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Organizations listed for
identification purposes

Mr. Kevin Morrill

Chief

Contracts Services Branch

Department of Health Care Services

1000 G Street, 4th Floor

Sacramento, CA 95899-7413

Subject: Request for Proposal # 19-96125 Medi-Cal Rx

Health Access California, the statewide health care consumer advocacy coalition committed quality, affordable health care for all Californians offers comments on both the DHCS stakeholder presentation with regard to the proposal for a state prescription drug purchasing pool, and the Request for Proposal for the Medi-Cal Rx program.

Support for Single State Purchaser for Prescription Drugs for Medi-Cal

Health Access supports a single state purchaser for prescription drugs for Medi-Cal. Our support for this concept aligns with a long history of working on prescription drug pricing issues, including supporting the Medicare program negotiating for prescription drugs in Medicare Part D rather ceding that responsibility to managed care plans. At the state level in 2004-6, Health Access sponsored ballot measures and bills to use Medi-Cal's purchasing power to get drug discounts for the uninsured. Health Access supports the Medi-Cal program using its purchasing power as a government purchaser to lower prices and also seeking supplemental rebates permitted under the federal Medicaid program.

California was a pioneer in obtaining supplemental rebates but mostly gave away that authority to the managed care plans when Medi-Cal managed care expanded in prior administrations. This was a less significant issue when most of those enrolled in Medi-Cal managed care were mostly healthy moms and healthy kids (with higher risk moms often in fee-for-services and higher risk kids in California Children's Services): it is a much more significant issue now after the transition to managed care of the Aged and Disabled, some of those dually eligible for Medicare and Medi-Cal, and the expansion population which includes a significant adult population aged 45-64: all three of these populations will use more prescription medications and more expensive prescriptions (brand name, specialty drugs) because of age or disability or both.

The 12 million enrollees in full scope Medi-Cal benefits should give it bargaining power comparable to entire nation states such as Belgium, Portugal or Sweden. The

enrollment in the Medi-Cal program is greater than the entire population of 46 states, including Pennsylvania, Illinois, Georgia, North Carolina, Michigan and New Jersey. Purchasing drugs on behalf of that many people should give the Medi-Cal program the ability to drive a good bargain.

Savings should be yielded not just from the consolidated purchasing power, but from streamlining and simplifying the system of purchasing drugs. Right now, the Department of Health Care Services subcontracts out the negotiation and buying of drugs to the Medi-Cal managed care plans, which in turn often contract with Pharmacy Benefit Managers, each with their own policies and procedures for providers to follow. We have yet to hear a good argument for why LA Care needs to have a different set of drugs needing authorization than Inland Empire Health Plan—or even two plans overlapping in the same jurisdiction with the same providers. We hope a single state formulary can identify and yield savings by simplifying and streamlining the process for patients and providers.

In the spirit of simplification, we note that the RFP does not reflect the fact that some prescription medications are already “carved out” from the managed care plans, as noted on p. 12 of the stakeholder presentation. Does DHCS intend to consolidate these carveouts with the Medi-Cal Rx program? Or to leave these carveouts as currently operating? Or perhaps we missed it?

On p. 12 of the RFP and p. 19 of the stakeholder presentation, DHCS notes that Medi-Cal managed care enrollment is 80% of total Medi-Cal enrollment. While factually accurate, this is misleading since about 1 million of those in Medi-Cal fee-for-service are undocumented Californians enrolled in restricted scope, emergency-only Medi-Cal in which these Californians do not have an outpatient drug benefit. In evaluating the impact of this proposal, it is more accurate to say that 90% of those with full-scope coverage are enrolled in Medi-Cal managed care.

340 B Program: Concerns of Community Clinics and County Hospital Systems

The Department of Health Care Services has stated that it is not its intent to change the 340B program as a result of this policy change to a single state purchaser. We urge the Department to consider the concerns of the community clinics and county hospitals systems about the proposal’s impact on the 340B program. While we support the concept of a single state purchaser for prescription drugs, we are concerned that an unintended consequence may be a major revenue loss to critical safety-net health providers. We hope and expect the Administration would share the concern about the impact on these vital elements of the safety net.

We appreciate the intent of the Governor’s proposal to keep clinics whole through other revenue streams, and we look forward to ensuring that effort is robust, sufficient, workable and timely.

In particular, we recognize that clinics with their own retail pharmacies have specific concerns. We think it is good policy to support those clinics that can provide consumers with access to key prescription drugs in the same location that they receive their medical care: this is particularly critical for communities which face language, cultural, and transportation barriers. We would not want an unintended consequence of this proposal to have community clinics close on-site retail pharmacies—as we suspect the Governor who has toured many such clinics would not want either.

90 Day Transition: Not Enough Time for High-Risk Individuals

A 90-day transition may be sufficient time for those using few medications or with well-managed chronic conditions. But as DHCS Director Kent frequently notes, Medi-Cal pays for care for some of the sickest people in our society.

For those who are higher risk or higher need, a longer period of time and provision that the individual not go through step therapy or prior authorization review would be important to keep stable those whose condition is stabilized or to allow better management of a serious condition or current treatment.

A non-exhaustive list of conditions/consumers that may well be high risk if their medications are disrupted:

- Hemophilia
- Cystic fibrosis
- Lupus
- Multiple sclerosis
- Rheumatoid arthritis
- Active cancer treatment
- Organ transplants
- Seizure disorder
- Dialysis
- Severe behavioral health conditions (other than psychosis or substance abuse treatment without comorbidities)
- Homeless individuals
- Opioid abuse treatment
- More than 6 prescriptions per month.

This list should be developed by clinicians and pharmacists: we suggest these conditions based on our prior work on prescription drug costs. We would include HIV/AIDS, Hepatitis C, psychosis and substance abuse treatment but medications for these conditions are already carved out and handled on a fee-for-service basis.

Clinical Review of Medical Necessity

While the fair hearing process is an appropriate process for many aspects of the Medi-Cal program, administrative law judges lack clinical expertise. Under Medi-Cal managed care, enrollees are eligible for an independent medical review in which clinicians review the medical necessity of a prescription, including whether it is appropriate for the individual in question. DHCS could accomplish a similar result by contracting with DMHC for independent medical review of denials of care for prescriptions. The results of such reviews should be incorporated into the work of the pharmacy and therapeutics committee.

PBMs: Conflicts of Interest, Data Mining

Several health plans have merged with pharmacy benefit managers, including Anthem with CVS and Cigna with Express Scripts. We think such entities should be disqualified because of inherent and unavoidable conflicts of interest. Anthem itself is a significant Medi-Cal managed care plan and Cigna competes with health plans that contract with the Department. There may well be other pharmacy benefit managers that have conflicts of interest.

Whichever entity is selected as a vendor should be required to be a fiduciary for the State of California, putting the State's first and the interests of stockholders second.

The draft RFP on pp. 35-37 makes no mention of such conflicts of interest as inherently disqualifying for a vendor: it should do so.

The RFP should also protect consumer privacy of the 12 million Californians with full-scope Medi-Cal benefits by prohibiting the vendor from engaging in data-mining or sharing data, even if de-aggregated and de-identified. This is a potentially lucrative contract: there is no reason to make it even more lucrative by handing over a huge volume of consumer data on a platter.

Clinical Management: Real-Time Data, Pharmacy and Therapeutics Committee?

Many of the concerns raised about this approach have dealt with concerns about clinical issues, including care management. Real-time data exchange seems a bare minimum for success but not alone sufficient to appropriately answer the concerns we have heard publicly and privately.

We are discouraged by the notion advanced by the health plans and others that the pharmacy data is perhaps their best source of information on their own patients—this reflects a much bigger problem with the care coordination that the plans are supposedly doing. Having the pharmacy data in real-time is essential for the health plans to provide the care coordination services that we want them to provide, and should be part of any final proposal.

We also suggest that something like a pharmacy and therapeutics committee might be an appropriate approach. This would allow pharmacists and medical directors from health plans, community clinics, and perhaps other stakeholders to advise the Department in the development of the statewide formulary. The Department would retain authority over policy and price negotiations but the formulary would be improved by broader input.

Bargain by Therapeutic Class, Not by Manufacturer

Historically DHCS negotiated the statewide formulary manufacturer by manufacturer rather than based on therapeutic class. While this was perhaps state of the art in 1989, the entities that bargain most effectively look at therapeutic class to assure an appropriate array of medications at the best price. This requires more work to develop and update the formulary but is better designed to achieve a balance of necessary clinical outcomes with achievable cost savings. Doing it manufacturer by manufacturer may leave money on the table unnecessarily.

Estimate of Savings: Underestimate?

Today the Medi-Cal managed care population is very different than the Medi-Cal managed care population in 2008. In 2008, the Medi-Cal managed care population essentially consisted of healthy parents and healthy kids. The high-risk kids were in California Children's Services while many of the high-risk moms were in fee-for-service. In contrast, today the Medi-Cal managed care population includes many high need/high risk individuals who are likely to have substantial prescription drug costs: this is true of the aged and disabled population as well as the childless adult expansion, particularly those over age 50. These populations not only use more drugs, they use more expensive brand name and specialty drugs. Given the likely differences in utilization and price, greater savings may be possible. We would encourage the Department not to set its sights too low when seeking to obtain supplemental rebates and to take steps, such as bargaining by therapeutic category rather than manufacturer, to accomplish the highest level of possible savings while maintaining access to medically necessary drugs.

24/7 Call Center

We support the requirement for a 24/7 call center to help consumers (and prescribers) navigate the single state formulary. We thought it odd that the RFP did not include requirements for experience, competence and capacity in running a call center that dealt with time-sensitive clinical issues, including for Californians with Limited English Proficiency. We urge inclusion of these factors in your consideration. Lack of experience would be worrisome. Lack of clinical capacity should be disqualifying. Reliance on a ATT Language Line rather than trained medical interpreters should be completely disqualifying. If DHCS retains a vendor without experience, clinical capacity or trained medical interpreters, we predict considerable frustration from consumers and providers—with some people's lives put at risk because of the lack of timely and appropriate access to medications.

Education and Outreach: Providers and Enrollees

This is a major transition: the outreach and education component will need considerable effort to minimize disruption of care. This effort requires input from providers, plans, and consumer stakeholders. Ideally, it would be accompanied by beta testing and focus groups to test materials and approaches in advance of the rollout. Given the compressed time frame, the opinion research that should undergird such an effort may be compressed in time but an effort should be made to go beyond the usual stakeholder process to research how Medi-Cal enrollees and providers view proposed materials and what outreach or education they would find helpful.

Summary: Support for Single Statewide Purchaser and Recommendations to Enhance its Likelihood of Success

Health Access supports the concept of a single statewide purchaser for prescription drugs for the Medi-Cal program. We support many of the elements laid out, and while we have some questions and concerns, we recognize that the proposal is still being rolled out with additional details to come. We have offered a number of suggestions aimed at improving the success of the program, including basing the formulary on therapeutic class rather than by manufacturer, creating

something like a pharmacy and therapeutics committee, allowing enrollees the ability to have denials reviewed for clinical appropriateness and other suggestions.

We also note what is not in the RFP, suggesting that significant elements of this proposal will be done in house at the Department of Health Care Services. We look forward to commenting on those details when they become available.

We look forward to continuing to work with the Department as the proposal moves forward.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Anthony Wright', written over a horizontal line.

Anthony Wright
Executive Director

CC: Dr. Richard Pan, Chair, Senate Budget and Fiscal Review Subcommittee on Health and Human Services
Dr. Joaquin Arambula, Chair, Assembly Budget Subcommittee on Health and Human Services
Health and Human Services Secretary Mark Ghaly
Director Jennifer Kent, Department of Health Care Services
Richard Figueroa, Deputy Cabinet Secretary