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Proposition 61: State Prescription Drug Purchases. Pricing Standards

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Proposition 61: State Prescription Drug Purchases. Pricing Standards.

Initiative Statute.

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I. EXECUTIVE SUMMARY

Proposition 61 seeks to lower the prices the State of California pays for prescription medications to the same price or less than what is paid by the Department of Veteran Affairs (VA) for any particular medication. The price paid by the VA is by far the lowest price paid to drug manufacturers by any government agency. Proposition 61 has the potential to save the state funds, but it is impossible to predict how prescription medication manufacturers will respond to this proposition should it be enacted. This measure exempts most of Medi-Cal's managed care plans, which provide health insurance coverage to the majority of the state's low-income individuals. Additionally, this measure restricts the state when buying prescription medications directly from pharmaceutical manufacturers or when reimbursing pharmacies for recipients' medications by setting a maximum price the state can pay. However, it is important to note that under federal law all Medicaid programs (Medi-Cal in California) are required to cover all medications that have been approved by the United States Food and Drug Administration (FDA), and, if manufacturers declined to offer prescription medications at the lowest price paid by the VA, the state would probably have to offer the medications anyway under federal law.

A YES VOTE means that any state agency would be prohibited from paying more for prescription medications than is paid by the VA for the same prescription medication. This measure exempts most Medi-Cal Managed Care Programs from the required spending limits.

A NO VOTE means that when state agencies are negotiating and paying for prescription medications, no reference to the prices paid by the VA would be required.

II. THE LAW

A. The Path To The Ballot

In the United States, we spend twice as much on healthcare per capita than other advanced countries, but we are not living any longer than those who are spending less.[1] In the 1990s, prescription medications accounted for 7 percent of total healthcare costs, including physician visits, prescription drugs, hospital care and home nursing care.[2] In recent years, the number has increased to 17 percent, according to the United States Health and Human Services Department.[3] The cost of medications varies between generic and brand name medications. Brand name medications are protected from competitors due to their patent and are typically more expensive.[4] Generic medications can be purchased for a cheaper rate, however, the price of generic medication depends on the competition for the medication in the market.[5] Once a patent

[1] Joint Senate and Assembly Health Committee Informational Hearing on Proposition 61, May 10, 2016. *Available at* http://senate.ca.gov/media-archive?title=&startdate%5Bvalue%5D%5Bdate%5D=05-10-2016&enddate%5Bvalue%5D%5Bdate%5D=05-10-2016# (on file with the *California Initiative Review*).
[2] Melody Peterson, *Here's Why Drug Prices Rise Even When There's Plenty of Competition*, L.A. TIMES (September 5, 2016), http://www.latimes.com/business/la-fi-mylan-price-hikes-20160830-snap-story.html (on file with the *California Initiative Review*).
[3] *Id*.
[4] *Id*.
[5] *Questions and Answers*, FDA U.S. FOOD & DRUG ADMINISTRATION (September 5, 2016), http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (on file with the *California Initiative Review*).

has expired, generic drug manufacturers will compete with the original patent holder to make the medication.[6] This competition used to drive down costs for medications, but today medication prices continue to rise.[7]

The price of an EpiPen, a device that counteracts life-threatening allergies by injecting epinephrine directly into someone experiencing an allergic reaction, has increased by 547 percent since 2007.[8] The EpiPen has gone from $94 in 2007 to $608 today, far exceeding the average rate of inflation.[9] Similarly, Daraprim, which treats patients with the parasite-borne disease toxoplasmosis, has increased from $13.50 per pill in 2015, to $750 per pill today.[10] The treatment regimen consists of two pills per day for two weeks, which equates to an increase from $1,130 to $63,000 for a treatment cycle.[11] A Hepatitis C medication, Sovaldi, has doubled in price since 2011, and another Hepatitis C medication, Harvoni, is even more expensive than Sovaldi.[12]

State legislation to bring light to the issue of medication pricing transparency has failed. Senator Ed Hernandez and Assemblyman David Chiu each introduced bills in the 2015-2016 regular session that would have helped bring prescription drug prices to the public's attention.[13] Assembly Bill 463 (Chiu) would have required manufacturers with medications with a cost of $10,000 or more annually to file a report.[14] Senate Bill 1010 (Hernandez) would have required health care service plans or health insurers to file cost specific information regarding the cost of prescription medications.[15] But, Sen. Hernandez pulled his bill due to amendments that limited its efficacy, and Assemblyman Chiu's bill was held in committee.[16]

Michael Weinstein, President of AIDS Healthcare Foundation, wanted to bring Proposition 61 to a vote of the people in the hope that it would lower the prices of prescription medications paid for by the state.[17] Based in Los Angeles, the AIDS Healthcare Foundation is the largest provider of AIDS/HIV healthcare services in the United States.[18] There is a difference in the financial campaigning power between the support and opposition. As of

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[6] Peterson, *supra* note 2.
[7] *Id*.
[8] *Id*.
[9] *Id*; Inflation Data: Average rate is 3.2 percent; Tim Mcmahon, *Long Term U.S. Inflation*. INFLATIONDATA.COM (September 10, 2016), http://inflationdata.com/Inflation/Inflation_Rate/Long_Term_Inflation.asp (on file with the *California Initiative Review*).
[10] Michael Hiltzik, *A Huge Spike in the Cost of an Old Drug Reignites the Pharma Pricing Debate*, L.A. TIMES (September 22, 2016), http://www.latimes.com/business/hiltzik/la-fi-mh-a-huge-spike-in-the-cost-of-an-old-drug-20150921-column.html (on file with the *California Initiative Review*).
[11] *Id*.
[12] *Id*.
[13] Tracy Seipel, *California's Prop. 61 Seeks to Lower Drug Prices, Increase Transparency, THE MERCURY NEWS* (September 6, 2016), (on file with the *California Initiative Review*).
[14] AB 462, 2016 Leg., 2015–2016 Reg. Sess. (Cal. 2016) (as amended on Jan. 4, 2016, but not enacted).
[15] SB 1010, 2016 Leg., 2015–2016 Reg. Sess. (Cal. 2016) (as amended on Aug. 16, 2016, but not enacted).
[16] Seipel, *supra* note 13.
[17] Andrew Pollack, *California Drug Price Plan is Criticized by Patient Advocates*, N.Y. TIMES (August 28, 2016) http://www.nytimes.com/2016/07/05/business/california-drug-price-plan-is-criticized-by-patient-advocates.html?_r=1 (on file with the *California Initiative Review*).
[18] *Id*.

October 2, 2016, the opposition has raised $86 million while support for this proposition has raised $14.5 million.[19]

Weinstein also initiated a similar initiative in Ohio, titled "Ohio Drug Price Relief Act."[20] The Ohio initiative process differs slightly from California. Ohio is an indirect initiative state, and Ohio law requires two installments of signatures.[21] The first installment requires the proponents to collect signatures totaling at least 3 percent of the votes in the last gubernatorial election to get the initiative to the legislature.[22] If the legislature does not move on the initiative, the proponents may collect additional signatures, totaling 3 percent of the vote in the last gubernatorial election, to be placed on the ballot for the people to vote on.[23] At the end of both installments, the total amount of signatures collected should equal 6 percent of the total votes in the last gubernatorial election.[24]

The Ohio Initiative was challenged for lacking sufficient signatures by Pharmaceutical Research and Manufacturers of America (PhRMA) and the Ohio Chamber of Commerce.[25] The Court initially upheld the challenge, but within another lawsuit regarding the same signatures, the court decided to count the signatures.[26] The Ohio Initiative was then allowed to proceed collecting more signatures to qualify for the ballot.[27] The initiative will be on the November 2017 ballot in Ohio.[28]

B. Possible Alternative Solutions

During an informational joint committee hearing on Proposition 61 held by the Legislature on May 10, 2016, Assemblymember David Chiu asked both supporters and opponents of Proposition 61 if they agreed that something must be done about prescription drug prices.[29] All parties were able to agree on that point.[30] However, when Assemblymember Chiu asked if the opponents had a better solution to propose, they were silent.[31] One of the solutions that Assemblymember Chiu suggested was that most other developed countries, like Canada, have set ratio limits on the amount of profit manufacturers are allowed to make on prescription medications.[32]

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[19] *California Proposition 61, Drug Price Standards (2016),* BALLOTPEDIA (August 22, 2016), https://ballotpedia.org/California_Proposition_61,_Drug_Price_Standards_(2016) (on file with the *California Initiative Review*).
[20] *Id.*
[21] *Ohio Drug Price Standards Initiative (2017),* BALLOTPEDIA (August 29, 2016), https://ballotpedia.org/Ohio_Drug_Price_Standards_Initiative_(2017) (on file with the *California Initiative Review*).
[22] OHIO CONST. art 2, sec. 1.
[23] *Id.*
[24] *Id.*
[25] *Ohio Drug Price Standards Initiative (2017),* BALLOTPEDIA (August 29, 2016) https://ballotpedia.org/Ohio_"Drug_Price_Relief_Act"_Initiative_(2017) (on file with the *California Initiative Review*).
[26] *Id.*
[27] *Id.*
[28] Joint Senate and Assembly Health Committee Informational Hearing on Proposition 61, *supra* note 1.
[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] *Id.*

Federal legislation attempting to link Medicaid prescription pricing to the VA in the past has failed, leaving most states attempting to resolve escalating prescription drug costs on their own. Vermont passed a law, S.216, requiring drug manufacturers to justify their price increases for some medications.[33] In Texas, House Bill Number 4002, will initiate a joint interim study to discover the reasons behind prescription drug pricing increases.[34] New York is also considering capping the prices its Medicaid program pays for some prescription medications.[35] Virginia, Oregon, Pennsylvania, North Carolina and Massachusetts had proposals regarding drug pricing transparency that have not passed.[36] For example, in Massachusetts, Senate No. 1048 was introduced to promote cost transparency.[37] Likewise, in Virginia, House Bill 113 would require drug transparency for medication with a wholesale acquisition of $10,000 or more to report costs associated with the drug to report to the Commissioner.[38]

C. EXISTING LAW

1. Overview of State Prescription Medication Spending

California pays for prescription medications for those who are covered by Medi-Cal County Organized Health Systems, Medi-Cal Fee-For-Service Programs, Medi-Cal for individuals with moderate to severe mental health disorders, current and retired state employees, students in the University of California and California State University systems, inmates, uninsured individuals who are HIV positive, state hospital patients and developmental center residents.[39] The state is the ultimate payer of medications when it either negotiates directly with manufacturers or reimburses pharmacies for drugs they have dispensed to patients covered under a state program.[40] Annual state drug expenditures totaled $3.8 billion in 2015–16.[41] State funds pay for half of overall state prescription drug spending and the remainder comes from the federal government and other non-state revenues.[42]

2. State Negotiation Strategies for Prescription Prices

The State has many strategies it may use when negotiating for discounted prices with manufacturers and wholesalers. State agencies may decide to negotiate together or

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[33] S 216, 2016 Leg., 2015–2015 Reg. Sess. (VT. 2016).
[34] HB 4002, 2015 Leg., 2015 Leg. Ses.. (TX. 2015) (as introduced Mar. 13, 2015, but not enacted).
[35] Ed Silverman, *NY Governor Andrew Cuomo Seeks to Cap Some Drug Prices*, STAT (September 2, 2016) *available at* https://www.statnews.com/pharmalot/2016/01/22/new-york-andrew-cuomo-drug-prices/ (on file with the *California Initiative Review*).
[36] Fran Quigley, *Disgusted with Sky-High Drug Prices, California Voters Take on Big Pharma*, TRUTHOUT (August 28, 2016) *available at* http://www.truth-out.org/news/item/37260-disgusted-with-sky-high-drug-prices-california-voters-take-on-big-pharma (on file with the *California Initiative Review*).
[37] Complete Text of Bill S.1048, https://malegislature.gov/Bills/189/Senate/S1048 (last visited October 18, 2016)
[38] Complete Text of HB 1113, https://lis.virginia.gov/cgi-bin/legp604.exe?161+ful+HB1113 (last visited October 18, 2016)
[39] CAL. SEC'Y OF STATE, OFFICIAL VOTER INFORMATION GUIDE: CALIFORNIA GENERAL ELECTION, TUESDAY NOVEMBER 8, 2016, *available at* http://vig.cdn.sos.ca.gov/2016/general/en/pdf/complete-vig.pdf ["NOVEMBER 2016 VOTER GUIDE"].
[40] *Id.*
[41] *Id.*
[42] *Id.*

individually.[43] When agencies decide to negotiate together, they are able to get better prices due to the larger population they serve.[44] Additionally, this lessens the administrative costs of negotiating prices.[45]

State agencies also negotiate for lower prices by removing administrative procedures that can create obstacles to prescribing medications, such as prior approval before the medication can be prescribed.[46] By agreeing to remove these administrative procedures, state agencies are also able to individually negotiate supplemental rebates that result in additional savings for the state on certain medications.[47]

3. Federal Prescription Medication Spending

a. Medicaid Price Ceilings

The federal government has placed price caps on the maximum prices that manufacturers can charge Medicaid programs.[48] Because Medi-Cal is the State's extension of Medicaid, those price caps on manufacturers apply directly to Medi-Cal.[49]

b. United States Department of Veteran Affairs Overview

The VA negotiates medication pricing with prescription manufactures based on federal contract laws and regulations.[50] The VA uses different categories of prices, negotiated based on how prescription manufacturers do business with their commercial customers. Under the Veterans Health Care Act of 1992, the VA pricing is either negotiated at the vendor's most favored commercial customer price or statutorily required pricing calculations.[51] There are two different categories of pricing that vendors can participate in. The first category is only available to the VA.[52] The second category of pricing, referred to by the VA as dual pricing, applies to other Government agencies.[53] The VA also uses a national contract program that allows the VA to obtain prices that are mostly lower than any other agency.[54] When the VA negotiates pricing, they are bound by confidentiality contracts that may not allow for final prices to be posted, therefore making it uncertain if the medication are lower than agencies.[55]

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[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] *Id.*
[47] *Questions and Answers*, CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES (September 4, 2016), *available at* http://www.dhcs.ca.gov/provgovpart/Pages/DrugRebateFAQ.aspx - 1 (on file with the *California Initiative Review*).
[48] NOVEMBER 2016 VOTER GUIDE.
[49] *Id.*
[50] *Pharmacy Benefits Management Services*, UNITED STATES DEPARTMENT OF VETERAN AFFAIRS (September 12, 2016), *available at* http://www.pbm.va.gov/PharmaceuticalPrices.asp (on file with the *California Initiative Review*).
[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] *Id.*

Part of the reason the VA is able to get lower prices on medication is because they only offer a selective list of medications the providers are permitted to prescribe to VA patients, which creates an incentive for manufacturers to offer lower prices in order for their medications to be offered to the VA's 9 million recipients.[56] However, according to studies cited at a joint committee hearing on this proposition, the VA actually pays more than other agencies for name brand, but less on generic medications.[57]

c. Confidentiality Agreements

Some of the VA's contracts are reviewable in a public database that is searchable, however, the actual price paid may not be disclosed.[58] According to federal regulations[59], the government is to treat all information in an offer as confidential.[60] There are many prices that the VA is able to negotiate that are lower than the searchable prices but they do not disclose due to confidentiality agreements with the manufacturer.[61]

D. PROPOSED LAW

Proposition 61 would prohibit state agencies from paying more for prescription medications from a manufacturer than the lowest price paid by the VA for the same drug, except as required by federal law.[62] Proposition 61 would apply to direct purchases by the state agency as well as indirect purchases where the agency is the "ultimate payer" of the medications.[63]

The State is the ultimate payer for prescription medications for those who are covered by Medi-Cal County Organized Health Systems, Medi-Cal Fee-For-Service Programs, Medi-Cal treatment for individuals with moderate to severe mental health disorders, current and retired state employees through CalPERS, Students in the University of California and California State University Systems, Inmates at State institutions, Uninsured individuals who are HIV positive, State Hospital patients and Developmental Center residents.[64]

With one out of three Californians enrolled in Medi-Cal, the different Medi-Cal programs represent a large percentage of the population that could be effected by Proposition 61.[65] Medi-Cal has two different types of programs, Fee-For-Service and Managed Care.[66] With Fee-For-Service coverage, providers and pharmacies are directly reimbursed for the services and medications they provide.[67] The Fee-For-Service Program covers roughly 12 percent of

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[56] *Id*.
[57] Joint Senate and Assembly Health Committee Informational Hearing on Proposition 61, *supra* note 1.
[58] *Id.*
[59] 48 C.F.R. § 3.104-3 (2012).
[60] Joint Senate and Assembly Health Committee Informational Hearing on Proposition 61, *supra* note 1.
[61] *Id.*
[62] NOVEMBER 2016 VOTER GUIDE.
[63] *Id.*
[64] *Id.*
[65] *Id.*
[66] *Id.*
[67] *Debating the New Ballot Measure to Control Prescription Drug prices*, CALIFORNIA HEALTHLINE, http://californiahealthline.org/news/debating-the-new-ballot-measure-to-control-prescription-drug-prices/ (on file with the *California Initiative Review*).

Californians enrolled in Medi-Cal.[68] The majority of Californians enrolled in Medi-Cal or 88 percent of Medi-Cal enrollees are covered by managed care programs.[69] Medi-Cal Managed Care differs from fee-for-service because the state pays a monthly fee to the health plans for per capita enrollment irrespective of use of health care services and the plans pay the cost of prescription medications.[70] Proposition 61 exempts most managed care plans but does apply to those covered under fee-for-service.

Additionally, Proposition 61 would apply to all other programs besides Medi-Cal where the state is the ultimate payer for medications.[71] The proponents claim this includes the 3 million Medi-Cal patients in the fee-for-service program, the 838,000 state current and retired employees, 294,000 teachers, and employees of the California State University and University of California systems.[72] The opponents suggest those impacted by this proposition will be only 4.4 million people.[73] On the other hand, proponents estimate the number of those affected will be closer to 5 to 7 million.[74]

For the populations that will be impacted by Proposition 61, only prescription drugs on the VA prescription list will have the fixed prices required by the measure.[75] The state may continue to contract as it has been for the prescription medications not on the VA prescription list.[76] This measure would go into effect the day after the measure passes; however, agencies will be required to comply by July 2017.[77]

III. DRAFTING ISSUES

A. Binds the State Without Binding Manufacturers to Comply

Proposition 61 only places a requirement on the state to buy a prescription drug at the lowest price offered paid by the VA; however, the measure does not require that the prescription drug manufacturers sell their products for VA list prices.[78] In this way, the measure ties the hands of the state without placing any obligations or penalties on drug manufacturers.[79] The proponents argue that this was deliberate in their drafting because only the federal government has the ability to bind manufacturers as the federal government currently requires certain levels

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[68] NOVEMBER 2016 VOTER GUIDE.
[69] *Id.*
[70] Joint Senate and Assembly Health Committee Informational Hearing on Proposition 61, *supra* note 1.
[71] NOVEMBER 2016 VOTER GUIDE.
[72] Seipel, *supra* note 13.
[73] *Id.*
[74] *Id.*
[75] *Debating the New Ballot Measure to Control Prescription Drug prices*, CALIFORNIA HEALTHLINE, http://californiahealthline.org/news/debating-the-new-ballot-measure-to-control-prescription-drug-prices/ (on file with the *California Initiative Review*); The VA prices can be viewed here: *Pharmacy Benefits Management Services,* UNITED STATES DEPARTMENT. OF VETERAN AFFAIRS (August 29, 2016), http://www.pbm.va.gov/PharmaceuticalPrices.asp (on file with the *California Initiative Review*).
[76] *Id.*
[77] NOVEMBER 2016 VOTER GUIDE.
[78] Joint Senate and Assembly Health Committee Informational Hearing on Proposition 61, *supra* note 1.
[79] *Id.*

of prices for Medicaid and the VA.[80] Because the federal government regulates prices that can be charged to Medicaid programs by manufacturers, the federal law would control instead of any attempt at the state level to restrict prices that manufacturers can charge.[81]

B. VA Confidentiality Creates Challenges for Enforcement

Prescription drug manufacturers have confidentiality agreements in their contracts with payers of prescription drugs, including the VA. Proposition 61 may be interpreted in one of two ways: 1) to require the confidential lower price the VA pays to be publicly disclosed in order for the state to purchase at those prices or 2) to require that the prices are publicly listed on the VA's searchable database. Although it is unknown if the database by the VA displays the most up-to-date lowest price paid for by the department, proponents claim that they are satisfied with "most" of the medications that are publicly displayed.[82]

The proponents have said that this measure is not about getting the VA to disclose their prices, but it is about ensuring California's prices are as low as possible when purchasing prescription medications from manufacturers.[83] At a public informational forum, presented by Capitol Weekly and Capital Weekly Radio, the proponents claimed that they are not concerned with the prices being disclosed to the public despite those confidentiality agreements.[84]

Authors of the proposition tried to file a Freedom of Information Act ("FOIA") request to the VA and were denied.[85] Additionally, the California Legislative Analyst Office (LAO) and other state agencies have contacted the VA several times and their requests for disclosure of the confidential prices have been denied.[86] During a joint committee informational hearing, LAO stated that the only agencies that have access to the private prescription drug costs have federal audit powers and that was the reason they were able to obtain the information.[87] The U.S. Government Accountability Office has published a report on VA spending, but the numbers they released on VA medications were normalized to reflect publicly known prices.[88]

The state agencies affected by Proposition 61 could interpret the proposition to mean that the price paid by the VA is the public price, rather than the confidential price.[89] This is mostly likely going to be the interpretation most agencies will employ because the VA maintains a public searchable database offering agencies' best opportunity to comply with the requirements of the measure. Additionally, the language of the proposition requires that the state pay the VA price or lower. If agencies interpret the proposition to mean they negotiate for the lowest public

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[80] Interview with Arif Aziz, Northern California Coordinator for Yes on Prop 61, September 16, 2016 (on file with the *California Initiative Review*).
[81] Erwin Chemerinsky, CONSTITUTIONAL LAW, PRINCIPLES AND POLICIES 410 (Wolters Kluwer, 5th ed. 2015).
[82] *Id.*
[83] *California Votes: 2016 Ballot Measure Forum*, THE CALIFORNIA CHANNEL (September 8, 2016) *available at* (on file with the *California Initiative Review*).
[84] *Id.*
[85] *Id.*
[86] Joint Senate and Assembly Health Committee Informational Hearing on Proposition 61, *supra* note 1.
[86] *Id.*
[87] *Id.*
[88] *Id.*
[89] *Id.*

price on medications, that would be higher than the price the VA actually pays and, thus, gives agencies more ability to negotiate.

Courts would likely uphold this interpretation because, "an administrative agency charged with its enforcement and interpretation is entitled to great weight unless it is either 'arbitrary, capricious or without rational basis' or is 'clearly erroneous or unauthorized."[90] This proposition is silent on whether the VA price should be defined as the private or public prices; therefore, it is highly unlikely a court would say either interpretation of which price level should apply would be "unreasonable or clearly erroneous."

IV. CONSTITUTIONAL ANALYSIS

When the federal government has chosen to pass laws or regulate a particular area of law, because of the supremacy clause in the constitution, the federal law is controlling.[91] This practice is referred to as preemption by the federal government. Under federal law, all state Medicaid programs are required to offer all prescription medications that are approved by the FDA to beneficiaries.[92] Medi-Cal, as the state's Medicaid program, will have to disregard the requirements of this proposition if manufacturers decline to agree to the VA's price on prescription medications.[93] The state, instead, will have to purchase medications at the best possible price they are able to negotiate for, regardless of whether the price they pay is less than the price paid by the VA.

V. PUBLIC POLICY CONSIDERATIONS

A. Programs That Will Be Impacted by This Proposition

Proposition 61 will have an impact on other health coverage programs because the restrictions on state spending apply whenever the state is the ultimate payer for prescription medications and not program categories as a whole. The proponents of the proposition claim that the measure will affect anyone who receives care through Medi-Cal fee-for-service programs, all current and retired state employees who are overseen by CalPERS, all inmates in corrections facilities, students that are covered through insurance options provided by the UC and CSU system, State Hospital patients, uninsured that are HIV positive, and developmental center residents.[94] However, they estimate that only 4.4 million people will be affected by this proposition.[95]

1. Managed Care Plans

The exemption of programs like Medi-Cal Managed Care is a direct result of the language in the proposition that it applies, "to all programs where the State of California or any state administrative agency or other state entity is the ultimate payer for the drug, even if it did

[90] *Yamaha Corp. of Am. v. State Bd. of Equalization*, 19 Cal. 4th 1, 6-7 (1998).
[91] Erwin Chemerinsky, CONSTITUTIONAL LAW, PRINCIPLES AND POLICIES 410 (Wolters Kluwer, 5th ed. 2015).
[92] *Id.*
[93] *Id.*
[94] NOVEMBER 2016 VOTER GUIDE.
[95] *Id.*

not purchase the drug directly."[96] However, by reading this language for its plain meaning the proposition has a different impact than the proponents claim. The State is the "ultimate payer" for medications when they either purchase medications directly from manufacturers or reimburse pharmacies.[97]

Medi-Cal has six different types of managed care models.[98] In 5 out of the 6 models of care delivery, the state essentially pays the plan premiums or a monthly fee cost of enrollment to the plans for Medi-Cal beneficiaries.[99] When the state pays the plans for a beneficiary's enrollment, the managed care plans pay for those beneficiaries' medications and, thus, negotiate directly with pharmaceutical manufacturers for the best price they will offer Medi-Cal recipients.[100] Under the managed care plan systems, the plans are the ultimate payer of medications, as opposed to the state.[101]

However, in the remaining type of managed care plan, called County Organized Health Systems (COHS), that cover recipients in 22 of California's 58 counties, the plans are created and overseen by that county's Board of Supervisors and all the Medi-Cal beneficiaries in that particular county are covered by the same county-run managed care plan.[102] In the 22 counties that use County Organized Health Systems, the state reimburses the county for all services and medications, making the state the ultimate payer for medications.[103] Because the state is the ultimate payer, the 1.9 million beneficiaries in COHS could be affected by the state's attempts to comply with this proposition.

The state is also the ultimate payer for medications in the Medi-Cal fee-for-service model because the state directly pays for the services and medications that are provided to beneficiaries.[104] An additional 4.2 million Medi-Cal beneficiaries in the fee-for-service program would be affected by the proposition because the State is the ultimate payer of medications and would have to comply with this proposition.[105]

2. Impact on Mental Health

Additionally, any Medi-Cal beneficiary who has a moderate to severe mental health disorder could also be affected by this proposition. Under Medi-Cal, plans cover most of a beneficiary's care, but those with moderate to severe mental health disorders receive treatment directly from the county where they reside.[106] The state then pays the cost of care for those with

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[96] *Id.*
[97] *Id.*
[98] *Medi-Cal Managed Care Program Fact Sheet*, DHCS, September 28, 2016. *available at* http://www.dhcs.ca.gov/provgovpart/Documents/MMCDModelFactSheet.pdf (on file with the *California Initiative Review*).
[99] *Id*.
[100] *Id*.
[101] *Id*.
[102] *Id*.
[103] *Id*.
[104] NOVEMBER 2016 VOTER GUIDE.
[105] *Id*.
[106] San Diego County Adult Medi-Cal Mental Health Severity Analysis. October, 3, 2016. (on File with *California Initiative Review*).

a mental illness directly to the counties.[107] The disorders that qualify as moderate to severe include schizophrenia, major mood disorders such as bipolar disorder, and major anxiety disorders.[108]

Any restrictions to medications or failure to prescribe certain medications as a result of this proposition passing would have a substantial effect on those who suffer from mental health issues.[109] A large percentage of those with mental illness depend on state funding for medication.[110] Of the 13 million Medi-Cal beneficiaries, 65 percent were on antidepressants for 12 weeks and 52 percent were on antidepressants for at least 6 months in 2015.[111] There is a very delicate balance of medications for those with mental health issues and any interruption in medications could have devastating effects.[112] According to the California Psychiatric Association, an interruption in medications is guaranteed to result in increased hospitalizations from self-harm and suicide attempts directly related to the symptoms of disorders.[113]

When someone with a mental illness experiences a gap in medications for just 1 to 10 days their risk of hospitalization doubles.[114] When the interruption in medications lasts 10 to 30 days the hospitalization risk triples.[115] When the interruption lasts longer than 30 days the hospitalization risk quadruples.[116] These hospitalizations are predictable results and are directly tied to the symptoms of the disorders people suffer from.[117] Getting hospitalized for a mental health issue is a high threshold for an adult. Someone must be evaluated and determined to be an immediate danger to themselves or others.[118] For adults this often takes an actual suicide attempt or self-harm.

Additionally, when there are gaps in medication for those with mental health disorders there is a lag of time between starting the medications again and the medications becoming fully effective.[119] Once someone is placed back on their medications it takes 4 to 6 weeks for most medications to become fully effective and to stabilize the symptoms of their condition.[120] Any gaps in medication as a result of Proposition 61 would have dangerous effects for those with mental health issues.[121]

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[107] Medi-Cal Mental Health Billing Guide. October 3, 2016. (on file with the *California Initiative Review*).
[108] San Diego County Adult Medi-Cal Mental Health Severity Analysis. October 3, 2016. (on File with *California Initiative Review*).
[109] *Id.*
[110] *Id.*
[111] *Medicaid in California Study*, Oct 5, 2016, *available at* https://www.medicaid.gov/medicaid-chip-program-information/by-state/stateprofile.html?state=california (on file with the *California Initiative Review).*
[112] *Id.*
[113] Joint Senate and Assembly Health Committee Informational Hearing on Proposition 61, *supra* note 1.
[114] *Id.*
[115] *Id.*
[116] *Id.*
[117] *Id.*
[118] CAL. WELF. & INST. CODE Sec. 5150 (1967).
[119] *Mental Health Medications*, NATIONAL INSTITUTE ON MENTAL HEALTH (Oct 6, 2016), *available at* https://www.nimh.nih.gov/health/topics/mental-health-medications/index.shtml (on file with the *California Initiative Review*).
[120] *Id.*
[121] Joint Senate and Assembly Health Committee Informational Hearing on Proposition 61, *supra* note 1.

B. Proponents Main Arguments

1. Prescription Prices for Medications are Overwhelming

It is no secret that the continuous increase in prices for medications is causing financial strain for the American people. The increases in prices are especially difficult to bear for those on fixed or low incomes such as retired individuals.[122] Studies have shown that the cost for specialty medications is higher than the average household income.[123] Additionally, a study by Professor Jeffrey S. Hoch of the Center for Healthcare Policy and Research at U.C. Davis found that the price of a cancer treatment was six times more than what oncologists thought was reasonable.[124] The proponents and opponents of this proposition both agree that prescription medication prices are a problem, they just disagree on how to solve this issue.[125]

2. Requires State to Get Lowest Price on Prescription Medications

Proponents hope that Proposition 61 will require the state to get the best price on medications to lower the state's overall drug expenditures. The VA generally pays an average of 20-24 percent less than other agencies and up to 40 percent lower than Medicare part D (Medi-Cal).[126] By requiring the state to pay either the same or lower prices as the VA pays for prescription medications, proponents anticipate that the cost savings will be passed on to taxpayers.[127] The savings could be beneficial to the state because this proposition would apply whenever the state pays for medications.[128] However, the VA does not always get the lowest price on all medications, as proponents claim. According to studies, the VA actually pays 136 percent more on name brand medications than the Department of Defense ("DOD").[129] However, those studies also found the DOD pays 60 percent more on generic medications than the VA.[130]

There is the risk with this proposition that the manufacturers of medications will not agree to sell their medications at the rate or lower than the rate paid by the VA. The proponents of this measure do not believe that this will be an issue. They argue that the manufacturers of medications will take a profit, even if it is less than they would like.[131]

C. Opponents Main Arguments

1. Hurt Veterans by Increasing Prescription Drug Prices

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[122] *Id.*
[123] *Id.*
[124] *Id.*
[125] *Id.*
[126] NOVEMBER 2016 VOTER GUIDE.
[127] *Id.*
[128] *Id.*
[129] Joint Senate and Assembly Health Committee Informational Hearing on Proposition 61, *supra* note 1.
[130] *Id.*
[131] Interview with Arif Aziz, *supra* note 80.

Opponents fear that the prices manufacturers charge the VA will increase if this measure is passed.[132] While federal law protects VA pricing, by requiring that the VA gets an automatic 24 percent discount on generic medications, there is still some cause for concern.[133] The VA frequently negotiates with prescription manufacturers to get an additional percentage of up to 40 percent.[134] Veterans fear that they will lose this additional bargaining power.[135]

The fear that VA prices will increase if the state is obligated to get the same price has proven to be true in the past. In 1990, Congress linked Medicaid prices for medications to the prices paid by the VA and the prices manufacturers charged VA increased so drastically that a year later, Congress repealed the connection.[136]

2. Reduce Patient Access to Medicines

The California Medical Association and CalPERS claim that this measure could interfere with access to the medications that patients are prescribed.[137] The state has negotiated contracts with pharmaceutical companies for discounted drug pricing, which may become invalid if this measure passes.[138] When manufacturers agree to lower prices for state agencies, the state agrees to remove administrative procedures that would normally be required to prescribe medications by placing the medication on a preferred list of prescriptions.[139]

If the contracts are voided and medications are removed from the preferred prescription list, then patients and doctors will have to go through a longer process before getting the prescription medications they need.[140] Before being prescribed medications that are not on the preferred prescription list, patients would have to try other medications until the doctor has decided that those medications are not treating the patient's problem or additional administrative

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[132] *Why Veterans Strongly Oppose Prop. 61*, NO PROP 61, *available at* http://www.noprop61.com/facts/impact-on-veterans (on file with the *California Initiative Review*).
[133] *California Votes: 2016 Ballot Measure Forum*, THE CALIFORNIA CHANNEL (September 8, 2016), *available at* http://www.calchannel.com/california-votes-2016-ballot-measure-forum/ (on file with the *California Initiative Review*).
[134] *Id.*
[135] *Id.*
[136] *Why Veterans Strongly Oppose Prop. 61*, NO PROP 61 (August 22, 2016), *available at* http://www.noprop61.com/facts/impact-on-veterans (on file with the *California Initiative Review*).
[137] *CMA Calls for Greater Transparency in Prescription Drug Costs,* CALIFORNIA MEDICAL ASSOCIATION (September 6, 2016), *available at* http://www.cmanet.org/news/detail/?article=cma-calls-for-greater-transparency-in (on file with the *California Initiative Review*); *see also Pension and Health Benefits Committee Agenda item 10,* CALPERS, https://www.calpers.ca.gov/docs/board-agendas/201606/pension/item-10.pdf (on file with the *California Initiative Review*).
[138] *Why Patient Advocates and Health Providers Oppose 61*, NO PROP 61 (August 22, 2016), *available at* http://www.noprop61.com/facts/impact-on-health-care-providers (on file with the *California Initiative Review*).
[139] Joint Senate and Assembly Health Committee Informational Hearing, *surpa note 1*
[140] *CMA Calls for greater Transparency in prescription drug costs*, CALIFORNIA MEDICAL ASSOCIATION (August 22, 2016), http://www.cmanet.org/news/detail/?article=cma-calls-for-greater-transparency-in (on file with the *California Initiative Review*).

procedures.[141] Because of these additional hurdles it is possible that treatment can be delayed or a patient's medications can be denied.[142]

3. Increase bureaucracy, red tape, lawsuits, and taxpayer costs.

The California Taxpayer Association is opposed to Proposition 61 and declared implementation of this measure would be costly and lead to more government work.[143] Additionally, the California Taxpayer Association claims that, clarifying the details of this measure will likely require legal challenges because the measure is silent on whether the public or confidential price paid by the VA would be controlling. The courts will also have to decide how to resolve any issues resulting from Medi-Cal having to offer all FDA approved medications, but manufacturers refusing to offer medications at a lower price.[144]

4. Increase state prescription drug costs.

Kathy Fairbanks, spokeswoman for the No on Proposition 61 campaign, argues that state agencies get a better deal on medications than the VA.[145] When asked to produce the documentation, none can be provided. State agencies get rebates for certain prescription medications that they use helping to offset the overall cost of prescription drug medications.[146] If this measure passes, those rebates could potentially be eliminated and the net price for prescription medications will increase.[147] The California Taxpayer Association also asserts that this proposition will eliminate the supplemental rebates received by the Medi-Cal fee-for-service program that total $233 million.[148]

D. Fiscal Considerations

There are too many factors to provide an estimate of any savings on the costs of medications should Proposition 61 be enacted by the voters. When asked for a fiscal analysis of the proposition, the LAO could not give an estimate because they cannot predict how

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[141] Joint Senate and Assembly Health Committee Informational Hearing, *surpa note 1*
[142] *Why Patient Advocates and Health Providers Oppose 61*, NO PROP 61 (August 22, 2016), http://www.noprop61.com/facts/impact-on-health-care-providers (on file with the *California Initiative Review*).
[143] *Cal Tax Positions on November 2016 Ballot Measures*, CALIFORNIA TAX PAYERS ASSOCIATION (October 3, 2016), *available at* http://www.caltax.org/action/elections.html (on file with the *California Initiative Review*).
[144] NOVEMBER 2016 VOTER GUIDE.
[145] *California Votes: 2016 Ballot Measure Forum*, THE CALIFORNIA CHANNEL (September 8, 2016), *available at* http://www.calchannel.com/california-votes-2016-ballot-measure-forum/ (on file with the *California Initiative Review*).
[146] NOVEMBER 2016 VOTER GUIDE.
[147] *California Votes: 2016 Ballot Measure Forum*, THE CALIFORNIA CHANNEL (September 8, 2016), *available at* http://www.calchannel.com/california-votes-2016-ballot-measure-forum/ (on file with the *California Initiative Review*).
[148] *Cal Tax Positions on November 2016 Ballot Measures*, CALIFORNIA TAX PAYERS ASSOCIATION (October 3, 2016), *available at* http://www.caltax.org/action/elections.html (on file with the *California Initiative Review*).

pharmaceutical manufacturers will respond to this measure.[149] Additionally, the state does not know exactly how much true cost of medications are for the VA.[150] State agencies may be paying more for some medications and less for others because of the different populations the state services compared to the population the VA covers.[151]

Scenario #1

If passed, one possible scenario is that the drug manufacturers will sell prescriptions to the state at the lowest price equal to what the VA pays. This is what the measure seeks to accomplish.[152] The State would be buying the same drug for the same cost, but only for the prescription drugs the VA purchases. However, it is impossible to estimate how much money the state would save because the private VA prices are unknown.[153]

Scenario #2

Another scenario is that drug manufacturers will refuse to sell at the prices the VA pays. This means the drug manufacturers would not be selling the lowest price paid for the same prescription medications from the VA to the State.

In response to this, agencies may offer other medications that are not on the VA's list without any concerns about violating the measure because the price restrictions only apply to medications that the VA offers.[154] However, for the medications that the VA does offer, Medi-Cal programs would be required to offer the medications at whatever price they are able to negotiate because they are required by federal law to offer all medications approved by the FDA.[155] Due to the federal obligation, the Department of Health Care Services may have to violate this measure in order to provide those medications.

Scenario #3

The last scenario the VA offered was that the drug manufacturers could just raise the prices of prescription medications sold to the VA to shift their potential losses from the state. Federal law provides that the VA gets an automatic 24 percent and up to an additional 40 off of generic medications.[156] The additional savings could be affected by this measure.

Ultimately, the LAO has not given any fiscal estimates because they feel any prediction would be based in uncertainty.[157]

VI. Conclusion

[149] Joint Senate and Assembly Health Committee Informational Hearing on Proposition 61, *supra* note 1.
[150] *Id.*
[151] *Id.*
[152] NOVEMBER 2016 VOTER GUIDE.
[153] *Id.*
[154] *Id.*
[155] *Id.*
[156] *Id.*
[157] *Id.*

If passed, Proposition 61 could have many unintended consequences. This proposition would bind the state to paying the same price as the VA on medications that the VA covers. However, the outcome of this measure is entirely dependent on how drug manufacturers respond. If manufacturers agree to offer the state the same prices as the VA, then there are potential savings that are impossible to predict because the confidential prices the VA pays for prescription drugs are unknown. Manufacturers could also respond by raising the prices they charge the VA to keep their profit levels consistent, as manufactures have done in the past when Congress attempted to extend the savings the VA receives to Medicaid programs. Alternatively, Manufacturers could respond by simply declining to offer the state the same prices the VA pays for medications. The state would not be allowed to offer the medications the VA offers, but could offer medications that are not on the VA's list.

However, all the Medi-Cal programs that will be implicated by this measure will likely have to disregard the measure because they are required by federal law to offer all medications that are approved by the FDA. It is possible that there could be litigation to reach a decision on this particular issue. Additionally, the possible changes in access to medications while the particulars of the application are sorted out could have a negative impact on the lives of Medi-Cal beneficiaries.