments under Medicare's inpatient prospective payment system; however, they must have a payer mix that would result in a DSH adjustment percentage greater than 11.75 percent. Facilities except critical access hospitals, Rural Referral Centers, and Sole Community Hospitals, must not obtain covered outpatient drugs through group purchasing.

[h]While PPACA explicitly added children's hospitals to the list of covered entities under the 340B program in the PHSA, they were originally made eligible under the Social Security Act through the Deficit Reduction Act of 2005. Pub. L. No. 109-171, § 6004, 120 Stat. 4, 61 (2006).

[i]Became eligible to participate in the 340B program under PPACA. Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302,124 Stat.1029, 1082.

Appendix III: Comments from the Department of Health and Human Services

Note: Page numbers in the draft report may differ from those in this report.

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

SEP 07 2011

Debra A. Draper
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Draper:

Attached are comments on the U.S. Government Accountability Office's (GAO) draft report entitled: "DRUG PRICING: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" (GAO-11-836).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

Jim R. Esquea

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

The Department appreciates the opportunity to review and comment on this draft report. We offer the following general comments on several content areas of the report:

The extent to which covered entities generate 340B revenue, factors that affect their revenue generation, and how entities use the program:

On Page 16, the report states that in Massachusetts where the state implemented universal health care, low-income patients gained private insurance, but "these patients often could not afford associated copayment or deductibles and the entity covered these costs". HRSA requests that the report reflect that this finding is consistent with the Health Resources and Services Administration's (HRSA) assessment that low-income patients will continue to require such assistance and the covered entities will provide valuable services to the safety net community.

On Page 18, the report states that "Even though the uses of revenue generated through the 340B Program were for similar purposes, some covered entities relied on 340B revenue more than others." The report goes on to state differences in revenue for FQHCs versus hemophilia centers. HRSA requests that the following explanation be incorporated into the report: Because each 340B entity type is unique in the types of services it provides and the patients it treats, the drug purchases of each entity type vary greatly (*i.e.*, generics versus brand or certain specialty drugs); therefore, their savings will also vary greatly.

Regarding how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers:

On Page 20, the report states that "One IVIG manufacturer reported that it restricted its distribution of IVIG by allocating its supply based on the amount of drug purchased by providers in 2004--allocating 95 percent of the projected monthly sales to non-340B providers and the remaining 5 percent to covered entities at the 340B Price" and "this manufacturer states that its distribution was fair and changing the distribution plans to increase the amount of IVIG drugs available at 340B prices could negatively affect non-340B providers' access to the drugs." HRSA requests that the report be edited to include:

> "HRSA does not believe that using the 2004 allocation of 95 percent to non-340B providers and 5 percent to 340B providers for a critical life saving drug is fair or sufficient. In 2005, there were 77 Hemophilia Treatment Centers and 591 Disproportionate Share Hospitals (DSH) purchasing IVIG through the 340B Program. This number has increased significantly to 99 Hemophilia Treatment Centers and

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GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

> 1,673 hospitals that now include children's hospitals, critical access hospitals, disproportionate share hospitals, free standing cancer hospitals, and rural referral centers. The allocation of IVIG drugs to 340B providers needs to be correlated to the increase in the 340B hospitals, as many of the same hospitals that purchased IVIG with no problems as non-340B providers in 2004 are now having tremendous difficulty in purchasing IVIG in 2011 as 340B providers. With 340B hospitals representing almost 33 percent of the hospitals of in the U.S. in 2011, 5 percent allocation for a life saving drug is not adequate."

On Page 21, the report states that some covered entities have stockpiled drugs when the price of a drug dropped. HRSA recommends that the report note that HRSA has worked with manufacturers in the past during an expected drop in price to develop an allocation process that is equitable across 340B and non-340B entities to prevent stockpiling. In addition, HRSA also encourages manufacturers to work with the agency to develop allocation processes to prevent issues with stockpiling.

HRSA's oversight of the 340B Program

On Page 24, the report states that HRSA has not issued guidance specifying the criteria under which hospitals that are not publicly owned or operated can qualify for the 340B program. HRSA requests that the report reflect that while HRSA has not published formal guidance in this area, HRSA has both criteria and a process in place to ensure hospitals satisfy 340B requirements. These criteria are utilized during the enrollment process and include:

- The criteria for hospital eligibility to participate in the 340B Program is outlined in section 340B(a)(4)(L)(i) which states the hospital "is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this title." This information is on the HRSA Office of Pharmacy Affairs (OPA) website.
- Prior to enrolling a hospital into the Program, OPA verifies that the hospital meets the three statutory requirements for participation in the 340B program: 1) non-profit status is verified by IRS documentation; 2) DSH eligibility, if applicable, is verified by the Medicare-cost report and 3) private hospitals must have a contract with state or local governments to provide health care services to low income

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the State plan of Title XIX of the Social Security Act. As part of the registration process, the hospital must submit a form that attests to the aforementioned statement that is signed by both an authorized public official and a hospital executive. Contracts are selectively reviewed if further clarification is necessary.

- OPA provides hospitals a list of recommendations during the enrollment process that can be used in developing a contract. HRSA strongly recommends and encourages the covered entity to seek legal counsel when preparing these contracts.

On page 24, the report states that some stakeholders expressed concern about the application of the requirements against non-discrimination. The conclusion of the report states that absent additional guidance, "access challenges covered entities have faced when manufacturers' have restricted distribution of certain drugs at 340B prices may continue." The language in the conclusion suggests that several challenges are known and identified; however, in its report the only access challenges identified involved IVIG. HRSA has been working with the Department of Justice (DOJ) to evaluate and improve access to IVIG for 340B entities. HRSA recommends that GAO provide additional detail regarding the access challenges found in order for HRSA to address these concerns and take appropriate action.

On Page 25, the report states that HRSA verifies eligibility for 340B at enrollment, but does not periodically recertify eligibility for all covered entity types. HRSA requests that the report reflect that HRSA has been meeting the statutory requirement; HRSA recertified and continues to recertify STD, TB, and HIV/AIDS programs annually as expressly required under section 340B (a)(7) of the Public Health Services Act (42 U.S.C. 256b). These were the only entities that required annual certification by the Secretary prior to the PPACA. In addition, HRSA monitors DSH percentages and FQHC grant status on a quarterly basis. Each quarter OPA verifies the proprietary status of participating hospitals by matching its list of participating hospitals with CMS's list of hospitals to ensure that ineligible private hospitals are not participating. As a result of the PPACA, HRSA is required to annually recertify all 340B covered entities. OPA's FY2011 budget of $4.4M will allow for the planning of and initiation of a phased approach to recertification to begin in fall of 2011.

On Page 31, footnote (a) states that no appropriation has occurred for annual recertification. HRSA recommends that this statement be replaced with the following, "HRSA program FY2011 budget of $4.4M will allow for the planning and initiation of a phased approach to recertification to begin in fall 2011."

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GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

On Page 32, the report states that the PPACA specifically requires HRSA to conduct selective audits of manufacturers but it did not establish the same requirement for audits of covered entities. HRSA requests that the report clarify that the agency has had the authority to audit covered entities under section 340B(a)(5)(C) of the Public Health Service Act since the inception of the program.

GAO Recommendations

HRSA agrees with the recommendations and will continue to build on program integrity efforts and work to prioritize efforts based on funding. Implementation of a cost recovery fee as outlined in the FY 2012 President's budget would allow for the initiation of the implementation of all recommendations and program integrity provisions outlined in PPACA. The 340B Drug Pricing program integrity risk assessment is scheduled to begin in the fall of 2011.

GAO Recommendation #1: *Conduct selective audits of 340B covered entities to deter potential diversion.*

HRSA Actions:

- HRSA and the manufacturers have the authority to audit 340B covered entities. HRSA will continue to work with the manufacturers to identify potential diversion and work with manufacturers to develop audit plans where evidence suggests potential diversion may be occurring.
- HRSA will develop and implement a comprehensive educational and communication plan which will build on existing tools and resources, such as targeted webinars on diversion, peer to peer learning, FAQs, policy letters to covered entities, and more assistance to covered entities in assessing risk.

GAO Recommendation #2: *Finalize new, more specific guidance on the definition of a 340B patient.*

HRSA Actions:

- HRSA will review the draft of the proposed patient definition guidelines in view of PPACA changes and develop revised guidelines for publication.

4

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

Recommendation #3: *Further specify its 340B non-discrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices.*

HRSA Actions:

- HRSA will develop and implement a comprehensive educational and communication plan which will specify the existing policy regarding 340B non-discrimination and drug distribution to include, webinars, and policy letters to manufacturers regarding non-discrimination guidance.
- HRSA will continue to work with manufacturers to provide clearer guidance for manufacturers on working with HRSA and develop specific allocation plans where needed.
- HRSA will continue to work with DOJ when fair, voluntary allocation plans are not developed.

Recommendation #4: Issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B Program.

HRSA Actions:

- HRSA will further publicize its existing criteria for hospital participation in the 340B program by placing the criteria and process on the program website and issuing policy letters to affected covered entities outlining these criteria.
- HRSA will initiate a phased approach to recertification for all participating entities, including hospitals, beginning in fall of 2011. This recertification process will enable HRSA to verify that hospitals continue to meet the statutory requirements for program participation.
- HRSA will develop and implement a comprehensive educational and communication plan which will build on existing tools and resources such as targeted webinars on the hospital criteria, peer to peer learning, FAQs, and letters to covered entities.

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Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Debra A. Draper, (202) 512-7114 or draperd@gao.gov

Staff Acknowledgments

In addition to the contact named above, Gerardine Brennan, Assistant Director; Jennie Apter; Kristin Ekelund; Kelli Jones; Dawn Nelson; Rachel Svoboda; and Jennifer Whitworth made key contributions to this report.

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EXHIBIT F

CALIFORNIA

California proposal would sideline a prolific ballot measure player

The ballot initiative would block one man from using his nonprofit to fund his political agenda.

Michael Weinstein has channeled upward of $100 million in recent years toward a wide array of state and local ballot measures and political causes. | Kevin Wolf/AP Images for AIDS Healthcare Foundation

By **CHRISTOPHER CADELAGO**
08/30/2023 12:58 PM EDT
Updated: 08/30/2023 07:29 PM EDT

SACRAMENTO, Calif. — California's trade group for landlords is preparing to spend millions on a ballot initiative to vanquish one man.

The new measure, reported first by POLITICO, would effectively forbid AIDS Healthcare Foundation founder Michael Weinstein from using the organization's coffers to advance his political agenda through the ballot. The tax-exempt nonprofit operates a massive network of clinics and pharmacies that serve millions of patients across dozens of countries. It also runs thrift stores.

Weinstein, the group's polarizing leader from Los Angeles, has channeled upward of $100 million in recent years toward a wide array of state and local ballot measures and political causes — some of which were only loosely tied to the central mission of the sprawling AIDS organization.

California's ballot wars have often featured monied interest groups and their high paid political mercenaries taking each other on with a veritable carpet-bombing of expensive TV ads. But a ballot measure like this — one to outlaw a single person — is highly unusual. It dispenses with pretense and puts the target right on Weinstein's back, with supporters unveiling an early November 2024 slogan: "Stop the Weinstein scam."

Leading the charge is the California Apartment Association, the nation's largest statewide association for rental owners and managers. Among those joining the coalition are Assemblymember Evan Low (D-Campbell), who also is helping

the ballot push to rescind California's Proposition 8 same-sex marriage ban from 2008 that was struck down in federal court in 2010.

"It's common sense: public tax dollars meant for patients should be spent on patients," Low said.

Low previously authored legislation to prohibit AHF from using state and federal funds or money from a federal drug-discount program for housing-related ballot measures or to bankroll litigation to gum up housing projects. Others have urged state investigations into the foundation's use of savings from the drug-discount program that is designed to help poor patients.

In a statement Wednesday afternoon, a spokesperson for the foundation assailed the California Apartment Association, saying the trade group "is so afraid of the voters that they need to muzzle renter advocates. They are classic bullies who can't deal with a fair fight."

Although he's enjoyed few, if any, electoral successes in the Golden State, Weinstein's spending alone on rent control, a housing development freeze, drug pricing and mandating condoms in adult films has made him a force to be reckoned with. Some of California's leading politicians and interest groups see him as an uncompromising pugilist with few allies outside his own organization.

For more than a decade in Sacramento and Los Angeles, they've complained that he's exploited a loophole allowing him to use AHF as his own political

piggy bank. But he's kept spending, and fighting. Weinstein, once a candidate for Los Angeles City Council, has mostly embraced his outsider role, arguing he's not trying to win a popularity contest and holding himself out as a one-man army willing to not only touch third rails but crash right through them.

Weinstein mercilessly attacked drugmakers. He waged a public battle against the pill to prevent HIV infection. He's fought landlords with repeated attempts at expanding rent control in California.

The new anti-Weinstein initiative — named the Protect Patients Now Act — would target Weinstein over how he amasses the money he spends on campaigning. AHF relies on the decades-old federal drug discount program designed to help hospitals and other healthcare nonprofits treat low-income patients. Known as 340B, it allows the organization to purchase prescriptions at a deep discount and charge public programs the standard amount. AHF has long argued that it spends 340B funds for their intended purpose and that the foundation is allowed to spend a certain percentage on political activity.

But its spending on campaigns, a growing portfolio of property and to bring in paid consultants such as former California Senate Pro Tem Kevin de León, now a member of the Los Angeles City Council, has drawn persistent scrutiny.

The new ballot measure is highly targeted. Specifically, it would apply only to drug program participants that have spent more than $100 million on issues other than direct patient care and have 500 or more health and safety violations on their low-income properties. POLITICO could find no other organizations that match that criteria.

The measure would require AHF to spend 98 percent of its taxpayer-generated revenues on direct patient care. It also would seek to prevent the group from overcharging government agencies for prescription drugs.

If AHF violated the new law, the state could strip its nonprofit status and make the organization ineligible for taxpayer dollars. Proponents say their internal polling on the measure conducted in July by FM3 Research found a solid majority supporting the proposal, with a quarter opposed at the onset.

Weinstein has been the subject of scorn in political circles and an enormously frustrating figure to critics, some of whom he's put on notice with barbed mailers. Still, he's far from a household name across a state of nearly 40 million. In April, POLITICO was the first to report that he'd taken the unusual step of paying $2 per signature for a letter to Gov. Gavin Newsom that demanded he do more to help lower the cost of housing and urged him to at least stay neutral on AHF's rent-control measure.

Ethics experts at the time contended Weinstein and AHF should have been transparent about paying people to get signatures for the draft letter, which referenced by name the proposed rent-control ballot initiative. AHF defended its use of the paid letter.

The governor himself has largely ignored Weinstein while taking aim at AHF's measures that lost big at the ballot box. Newsom opposed Proposition 21 in 2020, suggesting it was unnecessary since California had already passed sweeping rent control. Newsom similarly opposed Weinstein's Proposition 10 in 2018, saying it may have unintended consequences on housing production that could be deeply problematic for the state.

Weinstein blamed Newsom for his setbacks, and has offered sharp rebukes about the governor's tenure, including his handling of the pandemic.

The California Apartment Association and others involved in the latest Weinstein broadside pointed not just to the past statewide ballot losses, but to other activities as well. Weinstein sued California over affordable housing laws and was flagged by state officials for alleged improper negotiating tactics. Weinstein countered the state was retaliating against him for pushing for higher rates.

FILED UNDER: GAVIN NEWSOM, AIDS

POLITICOPRO

California Apartment Association moves millions into anti-Weinstein initiative

The rental housing industry is gathering signatures for a ballot proposal aimed at one group.

BY: JEREMY B. WHITE | 11/06/2023 05:34 PM EST

California's rental housing industry is moving millions of dollars to hamstring a longtime political foe.

The California Apartment Association on Friday channeled $2.3 million into qualifying a ballot measure that would shut down political spending by the AIDS Healthcare Foundation, a health care nonprofit that is pursuing its third rent control initiative in the past four election cycles.

Why it matters: With its latest contribution, the industry group is showing that it's serious about qualifying and pursuing an effort to clip divisive leader Michael Weinstein's wings. There is always the possibility that the political pressure will encourage Weinstein to withdraw the rent control initiative, although he has given no indication he intends to do so.

The background: The proposed ballot measure is aimed squarely at the AIDS

Healthcare Foundation and Weinstein, who has steered millions of dollars from a chain of clinics and pharmacies to state and local ballot measures — including nearly $8 million this year on another attempt to loosen state rent control restrictions after the previous two failed.

The ballot initiative backed by the Apartment Association would require organizations that draw revenue from a federal drug discount prescription drug program, as the AIDS Healthcare Foundation does, to spend almost all of that funds on patient care. The proposal's supporters argue Weinstein is abusing the system to advance his pet causes.

The AIDS Healthcare Foundation has countered that the apartment association is motivated by dodging rent control, saying in a statement on Monday that it was using its "bottomless fortune to try to silence the strongest organization advocating on behalf of struggling renters." It has filed a complaint with the state's Fair Political Practices Commission accusing the organization of violating campaign finance laws.

What's next? Paid signature gatherers will likely hit the streets to get the measure on the November 2024 ballot. If they succeed, voters will be weighing in on both the AIDS Healthcare Foundation's rent control initiative and the apartment association's anti-AHF push.

OPINION

Editorial: It's not OK for special interests to use the California ballot to attack each other

AIDS Healthcare Foundation President Michael Weinstein, right, and Vice President Mark Dyer at the opening of the Leland Hotel in downtown Los Angeles after it was converted into affordable rental units in September 2023. (Irfan Khan/Los Angeles Times)

By The Times Editorial Board

April 4, 2024 11:38 AM PT

How has California's direct democracy system been misused to serve narrow special interests? In just the last few years, there was the billionaire venture capitalist with the harebrained idea that California should be six — no, three separate states. There was the

labor union that spent millions of dollars on ballot measures — in three elections! — to punish the dialysis industry that wouldn't fall in line.

There was the referendum by the plastic-making industry that tried to undo California's ban on single-use plastic shopping bags. There was the politically motivated recall election of Gov. Gavin Newsom in 2021 that failed. And more recently Big Oil poured money into qualifying a measure for the November ballot to repeal a law banning oil drilling near schools and homes. These are just a few high-profile examples.

There are also dozens of failed attempts by those without the deep pockets or political organizational skills to gather enough signatures to qualify their idea (or obsession in some cases. Looking at you, ferret legalization guy) for the ballot.

This was never the intention of former Gov. Hiram Johnson, who in the early 20th century pushed for a system allowing California voters to bypass elected officials to make or repeal laws, should lawmakers become beholden to special interests. Instead, the special interests themselves — rich individuals, industries, lobbying groups and labor unions, among others — learned they could use this citizen democracy tool as well, with the right investment.

OPINION

Editorial: California still hasn't fixed its undemocratic recall rules

March 19, 2024

While voters have mostly seen through self-serving ballot initiatives, the misuse of the ballot continues and recently reached a new high — or rather, new low.

Last month, the California Apartment Assn. turned in more than enough signatures needed to place a measure on the November ballot for which the sole purpose appears to be stopping one guy from putting his own measures on future ballots. This one guy is Michael Weinstein, president of the Hollywood-based AIDS Healthcare Foundation,

who has used his organization's resources to fund three rent control initiatives (two failed, the third will be on November's ballot).

Weinstein says that this is clearly a measure intended to stop his efforts to expand rent control. And there are several reasons that support that assertion. The association's members include apartment owners, managers and investors who are typically opposed to rent control for obvious reasons. The campaign site protectcapatientsnow.com is subtitled "Stop the Weinstein Scam." The campaign video on the site features Weinstein as well, calling him a "predatory pharmaceutical middleman" and "slumlord." (The AIDS charity has a problematic history as a landlord of Skid Row housing for homeless people.)

OPINION

Editorial: John Eastman tried to help Trump overturn the 2020 election. Of course he should be disbarred

April 1, 2024

And, its name not withstanding, the Protect Patients Now Act's language seems tailored specifically to target the AIDS Healthcare Foundation. It applies only to healthcare providers that have spent more than $100 million in the last decade on anything not considered direct patient care *and* that operate multifamily housing with more than 500 high-severity health and safety violations. The AIDS Healthcare Foundation meets all of those criteria. Under the proposal, it would lose its tax-exempt status if it spends more than 2% of its revenue from 340B, a federal drug discount program, on anything other than healthcare.

Incredibly, the proponents insist that the measure is only about stopping abuse of the 340B program, which mandates that nonprofit healthcare providers serving low-income patients get discounts from pharmaceutical companies but are reimbursed for the full price of those drugs by public programs. The healthcare providers are allowed to use the difference to pay for other health services for their patients. Weinstein says that lack of

affordable housing is a healthcare issue, therefore using 340B revenue to support tenant protection measures is allowable.

OPINION

Editorial: Not everything should go to the ballot. Lawmakers, do your job

June 7, 2022

If there are problems with the federal drug discount program, the ballot is not the appropriate venue to resolve them. Besides, it seems clear that the 340B program is a straw man, even if nine patient groups have signed on to support it.

We don't love the fact that a single person or entity with deep pockets — be it a lobbying group, tech titan or the head of a nonprofit — can use the ballot to pass laws that serve their own agendas, but California election law allows it. What it may not allow is for a ballot measure to target a single individual.

The AIDS Healthcare Foundation has sued to block the Protect Patients Now Act, claiming it's a violation of state law. If the judge in the case allows it to remain on the ballot (it's not certain she will) it will be up to voters, once again, to make sense of a murky, self-serving ballot measure.

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July 8, 2024

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July 5, 2024

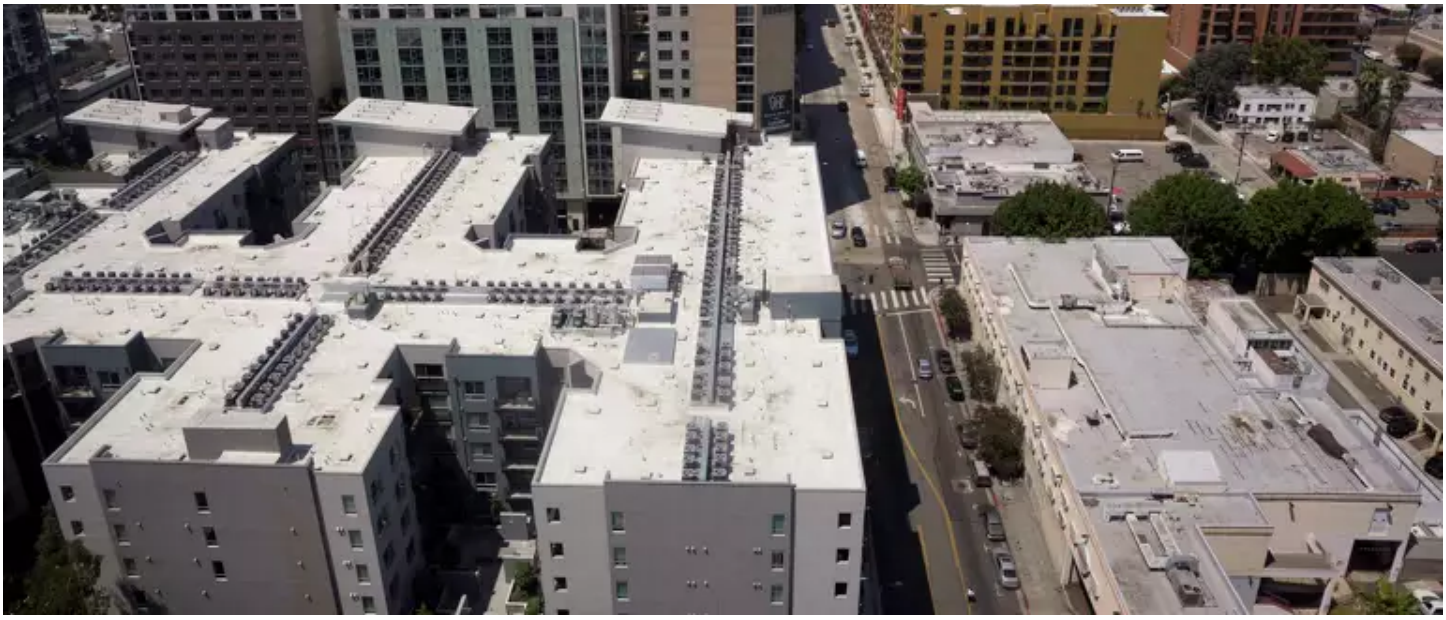
JUST IN 22 MIN AGO **Target to shutter East Palo Alto store, cutting 85 jobs**

POLITICS

California voters can decide ballot measure targeting L.A. nonprofit, state Supreme Court rules

By **Bob Egelko**, Courts Reporter

July 17, 2024



Several apartments line the streets as seen from the offices of the AIDS Healthcare Foundation in Los Angeles. The state Supreme Court on Wednesday refused to remove a measure from the November ballot targeting the L.A. nonprofit's political activity.

Damian Dovarganes/Associated Press

The California Supreme Court refused Wednesday to remove from the November ballot an initiative backed by apartment owners that would prohibit one man, a wealthy health care executive and supporter of rent control, from spearheading future ballot measures. The court declined to take up the executive's legal challenges before the election but could consider them if voters approve the initiative, Proposition 34.

The initiative does not identify its adversary, Michael Weinstein, president of the AIDS Healthcare Foundation. But if a medical organization met certain financial standards — which, by all indications, are met only by Weinstein's foundation — it would be required by Prop. 34 to spend 98% of its funds on health care.

The foundation, cofounded by Weinstein in 1987, is based in Los Angeles and is the nation's largest AIDS organization. According to its website, it serves more than 1.5 million patients in 45 nations, with more than 730 clinics providing care regardless of a patient's ability to pay.

Despite its nonprofit status, the foundation collects $2 billion a year in revenue, mostly from pharmacies and clinics it operates. It has been sued in multiple courts by tenants alleging poor conditions in apartments the foundation owns.

Weinstein crossed paths with property owners as an advocate of rent control. He linked it to health care in a court filing, saying his foundation "advocates for housing affordability because secure and stable housing is vital to positive health outcomes."

He has tried, unsuccessfully so far, to roll back the Costa-Hawkins Act, a 1995 California law backed by apartment owners that prohibited local governments from limiting rents on single-family homes, condominiums and new apartment

units.

Weinstein's 2018 initiative, Proposition 10, would have repealed Costa-Hawkins. His 2020 measure, Prop. 21, was somewhat more limited and would have allowed local governments to enact rent control for older housing units and those owned by large companies. Both were rejected by nearly 60% of the voters.

He is making a third attempt this November with Prop. 33, which would again seek to repeal Costa-Hawkins and allow local governments to enact rent control.

It will be Weinstein's last chance on the issue if voters approve the next measure listed on the ballot, Prop. 34.

Sponsored by the California Apartment Association and allied groups, Prop. 34 would limit the financial activities of any operator of a drug program that has spent more than $100 million in 10 years on projects other than direct care of patients and has operated multi-family housing with more than 500 serious health or safety violations.

The only organization that fits that description is the AIDS Healthcare Foundation. Prop. 34, if approved, would require the foundation to spend 98% of its funds on direct patient care — effectively prohibiting Weinstein from using foundation revenue to sponsor any future state or local ballot measures.

The initiative is an attempt "to muzzle a political adversary through a carefully targeted measure that will apply to one and only one regulatory target," Beverly Grossman Palmer, an attorney for Weinstein and his organization, said in a filing with the state Supreme Court.

She argued that Prop. 34 is a "bill of attainder" — constitutionally forbidden legislation designed to punish an individual or group without a trial — and should be removed from the ballot or returned to an appellate court for immediate review of the legal issues.

Lower courts have denied review of Weinstein's claims, saying they could be taken up after the election.

That has been the usual practice in California courts. But last month the state Supreme Court unanimously removed from the November ballot a business-sponsored initiative that would have required voter approval for any increase in state or local taxes or fees. The court said it was so far-reaching that it would be a "revision" of the state Constitution, which cannot be done by initiative.

In support of Weinstein, the advocacy group Consumer Watchdog told the court that Prop. 34 is "a poorly veiled attempt by the California Apartment Association to silence a political adversary. If it is allowed to be put to the voters, no organization in the future will be safe from similar retribution by monied opponents."'

But lawyers for the apartment owners said their goal was to require health care organizations to spend their funds on patients, not politics, and denied they were targeting Weinstein. They said their initiative, which they have titled the Protect Patients Now Act, has been endorsed by patient-advocacy groups including the San Francisco Women's Cancer Network, the Defeating Epilepsy Foundation and the California Senior Alliance.

Sean Welch, attorney for the ballot measure's sponsors, told the court that Prop. 34 is aimed at halting abuses of a federal program that allows health care providers to obtain drugs at a discount to provide to low-income patients and then seek full reimbursement from private insurers or the government.

The initiative "imposes requirements on state-licensed health care entities that divert large sums of (program) revenues — over $100 million in any 10-year period — toward purposes unrelated to direct patient care and have operated residential housing in a manner that jeopardizes public health and safety," Welch wrote.

The court issued a one-sentence order Wednesday denying review, with no indication of a dissent from any of its seven justices. Jacki Schechner, spokesperson for the AIDS Health Care Foundation, said afterward that pre-election challenges to ballot measures have "a very high bar" and that the constitutional challenges remain unresolved.

"We are confident that the voters will see through this obvious revenge initiative and vote it down," she said.

But Nathan Click, spokesperson for the Prop. 34 campaign, said the initiative "would simply ensure accountability and transparency for how public health

care dollars are spent. The fact that AHF, a billion-dollar pharmaceutical giant, is fighting so hard against basic transparency requirements should cause Californians great alarm."

The case is AIDS Healthcare Foundation v. Superior Court (Weber), S285602.

Reach Bob Egelko: begelko@sfchronicle.com; Twitter: @BobEgelko

July 17, 2024

Bob Egelko
COURTS REPORTER

Bob Egelko has been a reporter since June 1970. He spent 30 years with the Associated Press, covering news, politics and occasionally sports in Los Angeles, San Diego and Sacramento, and legal affairs in San Francisco from 1984 onward. He worked for the San Francisco Examiner for five months in 2000, then joined The Chronicle in November 2000.

His beat includes state and federal courts in California, the Supreme Court and the State Bar. He has a law degree from McGeorge School of Law in Sacramento and is a member of the bar. Coverage has included the passage of Proposition 13 in 1978, the appointment of Rose Bird to the state Supreme Court and her removal by the voters, the death penalty in California and the battles over gay rights and same-sex marriage.

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