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California Will Negotiate Drug Prices with Manufacturers in New Discount Drug Program

Recently passed legislation in California establishes a new discount drug program for qualified California residents and requires California's Department of Health Services ("DHS") to negotiate with pharmaceutical companies regarding the prices for drugs that will be offered through the discount program.¹ Eventually, beginning August 10, 2010, the participation of manufacturers of single source drugs in California's Medicaid program, known as Medi-Cal, may be negatively affected if they do not offer prices to the discount program that meet specified benchmarks. In addition, manufacturers of multiple source drugs may find themselves excluded from the discount program because of a competitive negotiation process to be undertaken by DHS. This client alert summarizes the key provisions of the newly enacted California Discount Prescription Drug Program ("the Program").

I. The California Discount Prescription Drug Program

The California Discount Prescription Drug Program ("the Program") is a new drug discount program designed to give eligible California residents access to prescription drugs at discount prices. For a \$10 annual fee, participants will be issued a discount drug card that they can use at participating pharmacies. The Program is open to three categories of California residents: 1) residents with family incomes not in excess of 300 percent of the federal poverty guidelines and without other drug coverage; 2) residents with family incomes not in excess of California's median family income and with unreimbursed medical expenses equal to at least 10 percent of the resident's family income; and 3) residents who have Medicare Part D coverage but whose prescription drugs are not covered by their Part D plans. DHS will issue Program participants an identification card entitling them to receive those outpatient prescription pharmaceuticals on the Program's formulary at prices negotiated by DHS.

II. Negotiations with Manufacturers

DHS must negotiate with manufacturers to attempt to obtain "the maximum possible discount" for Program participants. The new law permits DHS to limit the number of drugs available through the Program in order to obtain favorable discounts. However, DHS must attempt to ensure that the number and type of drugs available through the Program are sufficient to create a formulary similar to that offered through Medi-Cal or CalPERS (California's program for retired public employees). It is anticipated that manufacturers of multiple source drugs will have an incentive to negotiate in order to gain access to patients participating in the Program who need those multiple source drugs.

For single source drugs, DHS must attempt to negotiate a "volume weighted average discount" that is at or below one of three benchmarks: 1) eighty-five percent of the Centers for Medicare and Medicaid Services' published average manufacturer price for a drug; 2) the lowest price extended to

¹ Cal. Assemb. B. 2911, *An Act to Add Division 112 (commencing with section 130500) to the Health and Safety Code, Relating to Pharmacy Assistance*, 2006 Session (enacted Sept. 29, 2006), to be codified at CAL. HEALTH AND SAFETY CODE § 130500 et seq., available at http://www.leginfo.ca.gov/pub/bill/asm/ab_2901-2950/ab_2911_bill_20060929_chaptered.pdf.

any nonpublic entity in the state, to the extent that a Medicaid best price exists; or 3) the Medicaid best price, to the extent that one exists.

The new law defines the “volume weighted average discount” as “the aggregated average discount for the drugs from a manufacturer, weighted by each drug’s percentage of the total prescription volume of that manufacturer’s drugs.” Drugs that are excluded from the Program are not included within the volume weighted average discount.

III. Prior Authorization for Medi-Cal

The new law authorizes DHS to incentivize the participation of manufacturers of single source drugs in the Program by linking participation in the Program with patient access to the manufacturer’s drugs under Medi-Cal. Beginning on August 1, 2010, DHS will evaluate manufacturers to determine whether they have offered prices that meet the benchmarks described above. DHS may place prior authorization requirements on the drugs of manufacturers that have not met the benchmark before such drugs may be dispensed to patients under Medi-Cal.

Several factors may prevent the prior authorization provisions from ever taking effect. The prior authorization provisions will be used only if DHS has determined that voluntary manufacturer participation in the drug discount program has been insufficient to give eligible residents access to a formulary comparable to the Medi-Cal or CalPERS formularies. They will be instituted only if they will not increase the costs to Medi-Cal. Furthermore, even if the prior authorization provisions are implemented, Medi-Cal beneficiaries may not be denied continued use of drugs that are part of their prescribed therapy. Accordingly, if a beneficiary was on the drug at the time the prior authorization requirement was instituted, Medi-Cal would not be able to deny authorization.

IV. Patient Assistance Programs

The new California law contains provisions designed to encourage manufacturers to maintain their current Patient Assistance Programs (PAPs). It imposes reporting requirements on manufacturers, including reporting the total number and value of prescriptions provided to California residents through PAPs. DHS must also “encourage” manufacturers to maintain their PAPs, and may execute agreements with manufacturers to provide a single point of entry for eligibility determination and claims processing for drugs available through PAPs. DHS is required to “develop a system” to provide Program participants with the best discounts available to them through PAPs or the Program. To accomplish this goal, DHS may require Program applicants to provide information that will determine the applicant’s eligibility for a PAP, but DHS cannot make participation in a PAP a requirement for participation in the Program.

V. Conclusion

The incentive or risk of the restricted formulary and the potential linking of Program participation with Medi-Cal participation may encourage many manufacturers to participate in California’s new Program. Participation is entirely voluntary until August 1, 2010, but manufacturers may find participation advantageous if the population of participants is substantial and the Program’s formulary is designed to make participation competitively advantageous for manufacturers. Beginning in 2010, the risk of prior authorization provisions also may force manufacturers of single source drugs with substantial Medi-Cal business into the Program. However, the law’s restrictions on implementing the prior authorization provisions and anticipated legal challenges to those provisions remain significant questions to consider as the Program develops and is implemented.

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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our health care practice group:

Ethan Posner	202.662.5317	eposner@cov.com
Richard Kingham	202.662.5268	rkingham@cov.com
Michael Labson	202.662.5220	mlabson@cov.com
Anna Kraus	202.662.5320	akraus@cov.com
Ellen Flannery	202.662.5484	eflannery@cov.com
Keith Korenchuk	202.662.5385	kkorenchuk@cov.com
James Snipes	415.591.7071	jsnipes@cov.com
Stefanie Doeblner	202.662.5271	sdoebler@cov.com
Elizabeth Jungman	202.662.5327	ejungman@cov.com

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