DAVE JONES
Insurance Commissioner

April 14, 2015

Secretary Diana Dooley
Chair, Covered California and Board Members
1601 Exposition Blvd.
Sacramento, CA 95815

Re: Prescription Drug Formulary Cap Recommendations – Vote on Covered California's Standard Plan Design

Dear Chairperson Dooley and Covered California Board Members,

Your decision as to whether you will allow health insurers and health plans to place specialty drugs into a "high-cost tier" and if so, what out-of-pocket costs for policyholders must pay to obtain these drugs is critical to California consumers, as such a potentially discriminatory benefit plan design would place vital life-sustaining drugs out of reach for many Californians.

I have appreciated the opportunity for the Department of Insurance to work on this issue with Covered California, your staff, and the members of the Specialty Drug Work Group. During discussions leading to Covered California's staff recommendation, we have asked Covered California to establish a monthly cap of $200 on out-of-pocket costs for specialty tier drugs in order to spread the cost sharing amount over the coverage year. Unfortunately, however, your staff's recommendation to cap out-of-pocket expenses for specialty drugs at $500 per prescription per month falls short of what is needed. Capping out-of-pocket expenses at this level creates an affordability barrier for the average consumer, particularly those who struggle with chronic conditions that require multiple prescriptions. We urge Covered California instead to adopt a cap of $200 per prescription per month for specialty drugs, which we believe would provide considerable relief for those affected by the high costs of specialty drugs by spreading their costs over the plan year.

Discriminatory Benefit Design

Your proposed Standard Benefit Plan Design creates a 4-tier pharmacy benefit in which the fourth tier is, for most metal levels, treated differently than drugs on the other tiers. For example in the Silver plan (which is the plan with the highest number of policyholders in the individual market), the copay in tiers 2 ($50) and 3 ($70) are subject to a pharmacy deductible of $250 individual/$500 family, while tier 4 drugs are subject to a 20% coinsurance of up to $500 per

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prescription, which is applied over and above the pharmacy deductible. The Bronze (the plan with the second highest number of policyholders and the highest number of those who don't qualify for federal premium assistance) has a $500 maximum deductible per prescription for all tiers. In the Platinum plan, the first three tiers involve a copay, while the fourth tier involves a 10% coinsurance capped at $300 per script. In the Gold plan, a 20% coinsurance level for the fourth tier is capped at $500 per script.

The proposed Standard Benefit Plan Design sets criteria for Tier 4 drugs at footnote 19: one such criterion is the cost of the drug. Drugs with a cost in excess of $600 can be placed in Tier 4. This criterion can result in drugs vital to those with HIV/AIDS, multiple sclerosis, rheumatoid arthritis, Hepatitis C and other chronic or life-threatening conditions being placed in Tier 4, and thus subject to cost-sharing different from all other drug tiers. While footnote 20 provides that, in situations where there are at least 3 drugs in a drug class, at least one must not be in Tier 4, this provision does nothing to protect those with conditions for which there are less than three drugs.

Insurance Code §10753.05(h)(3) prohibits "...marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs or discriminate based on the individual's....health conditions." Cost-sharing requirements that place medically necessary care out of the reach of individuals with certain health conditions is discriminatory. In the last two years, as we have implemented the new Affordable Care Act (ACA) rules, the Department of Insurance has rejected some plan designs with co-insurance requirements on specialty drugs because of their discriminatory impact on those with certain medical conditions. We are concerned that the Standard Benefit Plan Design, as currently proposed, also implicates California anti-discrimination statutes because of its potentially disparate impact on the enrollment of those with significant health needs. In particular, the Silver plan, which imposes copays with a $250 maximum annual deductible in the first three tiers, imposes coinsurance with a cap of $500 per script.

It is also worth noting that in the preamble to the Federal Notice of Benefit and Payment Parameters for 2016 final rule, CMS sends a clear message about the types of benefit designs that would be prohibited under 45 CFR §156.125. This guidance is helpful to the Department of Insurance in highlighting areas where regulators may find discriminatory practices. It notes that "placing most or all drugs for a certain condition on a high cost tier without regard to the actual cost the issuer pays for the drug may often be discriminatory in application when looking at the totality of the circumstances, and therefor prohibited." (80 Federal Register 10823, Feb. 27, 2015)

The recommended cap does not ameliorate our concerns that significantly higher out-of-pocket costs borne by consumers using specialty drugs is, in fact, discriminatory.

Impact on Consumers

There is a significant body of research indicating that cost can significantly impact drug adherence for those with chronic conditions. We are therefore concerned that such a high cap will put important prescription drugs out of reach of many consumers, leading to decreased

treatment compliance and increased adverse health outcomes. For example, one research study found decreased treatment compliance when out-of-pocket expenses for certain multiple sclerosis treatments were greater than $200[1]. Most studies demonstrate that adherence drops off significantly when the cap is greater than $200.

A recently released report by the Kaiser Family Foundation (KFF) entitled, *Consumer Assets and Patient Cost Sharing*[2] made it clear that households are already struggling to meet their out-of-pocket expenses. According to the report, "Looking at the out-of-pocket limits, most households do not have sufficient liquid financial assets to meet either the lower or the higher limit. The percentage of households who have both low incomes and enough assets to meet either of the out-of-pocket limits is very low."[3] Further, they concluded that for families with incomes between 100% and 200% of Federal Poverty Level (FPL), "Only 32% of households with incomes between 100% and 250% of poverty can meet the lower deductible amounts, while one-in-five can meet the higher deductible amounts."[4]

It is not only lower income households who feel this squeeze. The report found that, "substantial shares of households with incomes between 250% and 400% of poverty would be unable to meet even the lower out-of-pocket limits with their current resources, and meaningful shares of households with incomes over 400% of poverty would have problems as well."[5]

The KFF report clearly demonstrates that many families of low and moderate incomes are struggling to meet their annual deductibles and therefore cannot afford to fill prescriptions for specialty drugs if their out-of-pocket cost is $500 per prescription per month.

Impact on Actuarial Value and Premium

I asked our actuaries to run options of capping the dollar amount per drug/per month through the 2016 Actuarial Value (AV) Calculator. They reported to me that capping Tier 4 coinsurance payments at $200 per prescription would have almost no impact on the AV. The plans would thus still comply with the required AV range for each metal level and significant changes in premium would not be justified. Even when your staff collected information from health carriers about what level of premium increase they would propose, the information you received from the health insurance carriers indicated that for some of them, capping the out-of-pocket cost for specialty drugs at $200 would have no impact on premium, and for others the maximum increase proposed was .77% for 2016 – the plan year for which you are setting the Standard Benefit Design. This proposed premium increase by the carriers of 0 -.77% associated with the $200 cap I am urging you to adopt is almost identical to the proposed price increase of 0 - .70 % for setting the cap at $500 as you propose.

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[1] Gleason, P. et al. (2009) Association of Prescription Abandonment with Cost Share for High-Cost Specialty Pharmacy Medications. Journal of Managed Care Pharmacy, 15(8):648-58.
[2] http://kff.org/health-costs/issue-brief/consumer-assets-and-patient-cost-sharing/
[3] Ibid, p6
[4] Ibid, p7
[5] Ibid, p13

In addition to our internal calculations, Milliman produced a recent report entitled, *Pharmacy Cost Sharing Limits for Individual Exchange Benefit Plans: Actuarial Considerations*, where they used California exchange data to model the impacts of per-prescription caps set between $100 and $200 and an annual prescription drug out-of-pocket (OOP) maximum set at 20% of the total OOP. The report concluded what our actuaries reported: "The average plan member would be expected to see very little change in their total expected healthcare spending (premiums plus out-of-pocket costs for medical and pharmacy services) upon implementation of any of the potential benefit design changes."[6]

Efforts in Other States to Prevent Specialty Drugs from Being Out of Reach for Policyholders

My recommendation for a $200 cap for specialty drugs is well in line with caps implemented by other states including Maryland, Florida, Delaware, Louisiana, and Montana. These states have caps between $100 and $250 per prescription per month. Colorado has a $500 cap, but they are by far the outlier. In 2010, New York went even further out of concern for policyholders with chronic conditions. Instead of implementing a cap, they prohibited specialty tiers altogether which, in effect, limits maximum cost-sharing to those of non-preferred brand name drugs.

Finally, my recommendation is consistent with ongoing legislative efforts in 5 states and the District of Columbia including Oregon, Kansas, Oklahoma, Illinois, and Connecticut. In fact, four of the five of those states are recommending caps of $100 per prescription per month. Given that Covered California is currently setting the Standard Benefit Design for California for both inside and outside the Exchange, we would urge that you set the $200 per prescription cap for specialty drugs.

Conclusion

If approved as recommended by your staff, the Covered California Standard Benefit Plan Design will put many Californians with chronic medical conditions in the position of being expected to pay thousands of dollars in the first few months of their policy year in order to receive life-saving prescription drugs. Of note, a $200 copay cap per prescription is consistent with the proposed benefit plan design for the Silver 100%-150% and 160%-200% FPL plans, showing such a cap can be achieved in the California context. We also know from California's $200 cap on the cost of oral cancer medications that this can be achieved.

The impacts of non-adherence to their prescription drug regime go beyond the health of the individual. Nationally, the annual cost of non-adherence resulting in emergency room visits and other preventable medical expenses was $290 billion or 13% of total health expenditures[7]. For people with chronic conditions that require specialty drugs, adopting a $200 cap is a prudent cost-saving measure for the system as a whole.

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[6] Milliman. Et al (2015). *Phormacy Cost Shoring Limits for Individual Exchange Benefit Plans: Actuorial Considerations*. p3.

[7] New England Healthcare Institute. (2009). *Thinking outside the Pill Box: A System-Wide Approach to Improving Patient Medication Adherence for Chronic Disease*.

A cap of $200 on specialty drugs would have almost no impact on actuarial value while providing a positive impact on consumer affordability and adherence to complicated drug regimens. Further, other states have demonstrated that it can be done successfully; such a cap is also consistent with what many insurers already do in the large group market.

I urge you to modify your staff's recommendation and impose a $200 cap per prescription on the out-of-pocket costs for specialty drugs, for the benefit of consumers throughout California who have health conditions that necessitate access to these drugs.

Sincerely,

DAVE JONES
Insurance Commissioner