June 6, 2022
Seung Oh, PharmD, President and all the Members of the State Board of Pharmacy, and
Anne Sodergren, Executive Officer California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100,
Sacramento, CA 95833

Re: SB 958 – Regarding Payer Mandated White Bagging.

Dear Dr. Oh, Members of the Board of Pharmacy and Ms. Sodergren

Because SB 958 would be overall detrimental to the health of many in California, I urge you to, on behalf of the California Board of Pharmacy, to take an OPPOSE position on SB 958 as it is currently written. The Board of Pharmacy should NOT support SB 958 UNTIL the Board of Pharmacy has had the opportunity to resolve the rare alleged problems that are attributed to the "Vendors", i.e., licensed pharmacies, that are under the Board's jurisdiction.

*(Note: At the end of this letter, I describe my extensive experience and success at controlling drug costs for millions of Californians.)

Here is why SB 958 is so problematic.
According to the National Academy of State Health Policy, and others, prescription drug costs are increasing at the most rapid rate of all health care costs. This is especially true when used in hospitals which have the highest proportion of health care spend. The US annual spend on drug and biologic therapy is over $350 Billion per year.

Though California has only about 12% of the US population it is the largest pharmaceutical market and substantially affects what happens in other states, i.e., if Calif. gets lower prices, then other states will expect the same and will be more likely to get them. SB 958 would virtually eliminate the ability of "Payers" to control California drug costs. Literally BILLIONS of increased CALIFORNIA health care costs are at risk because of SB 958.

SB 958 is ONLY about injectable and infused medications. These are already the most individually and collectively expensive of pharmaceutical and biologic therapies. Most of these products are called "Specialty Drugs". They can cost tens-to hundreds of thousands of dollars per treatment, or more.

These products collectively are **administered to only about 2% to 5% of patients BUT account for over 50%** of the total amount spent in the US on such therapies, according to "Evernorth" and other organizations that monitor and report on pharmaceutical cost and spend trends. Drug and Biologic care remain the fastest rising segment of all health care costs. As such, controlling their cost has top priority at the State and national level.

Increasing competition is the only proven way to control drug and biologic costs. Health Plans, Insurers and the intermediaries are truly the only entities that can achieve deep discounts

because of their Formularies and the MARKET SHARE and the huge volumes of product purchases they control. This is a fact recognized by the Governor with his combining of all MediCal, State Dept. of Corrections, etc., drug purchases and voluntarily County and local drug purchases, into one common program for bidding and contracting.

If SB 958 is enacted it will eliminate most of the competition among drug and biologic product suppliers. It has been said that SB 958 should be re-named "The Pharmaceutical and Biologic Manufacturers Enrichment Act of 2022".

SB 958 enactment would be to the detriment of patients, employers that provide employee coverage, tax payers that provide coverage directly (e.g. Medi-Cal) or indirectly (e.g., the "Marketplace") and to individuals and their families that cannot afford healthcare coverage.

As health care costs rise, health care and health care ***coverage*** become less and less affordable fewer patients have access to high quality disease prevention and care. Without access to care and Coverage, fewer patients will have early detection of disease, preventative care and less compliance with treatment. Many more will have to buy, and employers will have to provide, coverage with HIGH deductibles and HIGH copayments. California taxpayers will have to subsidize more and more coverage, i.e., via MediCal or the California Health Insurance Marketplace. More patients will simply have to go without care – until it means a visit to an Emergency Room or to a hospital, which are the most costly and dangerous places for all care.

Why is helping to contain drug cost a Board of Pharmacy (BoP) responsibility?
[Note: SB 958 defines a "Vendor" that supplies White Bagged products to a hospital, clinic, etc. as a "Pharmacy", i.e., an entity under the Board of Pharmacy's jurisdiction. Likewise for the PIC and pharmacists at such pharmacies.]

Some have remarked that the BoP has not been and is not responsible for considering cost. ***That is simply not true***.

The BoP is and has been responsible for decades for enforcing related statutes and regulations that help patients and the public with the issues of drug costs and "prices". The recently adopted Business and Professions Code (BPC) 4079 requires pharmacies to notify patients of the "Availability of a Lower Retail Price". The decades old BPC 4122 requires pharmacies to provide price information, "however …communicated", and even to post a notice of that rule. The BoP enforces price limitations for contraceptives per BPC 4052.3. BPC 4425 was adopted before MediCare Pat D to cover outpatient drugs and requires MediCal participating pharmacies to charge MediCare eligible patients only the MediCal price.

Plus, for decades the BoP has supported and enforced statutory provisions that also reduce drug costs. BPC 4073 was enthusiastically supported by the BoP decades ago. It allows pharmacists to substitute a Generic equivalent drug without the prescriber's authorization **but ONLY if the generic costs the patient less**. Likewise, more recently, the BoP supported BPC 4073.5 that allows the same for similar biologic products, i.e., "Biosimilars".

The BoP's recently enacted provisions in AB1533 have been about allowing pharmacists to provide the most cost-efficient, high quality of care based on a pharmacist's level of pharmaceutical care education, training, experience and ability that far exceeds any other health care provider group.

Controlling pharmaceutical costs is also the priority of the Governor, as reflected in his program to combine the purchasing power for a MediCal and State and local drug purchasing entities. Likewise, for the State's program to support competition for generic drugs by partnering with selected manufacturers to manufacture insulin and other generics.

In fact, these State programs, and related programs the National level, regardless of administration, indicate strong public policy for ***all*** heath care providers and their regulatory agencies to support controlling drug costs. At the National and state levels this now even includes considering importation by states with FDA approval of selected programs ***to increase competition***.

All this means that before the BoP supports any law that would raise costs because of *alleged* patient safety issues, those allegations must be "real" and "material" – meaning they are so prevalent and of a magnitude that requires raising healthcare costs. (Note: the author of the Cedar's letter, has indicated that Cedars has no direct experience with such incidents because it has NEVER allowed White Bagging. What *specific* "Vendor/Pharmacy" performances have been reported to the Board of Pharmacy – if any? And why haven't they been reported?

Board support should NOT be given UNLESS the Board of Pharmacy is confident it has done *all it can do* to resolve any alleged patient safety issues attributed its licensees before it supports cost-increasing statutes. Of course, the BoP cannot address problems attributed to a "Vendor"/pharmacy about which it has no detailed information – including the identity of the "Vendor"/pharmacy and the specifics of any incident.

So what can the Board of Pharmacy do?

The BoP has jurisdiction of all "Whlte Bagging" Vendors, the handling and labeling of products they supply and the pharmacists that prepared and/or approved them. The BoP has the authority to take action against any Pharmacies for repeated or egregious infractions. But has the BoP done so yet? Of course, it can do so only if the hospitals, clinics, etc. report any dangerous sub-standard actions to the Board. The Board cannot help resolve or prevent problems it does know about – especially if the hospitals, clinics, etc. will not provide specifics!

For example, the first "Concern" in the Cedar's letter is about delays in receiving delivery. If a Board licensed pharmacist or Pharmacy is responsible for an unacceptable delay the. Board has, ***and has used,*** Bus. & Professions Code **Section 733** to take corrective action.

If such a delay is caused by negligently addressing delivery to the wrong address or entity, the BoP has that jurisdiction. Since the "pandemic" we are now more than ever aware of how

deliveries can be made almost immediately regardless of the distance. Again, the responsibility for a proper address label is upon the "Vendor"/licensed pharmacy specifically and as in the Uniform Commercial Code, is the responsibility and liability of the "shipping" entity.

If the product arrives without proper consideration of environmental factors per the pharmacy standard of care, that also can be addressed by the BoP.

Of course, the BoP knows that the Pharmacist-In-Charge (PIC) at a receiving hospital or other entity is also responsible for doing what is supposed to be done. The PIC is also responsible to assure compliance with BPC 4059.5 (a) & (b) and especially subsection (c). Specifically, all deliveries must be delivered directly to a licensed pharmacy or other addressed licensed entity, eg. a licensed clinic. There is an exception for hospitals regarding delivery to central receiving location and then to the pharmacy in "one working day" but that means the hospital and the PIC is responsible for making provisions at the "*central receiving location*" for refrigerated, frozen, etc. items.

Some, Board input provided the "excuse" that the delivered package was not labeled properly and destined to a "pharmacy". Again, the responsibility for a proper address label is upon the "Vendor"/ licensed pharmacy specifically. When the BoP inspects a hospital, does it make sure that such provisions were made? Do the hospital's policies and procedures cover this responsibility? If not for Specialty Drugs, then what about insulin, vaccines and other such products?

Likewise, the letter expresses Concern about drugs dispensed by a California Licensed pharmacy that have passed the expiration date. Was the Board of Pharmacy notified of the Licensed Pharmacy that made such violation?

The success of these White Bagging programs is very, very important to the Payers and the public. I am very confident that such Payers would also provide immediate assistance to resolve unacceptable delays because deficiencies directly affect them. Likewise, the "Vendor" California Licensed Pharmacies also have high motivation to resolve any delays and prevent them and any other problems.

So, what is really behind SB 958?

The proposers of SB 958 get the White Bagged pharmaceuticals and biologic products. **"for free"**. Since they do not "Buy and Bill" for the products, they would not be able to **mark-up** their product costs for billing to the ***payers*** – i.e.,billing the Health Plans, Insurance Companies, Union Trust Funds, Self-funded employers and private citizens, either directly or through a "Third Part Administrator" or PBM. In practice such mark-ups usually ***far exceed*** the preparation and patient administration, handling, billing other costs associated with procuring, storing and administering products. In fact, those costs related to pharmaceutical products are traditionally included in the "daily rate" the hospital charges payor. The hospitals would have no related inventory investment and carring costs. Nor would they have losses because of

product expiration, damage, etc. Those costs can be very high for the Specialty Products but are borne by the "Vendor"/Licensed Pharmacies that supply the product.

Those hospital and clinic gross mark-ups have traditionally been as high a 100% to 500% of the product cost, or more. The hospitals, clinics, infusion centers and medical and other practices have grown accustomed to the excess revenue via their "Buy and Bill" or fee-for-service models for years. As the cost of Specialty Drugs and Biologics has grown exponentially over the cost of traditional drugs, those institutions have used those margins, and are looking forward to even larger gross margins, to fund way beyond their expenses to procure, receive prepare and administer those products. In fact, the higher the cost, the greater the real amount in the billing margin. **They literally have *no incentive* to negotiate for lower costs from the manufacturers**.

Here is an example. Historically, (e.g, in the '70s) high billing mark-up margins were common. Some oral pharmaceutical products may cost pennies or even $2 per tablet or more– which seems high. Even if marked-up 100% the cost to the payer of a $2 tablet is only $4. That margin "may" be justified to cover related administration, handling and other expenses. But if a "White Bagged", Specialty Drug's cost is $1000 or more (not unusual) the same mark-up, gross margin, is $1000 or more. Since the product's cost and other costs are a "pass through" in the hospital's "Fee For Service" or "Buy and Bill" system, there is a **natural incentive and ability to mark-up the cost as much as possible**. Not only does the hospital, clinic, infusion center, medical office, etc. have no incentive to negotiate a lower cost, but actually benefits financially from higher product costs.

The backers of SB 958 have tried to justify such practices by saying that using "pharmacy/drugs", i.e. the cost or drugs and biologics as a very traditional "profit center". The say it is necessary to pay for other costs for which the hospital does not receive "enough" payment. That is NOT transparency!

What are the other so-called costs whose burden is borne by the cost of drugs and biologics? Why are they not disclosed? Being the hospital's "cash cow" is not how the "pharmacy" services of such institutions should be treated! That is NOT transparency!

Hospital cost and price transparency has been and is now a high public policy priority. The public is very displeased with continued "surprise billing". Since January of 2021, federal law has explicitly required all hospital to "post" their prices. Yet as of this week, it has been reported that fewer than 14% have done so.

In Summary, - What the main problem with SB 958?
The ***only processes by which*** control or a reduction in pharmaceutical prices has proved materially successful are the Formulary and competitive bidding processes used by "Payers".

Manufacturers know that inclusion in the Payer's Formulary is vital, that there are competing products and it's the Payers that control Market Share. "Vendors"/pharmacies know they are

in competition for both their costs and fees they charge Payer and quality of service among competing Specialty Pharmacies, etc. They all have strong interests in making "White Bagging" work to help control costs – and thus increase access to disease prevention and quality healthcare.

What is needed is pharmacy leadership to help make it work. **That means using the tools and authorities they already have** – like being a partner in helping the orders from prescribers flow easily through the process. For example, BPC 4052(a)(2) allows a pharmacist to "Transmit a valid prescription to another pharmacist". That may mean a hospital pharmacist transmits the prescriber's order that has been entered into the hospital's computer system to the "Vendor"/Licensed Pharmacy's pharmacist instead of putting the burden on the prescriber to send it to the "Vendor" pharmacy – **AND in the process prevent or resolves any potential problems** in clarity, expected delivery times, etc. Remember, by accreditation standards every order already has to be pre-reviewed by a hospital pharmacist before product dispensing and administration. Or if a particular "Vendor" pharmacy is often used, use BPC 4071.1 for the prescriber or the pharmacist to enter the order directly into the Vendor' computer system. But pharmacy leadership it seems, is too often not looking for ways to help this new dynamic. It makes some wonder why that is?

Note: The traditional large mark-ups for drugs and biologics do NOT reflect misguided intent by the typical Hospital Director of Pharmacy or "Chief Pharmacy Officer" (CPO). Most are not even ***allowed*** to know by how much the cost of drugs and biologics are "marked up" by their institution's business office or how much the "pharmacy services" are profitable. The typical CPO is expected to run the pharmacy services on a "cost basis" only.

Another fact not readily disclosed, is the practice of "Clear Bagging". A practice so common that is has its own name. About 4 to 5 years ago it was reported the 60%+ of hospitals with 600 beds or more, have their own subsidiary or associated Specialty Pharmacy. Since then it is likely that this is more prevalent.

It is when the Hospital and or its associated clinics have their own OUTpatient "Specialty Pharmacy", they want to receive "White Bagged" products from them. Such pharmacies can be either "Not-for-Profit" or "For Profit" subsidiaries or associated entities with the hospital or clinics. A main feature of these "Clear Bagging" relationships is that when a high-cost drug is started INSIDE the hospital or clinic, very often therapy with that drug is repeated or continued after the patient's discharge from the hospital or clinic***. Sometimes FOR THE LIFE of the patient.***

Switching to another pharmacy or even to another safe and effective "therapeutically" or "generically" equivalent product after discharge is actually discouraged. Sometimes by law, it is not even allowed **without the prescriber's permission**. The payer is thereafter charged for the High Cost produc. **Sometimes for the rest of the patient's life**. During which hospital or clinic continues to reap the benefit of high gross margins.

This presents a clearly possible **Conflict of Interest** (**COI**) that would be more likely passed on to the Payer or the Public because of SB 958. Note: There is a preventions of COI relationships in law that prevent prescribers from owning and operating pharmacies because they would profit from the dispensing of drugs and biologics they prescribed for their patients. However, prescribers can have a financial interest or a professional interest in a hospital or clinic that owns a pharmacy which also presents a potential COI.

Many analysists have reported that the US has the highest cost healthcare but with near the lowest quality of care of all modern economies. Pharmaceutical costs are among the highest because of the monopoly of drug importation that pharmaceutical and biologic manufacturers have. Therefore, it is imperative that the Board of Pharmacy help control those costs and preserve broad access to High Quality Care and disease prevention.

As mentioned above, the evidence of this includes the Governor's consolidation the purchasing power of Medi-Cal pharmaceutical therapy for all State programs with those by county and local program pharmaceutical purchasing that want to participate. The goal is to increase competition among pharmaceutical suppliers. This is recognition of what the State's "Formulary" inclusion over Market Share actually means along with the volume of purchases. It indicates what at risk with SB 958.

Likewise National administration's support of Medicare Part D, Medicaid Formulary, VA, DOD and other Formulary programs are "THE" major power for increasing competition. The passage of FDA approval "Biosimilar" pathways to increase competition among Therapeutic equivalents – similar to increasing competition by allows better pathways for generic equivalents that have existed for decades - is one of the most important and will be that for decades.

Please Oppose SB 958 as it is currently drafted. It has "some" good features, but it is NOT ready for enactment.

Thank You

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As mentioned, here is a brief description of the experiences and responsibilities from which I have formed this letter.

First, let me state, I am NOT an owner, employee or representative of any Payer (e.g. Health Plan, Insurance Co., etc.) hospital, clinic, or "Vendor"/pharmacy, pharmaceutical company or any other organization that may have a conflict of interest with SB 958.

I am a very concerned citizen with over 40 years of helping to assure that High Quality of Care is Affordable. I was responsible for pharmaceutical contracting, procurement, warehousing and

distribution, a Central pharmacy and what is now called an “Outsourcing Pharmacy” serving over three million Southern California members of the State’s most well-known, fully integrated not-for-profit Health Care Service Provider and Plan.

It was (and still is) my passion to help assure that those members and as many California residents as possible have the most affordable pharmaceutical care possible. That means any unnecessary pharmaceutical expense will have reduce the other preventative and treatment care such covered patients are be able to receive. If enacted, the problems of SB 958 will last many years.

During that time, and now, we have learned by far that increasing competition among suppliers provides the highest value for the cost. This allowed that organization to achieve the lowest cost on pharmaceuticals more than any other organization. Yes, I am very proud of my career with that Medical Care organization, but, it will not be affected by SB 958 as the Bill exempts it as a “fully integrated health plan”. However, I am concerned about all the other patients in California, their employers, Trust Funds and taxpayers!