From: Pedi Mirdamadi <drpedi@oasishealthandmedicine.com>
Sent: Monday, January 27, 2025 6:32 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Title 16

Hey there,
I am a naturopathic Doctor Who has done over 5000 IV infusions. These IV infusions have been a pivotal part of my patients overcoming many challenges in their health. From malnutrition to overcoming long haulers, they have been truly life-changing for some. The fact that they may be removed from our tool kit, boggles my mind.

I have had zero adverse reactions to any of these infusions so based on my experience, they are absolutely safe.

I really hope this decision gets reversed as it could have a devastating impact on not only our profession, but all of those that are working with naturopathic doctors.

Thank you for your consideration,
Dr. Petty Mirdamadi

Sent from my iPhone

From: Marjorie Morgenstern <mmorgenstern@ci.cloverdale.ca.us>
Sent: Monday, January 27, 2025 2:21 PM
To: Damoth, Debbie@DCA <Debbie.Damoth@dca.ca.gov>
Subject: Email Opposing the Proposed Restrictions on Compounded Supplements & Medications

To the California Board of Pharmacy,

As a Lyme Patient that has found B12 & Glutathione injections imperative and beyond helpful in my treatment I am horrified that you are ignoring an abundance of intelligent public comments from MDs, Naturopaths, Veterinarians, and Pharmacists along with Firefighters regarding your proposed new restrictions on compounded supplements.

Your desire to tighten restrictions on compounded medications is senseless and overreaching. The current regulations are already enough to keep patients safe. Our firefighters that have been working diligently to save lives and homes in California deserve your support instead of your overly controlling restrictions. Please do not make it more difficult and more costly for our firefighters, immune compromised patients and pets to detox utilizing glutathione and other supplements. Your reasons for wanting to tighten restrictions are transparent and lack integrity. Medical Doctors do not need anymore needless restrictions from the board regarding how they choose to treat and help patients. Same with Pharmacists.

As a California Councilmember I am appalled at the fact that you are not listening to public comments. Listen to the people of California! Do better!!! I know I am not the only person in Sonoma County California that is appalled with your inability to listen to the public. The board is pretending they know best and that medical doctors and pharmacists do not. Come back down to earth and start listening to the residents and voters of California. Some of the condescending comments the board makes are offensive.

City of Cloverdale Councilmember Marjorie Morgenstern

Sent from my iPad

From: Carolyn Cohen <acrocaro@gmail.com>
Sent: Monday, January 27, 2025 5:51 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public comment re: proposed amendment to Title 16 CCR Sections 1735-1738

Dear Members of the California State Board of Pharmacy,

I write to you as a public citizen and a Primary Care Provider to voice my strong opposition to the proposed amendment to Title 16 CCR Sections 1735-1738, which would limit access to Category 1 sterile compounds, such as glutathione, methylcobalamin, and NAD+.

I have spent the past two weekends volunteering my time and expertise at health clinics for First Responders in Los Angeles. Our non-profit clinics provided nebulized and IV glutathione, in addition to a number of holistic and trauma-informed treatments.

The men and women who saved lives and battled blazes literally flooded our clinic requesting "the breathing treatment". They are struggling.
After the heavy toxic load they've encountered, they are wheezing, laboring to breathe. Some are vomiting and have daily headaches.

They felt the benefit of glutathione and were immensely grateful for our care. Glutathione treatments are the ONLY hope they have to avoid a toxic overload in their system, which their doctors have told them will likely lead to cancer.

Are you willing to bear responsibility for that outcome?
If your house is the next to burn, do you want a firefighter to question whether to save your house - or save themselves?

The Board of Pharmacy should exist to **protect** the public, not harm them and our First Responders by restricting access to safe, effective therapies.

Doctors, organizations, patients, and firefighters have repeatedly told you that they do not want these regulations. The Alliance for Pharmacy Compounding and numerous individual pharmacists have also voiced strong opposition.

LISTEN TO US.

LISTEN TO THE FIRST RESPONDERS.

Please STOP these proposed amendments - for the health and well-being of all Californians, and First Responders.

Thank you,
Carolyn Cohen, L.Ac.
HOLISTIC PRACTITIONER & EDUCATOR
Orthopedic & Constitutional Acupuncture
Manual Therapy
Holistic Injury Rehabilitation

From: Ken Grossberger Liz Peterson <kjg2@msn.com>
Sent: Saturday, January 18, 2025 12:44 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Title 16 CCR Sections 1735-1738

Dear Ms. Martinez,
I am opposed to the proposed regulations (Title 16 CCR Sections 1735-1738) which would severely limit access to widely used Category 1 sterile compounds like GSH and methyl B12, available in the rest of the USA. I have Lyme's and stand with everyone who struggles with this disease. Lyme's is becoming more and more widespread requiring everyone to pay attention and put resources towards providing patients with better testing and access to all treatments available. We cannot afford to have treatment options taken away from us when fighting this disease is hard enough as it is.

Sincerely,
Elizabeth Peterson
Cortlandt Manor, NY 10567

Dear Members of the California State Board of Pharmacy,

I'm writing to share my deep concern and strong opposition to the proposed regulations that would severely restrict access to Category 1 sterile compounds like glutathione (GSH) and methylcobalamin (methyl B12), which are still widely available across the United States. As a firefighter and someone who has personally experienced the transformative benefits of these therapies, I feel compelled to voice how detrimental this overreach could be to the health and well-being of countless Californians.

Glutathione and methyl B12 are not just supplements; they are lifelines. These compounds are staples in integrative and functional medicine practices, used safely and effectively to treat a range of conditions—from chronic fatigue to neurological disorders and immune deficiencies. For many patients, these therapies are the cornerstone of their health management, offering hope and significant improvements in their quality of life.

Chronic Illness: Compounded medications like glutathione and methylcobalamin are indispensable for managing chronic illnesses such as long COVID, Lyme Disease, and ME/CFS. These conditions are complex and debilitating, often leaving patients without effective conventional treatments. For many, these compounded medications are the only viable option to alleviate symptoms and maintain some semblance of normalcy. Taking these options away would only exacerbate suffering and hinder recovery for thousands of Californians.

Firefighters: These compounds are also crucial for detoxifying individuals exposed to hazardous chemicals—a reality I know all too well as a firefighter. In 2020, I responded to a lithium-ion bike fire in a warehouse, which exposed me to hundreds of toxic chemicals. A week later, I became severely ill, coughing up bloody sputum and struggling to recover. That incident marked the beginning of my journey into detoxification, supplements, and alternative medicine to heal myself. Compounded medications like glutathione were instrumental in helping me detoxify and regain my health. For firefighters, whose cancer risk is nearly double that of the general population, these therapies are not optional—they are essential to improving our odds and maintaining our health while we serve our communities.

Lack of Alternatives: There are no true alternatives to these compounded medications. Over-the-counter supplements simply do not offer the potency or bioavailability that compounded IV infusions or subcutaneous injections provide. Without access to these therapies, many patients will face worsening health crises and deteriorating quality of life. For individuals who have exhausted conventional options, these treatments are not just another choice—they are often the only effective solution.

Restricting access to these compounds would disproportionately harm those with complex medical needs who have no other viable treatments. It would force patients to either go without care or seek treatment outside of California, creating unnecessary hardship and deepening inequities in healthcare access.

Compounding pharmacies already operate under stringent regulatory standards, ensuring the safety and quality of their products. The current framework is robust and sufficient, and there is

no compelling evidence to justify additional restrictions on Category 1 sterile compounds. Instead, these proposed changes would create significant barriers for healthcare providers and patients alike, while straining an already overburdened system.

California has long been a leader in healthcare innovation and patient advocacy. By moving forward with these restrictive regulations, the state risks abandoning this legacy and falling behind the rest of the nation in providing patient-centered care. I urge the Board to reconsider the broader implications of these regulations and prioritize the needs of Californians who depend on access to these life-changing treatments.

Thank you for taking the time to hear my concerns. I ask you to think of patients like me—and so many others—who have experienced firsthand the profound impact these medications can have. Please reconsider these regulations and work collaboratively with providers and patients to ensure that Californians continue to have access to the therapies they need to thrive. I'm begging the Board to take a step back and hit the pause button and reassess this before they make a brash decision that may be impossible to undo.

Sincerely,

Wesley Hamik
Fire Apparatus Engineer/Hazmat Specialist
30154 Point Marina Dr.
Canyon Lake, CA 92587
707-953-2676
Hamik.wesley@gmail.com

From: Diana Barton V. <dr.dianabarton.nd@gmail.com>
Sent: Monday, January 27, 2025 10:18 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment on Proposed Amendments to Title 16 CCR Sections 1735-1738

Dear Members of the California State Board of Pharmacy,

I am writing in re: to the proposed amendments to Title 16 of the California Code of Regulations, Sections 1735-1738 which I believe are unnecessary.

As a naturopathic student and doctor I have seen the benefits of these Category 1 sterile compounds to chronic disease and conditions such as toxin removal (important for our firefighters in California), immune system support, direct bioavailability to patients with chronic gastrointestinal diseases who cannot process oral B12, etc.

There are other products on the market that are actually harmful and should be banned such as artificial food dyes, flavors, synthetic chemicals, etc. in medication and food (ie. Red 3 food dye ban).

Restrictions on these Category 1 sterile compounds will be detrimental to the patients who rely on these compounds for health and even staying alive.

Thank you for considering my comment.

Sincerely,
Diana Valdez, ND

To: California Board of Pharmacy, c/o Lori Martinez at: PharmacyRulemaking@dca.ca.gov
Re: Public Comment in Opposition to proposed regulations, “Title 16 CCR Sections 1735-1738”

Jan. 27, 2025

Dear California Board of Pharmacy,

I’m Sara Johnson, and I’m a patient expert with lived experience of Long Covid, ME/CFS, and other complex chronic conditions. The proposed regulations exceed the Board’s statutory authority, as they impose restrictions that are not supported by substantiated evidence or scientific justification. These regulations threaten millions of Californians with serious, disabling chronic conditions—patients with no FDA-approved alternatives, sterile or non-sterile. They also conflict with and obstruct leading medical research. Altogether, these regulations imply potential undue influence over the decision-making process, which fails to properly protect public health.

The Board has failed to substantiate the regulatory basis for these actions, which contravenes the requirement for evidence-based decision-making in rulemaking processes. These restrictions contradict federal guidelines for legally permitted FDA Category 1 substances, and the Board has provided no scientific justification, constituting an overreach of regulatory authority. A biased, inaccurate “education” presentation at the November meeting further reflects the Board’s lack of transparency.

As previously stated, these substances are vital for patients with Long Covid, ME/CFS, Chronic Lyme, and related illnesses, affecting over 20 million Americans and 400 million people worldwide. Restricting access harms patients and impedes critical research.

These regulations exceed FDA standards without demonstrating added safety benefits, as outlined in the Initial Statement of Reasons (ISOR). They would disrupt pioneering research by institutions such as Stanford, UCSF, Scripps, and the Open Medicine Foundation, global leaders in Long Covid and ME/CFS studies.

On Dec. 17, 2024, leading researchers from The Cohen Center for Recovery from Complex Chronic Illness (CoRE) at Mount Sinai explicitly stated the importance of these sterile compounds. They emphasized their significance in treating mitochondrial dysfunction, central to these conditions. Dr. David Putrino, the internationally recognized expert on Long Covid, said that to “flood the body with these materials allows the mitochondria to have more of it available to them," facilitating energy production and reducing cellular toxicity. Dr. Amy Proal, the renowned microbiologist and co-founder of PolyBio Research Foundation, highlighted that these substances must “circumvent the gut” to ensure bioavailability due to enzymatic breakdown.

Dr. Nicole Thibeau, a Board member, expert pharmacist, and patient expert with lived experience of ME/CFS, abstained from voting, citing that these regulations would harm disabled

patients. Her abstention reveals the Board's neglect of key stakeholders and its failure to uphold its mission. Without FDA-approved treatments for these conditions, patients depend on these therapies for survival, and researchers rely on them to advance science. Restricting access would delay relief for millions and hinder progress in addressing these debilitating conditions. Jeff Hughes, a Board member and firefighter advocate for cancer prevention, voted YES, undermining his life's work and experience with occupational cancer. His vote jeopardizes the safety of his brethren first responders, particularly as fires rage across the state today.

The fires burning across California, from the northern regions to Southern California, have already wreaked unprecedented damage and continue to pose immense public health risks. These fires release a staggering amount of toxic pollutants into the air, water, and soil, including benzene, formaldehyde, and particulate matter. These toxins contribute to oxidative stress, inflammation, and lung damage, causing long-term health risks for vulnerable populations and first responders.

For first responders, who are already at high risk of chronic respiratory conditions due to exposure, and vulnerable populations like children, the elderly, and those with pre-existing conditions, the need for treatments like nebulized glutathione is critical. Glutathione helps reduce oxidative stress and inflammation, and without access to it, individuals exposed to wildfire smoke are at risk of long-term health complications, including asthma, COPD, and lung cancer.

Maintaining access to sterile compounded medications like glutathione reduces long-term public health burdens. These medications help manage complex chronic conditions that contribute to broader health issues, such as obesity, type 2 diabetes, disability, and even suicide. By personalizing treatments to meet individual needs, compounded medications mitigate long-term physical and mental health consequences, improving patients' quality of life and reducing healthcare costs. When access to necessary treatments like compounded medications is restricted, it exacerbates these challenges, leading to poorer long-term outcomes for patients and adding strain to the healthcare system.

For example, the use of GLP-1 drugs in adolescents with obesity has been shown to lower the risk of suicidal ideation and attempts, compared to lifestyle interventions. This highlights the importance of making effective treatments accessible to people suffering from conditions like obesity, which are linked to increased suicide risk and other debilitating diseases.

Licensed compounding pharmacies follow strict USP <797> guidelines for sterile production and adhere to FDA-enforced cGMP standards for 503B outsourcing facilities, ensuring that compounded medications are manufactured to the highest safety standards. These rigorous quality checks at every step—from sourcing ingredients to final production—ensure that compounded medications are safe, sterile, and effective. Unlike mass-produced drugs, compounded medications are personalized, reducing the risk of allergens or adverse reactions, and are subject to more direct oversight to guarantee their quality.

By denying access to FDA Category 1 substances in sterile compounds, the California Board of Pharmacy will directly contribute to the worsening health crisis facing our state. The Board's actions will not only undermine public health but will increase suffering for millions of Californians who need these treatments to manage their health in the aftermath of an ongoing environmental disaster. This is especially concerning in a state like California, where wildfires are becoming increasingly frequent and severe, and the need for immediate, adaptable healthcare solutions is more urgent than ever.

The California Board of Pharmacy must act to ensure that residents and first responders have access to essential treatments like glutathione, especially during this ongoing public health crisis. I urge the Board to immediately revise or suspend these regulations and prioritize the health and safety of those most vulnerable in this emergency.

The Board has failed to provide compelling, documented evidence to justify these regulations, violating the requirement for evidence-based decision-making. These regulations contradict federal law and FDA guidelines, which already allow sterile compounding of substances. The Board is imposing unwarranted restrictions without legal grounds.

The proposed amendments exceed the legislative intent behind compounding laws, violating the principle that regulations must align with the law's original purpose. The regulations would limit access to critical, life-saving medications like glutathione and methyl B12, vital for patients with Long COVID, Lyme, and Alzheimer's, denying their right to necessary care.

New stability testing requirements will create undue financial hardship on pharmacies and patients, making life-saving medications less affordable and accessible. The Board has ignored the overwhelming public opposition and expert testimony, failing to address concerns from healthcare professionals and patients. The failure to accommodate patients with disabilities by restricting access to compounded medications and restricting their meaningful engagement as key stakeholders throughout the public rulemaking process violates their rights under the Americans with Disabilities Act (ADA).

The Board is making critical healthcare decisions without adequately engaging the medical, scientific, and lived expertise of stakeholders, undermining the integrity of the rulemaking process and the mission they swear to uphold. These regulations create barriers to treatment for patients who rely on compounded medications, potentially violating equal protection principles by discriminating against those without FDA-approved alternatives. These regulations and the actions of the Board imply regulatory capture by violating procedural norms, lacking evidence, and harming millions.

Thank you,

S. L. Johnson

Sara Johnson
Los Angeles, CA

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From: Toni Tizon-Damiano, MSN, APRN, ABAAHP, FNP-C <toni@rootswellnessfm.com>
Sent: Monday, January 13, 2025 6:22 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Title16CCR SECTION 1735-1738

Please allow us to still provide compounded glutathione and b12 to our patients. This has helped so many of our patients with liver issues and are better available to them through compounding pharmacies.

Toni Tizon-Damiano, MSN, APRN, ABAAHP, FNP-C
Call/Text - 805-906-2015

From: Walter Taylor <directorsoda9@gmail.com>
Sent: Saturday, January 18, 2025 9:20 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Cc: wharfrat111@comcast.net
Subject: My Public Comment in Support of the Continued Access of all Californians to Oral & Intravenous Vitamin B12, Glutathione, NAD and all other Adjunct Preparations Currently at Issue Before the Rule Making Board, Regarding Ending or Curtailing Access to th...

Saturday, 18 January 2025 @ 2119 PST

My Public Comment Submission to the Pharmacy Rule Making Board

I support full access to oral & IV Vitamin B12 and Glutathione because I use these efficacious medications to survive the ravages of an untreated Tick-Borne Relapsing Fever infection and the 2010 failed UCLA Infectious Disease Santa Monica Clinic's attempt to treat my Spotted Fever Group Ricketsia infection.

I most likely contracted these 'orphan' diseases working as a Land Surveyor in Central California & throughout the Western United States, in a similar fashion as would have wilderness and urban firefighters. Through our daily exposures to the hazardous conditions encountered throughout our average workday.

The California State Board of Pharmacy effort to deny patient access to oral & IV Vitamin B12 and Glutathione is a cynical and ill advised effort to deny medication access to inadequately treated tick-borne illness sufferers and smoke inhalation injuries suffered by wildland and urban firefighters to these efficacious medications.

The California State Board of Pharmacy effort to deny patient access to oral & IV Vitamin B12 and Glutathione offers no other affordable efficacious options to replace these vitally needed medications.

The California State Board of Pharmacy has offered the public no scientific or legal justification for blocking Californian's access to these vital Category 1 substances.

The California State Board of Pharmacy has been targeting the specialized pharmacies that compound & dispense these vital Category 1 substances.with increasingly harsh regulations and using taxpayer money to file lawsuits against eight of them, falsely claiming that they were dispensing Category 1 substances improperly.

Despite losing every case in court and even being admonished by one of the judges, The Board is now attempting to codify their extreme stance into policy, putting countless lives at risk.

As a Concerned California Citizen, I believe that the California Attorney General should investigate, to determine whether the funding methodology of the California State Board of Pharmacy is being corrupted by "Big Pharma",
much like the needed & long overdue investigation into and the dissolution of, the California Division of Oil Gas & Geothermal Resources (DOGGR) for institutional corruption of the highest magnitude.

This unprecedented effort by the California State Board of Pharmacy to deny patient access by filing 8 failed taxpayer paid for lawsuits against compounding pharmacies enabling that patient access to oral & IV Vitamin B12 & Glutathione should prompt an investigation of similar scope to the DOGGR investigation by the California Attorney General, to investigate whether "Big Pharma" is insidiously manipulating the California Board of Pharmacy decision making process,.

The California State Board of Pharmacy seeks to essentially defraud Citizens of California of despirately needed affordable & effective healthcare, in particular those suffering from inadequately treated tick-borne illnesses and those courageous wildland and urban firefighters, injured by smoke inhalation while heroically saving Los Angeles, our forests and the urban/forest interface environs from fire's deadly & catastrophic destruction.

The California State Board of Pharmacy,
Is attempting to defraud all Citizens of California by seeking to block their legitimately needed access to these vital & live sustaining alternative or adjunct therapies.

As I heard years ago that such a national effort would be forthcoming, I believe that the California State Board of Pharmacy, is setting an insidiously dangerous precedent, as part of a nationwide "putsch" by "Big Pharma", to eliminate, patent, control and then monopolize targeted compounding pharmacies & US health supplement industries, to ultimately control all American's access to these efficacious & affordable alternative or adjunct medical therapies.

This already known & previously disclosed "Big Pharma" conspiracy against the health supplement industry, has been insidiously planned for years to remove these efficacious & affordable alternative or adjunct medical therapies from the retail market, by them being declared "unregulated & therefore unsafe" by the "Big Pharma" corrupted State Pharmacy Boards across the United States.

The American Pharmaceutical Industry acknowledged years ago that their industry cannot patent these alternative or adjunct medical therapies, without them first being erroneously banned as "unsafe & unregulated" by all the infiltrated & monetarily influenced State Pharmacy Boards across the United States.

Then these efficatious & affordable alternative or adjunct medical therapies will be reintroduced by the American Pharmaceutical Industry, as "patented and safely manufactured pharmaceutical drugs" within there monopolized "Big Pharma" facilities and typically price gouged to the American Public, through their usual corporately controlled cutouts, the "pharmaceutical middleman".

This Denial of Access Pogrom by the California State Board of Pharmacy pitts this California Regulatory Agency against the very California Citizens, that the California State Board of Pharmacy was promulgated to protect, from the greed & corruption that the California State Board of Pharmacy has now, very predictably, fallen victim too.

I, Walter Hicks Taylor of Lompoc, California, ask that the Rule Making Committee acknowledge

the enormous public outcry and the 8 failed lawsuits, against the California State Board of Pharmacy effort to end patient access to oral & IV Vitamin B12 and Glutathione.

I ask that the Rule Making Committee, noting the vehement public outcry and the 8 failed lawsuits against California compounding pharmacies, ensure the patient access of all Californians to these efficatious and affordable FDA Class 1 drugs and refer this attempt to deny issue to the California State Attorney General for investigation of the California State Board of Pharmacy and their unpresidented effort to prosecute California Compounding Pharmacies.

Walter Hicks Taylor
1421 Riverside Drive
Lompoc, CA 93436
Cell: 805-757-3602

From: Mcconnell, Tera <tera.mcconnell@petnetsolutions.com>
Sent: Friday, January 24, 2025 1:50 PM
To: Martinez, Lori@DCA <Lori.Martinez@dca.ca.gov>
Subject: Comments on second modified text for radiopharmaceuticals

Hello Lori,

I am providing comments for the second modified text proposed to Title 16 CCR Sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738 et seq Related to Compounded Drug Preparations, Hazardous Drugs, and Radiopharmaceuticals.

- The proposed designated person language should align with the <825> definition in that one or more individuals should be able to be this designated person simply because the responsibilities are such that a single person would not be able to take a vacation otherwise. Furthermore, the language should mirror the <795> and <797> text. This language would be the following: Designated person (s) means one or more individuals assigned by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and the personnel as related to the preparation of radiopharmaceuticals. Nothing in this definition allows for a designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require the professional judgement of a pharmacist. Nothing in this definition prohibits the PIC from also serving as the designated person.
- With regards to 1738.5 Facilities and Engineering Controls (d), the intention of the hot cell can be the total of the SRPA because it provides a full physical barrier on the outside. This would eliminate the need for (1) under this section that reads: Except for walls, the SRPA's visible perimeter shall be at least 1 meter from all sides of the PEC or in a separate room.

Best Regards,

Tera McConnell, Pharm.D., R.Ph.
Regulatory Affairs Specialist
PETNET Solutions | A Siemens Company
email: tera.mcconnell@petnetsolutions.com
phone: 512-869-9703

www.usa.siemens.com/healthineers

From: m guevara <matisony@gmail.com>
Sent: Monday, January 20, 2025 8:53 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Opposition to Proposed Regulation Title 16 CCR Sections 1735-1738

Dear Lori Martinez,

I am writing today in strong opposition to the proposed regulation that would limit access to compounds such as glutathione and B12.

I am referring to Title 16 CCR Sections 1735-1738

In light of the devastating fires in Los Angeles, the importance of these compounds cannot be overstated. Firefighters who are on the front lines, saving lives and homes deserve better. They are exposed to smoke and structure fire pollutants that glutathione in particular has been shown to help combat.

Denying access to these compounds at this time is unconscionable.

I urge the board to reverse their proposed regulation and prioritize the health of our firefighters, first responders and others in need.

I trust you will act in the best interest of health.

Kind Regards,
Sarah Guevara

From: Nathaly Holt <holt.nathaly@gmail.com>
Sent: Sunday, January 26, 2025 11:13 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Public Comment regarding Title 16 CCR Sections 1735-1738

To the California State Board of Pharmacy:

I am writing in reference to Title 16 CCR Sections 1735-1738. PLEASE PLEASE PLEASE stop trying to take away access to or severely limit access to widely used Category 1 sterile compounds like Glutathione, methyl B12, NAD+ , etc which are available in the rest of the country! I have used nebulized glutathione before when I was in my 20's and I had several respiratory infections at the time from a compromised immune system and the glutathione was the only thing I could take because I don't react well to prescription medications. I get all the side effects when I have taken them in the past. You are limiting many people's ability to have easily accessible choices on how they can treat their diseases. Why would you do this to us? It leads me to believe you don't care about us and our choices. The state that so proudly yells "my body, my choice" seems to only be concerned with the choice to kill off a human being growing inside of a woman but THIS is where you want to take a hard stand? In saying we can't get access to glutathione and methyl b 12?!!?? Is there a list of people injured by these things? Or that have died from it?! I doubt you can produce a legit list. I need these alternative remedies to live and function on a day to day basis. I know others who do too. You are giving us a slap in the face by not supporting our choice to have these remedies for our illnesses.

Please remove these ridiculous regulations that you aren't even allowed to do yet you are giving compounding pharmacies fines from citations and intimidating compounding pharmacies by silencing them from speaking out due to fear of retaliation from you. You are not helping anyone by doing this except your own pockets. You are directly harming us by taking away our choices to treat our symptoms in a manner that fits our needs. I am seriously considering leaving CA because of freedoms being taken away like this one!! How is it that you know there are syringes all over SF of hard core drugs and weed is allowed everywhere for anyone but Glutathione and other category 1 sterile compounds is what you want to limit our access to. Why???!! It's so ass backwards! Please stop this. This is not okay. Your overreach is affecting disabled individuals, fire fighters, chronically ill patients, integrative doctors, athletes, compounding pharmacies, parents/caregivers, and many more.

The BOP has lost all 8 lawsuits related to glutathione and methyl b12 production so far, but ignored the ALJ decisions. You have the power to suspend and revoke licenses without oversight!!!! How is this possible??!!! This is how you create a culture of fear so that the compounding pharmacies don't speak up anymore for fear of retaliation from you! Assembly bill 973 DID NOT authorize the BOP to enforce non-existent regulations, which you stated doing anyway!

Remove the proposed regulations on these compounds; they are unnecessary and not limited in any other state!! STOP giving me more reasons to leave California!!! You must hate firefighters or chronically ill patients like myself, who benefit GREATLY from these types of alternative remedies and we rely on them because they do so much good and keep us alive and functioning. Like fire fighters don't sacrifice enough already you are intentionally giving them less access to remedies that could be of great benefit to them and help them breathe easier. If you insist on these regulations you have no compassion whatsoever for fire fighters or chronically ill people is what you are saying. Plain and simple. The DCA is turning a blind eye here...I hope that changes soon. You do not offer any scientific or legal justification for wanting to block access to an entire class of naturally compounded medicine. You are the ONLY state to take such an action.

PLEASE STOP THIS AND VOTE NO AT THE MEETING IN FEB.

Regards,
Nathaly Holt
(patient)

From: Matt D <bushidotnt@icloud.com>
Sent: Monday, January 27, 2025 2:18 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Title 16 CCR Sections 1735-1738

Title 16 CCR Sections 1735-1738

I am opposed to the proposed legislation because I've relied on B12 for 16 years now for a variety of medical conditions in a manner which it helps without having the harmful side effects of so many different pharmaceuticals.

This is unbelievable that California would be less progressive and more rigid than the rest of the country when it comes to common things used by functional and integrative doctors.

Respectfully,
Matt Domyancic
Sent from my iPhone

From: Maureen O'Neil <mmoneil@gmail.com>
Sent: Saturday, January 18, 2025 3:54 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: do NOT restrict patient access to IV and shot treatments

Hello
I, as a patient, have used IV vitamin treatments including glutathione in the past 10 years. I have sent several of my manual therapy clients to also receive these treatments. Why? this type of treatment is actually safer and more cost effective than vitamin supplements.

Here are client examples:
* a firefighter who has lung/organ stress from his job seeking to heal deeply and PREVENT cancer which is a HIGH RISK for firefighters
* a new mother who had a traumatic, highly medicalized birth. Treatment helped her recover more quickly and more effectively bond with her baby
* a pregnant woman who used the treatments to have a safe labor without the interventions of pitocin and potential cesarean; both proven to potentially have lasting negative effects on the baby and mom.

My own story is that these treatments have helped me recover from the physical effects of ongoing traumatic stress of parenting two boys with ADHD and other challenges. Treatments have also helped me with menopause symptoms and other medical challenges. Like many, I worry about the risks of developing cancer and dementia. I believe I have the right to receive preventative care.

These treatments are overseen by naturopathic physicians (NDs) and even allopathic physicians (MDs). All are administered by nurses.

warmly,
Maureen O'Neil
1553 Rainier Ave.
Petaluma, CA. 94954

--
Maureen O'Neil
BlissBrain Healing
Craniosacral & Neurofeedback
415-786-7637
45 San Clemente, Suite B200B
Corte Madera 94925

From: Maya Lindemann <mayalindemann@gmail.com>
Sent: Sunday, January 19, 2025 8:08 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Statement on Glutathione Access
RE: Title 16 CCR Sections 1735-1738

Dear Pharmacy Policy Makers,

I'm writing to you pleading to reinstate full access to Glutathione in California for the safety of patients and firefighters.

I contracted COVID March 2020 which has resulted in severe chronic health issues. By 2021 I became so severe I could not lift my head or speak as well as such extreme light sensitivity I required total darkness. In the last 4 years I've tried hundreds of interventions and medications. Weekly IV glutathione has been one of the most beneficial treatments so far. I'm now able to sit reclined and have short conversations.

Restricting the production of and access to Glutathione (along with NAD and B12) harms patients.

1-Removes critical treatments
These prescribed compounds are critical part of treatment plans especially for those of us, like myself, who have mitochondrial dysfunction and fatiguing illnesses. The decision to make any additional restrictions above national standards prevents patients from receiving necessary treatment.

2-Financial burden
The decision to restrict these critical treatments adds to the financial burden on patients many of whom are on fixed income and have to pay out of pockets. The additional regulatory hurdles you make on compounding pharmacies increase the cost passed down to patients.

These restrictions prevent Californian patients from getting prescriptions fills at cheaper prices in other states.

3-Endangers patients
In the name of "patient safety" the board is pushing these meds underground where they are more likely to be unsafe.

State hopping- Those fortunate to have dual state residences and able to receive prescription shipment in another state are forced to ship refrigerated medication multiple times, increasing exposure to volatile temperatures potentially making medications unsafe.

Alt sources-many other Californian patients whose lives depend on these medications and who have already affected by BOP that I've spoken to have resorted to alternative sources, such as *veterinarian or research grade* that has not been tested for human safety.

You are not stopping these medications you are making them UNSAFE and endangering patients.

Restricting these medications **harms patients**, removes access to necessary medication overseen by a doctor, adds an additional financial burden to patients, and promotes potentially hazardous and unsafe sources of medication.

Furthermore, the proposed action by BOP **harms Firefighters** -an interesting choice given the epic fires California continues to experience. Firefighters have an inherently hazardous job with prolonged and frequently exposures to carcinogens. The leading cause of death of active duty firefighters is cancer. A pilot study completed by Sonoma Volunteer Fire Foundation found glutathione reduced the total number of high range toxins by 73% and Glyphosate by 93%.

Glutathione should be made standard of care for firefighters. Instead of supporting the health of firefighters who risk their lives saving ours, the Board of Pharmacy wants to restrict a basic treatment that can reduce their cancer risk.

In the name of patient and firefighter safety, it's time to bring back the national standard of accessibility for Category 1 compounds. I'm begging you to put egos aside and do what right.

Thank you,
Maya Lindemann, RN
Santa Monica, CA

Sent from my iPhone

From: Kaitlyn Oleinik <kaitlyn_ko@yahoo.com>
Sent: Monday, January 27, 2025 3:02 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Title 16 CCR Sections 1735-1738

Hello,

My name is Sarah Kaitlyn Oleinik, and I am a Lyme Disease patient and survivor. I am writing to you to please do not limit access to Category 1 sterile compounds such as glutathione, methyl B12, and NAD+. I require these treatments weekly to stay in remission from Chronic Late Stage Lyme Disease. Although my levels are lower after years of treatment, I still deal with severe fatigue, post-exertional malaise, brain fog, and pain. These treatments keep me on track so I can continue my education as a Master's student with the hope of one day being able to work part or full-time in the future. With the help of these treatments, I have been able to go back to school, finish my Bachelor's degree, and move on to my Master's after withdrawing from school due to Lyme over 10 years ago. Please do not restrict access to these life-changing treatments.

Now, more than ever, it is not just people like me who need access to these treatments. With increasing wildfires in California, firefighters will need access to nebulized glutathione for cancer prevention. Please do not restrict these life-saving treatments from these heroes. I am asking you to do the right thing and allow anyone who is seeking these safe treatments to have access to them. Follow federal guidelines, and please- respectfully - do not overstep.

Thank you,

Kaitlyn Oleinik, Lyme survivor and advocate

Crystal A. Frost, PhDAA
January 27, 2025

#STOPTHEBOP
www.stopthebop.com

Public Comment on Proposed Amendments to Title 16 CCR Sections 1735-1738AA

Dear Members of the California State Board of Pharmacy,

I am writing this public comment on behalf of Stop the BOP, a nonpartisan patient-led movement advocating for the protection of access to sterile compounded medications that are essential to the lives of hundreds of thousands of Californians and utilized in countless medical communities across the nation and around the world.

The proposed amendments to Title 16 of the California Code of Regulations, Sections 1735-1738, impose unnecessary restrictions on access to Category 1 sterile compounds, such as glutathione, methylcobalamin, and NAD+. These regulations, as currently written, will devastate patient access to life-saving treatments in California, despite no evidence of safety risks warranting such measures.

In the wake of the Palisades and Eaton fires, Californians are grappling with the health consequences of prolonged toxic smoke inhalation, including toxin buildup in lung tissue. For many, the only effective treatment to address these toxins is nebulized and intravenous glutathione. These therapies are utilized by firefighters, Lyme Disease and Long COVID patients, and individuals with conditions like ME/CFS and methylation impairment. Denying access to these critical treatments endangers vulnerable populations and ignores the unique health challenges faced by our state.

At the January 8 Board Meeting, Board Member Maria Serpa claimed these regulations do not exceed USP and FDA requirements, but *this is patently false*.

- **USP does not require full stability studies for Category 1 or 2 sterile compounding.** These requirements only apply to Category 3 compounding. For the Board to mandate such studies—which can cost $10,000 to $30,000 per formulation—imposes an insurmountable financial burden on pharmacies. This will force them to limit offerings to the most generic formulations, eliminating the ability to create customized treatments based on individual prescriber orders.
- The **additional documentation of clinical circumstances** for APIs on the FDA's interim Category 1 list far exceeds FDA requirements. These APIs are

already treated like any other active ingredient under FDA guidelines, with no such documentation mandate.

- The requirement to perform multiple tests on APIs, including **tests listed in USP Chapters above 1000** (informational-only chapters), is both excessive and unprecedented. California would be the only state enforcing such standards on 503As, further restricting access without improving safety.

These burdensome regulations will have devastating consequences, especially for patients needing compounded treatments tailored to their specific health needs which is the entire purpose of 503A compounding pharmacies. For example, while pharmacies may justify the cost of stability studies for a generic glutathione multiple-dose vial, they will not be able to produce more individualized options such as essential preservative-free formulations or combinations. In essence, these regulations force 503A pharmacies to function as 503Bs which is, in a word, absurd.AA

Relevant Example and Public ProcessAA

What is most disturbing is the Board's persistence in moving forward with these harmful regulations despite overwhelming public opposition. This is not how a government body is supposed to operate.

USCIS Example

Recently, USCIS proposed changes to the naturalization process, including a multiple-choice civics test to replace the current oral exam. The same way the Board of Pharmacy has worked very hard on these widely opposed updates to Title 16, USCIS worked tirelessly on these naturalization updates which they believed would improve fairness. However, after USCIS received 1,300 public comments—fewer than the Board of Pharmacy has received in total—they chose NOT to proceed because the vast majority of comments opposed the changes. (Public commenters explained how, in fact, these updates would hold immigrants to a higher standard and presumes they have advanced westernized test-taking abilities.)

This is how the public process works: as a regulatory body, **your job is to listen to public comments and adjust your actions accordingly**. Under no circumstances is it appropriate to hold it against the public that the Board's hard work went into a proposal when said proposal ultimately harms the public interest. To force it on them anyway is petty and tyrannical.

Doctors, organizations, patients, and firefighters have repeatedly told you that they do not want these regulations. The Alliance for Pharmacy Compounding and numerous individual pharmacists have also voiced strong opposition. And yet, you continue to move forward, closing your ears to the outcry from those directly affected by your decisions. Ignoring public input and prioritizing the voices of a few individuals at the top—particularly taxpayer-funded lawyers at the Department of Consumer Affairs and an Executive Officer who clearly does not have the public's best interest in mind—suggests ulterior motives.

As California faces an unprecedented public health crisis due to widespread toxic smoke exposure, including asbestos, lead, microplastics, and potentially thallium, this Board has a moral and ethical obligation to protect the public. Instead of actively making it harder for Californians to access critical treatments, preserve access by fixing this proposal.

Our asks are simple:

1. A Align California's regulations with federal standards to ensure patients have access to essential Category 1 sterile compounded medications.
2. AAdhere to USP by allowing Category 2 compounding without requiring full stability studies, provided sterility and endotoxin testing is performed and a reasonable beyond-use-date (e.g., 45 days refrigerated) is applied.
3. AEliminate adherence to USP Chapters above 1000, which are not enforceable requirements and are meant for informational purposes only.
4. AAmend the language to specify that Title 16 sterile compounding regulations apply specifically to pharmacists and not to doctors.

The Board's mission should be to protect public health—not restrict access to therapies that enhance patient outcomes. I urge you to reconsider these proposed regulations and prioritize the well-being of Californians who depend on compounded medications for survival and quality of life.

Thank you for your attention to this critical matter.

Crystal A. Frost, PhD
Founder, Stop The BOP
email crystal@stopthebop.com
website stopthebop.com
phone +1 424 422 1807

California Rheumatology Alliance

Advocacy for Patient Access to Rheumatology Care

5230 Pacific Concourse Drive, Suite 100
Los Angeles California 90045
(tel) 310.536.0460
www.calrheum.org • info@calrheum.org

January 27, 2025

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

re: Proposed Regulations on Compounded Drug Preparations, Hazardous Drugs and Radiopharmaceuticals

Dear Ms. Martinez,

The California Rheumatology Alliance (CRA) appreciates the opportunity to provide additional comments on the proposed regulations on compounded drug preparation. Rheumatologists are medical professionals who specialize in diagnosing and treating conditions that cause inflammation in the joints, muscles, ligaments, tendons, and bones. For most rheumatology patients they are receiving treatment for their chronic conditions for years if not decades to help them manage their disease. Our goal is to improve the quality of life of our patients by reducing pain, preserving joint function, and helping them manage their rheumatic conditions.

We appreciate the Board reviewing our previous comments on December 9th. We have reviewed the staff responses to our comments and continue to be concerned with the applicability of the proposed regulations on physicians and their ability to "compound" medications in their offices. Although physicians may not be under the enforcement jurisdiction of the Board of Pharmacy, we believe the proposed regulations would change the standard of care for when physicians compound medications. This is also mentioned in the letter referenced in the staff comments from Reji Varghese of the Medical Board of California and quoted below.

> *It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine).*

We continue to be concerned that the proposed regulations change the standard of care and will not allow rheumatologists to buffer injection/infusion medications in-office. We are interpreting the proposed regulations to require a pharmacist be present or performing the buffering of the injection/infusion medications. Rheumatology practices

would not be able to afford to employ a pharmacist for this one purpose. This would lead to rheumatology practices no longer offering this service for our patients. Patients would then be forced to obtain their injection/infusions at a hospital or infusion center which would not only be less convenient for our patients, but it would be more expensive for the patient and the overall healthcare system.

We believe it is important to note we are not aware of any issues with rheumatologists "compounding" injection/infusion medications.

We would like to propose the Board of Pharmacy adopt the language suggested by the California Medical Association as shown below.

> **§ 1735.1:** In addition to the standards in USP Chapter 795 and, Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the compounding of a CNSP shall meet the following requirements of this article. **This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.**
>
> **§ 1736.1:** In addition to the standards set forth in USP Chapter 797 and Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the following requirements apply throughout this article. **This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.**
>
> **§ 1737.1:** In addition to the requirements in USP Chapter 800 and Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the following requirements apply to the compounding of Hazardous Drugs. **This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.**
>
> **§ 1738.1:** In addition to the standards in the USP Chapter 825, the processing of Radiopharmaceuticals shall meet the requirements of this section. **This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.**

We believe this will be the best approach to maintain a physician's ability to compound in the best interest of the patient. We appreciate your consideration of our requested changes.

Respectfully,

Samy Metyas, MD
President, California Rheumatology Alliance

CALIFORNIA HEALTH COALITION ADVOCACY

CaliforniaHealthCoalitionAdvocacy.org ● 901 H Street, Suite 120 #1061 ● Sacramento, CA ● 95814
916-572-4465 ● Advocacy@CaliforniaHealthCoalition.org

January 21, 2025

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Email: PharmacyRulemaking@dca.ca.gov

RE: Opposition to Proposed Regulations (Title 16 CCR Sections 1735–1738)

Dear Lori Martinez,

California Health Coalition Advocacy continues to have serious concerns regarding the newly proposed regulations under Title 16 CCR Sections 1735 - 1738. CHCA represents thousands of Californians and our mission includes protecting patient access to treatments and therapies. **These proposed regulations supersede the FDA and exceed US Pharmacopeia (USP) standards and would restrict access to treatments that Californians find essential to their health.**

Medications, including sterile compounds like glutathione, NAD^+, and vitamin B12, can be vital to personalized treatment plans, especially for patients with complex chronic and serious conditions such as ME/CFS, Long COVID, Lyme Disease, and some cancers. Because these medications are Category 1 bulk substances, the proposed regulations would make them inaccessible through 503a pharmacies and therefore no longer available to patients in California.

The adoption of these new regulations would cause harm to vulnerable patients, limit healthcare provider autonomy, and increase healthcare inequalities. Doctors should be able to prescribe treatments for their patients based on their expertise, research, and experience without interference from the California State Board of Pharmacy.

CHCA opposes these new regulations for these reasons and respectfully asks that they not be adopted without changes guaranteeing these essential substances remain available to Californians.

Sincerely,

Valerie Noble, President
California Health Coalition Advocacy

Mark Johnston, R.Ph
Executive Director, Pharmacy Advocacy and Regulatory Affairs
One CVS Drive
Woonsocket, RI 02895
401-601-1968
Mark.Johnston@cvshealth.com

1/22/25

California Board of Pharmacy,

I am writing to you in my capacity as Executive Director of Pharmacy Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in the state of California through our integrated offerings across the spectrum of pharmacy care that includes over 1,000 pharmacies located within California. We appreciate the opportunity to submit comments on the Board's proposed compounding regulations.

CVS Health greatly appreciates the collaboration that has led to numerous changes in pending language throughout this promulgation, including the addition of 1735.15, Flavoring Agents, in this Second Modified Regulation Text. In review of this new pending language, we suggest the following change, to harmonize terminology, reduce confusion, and streamline operations. 1735.15(a)(1) refers to a "compounding record", while 1735(b) refers to a "prescription record". The use of these two separate and undefined terms indicates that two separate records are required to be maintained for each flavoring, when we believe that one record suffices to protect public safety. We believe this requested change to be merely stylistic, and thus the acceptance of our request would not necessitate an additional comment period.

1735.15. Flavoring Agents.

(a)In addition to the standards in USP Chapter 795 and the Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) a facility that limits its compounding as described in Section 1735.1(i) shall establish the following SOPs:

(1) Provisions of accommodations as described in Personnel Preparation, Section 3.1 of USP Chapter 795.

(2) Provisions for cleaning and sanitizing designated compounding area when in use.

(3) Provisions to ensure documentation is available and maintained confirming that the quality of the medication is not impacted by adding the flavoring agent.

(4) Provisions for maintaining the elements of the compounding record to ensure information is readily retrievable upon request.

(5) Provisions to ensure the prescription label includes information that a flavoring agent was added.

(6) Provisions to ensure documentation is available to support the establishment of a BUD.

(b)A pharmacist may compound by combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of the patient or patient's agent without consultation with the prescriber or the prescriber's authorized agent. A pharmacist performing such compounding must document the compounding ~~on~~ in the ~~prescription~~ compounding record.

Sincerely,

Mark Johnston, R.Ph
Executive Director
Pharmacy Advocacy and Regulatory Affairs
CVS Health

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January 24, 2025

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste 100
Sacramento, CA 95834

Submitted via electronic mail to: Lori Martinez, California State Board of Pharmacy

RE: ***Compounded Drug Products Regulations***

Dear Ms. Martinez:

Kaiser Permanente appreciates the opportunity to respond to the California Board of Pharmacy's request for comments on the proposed regulations addressing nonsterile compounding, sterile compounding, and hazardous drugs. Kaiser Permanente comprises the non-profit Kaiser Foundation Health Plan, the non-profit Kaiser Foundation Hospitals; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan. These entities work together seamlessly to meet the health needs of Kaiser Permanente's nine million members in California. Kaiser Permanente's pharmacy enterprise in California is comprised of hundreds of licensed pharmacies that are staffed by thousands of individual pharmacy licentiates. The frontmatter of this letter comprises our general comments on the entirety of the proposed regulations; our comments on specific elements of the regulations are in the table that follows (in the table, Kaiser Permanente's proposed changes are denoted in red font with a strikethrough for deletions).

Throughout the rulemaking process, in our written comment letters and in verbal feedback during public Board meetings, we have highlighted the many cases in which the Board has failed to provide empirical evidence to support the need for additional regulations that exceed the requirements in the USP compounding chapters. We have also given several examples of the Board's failures to consider the behaviors that its proposed regulations will incentivize and the second order effects that those practices will likely precipitate. For the sake of brevity, we will not repeat our previous feedback in this letter, except that we continue to believe that the problematic second order effects that these regulations will cause coupled with the lack of evidence to support the proposed regulations will have a net negative effect of California patients and California pharmacies. Given these factors, Kaiser Permanente continues to support the following alternative approach:

1. The Board should accept the proposal to repeal sections 1708.3. 1708.4, and 1708.5 of Title 16, Division 17, Article 2 of the California Code of Regulations and to repeal 1735 et seq of Title 16, Division 17, Article 4.5 of the California Code of Regulations and to repeal 1751 et seq of Title 16, Division 17, Article 7 of the California Code of Regulations.
2. The Board should reject the proposal to add new sections 1735 et seq of Title 16, Division 17, Article 4.5 of the California Code of Regulations, and to add new sections/Article 1736 et seq of Title 16, Division 17, Article 4.6 of the California Code of Regulations, and to add new sections/Article 1737 et seq of Title 16, Division 17, Article 4.7 of the California Code of Regulations, and to add new sections/Article 1738 et seq of Title 16, Division 17, Article 4.8 of the California Code of Regulations.
3. The Board should enforce the provisions of the USP compounding chapters as required by California Business and Professions Code section 4126.8.

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If the Board elects to finalize the proposed regulations, we continue to encourage the Board to establish a rational effective date for these regulations that will provide the regulated public with ample time to come into compliance with these new requirements. In its previous response to our request for a delayed effective date, the Board rejected our proposal because the USP compounding standards have been in effect since November 1, 2023, and because some of the provisions in the proposed regulations are in the Board's current compounding regulations. Both of those observations, which we do not dispute, are immaterial to the work that organizations will need to do to come into full compliance with the proposed regulations. We expect that, if this regulation is finalized as written, Kaiser Permanente will need to make extensive updates to our policies and standard operating procedures, update our pharmacy information systems, and remodel some of our compounding facilities. These tasks are time-consuming, costly, or both and, as such, the Board should establish a delayed effective date for organizations to do the work needed to meet these requirements. We suggest that at least one year from the date that the regulation is filed with the Secretary of State would be a reasonable effective date.

Kaiser Permanente appreciates the opportunity to provide feedback in response to the proposed regulations addressing nonsterile compounding, sterile compounding, and hazardous drugs. If you have questions, please contact John Gray (562.417.6417; john.p.gray@kp.org) or Rebecca Cupp (562.302.3217; rebecca.l.cupp@kp.org).

Respectfully,

John P. Gray, PharmD, MSL
Director, National Pharmacy Legislative and Regulatory Affairs
Kaiser Permanente

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Section, Subdivision	Proposed Language	Recommendation/Comment
Article 4.5 Nonsterile Compounding		
Article 4.6 Sterile Compounding		
1736.1(b)	~~(b) (1) Except as allowed in paragraph (2), CSPs for direct and immediate administration as provided in the Chapter shall only be compounded in those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. Any such compounding shall be only in such quantity as is necessary to meet the immediate need of the patient. If not already documented in the patient's medical record, documentation for each such CSP shall also include identification of the CSP, the compounded date and time, number of units compounded, the patient's name and patient's unique identifier and the circumstance causing the immediate need of the patient. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available.~~ ~~(2) If the sterile compounding equipment or environment fail(s) to meet any required specification, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for 24 hours after such failure(s). All such failures must be documented in accordance with facility's SOP and shall be reported to the BOP within 72 hours.~~	During the January 8, 2025 full Board meeting, the Board indicated that this regulation is necessary to prevent pharmacies from routinely preparing compounded sterile products under immediate use conditions. However, throughout the rulemaking process, the Board has not presented any evidence that immediate use compounding, when it meets the required conditions in the "Immediate Use CSPs" section of the USP chapter, presents an unacceptable risk to California patients. In fact, the USP Expert Committee designed the chapter's immediate use provisions to balance the risks (i.e. the risk of microbial contamination) associated with immediate use compounding against the risks of delaying medication administration.[1] If the Board believes this regulation is necessary to prevent entities from "defaulting to immediate use provisions for all preparations," then the Board should provide evidence that shows how and why the USP expert committee has erred in allowing immediate use compounding without these stipulations. Additionally, the Board did not respond to our observation in our December 6, 2024 letter that continuing to enforce these requirements will incentivize organizations to shift compounding to non-pharmacy personnel in situations in which immediate use compounding is necessary. The Board should explain how shifting compounding to non-pharmacy personnel who are not subject to the Board's oversight will improve patient safety.
Article 4.7 Hazardous Drugs		
1737.5(c)	~~Effective [OAL insert six months following the effective date] a pass-through is not allowed between the hazardous drug buffer room into an unclassified space.~~	The California Building Standards Commission has proposed deleting the prohibition of a pass-through between a hazardous drug buffer room and an unclassified area in its 2024 Triennial Code Adoption Cycle, which will become effective on January 1, 2026.[2] The Building

[1] Leslie Hamlin, *Outsourcing IV Preparation: Addressing Patient and Caregiver Concerns*, Pharmacy Purchasing & Products, (Oct. 2024).

[2] California Building Standards Commission, *Initial Statement of Reasons for Proposed Building Standards*, https://www.dgs.ca.gov/-/media/Divisions/BSC/03-Rulemaking/2024-Triennial-Cycle/CAC/2024-07-30-HF/OSHPD-04-24-ISOR-PT2V1.pdf (last visited Jan. 21, 2025).

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Section, Subdivision	Proposed Language	Recommendation/Comment
		Standards Commission's recommendation is copied below for reference (***emphasis*** added): **1224.19.3.3.2.8 Pass-throughs.** HCAI proposes an amendment to remove the prohibition of a pass-through between the hazardous drug buffer room and any unclassified area and to add a restriction for refrigerator pass-through. The proposed amendment is to align with United States Pharmacopeia General Chapter, USP-GC Hazardous Drugs-Handling in Healthcare Settings (USP-GC). ***The USP-GC standards allow a passthrough from the buffer room to unclassified areas but not the refrigerator***. This revision will align with USP-GC. It will not cause financial burden to the facilities.[3] When the new building code goes into effect on January 1, 2026, only compounding suites that were permitted between January 1, 2020 and December 31, 2025 cannot have a pass-through between the HD buffer room and unclassified areas. If the Board chooses to adopt this restriction in its regulations, it will be cherry-picking a standard that is not included in current building code (as of 1/1/2026) and is not supported by the USP chapters. If the Building Standards Commission's recommendation alone is not persuasive, then logically evaluating the most significant source of microbial contamination should be. The personnel entering the sterile compounding suite present the greatest risk for microbial contamination in the cleanroom.[4] A pass-through reduces human traffic in and out of the buffer room thus reducing opportunities for microbial contamination in the sterile compounding suite.

[3] *Id*.

[4] Mateja Tršan, Katja Seme & Stanko Srčič, *The Environmental Monitoring in Hospital Pharmacy Cleanroom and Microbiota Catalogue Preparation*, 27 Saudi Pharm. J., 455-62 (Jan. 11, 2019).

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Section, Subdivision	Proposed Language	Recommendation/Comment
1737.7(c)	~~Outer gloves used for HD compounding shall be changed between each different HD preparation, unless preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient.~~	We acknowledge the changes to this section of regulation proposed by the Board in the second modified regulation text; however, anything short of deleting this section of regulation is inadequate. As we demonstrated in our comment letter dated May 31, 2024, based on a comprehensive literature review, there is no evidence to support the notion that requiring compounders to change their outer HD gloves more frequently than the USP 800 recommended frequency of every 30 minutes will prevent contamination with HD residues. Moreover, in our comment letter dated December 6, 2024, we outlined several negative second-order effects that this change will precipitate. Based on the rulemaking record, the Board has never weighed the ***purely speculative*** benefits of more frequent outer HD glove changes against the ***real*** negative outcomes that the regulation will cause. Correctly donning sterile gloves is critically important to safe compounding and is a significant risk point for introducing microbial contamination into the sterile compounding environment; consequently, facilities are required to perform initial gloved fingertip sampling "to ensure that personnel… put on sterile gloves without contaminating them."[5] Because each glove change carries some risk of microbial contamination, basic probability dictates that mandating that compounders change the outer HD glove more frequently increases the overall risk of contamination. For example, the two equations below give the respective probabilities of microbial contamination for two scenarios. The first equation, p_1, is the imagined probability of contamination for an individual who performs ten glove changes in a shift with the probability of contamination during any one glove change of 0.2%. The second equation, p_2, is the imagined probability of contamination for the same individual who now performs fourteen glove changes in a shift (an increased frequency of glove changes based on the Board's proposed regulation) with the probability of contamination during any one

[5] Melanie Dorey, *Gloved Fingertip Sampling and Demonstration*, Presentation at the Pacific Translational Science Association (April 2024), https://ptsa.ca/wp-content/uploads/2024/04/Gloved-Fingertip-Sampling-and-Demonstration-Contec-Melanie-Dorey-2024April.pdf.

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Section, Subdivision	Proposed Language	Recommendation/Comment
		glove change of 0.2%. The estimated probability of contamination for glove changes of 0.2% is a conservative estimate based on a study in the peer-reviewed literature that found a contamination rate of 0.34% for glove changes in a pharmacy sterile compounding suite when sterile gloves were used.[6] As demonstrated by equations below, the risk of microbial contamination during this fictitious employee's shift will markedly increase with more frequent glove changes: $p_1 = 1 - (0.998)^{10} = 1.98\%$ $p_2 = 1 - (0.998)^{14} = 2.76\%$ In addition to its failure to properly weigh the risks and benefits of this proposed regulation, the Board has also materially failed to meet the basic minimum procedural requirements of the California Procedure Act (APA). First, while the law allows a regulator to "aggregate and summarize repetitive… comments as a group… and… respond to repetitive comments… as a group," as described in *Sims v. Department of Corrections & Rehabilitation*, the regulator is still required to respond to each comment.[7,8] In our comment letter dated December 6, 2024, we highlighted three areas of concern with the proposed regulation: (1) the lack of evidence to support the proposed regulation, (2) the significant cost that the proposed regulation will impose on California businesses, and (3) the likely negative environmental impacts of the proposed regulation. In the Board staff's response to public comments, Kaiser Permanente's comments were aggregated with several other commenters.[9] The Board staff's response to the aggregated comments addressed the reasons why the Board does not believe that the use of a CSTD would obviate the need to the proposed requirement; however, there was no response to the three areas of concern outlined in Kaiser Permanente's

[6] Lawrence A. Trissel, et al., *Effect of Two Work Practice Changes on the Microbial Contamination Rates of Pharmacy-Compounded Sterile Preparations*, 64 Am J Health Syst Pharm, vol. 64, 837-41 (Apr. 15, 2007).
[7] Cal. Gov't Code § 11346.9.
[8] *Sims v. Dep't of Corr. & Rehab.*, 216 Cal. App. 4th 1059, 1069, 157 Cal. Rptr. 3d 409, 416-17 (2013).
[9] California Board of Pharmacy, Staff Recommended Response to Comments – Section 1737 et seq, https://www.pharmacy.ca.gov/meetings/agendas/2025/25_jan_bd_mat_hazar.pdf (last visited Jan. 21, 2025).

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Section, Subdivision	Proposed Language	Recommendation/Comment
		December comment letter. Therefore, the Board likely failed in its obligation to respond to each public comment received. As outlined in *Western States Petroleum Association v. Board of Equalization*, under the APA, regulators are required to "provide in the [rulemaking] record facts, evidence, documents, testimony, or other evidence upon which the agency relies to support its initial determination [of economic impact]."[10] Moreover, the regulator must demonstrate "that there was some factual basis for [its] determination," and this requirement is not met "by an opaque calculation unsupported by any facts or other evidence explaining its validity as a reasonable estimate."[11] In our December 6, 2024 comment letter, we attempted to correct a significant error in the Board's estimate of the cost of a pair of sterile gloves used for HD compounding. In the Modified Initial Statement of Reasons, the Board states, "an online search reveals that the cost of a pair of gloves is about $.14 [per] pair."[12] In our comments, we indicated that one pair of sterile, ASTM D6978 gloves (the gloves required for sterile HD compounding) cost between $1 and $4 per pair. The Board's erroneous estimate of the cost of sterile HD gloves likely contributed to its finding in the Modified Initial Statement of Reasons that there will be "minimal ongoing costs" associated with the proposed regulations including "up to $150,000 over a ten-year period for administrative and maintenance workload and Suppl[y] [costs]" and the overall determination "the proposed regulations will not have a significant statewide adverse economic impact…".[13] Therefore, the Board likely failed in its obligation to make an initial economic impact determination that is "supported by facts or evidence".[14]

[10] *W. States Petroleum Ass'n v. Bd. of Equalization*, 57 Cal. 4th 401, 427-28 (2013).
[11] *Id*, at 429, 431.
[12] California Board of Pharmacy, *Modified Initial Statement of Reasons Compounded Drug Products*, https://www.pharmacy.ca.gov/laws_regs/1708_1735_1751_misr.pdf (last visited Jan. 21, 2025).
[13] *Id*.
[14] *W. States Petroleum Ass'n, supra.*

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Section, Subdivision	Proposed Language	Recommendation/Comment
1737.15(a)	Deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents shall be used in accordance with manufacturers' specifications, or subsequent ~~manufacturer approved~~ published studies**,** and shall be surface compatible.	We appreciate the modifications that the Board made to the proposed regulation based on the recommendation in our December 6, 2024 comment letter. However, we are concerned that the phrase "manufacturer approved studies" is likely to limit the usefulness of this flexibility. Manufacturers are only likely to approve/sanction a study if they perceive both potential scientific and financial benefits associated with the study. Conversely, if a manufacturer believes that a study is a threat to one or more of their products, they may be less likely to support a study. Contrast that with the motivations of academic institutions and healthcare organizations that do not have the same financial incentives as a manufacturer. Therefore, we recommend changing the phrase "manufacturer approved studies" to "published studies" to ensure that published studies that are unrelated to a manufacturer may be used to support the selection of an alternative agent for deactivating, decontaminating, cleaning, disinfecting, and or and/or killing bacterial and fungal spores in the compounding suite.

Stanford MEDICINE | Health Care

January 24th, 2024

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Dr., Ste. 100
Sacramento, CA 95833

Re: Title 16. Board of Pharmacy Proposed Regulation

Dear Ms. Martinez,

We would like to express our gratitude to the Board for considering public comments and for its ongoing efforts to refine and improve the proposed regulations regarding compounding and hazardous drug handling.

We wish to reiterate our previously submitted concern regarding the requirement for compounding personnel to change outer hazardous drug (HD) gloves between each different HD preparation. Our comment is provided below:

Article 4.7 Hazardous Drugs		
1737.7(c)	*Outer gloves used for HD compounding shall be changed between each different HD preparation.*	**Comment:** While we acknowledge that Closed System Transfer Devices (CSTDs) do not completely eliminate contamination risks, they are specifically designed to prevent the escape of hazardous drugs or vapors outside the system. Most hazardous drug compounding in hospital practice involves the use of closed-system drug vials, which, when paired with CSTDs, further reduces the potential for contamination. Taken together, implementing a requirement for excessive glove changes, in addition to the use of CSTDs with closed-system vials, offers negligible added safety benefits to patients. The proposed requirement introduces operational burden and significant costs incurred for HD gloves and HD waste disposal. **Recommendation:** Remove language to be consistent with USP 800 or revise language to require changing outer HD gloves, between each different HD preparation, if compounding is performed without a CSTD.

Sincerely,

Mark Danek, PharmD
Director of Pharmacy – AR&L, Medication Safety, Quality mdanek@stanfordhealthcare.org

Peter Thai, PharmD, BCSCP
Compounding Compliance Manager
pthai@stanfordhealthcare.org

Alliance for Pharmacy Compounding

Compounding the Joy of Living®

January 27, 2025

Anne Sodegren, Executive Officer
Seung Oh, President
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear President Oh, Director Sodegren, and Members of the California State Board of Pharmacy:

We submit these comments on behalf of the Alliance for Pharmacy Compounding and our members. Thank you for another opportunity to provide input on the proposed regulations regarding compounded drug preparations, hazardous drugs, and radiopharmaceuticals, as outlined in Title 16, California Code of Regulations. We appreciate the Board's efforts to update and clarify these regulations and your consideration of public comments during this process.

We continue to have serious concerns regarding the pathway outlined in the proposed regulations for compounding with active pharmaceutical ingredients (APIs) included in FDA's Interim Category 1. While the pathway appears to establish a mechanism for compounding, the associated testing and documentation requirements you propose create significant barriers that make compounding for all necessary dosage forms and strengths impractical under the revised proposed regulations.

Stability Studies and API Testing Requirements

1. **Stability Studies**:
    - **USP Standards**: USP does not require full stability studies for sterile compounding under **Category 1 or 2**. Instead, USP aligns required tests with the beyond-use date (BUD) assigned to the compound. Full stability-indicating studies are only required for **Category 3**, which pertains to larger-scale compounding (typically batches of 250 units).
    - **California's Proposed Rules**: The requirement for full stability studies in all cases goes far beyond USP and FDA standards. Stability studies are expensive, costing **$10,000–$30,000 or more per formulation**.
    - **Impact on Pharmacies and Patients**: This requirement would force pharmacies to limit the formulations they produce, focusing only on the most common ones that justify the cost of stability studies. For example, a pharmacy might conduct a

study for **glutathione 200 mg/mL multi-dose vials**, which serve the largest number of patients (IV, IM, and inhalation use, even though preservatives should not be inhaled). However, more specialized formulations, such as **an NAC/glutathione inhalation combination** or **preservative-free individual inhalation vials**, would become financially unviable.

2. **API Testing Requirements**:
    - California proposes additional testing requirements for APIs that exceed what is required by USP or FDA.
    - These tests could be performed by the manufacturer, repackager, or wholesaler, but initial reviews suggest that these tests are not typically listed on Certificates of Analysis (COAs). This means pharmacies would likely need to perform the tests themselves, incurring additional costs and delays.

USP Chapters Above 1000

USP chapters numbered above 1000, such as **Chapter 1097** (which is referenced by the testing required for API in FDA's interim category 1), are intended for informational purposes and are not enforceable unless explicitly adopted. They contain no mandatory tests, assays, or requirements for compliance. Board member's claim that they are "just listing the tests required by USP" is inaccurate. While the state does have the authority to enforce requirements from chapters above 1000, doing so would make it an exception among the states.

Request to Align with National Standards

To ensure patient access to compounded medications while maintaining safety and quality, APC respectfully requests the Board to align its regulations with national standards:

1. **Treat APIs on FDA's Interim Category 1 List Consistently**: Allow pharmacies to compound under USP **Category 1 and 2** standards, as permitted in all other states, avoiding the need for full stability studies.
2. **Do Not Mandate Compliance with USP Chapters Above 1000**: Recognize these chapters as guidance, not enforceable regulations, to avoid imposing unnecessary burdens on compounding pharmacies. USP's General Notices plainly state that chapters numbered between 1000 and 2000 are for informational purposes only.

Additional Comments and Attachment

To illustrate the financial burden, we are attaching a **stability study quote of $40,000** for a commonly requested **NAC/glutathione combination**, used for its antioxidant effects to protect lung tissue from damage caused by free radicals and oxidative stress. This serves as a concrete example of how the proposed regulations would limit access to customized, specialized formulations that patients rely on.

We are also concerned about certain documentation requirements in the proposed regulations. For example, to use API in FDA's interim Category 1, the prescription must document the "clinical circumstances" that require the use of these medications. It would be helpful if examples of what appropriate documentation looks like to make sure that both pharmacies and inspectors know what to expect. Additionally, we respectfully request a Q&A or greater specificity regarding the documentation requirements for pharmacists to demonstrate verification of the need for a change to a compounded prescription under the "essentially a copy" sections of the proposed regulations. While FDA guidance calls for "documentation," the proposed California regulations require "verification." The addition of "verification" suggests the Board is looking for an additional level of accountability. Providing clear and satisfactory examples of acceptable documentation would greatly assist in ensuring compliance with these requirements.

Thank you for your time, attention, and continued consideration of our comments. We look forward to further discussions on how to achieve a balanced regulatory framework that ensures patient safety while preserving access to essential compounded medications.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer
scott@a4pc.org

Pharmacy – Glutathione / N-Acetylcysteine Stability Study Quotation

1/13/2025

Pharmacy
Address
City, St Zip
T: (XXX) XXX-XXXX
E: Pharmacy Representative Email
Attn: Pharmacy Representative

Dear Pharmacy Representative,

ARL Bio Pharma is committed to providing the industry's highest quality testing and customer service. We are FDA registered, DEA registered, and ISO 17025:2017 accredited (see certificate number 2992.01 for scope of accreditation). We offer both cGMP and non-cGMP services.

Please find the requested quotation attached. We appreciate the opportunity to provide this quotation and look forward to serving your needs. Please feel free to contact me with any questions about this proposal or any other services.

Thank you,

Technical Sales Representative
840 Research Parkway, Ste. 546
Oklahoma City, OK 73104
T: 405.271.1144
E: info@arlok.com

Project Scope

Pharmacy would like to demonstrate the stability of a Glutathione/N-Acetylcysteine inhalation solution. Pharmacy has asked ARL to develop and validate a stability indicating method for the quantitation of Glutathione and N-Acetylcysteine. After the method has been validated, ARL will evaluate the physical, chemical, and microbiological properties of the packaged product over a 90-day period. The testing requested by Pharmacy will be conducted under non-cGMP conditions.

Study Details

See tables below

- Table 1: Method Development and Validation Criteria
- Table 2: Stability Study Variables
- Table 3: Sample Requirements
- Table 4: Stability Study Pricing
- Table 5: Stability Study Specifications
- Table 6: Reference Standard Pricing
- Table 7: Summary of Charges

Table 1: Method Development and Validation Criteria[1]

Formula ID	Drug(s)	Concentration	Excipients
TBD	Glutathione	100 mg/mL	TBD
	N-Acetylcysteine	100 mg/mL	

[1]Enough drug and placebo must be provided by client for method development and validation. The exact amount will be determined by the project manager.

A stability indicating method will be developed and validated per USP <1225>. The validation includes Accuracy, Linearity, Precision (repeatability), Range, Specificity, and System Suitability. Specificity demonstrates non-interference from impurities and matrix components and involves stress studies/ forced degradation to demonstrate the method is capable of separating degradation products from the Active Pharmaceutical Ingredient (API).

Table 2: Stability Study Variables

Variable	Details
Drug Names and Concentrations	See Table 1
Dosage Form	Inhalation Solution, Single dose
Container Type(s)	3 mL Vials w/ 3 mL Fill
Secondary Packaging[1]	N/A
Storage Conditions	Refrigerated (5°C ± 3°C)
Lots	1
Time Points (Days)	0, 30, 60, 90

[1]The client is responsible for providing the necessary materials for any secondary packaging. If the client requests ARL to provide secondary packaging or additional labor is required due to the secondary packaging, ARL will contact the client about additional fees for materials and labor.

Table 3: Sample Requirements[1]

Test	# of Containers Designated per Test				# of Retains	# of Lots	# of Containers Requested per Test
	0	**30**	**60**	**90**			
Appearance	**	**	**	**	**	1	**
pH	3	3	3	3	3	1	15
Glutathione Assay	1	1	1	1	1	1	5
N-Acetylcysteine Assay	1	1	1	1	1	1	5
Sterility[2,3]	10	10	10	10	10	1	50
Endotoxin	1	1	1	1	1	1	5
Container Closure Integrity	11	11	11	11	11	1	55
Total # of Containers Requested							**135**

[1]The study samples will be supplied by the client. The sample requirements may be adjusted by the project manager.
[2]The client certifies that 10 articles of the finished product are required to satisfy USP <71> sterility testing requirements
[3]Requires suitability method. See summary of charges table for more information. Enough drug products must be provided by clients for method suitability. The exact amount will be determined by the project manager.
**Shared with the Stability test samples.

Table 4: Stability Study Pricing

Test	Method Type	Time Points[1] (Days)	# of Time Points	# of Lots	Total Units[2]	Unit Price	Total Price
Appearance	Visual	0, 30, 60, 90	4	1	4	$45	$180
pH	USP <791>	0, 30, 60, 90	4	1	4	$45	$180
Glutathione Assay	TBD	0, 30, 60, 90	4	1	4	$525	$2,100
N-Acetylcysteine Assay	TBD	0, 30, 60, 90	4	1	4	$525	$2,100
Sterility	USP <71>	0, 30, 60, 90	4	1	4	$190	$760
Endotoxin	USP <85>	0, 30, 60, 90	4	1	4	$110	$440
Container Closure Integrity	Vacuum Decay[3]	0, 30, 60, 90	4	1	4	$550	$2,200
						Total	**$7,960**

[1]The test dates will be determined from the date the stability samples are received. ARL will begin each test within 3 business days of the time point. The test results will be sent within 5 business days of completion.
[2]Total units = # of time points x # of lots
[3]If the client's sample is unable to be tested using ARL's current inventory of vacuum decay chambers, the client will be contacted for further quotation.

Note - Methods cited in USP general chapters or monographs are followed as directed. This includes system suitability or other inherent quality control tests that are specified in the cited method. Per 21 CFR 211.194(a)(2), users of analytical methods described in USP–NF are not required to validate the accuracy and reliability of these methods but merely verify their suitability under actual conditions of use. If additional suitability testing and/or validation is required that is not otherwise outlined in the test method cited please notify ARL.

Table 5: Stability Study Specifications

Test	Method Type	Specifications
Appearance	Visual	TBD
pH	USP <791>	Report Value
Glutathione Assay	TBD	TBD
N-Acetylcysteine Assay	TBD	TBD
Sterility	USP <71>	Sterile
Endotoxin	USP <85>[1]	See note below table
Container Closure Integrity	Vacuum Decay	Meets Test Criteria

[1]USP <85> can be cited if client provides Endotoxin limit or information to calculate MDV – average weight (kg), max dose/hour & route of administration.

Table 6: Reference Standard Pricing[1]

Reference Standard	Unit Price
Sigma Glutathione (PHR1359-500MG)	$167
Sigma N-Acetylcysteine (PHR1098-1G)	$154
Total	**$ 321**

[1]Additional reference standard units may be invoiced throughout the method work and the stability study. ARL will invoice for the reference standard at the time of purchase. ARL's fee for reference standard is calculated by adding tax, shipping, and handling to the vendor's list price. The fee in the table above reflects the current cost to client. If ARL's vendor changes their list price after the time this quotation was issued, the amount ARL charges the client will also change. If additional reference standards are required that have not been listed in this quotation, ARL will contact the client with a revised quotation.

Table 7: Summary of Charges

Item	Cost
Method Development and Validation x 2 APIs @ $15,825 each	$31,650
Reference Standards	$321
USP <71> Sterility Method Suitability[1]	$570
Stability Study (Table 4)	$7,960
Stability Study Summary Report	$500
Total	**$41,001**

[1]USP <71> method suitability based on a maximum batch size of 250 units.

Payment Milestones

- To accept this quotation, please return a signed copy.
- Method Development and Validation will be invoiced when a project manager is available. Payment is due upon receipt.
- USP <71> Sterility Method Suitability will be invoiced upon completion.
- Stability Study Time Points will be invoiced upon completion.
- Stability Study Summary Sheet will be invoiced upon completion.

Project Timeline

- The initiation and completion dates will be determined when client is ready to execute quote

Sending a signed copy of this quotation to ARL certifies that: (1) all information provided in this quotation is true and correct; (2) you have reviewed the Terms and Conditions attached to this quotation; (3) you agree to be bound by the Terms and Conditions; and (4) if you are submitting this quotation on behalf of a company or other entity, you have the authority to bind that company or entity to the Terms and Conditions.

ARL BioPharma, Inc.
840 Research Parkway, Suite 546
Oklahoma City, OK 73104
T: 405.271.1144 F: 405.271.1174
E: info@arlok.com
Submitted by:

Technical Sales Representative
Date: 1/13/2025

Pharmacy
Address
City, St Zip
T: (XXX) XXX-XXXX
E: Pharmacy Représentative Email
Accepted:

_____
Pharmacy Representative
Date: _____

1. Interpretation.
1.1 For the purposes of these Terms and Conditions; "Client" shall refer to any person or entity engaging ARL's services whether or not subject to a Quote, "Quote" shall refer to an agreement of custom services and fees negotiated and executed by ARL and the Client.
1.2 These Terms and Conditions shall control over all clients. These Terms and Conditions shall control to the extent they do not conflict with any terms within a Quote. To the extent any terms herein conflict with a Quote, the Quote shall control.

2. Conduct of the Services. ARL Bio Pharma, Inc., an Oklahoma corporation ("ARL") will perform testing, prepare a Certificate of Analysis, and all other services agreed to by ARL and Client (collectively, the "Services") in accordance with generally prevailing industry standards of professional conduct. For non-compendial testing, the specification(s) are for informational purposes only. For analytical testing, the analyte is reported as it was calculated to derive the result. Client shall verify that the specification and analyte reported are correct for the formulation. For Services to be performed pursuant to a Quote, ARL will perform the Services in accordance with the standards set forth in the Quote. For cGMP Services, a Quality Agreement may be executed by Client and ARL in addition to the Quote. In such instance, ARL will perform the Services in accordance with the Quote, cGMP, and the Quality Agreement. ARL will not be required to perform any Services in accordance with cGMP unless a Quality Agreement exists.

ARL makes no representations or warranties regarding the release of any Client product. The test results and underlying data of the test results are insufficient to determine whether to release any pharmaceutical products for distribution. The test results and underlying data of the test results only relate to the sample that was tested.

3. Test Material. Client is responsible for selecting the samples or other materials ("Test Material") that Client sends to ARL for Services in compliance with all applicable laws, regulations, and rules of the relevant governmental regulatory authorities. Client will provide ARL (at no cost to ARL) sufficient amounts of Test Material necessary to perform each test, as well as such data and other information as may be necessary or useful for ARL to perform the Services and to apprise ARL of the stability, proper storage, and safe handling requirements with respect to the Test Material, including a Safety Data Sheet (SDS) or equivalent documentation. Client will promptly send to ARL any additional Test Material requested by ARL for completion of the Services. Client will be responsible for the shipping and handling of all Test Material sent to ARL. Thirty (30) days following the completion, termination, or suspension of any Services, ARL will discard any remaining Test Material unless Client advises ARL in writing prior to the expiration of the thirty (30) day period that Client wants the remaining Test Material returned and provides ARL with instructions in writing and payment for the return of the remaining Test Material. Client will not use, nor cause another person or entity to use, any Test Material for human or animal consumption or use.

4. Change in Scope. Client may request a change in scope of any Services, but ARL must agree to such change prior to implementing the change, and ARL may revise the fee for the Services affected by the change in scope.

5. Termination of Routine Testing.
5.1 Client may terminate a routine test at any time prior to ARL's commencement of the routine test. In such event, ARL, in its sole discretion, may charge a termination fee of $20 per canceled test for any testing terminated by the Client after ARL's receipt of the relevant Test Material.

5.2 ARL may terminate a routine test at any time, including in process testing.

6. Termination of On-Going Studies. Client may terminate any on-going studies performed by ARL at any time without cause upon fifteen (15) business days prior written notice to ARL. In such event, Client shall pay ARL for all Services rendered through the effective date of termination, together with any additional expenses incurred by ARL in connection with the termination of the study, including those which were previously committed to by ARL for completion of the study. ARL may terminate any on-going studies performed at any time without cause, however if ARL terminates any routine test without cause ARL shall refund to Client any Fees paid for Terminated Services and return any remaining Test Materials.

7. Personnel. To the best of ARL's knowledge, none of its employees who will participate in testing have been debarred, or are under consideration to be debarred, by the Food and Drug Administration from working in or providing Services to any pharmaceutical or biotechnology company under the Generic Drug Enforcement Act of 1992, as amended.

8. Inspections. Once per year, upon thirty (30) days advance notice to ARL, Client or its designated representative, if such representative is reasonably acceptable to ARL, may visit ARL's facilities to observe the testing. The visit must be during normal business hours and occur at a mutually agreeable time. Client is responsible for any and all of its costs incurred to perform the inspection.

9. Test Records and Reports. ARL will keep complete and accurate records of each test for five (5) years after completion of the test.

10. Fees.
10.1 Client shall promptly pay all fees ("Fees") for Services when due and payable. All payments must be in US Dollars. If Client requests a rush for the performance of any Service, ARL may, in its sole discretion, add a surcharge to the rushed Services.

10.2 Each new Client must request a credit review. Once ARL establishes a credit limit for Client, ARL will invoice Client for Services and Client must pay each invoice within thirty (30) days of the date of the invoice.

10.3 For Services performed pursuant to a Quote, Client must pay the amounts specified in the Quote. The pricing of each Quote is valid for ninety (90) days from the date of the Quote. Client shall pay all invoices and other amounts due under the Quote within thirty (30) days of receipt of the relevant invoice unless otherwise specified in the Quote. Any changes in the Fees must be mutually agreed to by the parties in a written amendment to the Quote.

10.4 All Fees for all Services, whether or not performed pursuant to a Quote, must be paid by the applicable due date. All Fees not paid will bear interest at a rate of one and one-half percent (1.5%) per month from the applicable due date until paid. If Client does not pay each invoice when due, ARL may elect to suspend any Services, including, but not limited to, any testing that may be in progress, delaying the

start of new testing, and withholding reports or other deliverables. Additionally, Client shall reimburse ARL for all costs related to collection of unpaid Fees, including reasonable attorneys' Fees and costs, and costs for storage or disposal of Test Material under Section 3.

10.5 Any costs incurred by ARL for any work permits, licenses, fees, disposal costs, or other government approvals, registrations, permits, or licenses which may be required to fulfill its obligations and which are specific to a Quote or to the samples being tested shall be attributable to Client. This Section 10.5 however, excludes all general fees associated with standard licenses, permits and registrations required to operate a business in the industry in which ARL is engaged.

10.6 Payments can be made via check, ACH, credit card or wire transfer. Credit card payments will be subject to a surcharge of 2.9% (subject to change). Wire transfers will be subject to a $25 fee (subject to change).

10.7 ARL is entitled to all Fees irrespective of the results or conclusions reached in any report.

11. Subcontractors. ARL may outsource or use contractors for any or all Services.

12. Confidentiality. If the parties have executed a confidentiality agreement prior to the commencement of Services, that confidentiality agreement will control the disclosure of confidential information between the parties through the performance of Services. If the parties have not executed such an agreement, these Terms and Conditions control the exchange of Confidential Information between the Parties.

In the event there is no confidentiality agreement between the parties, the parties anticipate that they may exchange proprietary and confidential information (the "Confidential Information") related to the performance of Services. All Confidential Information must be identified in writing as confidential. Each party will use commercially reasonable efforts to maintain the other party's Confidential Information in confidence and will employ reasonable procedures to prevent its unauthorized publication or disclosure to third parties. No party may use the other party's Confidential Information for any purpose other than performance of the Services.

Following the completion, termination, or suspension of any Services, if requested by the client, ARL will promptly return or destroy the Confidential Information in ARL's possession. Client will be responsible for the costs of return the Confidential Information or any costs incurred by ARL for the destruction of the confidential material. However, ARL may retain one copy of the Client's Confidential Information for legal or regulatory compliance reasons and will not be required to access or delete electronic backup, active archive, or achieved copies of the Client's Confidential Information that were generated in accordance with the Client's bona fide backup or archiving practices.

13. Warranties. Client warrants that it owns all rights, title, and interest in and to all Test Material and intellectual property related thereto, and that ARL's use of any and all such Test Material in connection with the Services does not infringe any copyrights, patent rights, trade secrets, or other intellectual property rights of any third party. Client also warrants that it will comply with all applicable laws, regulations, and rules of the relevant governmental regulatory authorities related to the sale, distribution, final product release, or other use of any Test Material.

ARL warrants to Client that all Services provided to Client will be in accordance with generally prevailing industry standards of professional conduct and comply with all applicable laws, regulations, and rules of the relevant governmental regulatory authorities. If Services are performed pursuant to a Quote, ARL also warrants that the Services will conform to the specifications in the Quote. These warranties of ARL are made only to Client, are not transferable, and do not extend to the benefit of any other person or entity. OTHER THAN THE FOREGOING WARRANTIES, THE SERVICES ARE SOLD AND PROVIDED "AS IS," WITHOUT WARRANTY OF ANY KIND, WHETHER STATUTORY, EXPRESS, OR IMPLIED. THE WARRANTIES PROVIDED IN THIS PARAGRAPH ARE ARL'S SOLE AND EXCLUSIVE WARRANTIES WITH RESPECT TO THE SERVICES AND IN LIEU OF ALL OTHER WARRANTIES, WHETHER STATUTORY, EXPRESS, OR IMPLIED. ALL OTHER WARRANTIES ARE EXPRESSLY DISCLAIMED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, AND RESULTS OBTAINED (INCLUDING, WITHOUT LIMITATION, ANY CLAIM OF INACCURATE, INVALID, OR INCOMPLETE RESULTS), WHETHER ARISING BY STATUTE, OTHER SOURCES OF LAW, OR FROM COURSE OF PERFORMANCE OR DEALING, OR USAGE OF TRADE.

14. Limitation of Liability. ARL WILL NOT BE LIABLE FOR PENALTIES OR LIQUIDATED DAMAGES, OR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL, COLLATERAL, PUNITIVE, EXEMPLARY, OR OTHER DAMAGES OR LOSSES OF ANY TYPE OR KIND (INCLUDING, WITHOUT LIMITATION, LOSS OF USE AND LOST PROFITS) REGARDLESS OF WHETHER ANY SUCH LOSSES OR DAMAGES ARE CHARACTERIZED AS ARISING FROM BREACH OF CONTRACT, BREACH OF WARRANTY, TORT, STRICT LIABILITY, OR OTHERWISE, EVEN IF ARL IS ADVISED OF THE POSSIBILITY OF SUCH LOSSES OR DAMAGES, OR SUCH LOSSES OR DAMAGES ARE FORESEEABLE.

NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THESE TERMS AND CONDITIONS, CLIENT'S SOLE AND EXCLUSIVE REMEDY FOR ARL'S BREACH OF WARRANTIES SET FORTH IN THESE TERMS AND CONDITIONS WILL BE, AT ARL'S SOLE AND ABSOLUTE DISCRETION: (i) RE-PERFORMANCE OF THE SERVICES AFFECTED BY THE BREACH OF WARRANTY AT ARL'S SOLE COST AND EXPENSE, OR (ii) REFUND OF THE SERVICE FEES PAID TO ARL BY CLIENT FOR THE SERVICES AFFECTED BY THE BREACH OF WARRANTY. FOR ALL OTHER CLAIMS ASSERTED BY CLIENT AGAINST ARL RELATED TO THE SERVICES, THE APPLICABLE QUOTE (IF ANY), OR THESE TERMS AND CONDITIONS (INCLUDING CLAIMS FOR INDEMNIFICATION), ARL'S MAXIMUM LIABILITY FOR ANY DAMAGES OR LOSSES, REGARDLESS OF THE FORM OF ACTION OR PROCEEDING, WILL NOT EXCEED THE TOTAL SERVICE FEES PAID BY CLIENT FOR THE SERVICES GIVING RISE TO THE DAMAGES OR LOSSES.

UNLESS OTHERWISE STATED IN A QUOTE, SAMPLES ARE AND REMAIN AT ALL TIMES (INCLUDING, WITHOUT LIMITATION, WHILST AT ARL'S

FACILITIES AND DURING TRANSPORTATION TO AND FROM ARL'S FACILITIES) AT THE ENTIRE RISK OF THE CLIENT WHO SHALL BE RESPONSIBLE FOR EFFECTING AND MAINTAINING ITS OWN INSURANCE COVER IN RELATION THERETO, IT BEING HEREBY ACKNOWLEDGED BY THE CLIENT THAT THE FEES OF ARL DO NOT INCLUDE INSURANCE.

15. Indemnification. Subject to the Limitation of Liability contained herein, ARL shall indemnify Client and its respective directors, officers, employees, and agents (collectively, the "Client Indemnitees") from and against any losses, damages, fines, and liabilities, including attorney fees and litigation expenses (collectively, "Damages"), incurred by the Client Indemnitees as a result of any third-party claims, demands, suits, actions, or causes of action (collectively, "Claim") arising from: (i) ARL's breach, violation, non-compliance, or non-performance of these Terms and Conditions or Quote (if applicable); and (ii) ARL's gross negligence or willful misconduct in the performance of Services.
. ARL will pay any Damages which are assessed against the Client Indemnitees by final judgment after exhaustion of all reasonable appeals. ARL will pay any Damages subject to the Limitations of Liability set forth herein.

Client shall indemnify and defend ARL and its respective directors, officers, employees, and agents (together, the "ARL Indemnitees") from and against any third-party Claim, and any Damages resulting from such Claim, against an ARL Indemnitees arising from: (i) Client's breach, violation, non-compliance, or non-performance of these Terms and Conditions or Quote (if applicable); (ii) Client's gross negligence or willful misconduct; (iii) the marketing, labeling, recall, manufacture, distribution, use, sale, or other disposition by Client or any distributor, customer, sublicensee, or representative of Client, of any Test Material, product, process, technology, or other material or information that Client provides to ARL (collectively, the "Client Supplied Materials and Technology"); (iv) any assertion that the Client Supplied Materials and Technology or an ARL Indemnitee's use of the Client Supplied Materials and Technology infringes the know-how, trade secrets, patent rights, copyrights, or other intellectual property rights or confidential information rights of a third party. If Client breaches its duty to defend an ARL Indemnitee against such a third-party Claim, Client shall reimburse that ARL Indemnitee for the reasonable attorney fees and litigation expenses incurred by that ARL Indemnitee in defending the Claim, and the reasonable attorney fees and litigation expenses incurred in recouping the defense attorney fees and litigation expenses from Client.

16. Ownership. ARL will exclusively own all techniques, methods, processes, models, tools, assays, test results, and the underlying data of the test results that are developed, generated, conceived, or utilized in the performance of the Services.

17. Licenses. Client grants to ARL a non-exclusive, irrevocable, fully paid-up, worldwide license (including the right to sublicense to any subcontractor for that subcontractor's performance of any Services) to use and duplicate any proprietary technology and Test Material disclosed to ARL solely to the extent necessary to perform the Services.

Upon the Client discharging all obligations contained in these Terms and Conditions (and all obligations found in any applicable Quote)and payment of all Fees relating to the specific test results of specific Test Material, ARL grants to Client a non-exclusive, irrevocable, fully paid-up, worldwide license (including the right to sublicense) to use, duplicate, and disseminate the test results and underlying data of the test results that are disclosed by ARL to Client in connection with the Services.

18. Controlling Terms. In the event that there is any conflict between these Terms and Conditions and the Quote, the terms in the Quote will apply.

19. Independent Contractor. The business relationship of the parties is that of independent contractors and not of partners, joint venturers, employers, employees, or any similar kind of relationship.

20. Force Majeure. ARL will not be liable for any delay or failure of performance, including, without limitation, failure to perform a Service, where such delay or failure arises or results from any cause beyond ARL's reasonable control, including, but not limited to, flood, fire, explosion, natural catastrophe, military operations, war, computer or other equipment failure, severe weather, earthquake, tornado, or other act of God, power loss or reduction, labor disputes of any kind (whether relating to its own employees or others), embargos, governmental regulation, or an inability or delay in obtaining materials. In the event of any such delay or failure of performance, ARL will have additional time to perform the Services as reasonably necessary under the circumstances.

21. Applicable Law, Jurisdiction, and Venue. The Services, these Terms and Conditions, and any applicable Quote are governed by, and construed in accordance with, the laws of the State of Oklahoma, USA, without regard to any choice of law principle that would dictate the application of the law of another jurisdiction. Venue of all disputes regarding the Services, these Terms and Conditions, or an applicable Quote must be brought in the District Court for the State of Oklahoma, Oklahoma County. Each party waives any right to or option for a trial by jury.

22. Shortened Statute of Limitations. Any claim against ARL for breach of warranty, or any other claim related to the Services, a Quote, or these Terms and Conditions (including a claim for indemnification), must be brought within one (1) year from the date the cause of action arose

23. Entire Agreement. These Terms and Conditions and the Quote (if any) constitute the complete, final, and exclusive expression of the agreement between the parties, superseding any and all previous agreements and understandings, whether oral or written.

24. Modification and Waiver.
24.1 No modification or waiver of the provisions of these Terms and Conditions or a Quote will be valid or binding on either party unless set forth in a writing signed by both parties. No waiver of any term, right, or condition of these Terms and Conditions or a Quote may be construed or deemed to be a waiver or continuing waiver of any such term, right, or condition on any subsequent occasion, or a waiver of any other term, right, or condition.

24.2 No failure or delay by ARL to exercise any right, power, or remedy will operate as a waiver of it nor will any partial exercise preclude any further exercise of the same or of some other right, power, or remedy.

25. Severability. If any of the provisions of these Terms and Conditions or an applicable Quote are deemed to be invalid or prohibited under applicable law, such provisions will be ineffective to the extent of such invalidity or prohibition, without invalidating the remainder of such provision or the remaining provisions of these Terms and Conditions or the Quote.

26. Voluntary Agreement. Each party represents that they have carefully read and understand all provisions, terms, and aspects of these Terms and Conditions and the applicable Quote (if any), and have knowingly and voluntarily agreed to be bound by them. Each party also represents that they have had the opportunity to review these Terms and Conditions and the applicable Quote (if any) with legal counsel of such party's choice.

Revised 10/2024

Section, Subdivision	Proposed Language	Recommendation / Comment
Non-Sterile Compounding		
CCR 1735.7 Master Formulation and Compounding Records. subsection (c)(1):	(c)(1) The manufacturer, lot number, and expiration date for each component for the CSP.	**Rationale:** We resubmit our previous comment to this proposed regulation due to the absence of a response to our previous comment inclusive of a rationale for rejecting the comment. We therefore resubmit our comment that this proposed rule is duplicative of the USP 795 requirement which states: "Name, vendor or manufacturer, lot number, and expiration date of each component." **Recommendation(BOLD):** To strike this line from the regulation. ~~**(c)(2) The manufacturer, lot number, and expiration date for each component for the CSP**~~.
Sterile Compounding		
CCR 1736.1 Introduction and Scope. Subsection (b):	(b) (1) Except as allowed in paragraph (2),CSPs for direct and immediate administration as provided in the Chapter shall only be compounded in those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. Any such compounding shall be only in such quantity as is necessary to meet the immediate need of the patient. If not already documented in the patient's medical record, documentation for each such CSP shall also include, the compounded date and time, the patient's name and patient's unique identifier and	**Rationale:** The previous regulations have not served us well and we thank the board for acknowledging the serious shortcomings with the previous line of thinking and subsequently making changes to this section that addresses longstanding concerns for patient safety during medical emergencies. Public meeting discussions related to this proposed requirement have included the Board's opinion that this proposed rule is like the current requirement in CCR 1751.8(c) and deletion of this rule is a step back from a stricter rule in existence. This confounding opinion is made repeatedly while major alterations are being made after multiple and ongoing attempts by the public to request a change to an antiquated rule that is based off an old standard. It must be noted that new evidence and science was taken into consideration by USP which led it to recognize that the previous expectations regarding immediate use were faulty. As such, USP removed the expectation for emergency use associated with emergencies and adjusted the new BUD to four hours.

	the circumstance causing the immediate need of the patient. Such documentation need not be redocumented by the compounding staff if already available. (2) If the sterile compounding equipment or environment fail(s) to meet any required specification, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for 48 hours after such failure(s). All such failures must be documented in accordance with facility's SOP and shall be reported to the Board within 72 hours. (3) If the sterile compounding equipment or environment fail(s) to meet any required specification in a critical access hospital, as defined in the Social Security Act 42 U.S.C. 1395i-4 section (c)(2)(B), after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering or an identifiable patient. This provision may be used for 120 hours after such failure(s). All such failures shall be documented in accordance with facility's SOPs and shall be reported to the Board within 72 hours.	There is an allowance for USP to utilize immediate-use compounding in a vast variety of clinical settings. USP does not mandate that all sterile compounding take place in classified facility. USP does not require the need for emergent situations in order to perform immediate-use compounding. USP does not need to make allowances for when facilities and equipment are down because immediate-use is already available. Discussions during the Board of Pharmacy meetings have indicated that emergency-use is needed and that it would benefit patients. However, these regulations place many barriers on those who are caring for patients, that it is detrimental to those we are serving. To assist with understanding the USP requirements they are listed below: *1.3 Immediate-Use CSPs* *When all of the following conditions are met, compounding of CSPs for direct and immediate administration is not subject to the requirements for Category 1, Category 2, or Category 3 CSPs:* *1. Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.* *2. Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.* *3. The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g., approved labeling, stability and compatibility studies).* *4. The preparation involves not more than 3 different sterile products.* *5. Any unused starting component from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient.* *6. Administration begins within 4 h following the start of preparation. If administration has not begun within 4 h following the start of preparation, it must be promptly, appropriately, and safely discarded.* *7. Unless directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP must be labeled with the names and amounts of all*

		active ingredients, the name or initials of the person who prepared the preparation, and the 4-htime period within which administration must begin. *Handling of sterile hazardous drugs (HDs) must additionally comply with (800).* As noted, there are no requirements for immediate-use compounding that limits its utilization for routine use. In fact, USP was changed so that it removes barriers for healthcare personnel so that they can care better for patients. The basis for the proposed requirement erroneously presumes the utilization of immediate-use is only for emergencies. To continue with the proposed requirement, in essence, means California pharmacists will be the only licensed professionals banned from utilizing the USP immediate-use allowance while every healthcare professional in United States of America is allowed to routinely use it. As stated on multiple occasions by us and others during the rulemaking process, we once more reiterate our position that the newly proposed requirement to report each instance of immediate use compounding associated with a temporary engineering control malfunction will place a burden on both pharmacy personnel and board staff. The benefit of reporting each minor malfunction to the board is questionable and it is difficult to see how reporting to the board a temporary operational decision to utilize immediate-use compounding to care for patients while an issue is addressed with engineering controls will add value and enhance the safety of the public. Reporting of issues to regulatory agencies are usually reserved for serious matters and only those issues that are within the regulatory agency's' jurisdiction to act. It must be pointed out that immediate use compounding is an allowable action under USP797 standards, it is utilized routinely, regularly and safely in healthcare practice settings worldwide. Performing a simple and safe immediate-use compound for a patient by a pharmacy licensee while an engineering control malfunction is being addressed is not serious enough to warrant a report to the board. There is a possible unintended consequence of entities shifting this simple temporary task to disciplines functioning outside the scope of these regulations and the jurisdiction of the Board. Requiring reporting of each instance of compounding of an immediate-use CSP will lead to increased administrative requirements, increased personnel needs, and will have the

		unintended consequence of potentially diverting resources from patient care activities or worse patients will be unable to access compounded medications due to onerous requirements and fear of inability to comply. It is further disconcerting that other than stating that "this is existing language at section 1751.8(e)…" there are no reasons provided in the ISOR for the requirement that CSPs used for immediate administration be limited to situations where the failure to administer could result in loss of life or intense suffering. This requirement was created based on the old USP standards when there was limited understanding of the applicable microbiological principles and the wide clinical barriers it creates as it relates to immediate-use. It is important that the board consider the negative impact on patient care that this antiquated rule creates. We wish to further comment of the attempt to address concerns with the ability of rural hospitals' ability to admit and care for patients in the event that there is a malfunction with SEC's or PEC's. The proposed change erroneously assumes that all rural hospitals are critical access hospitals. This is not the reality since there are many hospitals that are rural that are not designated as critical access hospitals. During the board's discussion about the topic, a board member mentioned that large institutions like the University of California have ownership and access to multiple cleanrooms under their authority. In the absence of demonstrated evidence that all large hospitals have access to multiple clean rooms, it is a supposition that we don't believe is universally applicable. While there are situations where a large facility might have more than one cleanroom, there are also many situations where there is reliance on one large centralized model. The hypothetical assumption that pharmacies with cleanrooms must have an emergency plan for when sterile compounding operations are down, sounds great on paper and in theory, practically, there are just not that many options available to health systems particularly if it's a rural hospital. Elimination of immediate use authority creates additional hurdles to acquiring the medication that might be insurmountable and therefore jeopardize patient safety. The Board failed to capture the economic impact to health systems in their ISOR. The board's response to the question of "Business Impact" in ISOR states; "the board anticipates minimal ongoing costs ranging from approximately $5,700 to $15,000 per

		year related to administrative and maintenance workload." This statement applies to the multiple proposed regulations requiring the addition of new administrative procedures, reporting requirements, and enhanced testing. The amount stated is a gross underestimation of the true cost to health systems. Understandably the Board lacks the internal expertise to accurately reflect those anticipated costs associated with development of policies and procedures, monitoring implementation of those procedures, correctly reporting to the Board as proposed by this regulation and others, cost of monitoring visits by the Board, elanced testing requirements, purchase of additional inventory for PPE, implementation of technology to support the deployment of the policies and procedures and hiring of additional staff to support compliance with the proposed regulation. The Board further states in the ISOR under the header of "Business Impact" as it relates to the issue of cost the following: "This initial determination is based on the absence of testimony to that effect during the public discussion and development of the proposed regulation." The public meetings mandate testimony be limited to a few minutes and attendees tend to focus their input on the specific wording of the proposed regulation and not the cost. It is incumbent on the Board to actively pursue input from those that can accurately project the cost to health system of the proposed regulation. The Board should, during public meetings, or by other means seek input from experts who can inform the Board's ISOR development as it relates to both "Business Impact" and Economic Impact Assessment" to ensure the ISOR is an accurate reflection of the impact to health systems on cost and health care access. We wish to further point out that the board has not responded to our comments regarding the economic impact of this proposed rule since they have not approached senior health system leaders who are best situated to assess and assist them with economic impact of this rule. Neither has the board shared their assessment of how this rule will increase their cost of enforcement of the proposed rule. USP 797 provides sufficient guidance in their improved and updated standards for immediate-use compounding, and we once more implore the board to require USP's standards and not engage in additional regulations that are not based on an articulated and proven evidence that such proposed regulations will enhance patient safety efforts beyond the national standards.

		We appreciate the complexities of regulating sterile compounding across the diversity of health system procedures and processes and we would like to invite board members and staff to consider doing site visits to gain a greater appreciation for how health systems promote patient safety and quality of compounded drug preparations. We would be happy to set up those site visits with our members. **Recommendation:** Remove the requirement limiting the use of immediate-use CSP's to situations where failure to administer could result in loss of life or intense suffering due to this being deleted from the new USP 797 standards and the profound negative impact on patients. This will subsequently remove the need for reporting to the board as well as the allowance given to rural hospitals. **Delete 1736.1(b) [BOLD]** **~~b) (1) Except as allowed in paragraph (2),CSPs for direct and immediate administration as provided in the Chapter shall only be compounded in those limited situations where the failure to administer such CSP could result in loss of life or intense suffering of an identifiable patient. Any such compounding shall be only in such quantity as is necessary to meet the immediate need of the patient. If not already documented in the patient's medical record, documentation for each such CSP shall also include, the compounded date and time, the patient's name and patient's unique identifier andthe circumstance causing the immediate need of the patient. Such documentation need not be redocumented by the compounding staff if already available. (2) If the sterile compounding equipment or environment fail(s) to meet any required specification, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for 48 hours after such failure(s). All such failures must be documented in accordance with facility's SOP and shall be reported to the Board within 72 hours.~~** **~~(3) If the sterile compounding equipment or environment fail(s) to meet any required specification in a critical access hospital, as defined in the Social Security Act 42 U.S.C. 1395i-4 section (c)(2)(B), after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering or an identifiable patient. This provision may be used for 120 hours after such failure(s). All such failures shall be~~**

		~~**documented in accordance with facility's SOPs and shall be reported to the Board within 72 hours**~~
CCR 1736.11 Master Formulation and Compounding Records. subsection (c):	(1) The assigned internal identification number, which shall be unique for each CR. (2) The manufacturer, lot number, and expiration date for each component for the CSP. (3) The total quantity compounded including the number of units made and either the volume or the weight of each unit. (4) The identity of personnel performing the compounding, pharmacist who has direct supervision and control of compounding, and pharmacist verifying the final drug preparation, if different. (5) When applicable, endotoxin level calculations and results.	**Rationale:** Current language in CCR 1735.3 below has a provision for CSPs compounded in health facilities to prevent delays in care to acutely ill patient, i.e. infections, cancer, critical care, etc. The current language states: (F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply. (i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference. Caring for patients in the fast-paced dynamic environment of a hospital is hampered by this restrictive proposed rule. Every additional requirement for documentation and additional information takes pharmacy staff away from patient care while not adding value for patient safety. To help pharmacy staff and hospitals take care of patients, we propose a change to our original proposal below. **Recommendation (BOLD):** We once more reiterate the comments by both us and others at various stages through this rulemaking process that USP standards adequately provide for safe and quality compounding of medications. The addition of this regulation exceeds the national standards in a manner that fails to demonstrate the benefit to patients. Add back the language above: 1736.11 Master Formulation and Compounding Records, subsection(c): (1) The assigned internal identification number, which shall be unique for each CR. (2) The manufacturer, lot number, and expiration date for each component for the CSP.

		(3) The total quantity compounded including the number of units made and either the volume or the weight of each unit. (4) The identity of personnel performing the compounding, pharmacist who has direct supervision and control of compounding, and pharmacist verifying the final drug preparation, if different. (5) When applicable, endotoxin level calculations and results. (c)(2) The manufacturer, lot number, and expiration date shall be recorded for each component for CSPs. **(6) Exempt from the requirements in this paragraph are sterile preparations compounded for administration within twenty-four (24) hours to a single patient in a health care facility licensed under section 1250 of the Health and Safety Code.**
CCR. 1736.18 Quality Assurance and Quality Control subsection (c)	(c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse drug experiences shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence of the adverse drug experience. Such review shall be documented and dated as defined in the SOPs.	**Rationale:** It must be noted that the board failed to include either an explanation of how the proposed action has been changed to accommodate our comment or state the reasons for rejecting our comment. In summarizing and responding to our comments, the board did not demonstrate that it understood and considered the comment in that it only responded to the part where 3 business days was recommended. There was no acknowledgement of understanding of our concern that the language seems to suggest that the review must be completed within a 72 hours timeframe. We pointed out that a review can start within 72 hours but it can take longer to complete once further investigation is needed. We would like to recommend again that the word "shall start" be added to the language. Herewith our previous comment as submitted for reference: The way that the proposed regulation is written, seems to suggest that the review must be completed within 72 hours since it states that "such review shall be documented and dated as defined in the SOPs." The proposed language requirement for a documentation and dating of the review together with the preceding sentence's requirement for review within 72 hours from the receipt of the compliant could be seen as requiring the review to be completed within the 72 hours timeframe. A requirement of 72 hours may not provide sufficient time for pharmacies to thoroughly investigate and determine root causes. It is reasonable to expect that a review after a complaint be started within three business days. Investigation could take longer than this due to many factors involved in such an investigation that needs to be looked at. Many of these may not be available or apparent within this timeframe.

		Recommendation (BOLD): We recommend that the intent of this proposed regulation be clarified with the following proposed language: (c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse drug experiences shall be reviewed by the pharmacist-in-charge **and shall start** within 72 hours of receipt of the complaint or occurrence of the adverse drug experience. Such review shall be documented and dated as defined in the SOPs.
Hazardous drugs		
1737.5 Facilities and Engineering Controls. Subsection (c)	(c) Effective [OAL insert six months following the effective date] a pass-through is not allowed between the hazardous drug buffer room into an unclassified space.	**Rationale:** We once more reiterate the comments by both us and others at various stages through this rulemaking process that USP has sufficient standards to promote and protect patients and this regulation doesn't enhance patient safety expectations in a meaningful way. Additionally, USP 800 does not prohibit using a pass-through between a classified space and an unclassified space. Board staff noted in their response that this proposed regulation aims to mimic that of the California Code of Regulations, Title 24. Information provided by a caller at the last board meeting, informed the board that the regulation in the building code is being revised. **Recommendation (BOLD):** Delete this requirement. If the board feels that this regulation must replicate that of the building code, it should reference the code and include it in the pharmacy law book since it is not currently in the pharmacy lawbook. This way there will not be a discrepancy when there is a change in the building code. ~~**Effective [OAL insert six months following the effective date] A a pass-through is not allowed between the hazardous drug buffer room C SEC into an unclassified space.**~~
CCR 1737.7. Personal Protective Equipment (PPE), subsection (c).	(c) Outer gloves used for HD compounding shall be changed between each different HD preparation, unless preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient.	**Rationale:** We once more reiterate and re-state our request as before. It must be noted that the board failed to include either an explanation of how the proposed action has been changed to accommodate our comment or state the reasons for rejecting our comment. In summarizing and responding to our comments, the board did not demonstrate that it understood and considered the comment in that it only responded to our comment regarding CSTD's. the board did not demonstrate that it understood and considered the comment the risk to staff created via repeated change of outer gloves. The board did not demonstrate that it understood and considered the

		comment regarding the increase in waste. The board did not demonstrate that it understood and considered the comment regarding the inappropriateness of the use of online prices for gloves. We would like to request that the board make public their source of information and the brand name, type and quality of the gloves they found online. The board did not demonstrate that it understood and considered the comment regarding contracting and the difference in pricing available to pharmacies. The board did not demonstrate that it understood and considered the comment regarding the need to purchase gloves at increased prices for staff that are allergic to cheap gloves. The board did not demonstrate that it understood and considered the comment regarding the fact that this economic impact was inadequately addressed in the economic impact section of the ISOR. Double-gloving is primarily designed to offer extra protection against hazardous drug compounds, with the outer glove serving as a first line of defense. If the outer glove is repeatedly removed or exposed to rough conditions, it may wear down, possibly increasing the risk of puncturing or compromising the inner glove. This could lead to reduced protection, especially when handling hazardous drug compound Frequent removal and disposal of outer glove changes creates significant waste. Board staff's response that they performed an online search of the pricing and availability of appropriate gloves reflects a lack of understanding of the practice of pharmacy and the intricacies of purchasing contracts at large organizations. Pharmacies cannot simply go to an online vendor of these sterile gloves and buy it on a credit card. Purchasing is usually done on contracts with vetted suppliers to ensure supply chain integrity. Due to this, the pricing advertised online from unvetted suppliers, is generally unavailable to organizations. Furthermore, the cheapest online price may not reflect the product that is selected for use by the pharmacy since there are factors to be considered such as ease of use, quality of the product and in some cases, impact on staff that could experience allergic skin reactions to cheap products. The board response regarding the price of gloves highlights board staff's limited understanding of pharmacy business. The one-dimensional view of product price as an economic impact fails to consider indirect costs associated with this proposed regulation such as increased time it will take to compound hazardous drugs and the associated cost

		of labor. It further fails to consider the economic impact of slower compounding on reduced turnover in chairs at infusion centers. These are only to name a few economic impacts that the board fails to take into consideration and illustrates our point that the board lacks the internal expertise to accurately reflect those anticipated costs. Yet, board staff's comments regarding this section and others reflects a high level of misguided confidence in the ability to determine impacts on the topic of economics at a level sufficient to make such determinations. We would like to invite the board to engage with CSHP and our health system leaders with the knowledge, experience, and expertise to gather the true economic impact of this proposal. As noted with other proposed regulations the "business impact" and "economic impact" of the ISOR fails to accurately reflect the cost and impact to businesses by this and other regulations. The board's response to the question of "Business Impact" in the Initial Statement Of Reasons (ISOR) states; "the board anticipates minimal ongoing costs ranging from approximately $5,700 to $15,000 per year related to administrative and maintenance workload." This statement applies to the multiple proposed regulations requiring the addition of new administrative procedures, increased purchase of PPE, increased testing and enhanced reporting requirements. The amount stated is a gross underestimation of the true cost to health systems. Understandably the Board lacks the internal expertise to accurately reflect those anticipated costs associated with development of policies and procedures, monitoring implementation of those procedures, correctly reporting to the Board as proposed by this regulation and others, cost of monitoring visits by the Board, implementation of technology to support the deployment of the policies and procedures and hiring of additional staff to support compliance with the proposed regulation. The Board further states in the ISOR under the header of "Business Impact" as it relates to the issue of cost the following: "This initial determination is based on the absence of testimony to that effect during the public discussion and development of the proposed regulation." The public meetings mandate testimony be limited to a few minutes and attendees tend to focus their input on the specific wording of the proposed regulation and not the cost. It is incumbent on the Board to actively pursue input from those that can accurately project the cost to health system of the proposed regulation. The Board should, during public meetings, or by other means seek input from experts who can

		inform the Board's ISOR development as it relates to both "Business Impact" and "Economic Impact Assessment." **Recommendations**: We once more reiterate the comments by both us and others at various stages through this rulemaking process that USP has sufficient standards to promote and protect patients and this regulation fails to demonstrate its expected enhancement of patient safety efforts. Delete the proposed language: ~~**(c) Outer gloves used for HD compounding shall be changed between each different HD preparation., unless preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient.**~~
Radiopharmaceutical- Preparation, Compounding, Dispensing, and Repackaging		
CCR 1738.10. Preparation subsection (c)	(c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825) an SOP shall at least define the circumstances that necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, include patient need or facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.	**Rationale:** The proposed language is inconsistent with USP 825 recommendations, and will require health-systems to incorporate patient need which may not be pertinent information. **Recommendation(BOLD):** We once more reiterate the comments by both us and others at various stages through this rulemaking process that USP has sufficient standards to promote and protect patients. This proposed regulation fails to demonstrate the necessity for patient safety beyond that required by USPR. We recommend that this subsection be deleted. ~~(c) **When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825) an SOP shall at least define the circumstances that necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, include patient need or facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclides purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.**~~

CCR 1738.14. Quality Assurance and Quality Control subsection (c)	(c) In addition to subsection (b), all complaints related to a potential quality problem with a radiopharmaceutical and all reported adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	**Rationale:** It must be noted that the board failed to include either an explanation of how the proposed action has been changed to accommodate our comment or state the reasons for rejecting our comment. In summarizing and responding to our comments, the board did not demonstrate that it understood and considered the comment in that it only responded to the part where 3 business days was recommended. There was no acknowledgement of understanding of our concern that the language seems to suggest that the review must be completed within a 72 hours timeframe. We pointed out that a review can start within 72 hours but it can take longer to complete once further investigation is needed. We would like to recommend again that the word "shall start" be added to the language. Herewith our previous comment as submitted for reference: The way that the proposed regulation is written, seems to suggest that the review must be completed within 72 hours since it states that "such review shall be documented and dated as defined in the SOPs." The proposed language requirement for a documentation and dating of the review together with the preceding sentence's requirement for review within 72 hours from the receipt of the compliant could be seen as requiring the review to be completed within the 72 hours timeframe. A requirement of 72 hours may not provide sufficient time for pharmacies to thoroughly investigate and determine root causes. It is reasonable to expect that a review after a complaint be <u>started</u> within three business days. Investigation could take longer than this due to many factors involved in such an investigation that needs to be looked at. Many of these may not be available or apparent within this timeframe. **Recommendation (BOLD):** We recommend that the intent of this proposed regulation be clarified with the following proposed language: *(*c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse drug experiences events shall be reviewed by the pharmacist-in-charge **and shall start** within 72 hours of receipt of the complaint or occurrence of the adverse drug experience. Such review shall be documented and dated as defined in the SOPs.

wedgewood

01/24/2025

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
PharmacyRulemaking@dca.ca.gov
(916) 574-8618

Re: Notice of Proposed Action: Compounded Drug Products

Dear President Oh and Board Members,

We would like to commend the Board for listening to stakeholders and revising the draft regulations. The new draft is a significant improvement, and we appreciate the effort that has gone into the review process. However, ambiguity remains in certain areas described below that will lead to compliance uncertainty. We also continue to advocate that the compounding standards should default to the clinical standards set by the United States Pharmacopeia in USP 795, 797, and 800 which have been adopted by most states with no additional requirements. We do not believe that reasonable clinical, or policy-based, justifications for exceeding these standards has been presented, which puts California residents' (both human and animal) access to safe and effective compounded medications prescribed by California-licensed providers at risk.

Wedgewood Pharmacy is the largest animal compounding pharmacy in the United States. We have been in the business of compounding for animal patients for almost 40 years and helped to treat millions of pets, horses, zoo animals, pocket pets, and many other animals. Our mission is to improve the lives of animals and make it easier for owners to secure clinically appropriate and effective medications for their pets and animals. In the last year our compounds have helped improve medication therapy compliance for approximately 65,000 California based customers and many more nationally. We are capable of preparing 45,000 unique compounds in a variety of dosage strengths, flavors, concentrations and administration alternatives specifically designed to be clinically effective and improve medication compliance to support the well-being of our animal patients.

Commented [BD1]: I want to consider a broader phrase like "support the well-being" -- thoughts?

We previously commented on the inconsistencies, ambiguity, and challenges of the proposed definition of Essentially a copy. The Board staff did not recommend accepting the comment indicating in the Staff

Recommended Responses that the current definition allowed a pharmacist to use their professional judgement when determining whether a compound is essentially a copy. While we appreciate that clarity in the notes, the definition remains ambiguous to that intent and as such, we request that a clarifying statement be added to that effect. Without that clarity, enforcement action could be taken against a pharmacist if their professional judgement were called into question. Additionally, we argue that it is a fact, not an opinion, that a licensed prescriber who executes a valid prescription for a compounded medication has made the clinical determination within their scope of practice, expertise, and licensure that the medication prescribed produces a clinically significant difference for that patient. Absent indications within the scope of a pharmacist's licensed scope of practice and professional judgement, a pharmacist cannot be required to make inquiries to the clinical rationale and professional judgement of the prescriber as the pharmacist is neither qualified nor licensed to make such a judgement and even attempting to endeavor to do so could be characterized as unlicensed and prohibited clinical practice. The Board is not authorized to require pharmacists to exercise clinical judgement outside of the practice of pharmacy.

We previously commented on 1735.1(d) regarding compounding for veterinary office use. We appreciate the Board's recognition of Office Use (Stock) as an important service provided by pharmacies to veterinary medicine professionals and we appreciate the expansion of the ability to dispense from Office Stock to 14 days. We are concerned about the continuing ambiguity of the phrase "reasonable quantity" as it remains undefined in this draft. We are not opposed to placing limitations, but a lack of definition creates ambiguity, risks inconsistent enforcement, and further calls on pharmacists to exceed their scope of licensed practice. In the Board's response to our comment it was noted, "As the commenter notes, reasonable quantity is further clarified in paragraphs (1) and (2)". We interpret this to mean that the veterinarian's purchase order indicating that the order is for office administration, or application, and for dispensing no more than 14 days' supply constitutes a reasonable quantity and will proceed under that assumption unless further clarity is provided. As such, we will not be required to make a determination of whether the licensed prescriber "fairly estimated" the days' supply ordered.

Commented [BD2]: Let's just let it go.

We are grateful for the Board's clarification on the inclusion of the AMDUCA reference. While we appreciate the clarity provided, we are concerned that a direct reference to a Guidance Document (GFI 256), including a specific dated version, could be problematic should that document be modified or repealed. Rather than reference a specific document, we would recommend removing the language or changing it to simply reflect "applicable industry guidance" as noted below

The table below outlines our specific comments and language recommendations.

Comments Regarding The Notice of Proposed Regulatory Action Concerning: Compounded Drug Products		
Section, Subdivision	Proposed Language	Recommendation/Comment
1735 (d)	"Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as ~~determined~~ verified and documented by the pharmacist ~~prescribing practitioner,~~ between that compounded preparation and the comparable commercially available drug product.	Prescribers' submission of a compounded preparation to a compounding pharmacy should be sufficient documentation to that an essentially a copy produces for that patient a clinically significant difference.
1735.1(d) & 1736.1(d)	(d) A reasonable quantity of a compounded drug preparation may be furnished to a veterinary office for use by the veterinarian that is sufficient: (1) for administration or application to veterinary patients solely in the veterinarian's office (2) for furnishing of no~~t~~ more than ~~7-day supply, or up to no more than~~ 14 days ~~for antibiotics~~, for an individual patient, as fairly estimated by the prescriber, and	Based on staff comments an amount of compounded drug may be furnished to a veterinarian based on the estimated need of the veterinarian as submitted on a purchase order will be considered the determination of a reasonable quantity.

	documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing for an individual patient.	
1735.1 (e)(2) & 1736.1 (e)(2)	Is made with any component not suitable for use in a CNSP for the intended veterinary population, unless allowable under the Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). When a veterinarian, acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal, a pharmacy may use a bulk drug substance to compound an animal drug. This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.	The reference to a specific edition of a Guidance Document is troubling. Recommendation: This compound shall be in compliance with current industry guidance. ~~the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022~~.

Thank you for your consideration.
Sincerely,

Erik Clausen, PharmD/MBA
Vice President of Pharmacy Quality and Compliance

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Plattsburgh, NY, 12901 USA
Toll Free 1-800-932-1039
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January 27, 2025

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95834

RE: Response to Proposed Modifications Concerning Division 17 of Title 16 of the California Code of Regulations: Compounded Drug Preparations

Dear Ms. Martinez and Members of the California State Board of Pharmacy:

Thank you for the opportunity to comment on the Notice of Proposed Modifications Concerning: Compounded Drug Preparations issued by the California State Board of Pharmacy.

This comment is in response to the Board's correspondence regarding proposed amendments and repeals to Section 1736.17(a) in Division 17 of Title 16 of the California Code of Regulations. Medisca Inc. agrees with the Board's proposed amendment to Section 1736.17(a)(2) to include subsection (F), allowing compounders to use documentation as evidence of testing required by subsection (E). Medisca respectfully requests that the Board further amend Section 1736.17(a)(2)(E) to account for the fact that the testing requirements therein are applicable at different stages of the compounding process. Namely, testing required under subsections (ii) and (iii) can be performed on the bulk drug substance by manufacturers and/or wholesalers, while testing required under subsections (i) and (iv) is more appropriately performed on the compounded product by the compounder.

Whether or not testing required by subsections (i) and (iv) is performed by the manufacturer and/or wholesaler, the tests will need to be ran and confirmed again on the compounded product. Medisca respectfully requests that the Board amend the regulations to provide that documentation, like the Certificate of Analysis, will be considered sufficient to satisfy subsections (ii) and (iii) whenever the required testing was conducted. However, if any of the required tests were not conducted by the manufacturer and/or wholesaler, the onus should be on the compounder to ensure that both the bulk drug substance(s) used and the compounded product meet all of the requirements.

Thank you for your attention to our concerns. We look forward to a constructive dialogue and are happy to provide any additional information if needed. Please do not hesitate to reach out to me at mdestefano@medisca.com and (514) 333-7811, EXT. 1301 with any questions or to continue this important dialogue.

Institution/Contact Name	Medisca Inc.	Maurizio De Stefano, VP Compliance & Education
Section, Subdivision	**Proposed Language**	**Recommendation/Comment**
1736.17(a)(2)(E) and (F)	In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding. (a) Standard operating procedures (SOPs) for sterile compounding shall be followed and shall: (1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding; and (2) Define the following: (A) Methods by which the pharmacist compounding or supervising the compounding will ensure the quality of compounded drug preparations; (B) If applicable, procedures for handling, compounding, and disposal of infectious materials. The SOPs shall describe the facility protocols for cleanups and spills in conformity with local health jurisdictional standards; (C) The methods used to determine and approve the ingredients and the compounding process for each preparation before compounding begins; and (D) The method for complying with all other requirements specifically defined in the SOPS. (E) The methods by which the pharmacist	Medisca agrees with the Board's proposed amendment to Section 1736.17(a)(2) to include subsection (F), allowing compounders to use documentation as evidence of testing required by subsection (E). Medisca respectfully requests that the Board further amend Section 1736.17(a)(2)(E) to account for the fact that the testing requirements therein are applicable at different stages of the compounding process. Namely, testing required under subsections (ii) and (iii) can be performed on the bulk drug substance by manufacturers and/or wholesalers, while testing required under subsections (i) and (iv) is more appropriately performed on the compounded product by the compounder. Whether or not testing required by subsections (i) and (iv) is performed by the manufacturer and/or wholesaler, the tests will need to be ran and confirmed again on the compounded product. Medisca respectfully requests that the Board amend the regulations to provide that documentation, like the Certificate of Analysis, will be considered sufficient to satisfy subsections (ii) and (iii) whenever the required testing was conducted. However, if

		compounding or supervising the compounding pursuant to 1736.9(f) related to use of a bulk drug substance published in the 503A Category 1 bulk substances list, will ensure each lot of the bulk drug substance is representatively sampled per USP 1097 (bulk powder sampling procedures), tested, and found to be in compliance with at least: (i) USP Chapter 1, Injections and Implanted Drug Products (Parenterals) – Product Quality Tests (ii) USP Chapters 232 and 233 related to Elemental Impurities, (iii) USP Chapter 467 – Residual Solvents, (iv) USP Chapter 85 – Bacterial Endotoxins and (v) any other USP Chapters deemed appropriate based on the clinical judgment of the pharmacist developing the SOPs. (F) Nothing in paragraph (E) requires the facility to perform this testing when it is performed by the manufacturer, repackager,	any of the required tests were not conducted by the manufacturer and/or wholesaler, the onus should be on the compounder to ensure that both the bulk drug substance(s) used and the compounded product meet all of the requirements.

		or wholesaler and appropriate documentation of such testing is provided to the facility.	

Sincerely,

Maurizio De Stefano
VP, Compliance & Education
Medisca Inc.

UC San Diego Health

January 27th, 2025

California Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear Anne Sodergren,

This letter is to provide comments on the proposed California Code of Regulations 1737.5(c)

1. 1737.5 Facilities and Engineering Controls. Subsection (c)
    a. **Proposed Regulation***: (c)Effective [OAL insert six months following the effective date] A a pass-through is not allowed between the hazardous drug buffer room C-SEC into an unclassified space*

    b. **Comments:**

- One written comment response I would like to address is on 1737.5(c) that prohibits a pass through between a classified space and unclassified space. The board response is title 24, section 122 prohibits passthrough between classified and unclassified spaces in HD environment.

- This was an update to title 24 in 2022. The problem with putting building codes into pharmacy law is building codes apply at the time of permitting so if I applied for permits in 2018 those permits would apply not 2022. In fact, the change in 2022 was the result of a misreading of USP 800 by the California Building Standards Commission where USP says no pass-through refrigerator and not pass throughs. This has actually been corrected in the latest Title 24 version 2024 now is amended. The code now says:

    - *Section 1224.19 "This section to align with USP which allows a passthrough from the buffer room to unclassified area but not the refrigerator"*

a. **Recommendation**: Revise language to be consistent with USP 800 or FDA language.

I would ask the board align with USP 800 similar to the California Building Standards Commission and the FDA and allow for a pass through between hazardous classified and unclassified space. The provision on no pass-through refrigerator can replace the current proposed language. To have all products go through the ante room vs a pass through creates more of a non-sterile environment in the compounding clean room and creates operational inefficiencies which are two things I don't think lead to better patient care. Thank You.

Sincerely,

Sam Martinez

Sam Martinez, PharmD, BCOP
Outpatient Infusion Pharmacy Manager
UC San Diego Health

January 27, 2025

Department of Consumer Affairs, Board of Pharmacy
First Floor Hearing Room
2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833

Re: Novo Nordisk Inc. Comments to California Board of Pharmacy Notice of Proposed Regulatory Action Concerning Compounded Drug Products, Second Modified Text

To Whom It May Concern:

Novo Nordisk Inc. ("NNI") appreciates this opportunity to submit comments in response to the California Board of Pharmacy (the "Board") Notice of Proposed Regulatory Action Concerning Compounded Drug Products, Second Modified Text ("Proposed Rule" or "Second Modified Text").[1]

Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat serious chronic diseases, like diabetes and obesity. NNI is the only company in the United States with FDA-approved medicines containing semaglutide. Semaglutide is the foundational molecule that serves as the primary ingredient for Novo Nordisk's well-known, prescription only medicines: Rybelsus® (semaglutide) tablets to improve glycemic control in adults with type 2 diabetes, Ozempic® (semaglutide) injection to improve glycemic control in adults with type 2 diabetes and to reduce the risk of major adverse cardiovascular events ("MACE") in adults with type 2 diabetes and established cardiovascular disease, and Wegovy® (semaglutide) injection to reduce the risk of MACE in adults with established cardiovascular disease and either obesity or overweight or for chronic weight management in adult and pediatric patients with obesity or adults with overweight.

NNI appreciates the Board's efforts to align its regulations with USP standards and to build upon those standards to further enhance the health and welfare of Californian patients who are given compounded drug products. The risks posed by compounded drugs are growing as compounders have expanded their reach by entering into new and unanticipated commercial

[1] Notice of Proposed Regulatory Action Concerning: Compounded Drug Products, https://www.pharmacy.ca.gov/laws_regs/1735_npa_24.pdf; Second Modified Text, https://www.pharmacy.ca.gov/laws_regs/1708_smrt.pdf.

agreements to engage in aggressive nationwide distribution, including the mass distribution of unapproved and clinically untested compounded "semaglutide." While there are no verified estimates of how many patients are using compounded "semaglutide," some "industry officials" have recently estimated that the number of patients on compounded "semaglutide" could be in the millions.[2] These compounders are compounding "semaglutide" without adhering to all the legal guardrails intended to ensure that compounding occurs only in appropriate circumstances and are engaging in these operations without the supply chain integrity and pharmacovigilance protections provided by sponsors of FDA-approved medications. We thus urge the Board to continue to bolster patient-centered policies at the state-level to protect patients from the risk of harm from compounded products.

We provide our comments on the Board's Proposed Rule, using the Board's requested format, below.

Section, Subdivision	Proposed Language in Second Modified Text	Comment / Recommended Language Revision
1735(d)	"Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as ~~**determined**~~ **verified and documented** by the **pharmacist**	**Comment:** We support the Board's revisions to the definition of "essentially a copy" in the nonsterile compounding regulations. In particular, the requirement that the prescriber determination of a clinically significant difference for an identified individual patient be verified and documented by the pharmacist is consistent with FDA's 503A Copies Guidance.[3] The agency's guidance provides that a compounder should maintain records to show compliance with section 503A(b)(1)(D) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), which is the restriction on compounding "essentially copies of a commercially available drug product." FDA states in its guidance that, for example, "records should be kept of notations on prescriptions for identified individual patients that a prescriber has determined that the compounded drug has a change that produces a significant difference for the identified patient."[4] Further, we agree that pharmacists should take steps to verify those

[2] *See* Dani Blum, *More People Are Overdosing on Ozempic Alternatives*, NY TIMES (Aug. 6, 2024), https://www.nytimes.com/2024/08/06/well/ozempic-semaglutide-overdose-risks.html; *see also* Arthur Allen, *Why Millions Are Trying FDA-Authorized Alternatives to Big Pharma's Weight Loss Drugs*, KFF HEALTH NEWS (July 23, 2024), https://kffhealthnews.org/news/article/glp1-compounding-pharmacies-wegovy-zepbound-copycat-drugs-shortages/.

[3] FDA, *Guidance for Industry: Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act* 11 (2018), https://www.fda.gov/files/drugs/published/Compounded-Drug-Products-That-Are-Essentially-Copies-of-a-Commercially-Available-Drug-Product-Under-Section-503A-of-the-Federal-Food--Drug--and-Cosmetic-Act-Guidance-for-Industry.pdf.

[4] *Id.*

Section, Subdivision	Proposed Language in Second Modified Text	Comment / Recommended Language Revision
	~~**prescribing practitioner**~~, between that compounded preparation and the comparable commercially available drug product.	determinations. The Board's updates to the definition of "essentially a copy" help to ensure that patients receive the benefit of the prescriber determination requirement, which is an important check on the compounding of unapproved compounded drug products. Specifically, the prescriber determination is intended to ensure that compounding of drug products is based on the legitimate medical need of an individual patient. We recommend adding to the definition of "essentially a copy" at Section 1735(d) the requirement that documentation of the prescriber determination be maintained in a readily retrievable format. This requirement was originally at Section 1735.1(e)(1) of the Second Modified Text, and our recommendation in this regard is not intended to make any substantive change to that requirement. Rather, we propose merely to relocate that language as a result of our recommended changes to Section 1735.1(e)(1), described below. **Recommended language revision:** "'Essentially a copy' of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as verified and documented by the pharmacist, between that compounded preparation and the comparable commercially available drug product. Such documentation must be maintained in a readily retrievable format."
1735.1(e)(1)	(e) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, unless:	**Comment:** We recommend that the Board update Section 1735.1(e)(1) to state only the prohibition on compounding of "essentially a copy of one or more commercially available drug products," as defined at Section 17735(d). The exceptions to the copies restriction at (e)(1)(A) in the Second Modified Text – related to shortage lists and inability of a health care facility to obtain a drug – are overly permissive and inconsistent with federal law and policy. The state regulations, as currently proposed, would allow drugs to be compounded under circumstances that are inconsistent with FDA's current interpretation of Section 503A of the FDCA stated in the

Section, Subdivision	Proposed Language in Second Modified Text	Comment / Recommended Language Revision
	(A) the drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding or **within 60 days of the end of the shortage ~~and at the time of dispensing~~**, or **in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or** (B) The pharmacist **~~determines~~ verifies** and documents that the compounding produces a clinically significant difference for the medical need of an identified individual patient**~~, as determined by:~~** **~~(i) the prescribing practitioner,~~** **~~(ii) the compounding pharmacist, and~~** **~~(iii) the dispensing pharmacist(s). (C)~~**	agency's 503A Copies Guidance.[5] In that guidance, FDA states that the agency does not consider a drug to be "commercially available" within the meaning of the federal copies restriction if it is present on FDA's drug shortage list, and when the drug product has been discontinued and is no longer marketed.[6] The Board's proposed regulations go even further, and would also permit compounding of copies when a drug product appears on the ASHP list, and when a health care facility "cannot obtain" a drug from the manufacturer or wholesaler. These broad exceptions are inconsistent with federal law and current policy and could lead to compounding of unapproved drug products when the FDA-approved drugs are available to meet the patients' needs. Thus, the exceptions undermine a key check on compounding of unapproved drug products, posing risks to patient safety and the public health, and should be updated accordingly. Additionally, the requirement in the Second Modified Text that the compounding pharmacist verify and document the prescriber determination of a clinically significant difference for an identified individual patient is duplicative of the requirement stated in the definition of "essentially a copy" at Section 1735(d), and is thus unnecessary. Finally, as described above, we have proposed to add the requirement that documentation of the prescriber determination be maintained in a readily retrievable format to Section 1735(d). Therefore, we recommend that Section 1735.1(e)(1) be updated to state only the prohibition on compounding copies, referencing the relevant definition in the regulations. **Recommended language revision:** "(e) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, as defined at Section 17735(d) of this article."

[5] FDA, *Guidance for Industry: Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act* 5 (2018), https://www.fda.gov/files/drugs/published/Compounded-Drug-Products-That-Are-Essentially-Copies-of-a-Commercially-Available-Drug-Product-Under-Section-503A-of-the-Federal-Food--Drug--and-Cosmetic-Act-Guidance-for-Industry.pdf.

[6] *Id.*

Section, Subdivision	Proposed Language in Second Modified Text	Comment / Recommended Language Revision
	~~Documentation describing the conditions in (1)(A) & (1)(B) is maintained in a readily retrievable format.~~ (C) Documentation describing the conditions in (1)(A) & (1)(B) is maintained in a readily retrievable format.	
1735.11(a)(2)	(a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and shall: (2) Also describe the following: (F) The pharmacist responsible for the review of all complaints related to a potential quality problem with a CNSP **~~and all adverse drug experiences~~** in the event the PIC is not available within 72 hours of the receipt of the complaint or occurrence.	**Comment:** Aligned with our comments for sections 1735.2(b) and 17.35(c) below, we recommend that the Board reinsert reference to adverse drug experiences, as specified below, to ensure SOPs state that the pharmacist is responsible for reviewing complaints related to potential quality problems and adverse events. We also recommend that the Board require that SOPs describe written procedures for the surveillance, receipt, evaluation, and reporting of adverse drug experiences. Compounding pharmacies are not held accountable by FDA for any pharmacovigilance obligations. As such, they likely do not have the policies and procedures in place to conduct pharmacovigilance, including to ensure that adverse event reports are shared with the Board and FDA and to assess adverse event reports and take corrective action. A requirement for SOPs to include written procedures related to adverse drug experiences will help compounding facilities implement the Board's quality assurance and quality control provisions. Such a requirement also will ensure that compounding facilities are taking steps to protect patients from unnecessary harm from the use of unsafe and unapproved compounded products, as we describe further below. **Recommended language revision:** "(F) The pharmacist responsible for the review of all complaints related to a potential quality problem with a CNSP and all adverse drug experiences in the event the PIC is not available within 72 hours of the receipt of the complaint or occurrence."

Section, Subdivision	Proposed Language in Second Modified Text	Comment / Recommended Language Revision
		[NEW] "(H) Written procedures for the surveillance, receipt, evaluation, and reporting of adverse drug experiences to the Board."
1735.12(b)	The Board shall be notified in writing within ~~72~~ 96 hours of the facility's receipt of a complaint of a potential quality problem ~~or the occurrence of an adverse drug experience as defined in 21 CFR 310.305(b) drug event~~ involving a CNSP.	**Comment:** We appreciate the Proposed Rule's quality assurance and quality control provisions to address quality issues with compounded nonsterile products. Aligned with our comments for section 1735.12(c) below, we recommend that the Board reinsert reference to adverse drug experiences, as specified below, to ensure that compounding facilities are required to notify the Board of adverse events involving nonsterile compounded products. Unlike sponsors of FDA-approved medicines that are subject to expansive postmarketing reporting of adverse drug experiences,[7] compounding pharmacies do not do surveillance, evaluation, or reporting of adverse events to FDA. In the wake of unprecedented demand for GLP-1 medicines, compounding facilities are mass marketing unsafe and unapproved compounded "semaglutide" products to patients, raising the risks of adverse events that go unreported. The rampant compounding of "semaglutide" is putting patients at risk. FDA's adverse event reporting system ("FAERS") database shows that 619 adverse events, including 144 hospitalizations and 12 deaths, have been reported to the Agency following use of a compounded "semaglutide" product.[8] This is more than double the number of adverse events that FDA received for all compounded drugs in 2022.[9] Yet the adverse events reported in FAERS are expected to be only a small portion of the adverse events patients are experiencing after taking compounded "semaglutide." Indeed, FDA has stated that "it is likely that adverse events from compounded versions of these drugs are

[7] 21 C.F.R. § 314.80.

[8] *See* FDA, FAERS Database for Compounded Semaglutide (accessed Nov. 4, 2024), https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/33a0f68e-845c-48e2-bc81-8141c6aaf772/state/analysis.

[9] *See* FDA, Mitigating Risks of Compounded Drugs Through Surveillance (content current as of Sept. 20, 2023), https://www.fda.gov/drugs/human-drug-compounding/mitigating-risks-compounded-drugs-through-surveillance.

Section, Subdivision	Proposed Language in Second Modified Text	Comment / Recommended Language Revision
		underreported,"[10] underscoring the importance of the Board instituting a requirement that compounding facilities report all adverse events associated with compounded products to the Board. **Recommended language revision:** "The Board shall be notified in writing within 96 hours of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug experience as defined in 21 CFR 310.305(b) involving a CNSP."
1735.12(c)	All complaints made to the facility related to a potential quality problem with a CNSP ~~and all adverse drug experiences events~~ shall be reviewed consistent with the facility's SOPs ~~by the pharmacist-in-charge~~ within 72 hours of receipt of the complaint ~~or occurrence of the adverse drug experience event~~. Such a review shall be documented and dated as defined in the SOPs.	**Comment:** Building on our comments for section 1735.12(b) above, we recommend that the Board reinsert reference to adverse drug experiences, as specified below, to ensure that compounding facilities are required to review adverse events involving nonsterile compounded products along with other quality problems as specified in the Proposed Rule. It is essential that compounding facilities review quality problems and adverse drug experiences to protect patients from unnecessary harm. Testing results have shown that certain compounded "semaglutide" samples have substantially lower or higher strengths than labeled. Testing results from compounding pharmacies marketing sublingual semaglutide products reveal high levels of impurities and inconsistencies between the labeled strength and calculated semaglutide content. One compounded sublingual "semaglutide" sample contained 170% of the labeled strength, while testing results from a different pharmacy's compounded sublingual "semaglutide" contained only 42% of the labeled strength. Some of these compounded sublingual samples had total impurities up to 41% of the sample. Subpotent and superpotent samples pose serious risks to patients. The reduced strength of compounded semaglutide formulations render such products potentially less effective than the FDA-approved semaglutide products. On the other hand, administering too much compounded semaglutide could lead to serious adverse events or even hospitalization, especially if the patient accidentally overdoses on a superpotent product.

[10] FDA, FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss (content current as of Dec. 18, 2024), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

Section, Subdivision	Proposed Language in Second Modified Text	Comment / Recommended Language Revision
		These differences and inconsistencies illustrate that compounding semaglutide dosage forms is a complex endeavor and are likely to lead to an adverse effect on the safety and efficacy of the drug products. Compounding facilities should take steps to address this growing and present risk posed by compounded drugs. Doing so requires that compounders assess reports of quality problems and adverse events and take corrective action. By reinserting reference to adverse drug experiences, the Board can ensure that compounders assume this responsibility to protect patients. **Recommended language revision:** "All complaints made to the facility related to a potential quality problem with a CNSP and all adverse drug experiences shall be reviewed consistent with the facility's SOPs within 72 hours of receipt of the complaint or occurrence of the adverse drug experience. Such a review shall be documented and dated as defined in the SOPs."
1736(e)	"Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as ~~**determined**~~ **verified and documented** by the **pharmacist** ~~**prescribing practitioner**~~, between that compounded preparation and the comparable commercially available drug product.	**Comment:** We support the Board's revisions to the definition of "essentially a copy" in the sterile compounding regulations for the same reasons as described in our comments regarding the updates to that definition at Section 1735(d) in the nonsterile compounding regulations. Requiring the pharmacist to verify and document the prescriber determination is consistent with FDA's 503A Copies Guidance and helps implement an important check on compounding of unapproved drug products. Additionally, consistent with our comments regarding Section 1735(d) above, we recommend adding to this Section 1736(e) the requirement that the documentation of the prescriber determination be maintained in a readily retrievable format, rather than including that requirement at Section 1736.1(e)(1). Our recommended changes to Section 1736.1(e)(1) are described directly below. **Recommended language revision:** "'Essentially a copy' of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as verified and documented by the pharmacist, between that compounded preparation and the comparable commercially available drug product. Such

Section, Subdivision	Proposed Language in Second Modified Text	Comment / Recommended Language Revision
		documentation must be maintained in a readily retrievable format."
1736.1(e)(1)	(e)(1) In addition to prohibitions and requirements for compounding established in federal law, no CSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, unless: (A) the drug product appears in an American Society of Health-System Pharmacists (ASHP) or FDA Drug Shortages Database that are in short supply at the time of compounding or at the time of dispensing, or in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained, or (B) The pharmacist ~~**determines**~~ **verifies** and documents that the compounding produces a clinically significant difference for the medical need of an identified individual patient~~, as determined by:~~ ~~(i) the prescribing practitioner,~~ ~~(ii) the compounding pharmacist, and~~	**Comment:** We recommend that the Board amend Section 1736.1(e)(1) to state only the prohibition on compounding of "essentially a copy of one or more commercially available drug products," as defined at Section 17736(e), for the same reasons as described above in our comments on Section 1735.1(e)(1) of the nonsterile compounding regulations. The shortage provisions in the Second Modified Text are inconsistent with federal law and policy, and are overly permissive such that they would pose risks to patient safety and the public health. Here again, the requirement at Section 1736.1(e)(1) of the Second Modified Text that the compounding pharmacist verify and document the prescriber determination of a clinically significant difference for an identified individual patient is duplicative of the requirement already stated in the definition of "essentially a copy" at Section 1736(e), and thus is unnecessary. Additionally, as noted above, we have proposed to add the requirement that documentation of the prescriber determination be maintained in a readily retrievable format to Section 1736(e), and it is therefore unnecessary here. Thus, we recommend updating Section 1736.1(e)(1) to state only the prohibition on compounding copies, and remove all other content. **Recommended language revision:** "(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, as defined at Section 17736(e) of this article."

Section, Subdivision	Proposed Language in Second Modified Text	Comment / Recommended Language Revision
	~~(iii) the dispensing pharmacist(s). (C) Documentation describing the conditions in (1)(A) & (1)(B) is maintained in a readily retrievable format.~~ (C) Documentation describing the conditions in (1)(A) & (1)(B) is maintained in a readily retrievable format.	
1736.9(d)	In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding. (d) All APIs ~~and excipient components~~ used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA), and be suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, the grade of the material, and the applicable compendial designations on the COA, must be received and evaluated prior to use, unless components are commercially available drug products. When the COA is	**Comment:** We appreciate the Proposed Rule's provisions requiring Certificates of Analyses (COAs) for API used to compound sterile products. We offer three recommendations to further bolster the Proposed Rule's provisions on COAs. First, we recommend that the Board reinsert reference to excipient components to ensure that all components used to compound sterile products are accompanied by a COA. Excipient components in compounded products can cause dangerous adverse events and result in serious harm to patients. For example, FDA published a Compounding Risk Alert after receiving an adverse event report concerning a patient who experienced cardiac arrest and died after IV administration of a curcumin emulsion product compounded by ImprimisRx.[11] FDA identified the presence of an impurity in PEG 40 castor oil, an excipient used in the compounded product that may have caused the adverse event. The PEG 40 castor oil used was ungraded and not suitable for human consumption or therapeutic use. FDA thus warned against the "risks associated with compounded drugs, particularly those that use non-pharmaceutical grade components and ingredients lacking a USP monograph."[12] The Board can help to protect against these risks by reinserting COA requirements for excipient components used to compound sterile products.

[11] FDA, FDA investigates two serious adverse events associated with ImprimisRx's compounded curcumin emulsion product for injection (content current as of June 21, 2018), https://www.fda.gov/drugs/human-drug-compounding/fda-investigates-two-serious-adverse-events-associated-imprimisrxs-compounded-curcumin-emulsion.

[12] *Id.*

Section, Subdivision	Proposed Language in Second Modified Text	Comment / Recommended Language Revision
	received from a supplier, it must provide the name and address of the manufacturer. An API ~~and excipient components provided~~ with a COA without this data shall not be used in a CSP.	Second, we recommend that the Board adjust the Proposed Rule's carveout for components of commercially available drug products to ensure that the carveout only applies to ingredients sourced from and provided by the manufacturer of the commercially available drug product. Requiring the COA with the specified content in all other circumstances is critical to ensuring that ingredients used by compounding facilities do not lead to unsafe and ineffective compounded drugs. Third, we recommend that the Board add a requirement that the COA of any API that claims to be a component of an approved drug show that the API was manufactured by the process specified in the labeling of the approved drug. The importance of this requirement is particularly acute for the bulk "semaglutide" used in compounding. The FDA-approved labeling for semaglutide medicines explains that the "peptide backbone is produced by yeast fermentation." Unlike the yeast-produced semaglutide in NNI's FDA-approved semaglutide medicines, the "semaglutide" in compounded drugs is produced using synthetic semaglutide unaffiliated with any approved application. Use of such API can introduce peptide-related impurities and other complexities and expose patients to safety and effectiveness risks. Indeed, testing revealed that compounded "semaglutide" samples contained high levels of impurities.[13] The peptide-related impurities[14] identified in the samples have the potential to stimulate immunological processes to produce antibodies against semaglutide peptides, potentially posing immunogenicity risks that can lead to serious and life-threatening reactions like anaphylaxis.[15] This data reinforces the importance of requiring that the COA demonstrate that any API that claims to be a component of an FDA-approved drug was

[13] Morten Hach et al., *Impact of Manufacturing Process and Compounding on Properties and Quality of Follow-On GLP-1 Polypeptide Drugs* at 8, PHARM RES. (2024), https://pubmed.ncbi.nlm.nih.gov/39379664/; *see also* Novo Nordisk, Dear HCP letter (Feb. 2024), https://www.novomedlink.com/content/dam/novomedlink/semaglutide/Compounding-Letter.pdf.

[14] *See* Novo Nordisk, Novo Nordisk escalates legal actions to safeguard patients from potentially harmful compounded "semaglutide" drugs (May 2024), https://www.novomedlink.com/content/dam/novomedlink/semaglutide/May-30-2024-Company-Statement.pdf.

[15] Morten Hach et al., *Impact of Manufacturing Process and Compounding on Properties and Quality of Follow-On GLP-1 Polypeptide Drugs* at 8, PHARM RES. (2024), https://pubmed.ncbi.nlm.nih.gov/39379664/.

Section, Subdivision	Proposed Language in Second Modified Text	Comment / Recommended Language Revision
		manufactured by the same process described in the FDA-approved drug labeling. The Board should thus (1) ensure that all components used to compound sterile products, including excipients, are accompanied by a COA; (2) limit its exemption to circumstances where a compounding facility sources and obtains its API from the manufacturer of a commercially available drug product; and (3) require that the COA show that any API that claims to be a component of an approved drug was manufactured by the process specified in the labeling of the approved drug. Adhering to these standards is critical to ensure that patients do not receive unsafe and ineffective compounded products that are unaffiliated with approved drug products. **Recommended language revision:** "(d) All APIs used to compound a CSP shall be manufactured by an FDA-registered facility. All APIs and excipient components used to compound a CSP shall be accompanied by a Certificate of Analysis (COA) and be suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, where one exists, the grade of the material, and the applicable compendial designations on the COA, must be received and evaluated prior to use, unless components of the CSP are commercially available drug products that are sourced from and provided by the manufacturer of the commercially available drug product. The COA for any API used to compound a CSP that claims to be a component of an FDA-approved drug must show that the API was manufactured by the process specified in the labeling of the FDA-approved drug. When the COA is received from a supplier, it must provide the name and address of the manufacturer. An API and excipient components provided with a COA without this data shall not be used in a CSP."
1736.9(e) and 1736	(e)(1) Except as provided in (2), ~~When~~ when a bulk drug substance or API is used to compound a CSP, it shall comply with a USP drug monograph, be the active substance of an FDA approved drug, or be listed in 21 CFR 216, or unless	**Comment:** We recommend that the Board revise its provisions in 1736.9 related to the conditions under which sterile compounding can occur. By adopting this recommendation, the Board will align its Proposed Rule with Federal Food, Drug, and Cosmetic Act section 503A(b)(1)(A). We also recommend that the Board add a definition for "component of a drug approved by the FDA" to ensure that API used to compound sterile drugs is the same API used to manufacturer FDA-approved drug products. In addition, for

Section, Subdivision	Proposed Language in Second Modified Text	Comment / Recommended Language Revision
	authorized by a public health official in an emergency use situation for a patient-specific compounded sterile preparation.	the reasons noted for section 1736.9(d) above, the Board should add a requirement that API that claims to be a component of an approved drug must be manufactured by the process specified in the labeling of the approved drug. **Recommended language revision:** 1736.9: "(e)(1) Except as provided in (2) or (4), when API is used to compound a CSP, it shall – (i) comply with a USP monograph; (ii) if such a monograph does not exist, be an API that is a component of a drug approved by the FDA; or (iii) if such a monograph does not exist and the API is not a component of a drug approved by the FDA, be listed in 21 C.F.R. § 216.23." *[NEW]* "(4) A drug product may be compounded if authorized by a public health official in an emergency use situation for a patient-specific compounded sterile preparation. (5) API used to compound a CSP that claims to be a component of an FDA-approved drug must be manufactured by the process specified in the labeling of the FDA-approved drug." 1736: *[NEW]* "(i) 'Component of a drug approved by the FDA' means an API that is the same as the API used in the manufacture of the approved drug, ."
1736.17(a)(2)	N/A	**Comment:** Aligned with our comments for section 1735.11(a)(2) above, NNI recommends that the Board require that SOPs describe written procedures for the surveillance, receipt, evaluation, and reporting of adverse drug experiences involving sterile compounded products. **Recommended language revision:** *[NEW]* "(G) Written procedures for the surveillance, receipt, evaluation, and reporting of adverse drug experiences to the Board."

Thank you for the opportunity to provide comments on this Proposed Rule. We would be pleased to provide further input or clarification of our comments if needed.

Sincerely,

Robert B Clark

Robert B. Clark
Vice President, Regulatory Affairs
Novo Nordisk Inc.

SAFE ▪ EFFECTIVE ▪ SOLUTIONS

OFA

OUTSOURCING FACILITIES ASSOCIATION

January 27, 2025

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Re: Notice of Proposed Action: Compounded Drug Products Second Modified Text

The Outsourcing Facilities Association ("OFA") is the trade association representing FDA-registered outsourcing facilities operating pursuant to Section 503B of the Federal Food, Drug, and Cosmetic Act ("FDCA"). OFA's members provide compounding and repackaging services to patients, healthcare providers, and healthcare facilities, and strive to ensure the specific needs of both providers and patients are met with safe and effective compounded and/or repackaged medications under the current Good Manufacturing Practices standards and guidance of the Food and Drug Administration and in compliance with all applicable laws and regulations.

OFA submits this comment concerning the second modified text of certain proposed amendments to Title 16 of the California Code of Regulations, as follows:

Outsourcing Facilities Association; c/o: Victoria Weatherford		
Section, Subdivision	Proposed Language	Recommendation / Comment
Proposed § 1735.1(e)	(e) In addition to prohibitions and requirements for compounding established	The proposed amendment should be revised for additional clarity, for the reasons stated below

	in federal law, no CNSP shall be prepared that: (1) Is essentially a copy of one or more commercially available drug products, unless: …, or (B) The pharmacist verifies and documents that the compounding produces a clinically significant difference for the medical need of an identified individual patient.	

On December 9, 2024, OFA submitted a comment (the "December 2024 Comment") addressing prior proposed text of § 1735.1. The December 2024 comment explained, *inter alia*, that a requirement that a finding of clinically significant difference be made by "the prescribing practitioner," "the compounding pharmacist," and "the dispensing pharmacist(s)" was arbitrary, capricious and contrary to law. The proposal demanded that pharmacists engage in the practice of medicine in contravention of California law, imposed obstacles to federal policies under the FDCA in contravention of federal law, and operated in erratic ways for no rational policy objective. The December 2024 Comment is incorporated here by reference.

The Second Modified Text, published on or about January 10, 2025, appears in relevant part intended to address OFA's objections or at least those along similar lines. The Second Modified Text of Proposed § 1735.1 avoids demanding that pharmacists practice medicine by requiring only that a "pharmacist verifies and documents" a clinically significant difference, rather than make the *determination* of clinically significant difference, which the prescribing practitioner must do under federal law. With the text so understood, the objections stated in the December 2024 Comment would be resolved.

However, the Second Modified Text of Proposed § 1735.1(e) may fall short of achieving these objectives because it is arguably ambiguous concerning (1) what is to be verified and documented and (2) what verification and documentation is required.

First, the shift from a *determination* standard to a *verification and documentation* standard indicates that the pharmacist under the Second Modified Text need only verify and document that a prescribing practitioner has made a finding of clinically significant difference. But there is an arguable ambiguity: the draft text's reference

to verifying and documenting directly "that the compounding produces a clinically significant difference" could be misunderstood to require that pharmacists find an actual clinically significant difference in possible conflict with doctors' findings, which would raise all the flaws identified in the December 2024 Comment and be unlawful on the grounds stated there. The text should be revised to make clearer that the pharmacist must verify and document that *the prescriber* has made such a determination.

Second, the Second Modified Text is also arguably ambiguous as to what type of verification and documentation is sufficient. As drafted, the Modified Text of Proposed § 1735.1(e) may be misunderstood to require onerous, impractical, vague, or inconsistent verification and documentation requirements that prove unworkable or overly burdensome in practice. That, again, would raise all the flaws identified in the December 2024 Comment. This ambiguity can be resolved, however, by making clear that a pharmacist who verifies, from a notation documented on the prescription itself or other similar communication from the prescriber to the pharmacist, that the prescriber has determined the clinically significant difference of the prescription—and adds a notation to the pharmacist's patient file recording this fact—meets the verification and documentation requirement of Proposed § 1735.1(e).

The Board should clarify the text of Proposed § 1735.1(e) along the lines proposed above. At a minimum, it should clarify in the preamble of any final action promulgating this rule or in concurrently issued guidance that, under this provision, a pharmacist need only verify and document that a prescribing practitioner has made a finding of clinically significant difference in the manner described above.

Respectfully submitted, January 27, 2025

/s/ Victoria Weatherford

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Lori Martinez
Board of Pharmacy
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January 26, 2025

Dear Members of the Board of Pharmacy,

Thank you for the opportunity to comment, again, on the proposed rules related to compounding. I sincerely appreciate the opportunity to participate in the rule-making process and to educate the Members of the Board regarding practical and reasonable practices in compounding.

For those of you who are new to the Board, I have been a compounding pharmacist for 25 years and both PIC and owner of Pacific Compounding Pharmacy in Stockton for the last 19 years. I taught the Advanced Compounding Elective at UOP for 17 years, and I have extensive experience in both non-sterile and sterile compounding. I have been actively involved in the rule-making process with the Board since at least 2015. I am hopeful that my recommendations do not fall on deaf ears.

Though it is clear I do not hold the “popular” opinion, I strongly urge you to REJECT the Recommended Second Modified Text of Compounded Drug Products dated January 9, 2025. After three years of discussions and revisions, there are still significantly problematic issues in these proposed rules, (as well as annoying typos, misnumberings, and duplications). This is indicative of how difficult the process has been, but despite all the hard work, these proposed rules are NOT ready for implementation!

As an alternative, I RECOMMEND that you move forward with a repeal of sections 1735-1735.8 of Article 4.5 and repeal sections 1751-1751.12 of Article 7 without any additional revision or adoption of rules. All of the USP compounding chapters are already codified in BPC Section 4126.8 and can stand on their own until such time as rulemaking can re-commence. (As quickly as the April 2025 Board meeting?)

I have heard your concern at the meetings about complying with BPC Section 4127(c) to review the revision to Chapter 797 not later than 90 days after the revision becomes official. You have accomplished this! And it is clear that you have determined that amendments are necessary; but you have also experienced the complexity of creating rules for the diverse practice of compounding. Notably, Section 4127(c) does not require that you craft and implement the amendments in a specific timeline. So please DON’T RUSH THIS, take the time to do it right!

I believe that if you informally poll your licensees who compound regularly, you will find that a huge majority (if not 100%) will be happy to comply with all the rules and requirements of the USP chapters. What a step up from where we have been!

Respectfully submitted,

Marie Cottman, Pharm.D.
Owner/PIC

Marie Cottman, Pharm.D. Owner Pacific Compounding Pharmacy.

Subdivision	Board Proposed Language	Recommendation / Comment
1735.1(c)	(c) Notwithstanding subdivision (a), a limited quantity of a CNSP may be prepared and stored in advance of receipt of a patient specific prescription document where it is necessary, and solely in such quantity, as is necessary, to ensure continuity of care of individual patients based on a documented history of prescriptions for those patient populations.	Remove duplication of language "is necessary" because having the phrase twice in the same sentence is confusing. **Recommend revision:** (c) Notwithstanding subdivision (a), a limited quantity of a CNSP may be prepared and stored in advance of receipt of a patient specific prescription document where it is necessary, and solely in such quantity, ~~as is necessary,~~ to ensure continuity of care of individual patients based on a documented history of prescriptions for those patient populations.
1735.3(a)	(a) Facilities shall require individuals entering the compounding area to report if the rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or any other medical condition, to determine if such condition could contaminate a CNSP or the environment per the facility's SOPs. Prior to admitting any personnel into a compounding area, the supervising pharmacist shall evaluate whether compounding personnel is experiencing any of the above conditions could contaminate a CNSP or the environment. After such evaluation and determination, the supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area.	Fix typo: (a) Facilities shall require individuals entering the compounding area to report if the**y have** rashes… (and other grammatical issues) In practice, the supervising pharmacist will not be doing employee inspections looking for rashes, tattoos, or sores. Please remove the requirement for the supervising pharmacist to evaluate for these conditions. **Recommend revision:** (a) Facilities shall require individuals entering the compounding area to report if they have rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or any other medical condition, to determine if such condition could contaminate a CNSP or the environment per the facility's SOPs. ~~Prior to admitting any personnel into a compounding area, the supervising pharmacist shall evaluate whether personnel is experiencing any of the above conditions could contaminate a CNSP or the environment.~~ After ~~such~~ evaluation and determination, the supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area.
1735.3(e)	(e) Reusable garb and equipment shall be cleaned with a germicidal cleaning agent and sanitized with 70% isopropyl alcohol at least daily and before use by different personnel use.(1) Any reuseable gowns must be laundered, per the facility's SOPs before reuse	Though USP uses the term "reusable," your original term "Non-disposable" makes much more sense for this additional requirement. A compounder may reuse a mask, paper-gown, or booties during their compounding shift. These items will not tolerate (nor be effectively cleaned) by germicidal agent and IPA. Also the wording of "before **use** by different personnel **use.**" is awkward and confusing. **Recommend revision**: ~~Reusable~~ Non disposable garb and equipment shall be cleaned with a germicidal cleaning agent and sanitized with 70% isopropyl

		alcohol at least daily and before use by different personnel ~~use before re-use~~.(1) Any reuseable gowns must be laundered, per the facility's SOPs before reuse.
1735.9(c)	The label for any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.	**Recommend to remove this section.** This is completely redundant. It just restates laws that already exist. As Compounding CNSPs are drugs, they already require all the labelling specified in 4076 and 1707.5. There is no implied exemption from labelling requirements in USP 795. (If one of your licensees thinks they only have to comply with USP and they can ignore the other body of laws relative to the practice of pharmacy in CA, you will have much bigger problems than the label.)
1735.10(b)(1)	(b) A CNSP's BUD shall not exceed any of the following: (1) The chemical and physical stability data of the active pharmaceutical ingredient (API) and any added component in the preparation,	This proposed rule is far too restrictive. What if no data exists? The study to determine chemical and physical stability data is literally $30,000 or more! Under this rule, when a prescriber is identifying a novel drug delivery solution for a unique patient experience, compounders will be unable to compound a new preparation because there is no existing DATA to demonstrate stability. Even if the pharmacist were to apply a conservative 14 day refrigerated BUD, without data, they would be in violation of this rule and subject to action against their license. *This will limit access to potential solutions for patients with unique needs!* USP 795 Chapter 10 allows for considerations to be used in determining a BUD, which MUST be conservative. **Recommend to remove this section (USP already addresses what to consider when determining BUDs.)** **If you won't remove it, allowing recommendations in USP to stand on their own merit, then please consider rewrite:** *(b) A CNSP's BUD shall be conservatively assigned when data is not readily available to validate chemical and physical stability or compatibility and degradation with the container-closure system.*

1735.10(b)(2)	(b) A CNSP's BUD shall not exceed any of the following: (2) The compatibility and degradation of the container–closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions),	I have concerns that the inspectors could abuse this rule because it is not clear who has the burden of proof that the CNSP is non-reactive with the container-closure system. And again, the testing to provider proof is many $1,000s! Under this rule, when a prescriber is identifying a novel drug delivery device for a unique patient experience, compounders will be unable to package the compound they don't have proof (even if there is good similar data available). If the pharmacist were to apply a conservative 14 day refrigerated BUD, without specific data, they could be in violation of this rule and subject to action against their license. *This will limit access to potential solutions for patients with unique needs!* **Recommend to remove this section (USP already addresses what to consider when determining BUDs.)** **If you won't remove it, allowing recommendations in USP to stand on their own merit, then please consider rewrite:** *(b) A CNSP's BUD shall be conservatively assigned when data is not readily available to validate chemical and physical stability or compatibility and degradation with the container-closure system.*
1735.11(a)(2)(C)	(a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and shall: (2) Also describe the following: (C) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins.	Chapter 795 Section 6.2.3 already addresses evaluation of a component prior to use (compounding). It specifically states: "Before use, compounding personnel must visually re-inspect all components. Each packaging system must be inspected to detect any container breakage, looseness of the cap or closure, or deviation from the expected appearance or texture of the contents that might have occurred during storage. Compounding personnel must ascertain before use that components are of the correct identity based on the labeling and have been stored under required conditions in the facility. If the identity, strength, purity, and quality of components intended for preparation of CNSPs cannot be verified (e.g., containers with damaged or incomplete labeling), the components must be immediately rejected. Any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal. 1735.11(a)(2)(C) is redundant and unnecessary. **Recommend to remove.**

1735.11(a)(2)(D)	(a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and shall: (2) Also describe the following: (D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPs as described in this article.	This is hard to read and comprehend. If I understand it correctly, it means to have additional SOPs addressing all the requirements in this chapter. **Recommend to remove or rewrite:** (a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and shall: (1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. (2) ~~Also describe the following:~~ Comply with the additional requirements described in this chapter. (~~2~~3) Also describe the following: (leave other lettered items) ~~(D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPs as described in this article.~~
1735.12(a)	(a) The facility's quality assurance program shall comply with section 1711 and the….	For clarity, **Recommend adding location of section 1711:** (a) The facility's quality assurance program shall comply with BPC Title 16, section 1711 and the
1735.12(a) (2nd comment)	(a) The facility's quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the program shall include a written procedure for scheduled action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, quality, or labeled strength.	Recalls, out of spec results are NOT scheduled. **Recommend to remove the word scheduled.** …In addition, the program shall include a written procedure for ~~scheduled~~ action, such as a recall, in … (this is also consistent with a change made in proposed rule 1736.18)

1735.11(b)	(b) The Board shall be notified in writing within 96 hours of the facility's receipt of a complaint of a potential quality problem involving a CNSP.	I really don't think you want to open this can of worms. Potential quality problems are not ACTUAL quality problems. If a patient calls and complains that their bleaching cream is not working after 4 weeks… is that a potential quality problem? It could be, but it also might be that they didn't allow enough time (8-12 weeks to see results), or they just cannot see the subtle results, or they left the product at room temperature when it should have been refrigerated, but they are too ashamed to tell you so. Either way, since it COULD be a Potential quality problem, I would report it. I don't have a problem with sharing a TRUE quality issue— topical preparation caused a skin infection, oral medication got moldy before the BUD, an MBK suppository crumbled and could not be used… but what does the Board define as a potential quality? The existing complaint programs and BPC section 1711 already have documentation/evaluation requirements. **Recommend to remove or rewrite with clarity of what you really want to be reported.**
1735.13	1735.13. CNSP Packaging and Transporting. In addition to the standards set forth in USP Chapter 795, the facility shall ensure appropriate processes for storage, shipping containers and temperature sensitive CNSPs as provided for in the facility's SOPs.	This is redundant because it is already required by 795. USP 795 13.1 Packaging of CNSPs states: "The facility's SOPs must describe packaging of CNSPs. Personnel should select and use packaging materials that will maintain the physical and chemical integrity and stability of the CNSPs. Packaging materials must protect CNSPs from damage, leakage, contamination, and degradation, while simultaneously protecting personnel from exposure. And 13.2 Transporting of CNSPs "If transporting CNSPs, the facility must have written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed." **Recommend to remove.**
1735.15	(a) In addition to the standards in USP Chapter 795 and the Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) a facility that limits its compounding as described in Section 1735.1(i) shall establish the following SOPs: …	Since compounders who only add flavoring are exempt from 1735.2-1735.12, they would not be required to comply with 1735.12, reporting quality issues. **Recommend adding an SOP requirement similar to 1735.12**

1736	The definitions in this section shall be applicable to this Article and supplement the definitions provided in United States Pharmacopeia (USP) General Chapter 797 (USP Chapter 797), titled Pharmaceutical Compounding – Sterile Preparations. The following definitions apply to this article and supplement the definitions provided in USP Chapter 797 for compounded sterile preparations (CSPs).	**Recommend removing duplicate language.** The definitions in this section shall be applicable to this Article and supplement the definitions provided in United States Pharmacopeia (USP) General Chapter 797 (USP Chapter 797), titled Pharmaceutical Compounding – Sterile Preparations. ~~The following definitions apply to this article and supplement the definitions provided in USP Chapter 797 for compounded sterile preparations (CSPs).~~
1736(g)	(g) "Quality" means the degree to which the components and preparation meets the intended specifications, complies with relevant law and regulation, and means the absence of harmful levels of contaminants, including but not limited to filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record as specified in USP 797.	This definition is different than the definition of quality in Section 1735 for CNSPs, which seems odd. What is the "degree" to which PICs, DPs, and compounding personnel should aim for to meet this definition of quality? Requirements for sterility, bacterial endotoxin limits, lack of particulates, and characteristics of the preparation must already be met through the application of USP 797. Who defines the standard, the "degree," and what the "intended specifications" are for a particular CSP? Further, even without the confusing language, the definition still has the phrase, "including but not limited to" which allows very broad enforcement. **Recommend to remove vague/undefined language and match CSP definition of Quality with CNSP definition of Quality.** (g) "Quality" means ~~the degree to which the components and preparation meets the intended specifications, complies with relevant law and regulation, and means~~ the absence of harmful levels of contaminants, including but not limited to filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record as specified in USP 797.
1736.1(b) 2 & 3	(2) If the sterile compounding equipment or environment fail(s) to meet any required specification, after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient. This provision may only be used for 48 hours after such failure(s). All such failures must be documented in accordance with facility's SOP and shall be reported to the Board within 72 hours. (3) If the sterile compounding equipment or environment fail(s) to meet any required specification in a critical access hospital, as defined in the Social Security Act 42 U.S.C.	I have no objection to these sections being present, however, I do not understand the rationale of differing timelines. Both allowances provide "an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering of an identifiable patient." But a critical access hospital has 5 days to get fixed and everyone else only 2 days. If the outcome of the patient is the same, loss of life or intense suffering, why the differential time line? **Recommend to pick either 48 or 120 hours and make one rule for everyone.**

	1395i-4 section (c)(2)(B), after attempts to remediate pursuant to the facility's SOPs are unsuccessful, an immediate use CSP may be compounded without the requirement for there to be loss of life or intense suffering or an identifiable patient. This provision may be used for 120 hours after such failure(s). All such failures shall be documented in accordance with facility's SOPs and shall be reported to the Board within 72 hours.	
1736(e)(4)	(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP may be compounded that: (4) Requires end product sterilization unless sterilization occurs within the same licensed compounding location.	This is duplicated in proposed 1736.10(e) (the section on sterility– more appropriate location). It also could be more direct if it needs to be in 2 places. **Recommend to remove 1736(e)(4) in favor of leaving in 1736.10(3).** **If not removed, consider rewording:** (e) In addition to prohibitions and requirements for compounding established in federal law, no CSP may be compounded that: (4) Requires end product sterilization ~~unless sterilization occurs~~ that cannot be completed within the same licensed compounding location.
1736(g)	(g) In addition to the provisions in Section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling and disposal of the CSP and related supplies furnished.	This is largely not "in addition to." 1707.2(c)When oral consultation is provided, it shall include at least the following: (1) directions for use and storage and the importance of compliance with directions;... (4) precautions for preparation and administration by the patient… Further, 1707.2(e) allows an out for when the patient or the patient's agent refuse consultation. By having this special consultation for CSPs in section 1736, it becomes a SHALL ***always***, even when the patient doesn't want it. This rule would be much better added to 1707.2 as an additional requirement. As a licensee, it is always frustrating to have to identify multiple sections that address the same requirements! **Recommend to remove and add rule making to add this language to 1707.2.**
1736.4(e)	(e) No CSP shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs.	This is not congruent with 1736.1(b)2&3. **Recommend to reword:** (e) No CSP shall be compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs unless designated as immediate use only in compliance with 1736.1(b)(2) or 1736.1(b)(3).

1736.6	Environmental sampling shall be done in compliance with Controlled Environment Testing Association's Certification Application Guide USP <797> Viable Environmental Monitoring for Sterile Compounding Facilities (CAG009, Revised September 2020), which is hereby incorporated by reference.	Comment: Great that this reference is incorporated– glad to know the standard! However, access to this standard costs $295. As many compounders are conducting their own monthly sampling, we will have to purchase yet another reference. It is NOT readily available.
1736.8	In addition to the requirements in USP Chapter 797, the following requirement applies to sterile compounding. Introducing items into the SEC and PEC shall comply with the SOPs as required in section 1736.17.	This is not "in addition to the requirements of USP Chapter 797," rather it is a restatement of proposed rule 1736.17. Having the same rule in two locations just complicates things! **Recommend remove, 1736.17 is clear enough.**
1736.9(d)	(d) All APIs used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA), and be suitable for use in sterile pharmaceuticals. A COA that includes the compendial name, the grade of the material, and the applicable compendial designations on the COA, must be received and evaluated prior to use, unless components are commercially available drug products. When the COA is received from a supplier, it must provide the name and address of the manufacturer. An API provided with a COA without this data shall not be used in a CSP.	This is a misplaced rule! It belongs in the rules that wholesalers must comply with. The inspectors are aware that PCCA will not provide original COA nor reveal the manufacturer, except when requested by a Board Inspector. PCCA has a rigorous process to vet manufacturers, including that they are registered with the FDA. Further, they have a process of validating their wholesaler's COAs and rejecting components that don't meet standards (even if the COA says it does). **Recommend to move this requirement to BPC Article 11 in the Wholesaler chapter for rules.**
1736.17(a)(2)(E)	(E) The methods by which the pharmacist compounding or supervising the compounding pursuant to 1736.9(f) related to use of a bulk drug substance published in the 503A Category 1 bulk substances list, will ensure each lot of the bulk drug substance is representatively sampled per USP 1097 (bulk powder sampling procedures), tested, and found to be in compliance with at least: …	1736.9(f) does not exist in the most recent version of the proposed rules. **Recommend to remove.**

1737	General statement of In addition to the standards in the USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed. Vs. In addition to the standards in the USP Chapter 800, the following requirements apply to the compounding of HDs or performing crushing or splitting tablets or opening capsules of antineoplastic HDs.	1) This statement is used inconsistently throughout the proposed rules for hazardous compounding. **Recommend you create a consistent statement that can be used at the beginning of each numbered rulemaking. Delete redundant and repetitive phrasing.** 2) The expanded statement about crushing or splitting tablets is not included, but seems appropriate for sections 1737.2, 1737.7 PPE, 1737.8 Hazard Communications, 1737.12 Dispensing final dosage form, 1737.15 Deactivating, Decontamination, Cleaning and Disinfecting, 1737.16 Spill Control
1737.1(a)	(a) In addition to the provisions in section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning handling and disposal of an compounded HD or related supplies furnished. A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge compounded medications which meets the requirements of Business and Professions Code Section 4074.	1707.2(e) allows an out for when the patient or the patient's agent refuses consultation. By having this special consultation for HDs in section 1737.1(a), it becomes a SHALL ***always***, even when the patient doesn't want it. This rule would be much better added to 1707.2 as an additional requirement. As a licensee, it is always frustrating to have to identify multiple sections that address the same requirements! **Recommend to remove and add rule making to add this language to 1707.2.**
1737.6	The premises shall consider environmental wipe sampling and SOPs shall describe provisions for environmental wipe sampling for HD surface residue. Nothing in this section is intended to require the use of environmental wipe sampling.	If 1737.6 does not require the use of environmental wipe sampling, what is the point of writing ANOTHER SOP? Documentation of consideration should be sufficient. **Recommend to reword:** The premises shall consider environmental wipe sampling and <u>if implemented,</u> SOPs of a premises where HDs are handled shall address describe provisions for environmental wipe sampling for HD surface residue, its frequency, and areas of testing, levels of measurable contamination, and actions when those levels are exceeded. Nothing in this section is intended to require the use of environmental wipe sampling.

1737.7(b)	(b) The outer pair of chemotherapy gloves that meets the ASTM D-6978 standard shall be changed as recommended by the manufacturer's documentation. Documentation from the manufacturer shall be readily retrievable. For sterile HD compounding, both pairs of gloves labeled to meet the ASTM D-6978 standard shall be sterile.	In section A, the phrase "chemotherapy gloves that meets the ASTM D-6978 standard" is also used. But at the end of this provision, there is a sneaky distinction that the gloves be "labeled to meet ASTM D-6978." NOT ALL ASTM compliant gloves are ***labeled*** as such. The ASTM designation is a 'pay to play' label and many gloves meet the standard as is indicated in their COA, but do *not* pay to have the ASTM label. Further, USP 800 section 7 already requires "/…two pairs of chemotherapy gloves are required for compounding sterile and nonsterile HDs." **Recommend to revise by removing "labeled to meet the ASTM standard".** (b) The outer pair of chemotherapy gloves that meets the ASTM D-6978 standard shall be changed as recommended by the manufacturer's documentation. Documentation from the manufacturer shall be readily retrievable. For sterile HD compounding, both pairs of gloves ~~labeled to meet the ASTM D-6978 standard~~ shall be sterile.
1737.7(c)	(c) Outer gloves used for HD compounding shall be changed between each different HD preparation, unless preparing multiple HD preparations of the same drug or preparing multiple HD preparations for a single patient.	As was presented to the board previously, this is an expensive and unnecessary rule. Either the compounder can prepare sterile preparations without cross contamination, or they cannot, and gloves should be changed for every different preparation (HD or NOT)! Sterile gloves are costing $1.50 to $3.85 / pair. In addition to the expense, the change in process for all sterile compounders might result in a shortage of gloves because the use will not double, but it might increase by 10 or 20 fold! IF you cannot provide evidence of the NEED to change the gloves more often than required by the manufacturer, then **Recommend to remove.**

1737.7(d)	(d) PPE removal process shall be done in a manner to avoid transferring contamination to skin, the environment, and other surfaces. Outer PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPs shall detail the donning and doffing of PPE and where it takes place in the C-SEC.	This is a ***non-functional*** rule for facilities designed with a designated HD anteroom connected to a C-SEC HD Buffer Room. In practice, without pass-throughs (which are frowned upon), the compounder may need to return to the anteroom between compounds for additional supplies or to remove excess materials from the work area. An anteroom as defined by USP, is a transitional area for activities that generate particles (such as doffing) A) If the compounder must doff in the C-SEC, then the ungowned/dirty compounder will re-enter the "clean side" of the anteroom ungarbed thus eliminating the possibility of a clean and dirty side to the HD ante room (which is still required in USP)! B) Doffing as required in this proposed rule will generate an unnecessary particulate load to the C-SEC increasing the risk of contamination as doffing is an activity that produces a lot of particulates! C) It is unreasonable to require doffing within the C-SEC when the facility has a dedicated HD anteroom. D) If this remains in place, in an effort to avoid doffing and wasting gowns (in HD, gowns cannot be reused) compounders may take in too many materials at one time increasing an opportunity for errors. USP 800 states (emphasis added) "Although ***not*** a recommended facility design, ***if*** the negative-pressure HD buffer room is entered through the positive-pressure ***non***-HD buffer room, the following is also required: • A line of demarcation must be defined within the negative-pressure buffer room for donning and doffing PPE" This is the ONLY situation to require doffing within the buffer room (aka C-SEC). USP 797 states "The area within 1 m of the PEC should be dedicated only for sterile compounding (e.g., not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities such as patient care)." **I recommend that you remove section 1737.7(d) and allow USP 800 section 5.3.2 to stand as written**.
1737.11(b)	(b) All compounded antineoplastic HDs shall be transported from the facility in an impervious plastic container and labeled as Hazardous Drugs on the outside of the container.	This is limiting. Impervious plastic chemo bags have "CHEMOTHERAPY" printed on the bag. Would we be required by this proposed rule to ALSO add a label that says HAZARDOUS DRUGS?? **Recommend to add "or Chemotherapy" to this wording.** (b) All compounded antineoplastic HDs shall be transported from the facility in an impervious plastic container and labeled as Hazardous Drugs or Chemotherapy on the outside of the container.

1737.12	Equipment used in nonsterile HD compounding shall be dedicated for use with HDs and shall be decontaminated after each use.	But what if the equipment is being used for the same HD, different strength? For example, Progesterone capsules. First preparation is progesterone 5mg capsule, second preparation is progesterone 50mg capsule. Decontaminating the capsule plates is a process that involves wetting the plates. This will prevent further compounding using that equipment for no less than an hour. (capsules melt when exposed to liquids– the plates must be 100% dry!) **Recommend wording change to allow for equipment to be used without full decontamination for the same HD.** Equipment used in nonsterile HD compounding shall be dedicated for use with HDs and shall be decontaminated ~~after each use~~.prior to use with a different HD and at the end of the shift.
1737.13(a)	(a) If a disposable preparation mat is used for compounding a CSP it must be sterile and it must be changed immediately if a spill occurs, after each different HD preparation unless multiple preparations of the same drug or single patient is occurring, and at the end of the daily compounding activity	a) Changing the mat if a spill occurs is already required in section 13, USP 800. b) It is excessive and wasteful to change the mat when no spill or contamination is present. Sterile prep mats cost ~$3.00 each. In addition to the expense, the change in process for all sterile compounders might result in a shortage of mats because the use will not double, but it might increase by 10 or 20 fold! c) If you have to spell out that the mat has to be removed at the end of the compounding activity, likely your compounders are not cleaning! (you cannot clean the PEC if there is a mat in it!) IF you cannot provide evidence of the NEED (not assumption) to change the mat for EVERY preparation, then **Recommend to remove.**
1737.14(b)	(b) When dispensing a compounded antineoplastic HD to a patient or patient's agent, the pharmacy shall provide, or offer for purchase, a sufficient supply of ASTM D-6978 standard chemotherapy gloves, to allow for appropriate administration, handling, and disposal of the HD. A compounded antineoplastic HD preparation that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code is exempt from this requirement.	This is poorly phrased. Gloves to not allow for appropriate administration or disposal of the HD. Gloves are merely used to handle the compound during administration or disposal. **Recommend to reword:** (b) When dispensing a compounded antineoplastic HD to a patient or patient's agent, the pharmacy shall provide, or offer for purchase, a sufficient supply of ASTM D-6978 standard chemotherapy gloves, to allow for appropriate ~~administration,~~ handling~~, and disposal~~ of the HD during administration and disposal. A compounded antineoplastic HD preparation that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code is exempt from this requirement.

1737.17(a), (b), and (c)	(a) A facility shall maintain and follow written SOPs for all situations in which HDs are compounded or crushing or splitting tablets or opening capsules of antineoplastic HDs is performed. (b) A facility where compounding of HDs is performed or where crushing or splitting tablets or opening capsules of antineoplastic HDs is performed shall have SOPs that include at least the following: (1) Hazard communication program (2) Occupational safety program (3) Designation of HD areas, if compounding (4) Receipt, if compounding (5) Storage, if compounding (6) Compounding, if applicable (7) Use and maintenance of proper engineering controls (e.g., C-PECs, C-SECs, and CSTDs), if applicable (8) Hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, manipulation, administration, spill, and disposal), as applicable (9) Deactivation, decontamination, cleaning, and disinfection (10) Dispensing, if applicable (11) Transport, if compounding (12) Administering, if applicable (13) Environmental monitoring (e.g., wipe sampling), if compounding (14) Disposal, if compounding (15) Spill control, if compounding (16) Medical surveillance, if compounding (c) The pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable, shall work with the facility designated person to ensure SOPs are reviewed at least every 12 months and this review is documented. Documentation of compliance with the subdivision shall be maintained for three years.	This is overly repetitive and poorly worded. **Recommend to consolidate and renumber.** (a) A facility shall maintain and follow written SOPs <u>that include at least the following</u> for all situations in which HDs are compounded or crushing or splitting tablets or opening capsules of antineoplastic HDs is performed. ~~(b) A facility where compounding of HDs is performed or where crushing or splitting tablets or opening capsules of antineoplastic HDs is performed shall have SOPs that include at least the following:~~ (1) Hazard communication program (2) Occupational safety program (3) Designation of HD areas, if compounding (4) Receipt, if compounding (5) Storage, if compounding (6) Compounding, if applicable (7) Use and maintenance of proper engineering controls (e.g., C-PECs, C-SECs, and CSTDs), if applicable (8) Hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, manipulation, administration, spill, and disposal), as applicable (9) Deactivation, decontamination, cleaning, and disinfection (10) Dispensing, if applicable (11) Transport, if compounding (12) Administering, if applicable (13) Environmental monitoring (e.g., wipe sampling), if compounding (14) Disposal, if compounding (15) Spill control, if compounding (16) Medical surveillance, if compounding ~~(c)~~ <u>(b)</u>The pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable, shall work with the facility<u>'s</u> designated person to ensure SOPs are reviewed at least every 12 months and this review is documented. Documentation of compliance with ~~the~~ <u>this</u> subdivision shall be maintained for three years.

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Dr. Seung Oh
President
California State Board of Pharmacy
2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833

January 27, 2025

President Oh and Members of the California State Board of Pharmacy,

First let me express my deep gratitude to this Board for listening to the concerns of it's licensees and, more importantly, addressing an issue that is directly affecting children's health in California. I know we have had much discussion on the topic of medication flavoring and you're likely ready to move on to more serious and consequential matters. But to the young children struggling to take their medicine because it tastes awful, there is nothing you could do this year that is more important than helping to get flavoring back in California's pharmacies. For that reason, I applaud you for taking another look at how flavoring is regulated in California, and providing pharmacies with relief from unnecessary and over-burdensome rules.

I have provided our comments per your preferred format on the ensuing page. Thankfully, they are brief, which is a good indication that the language you are proposing is solid. I look forward to the next discussion, which I hope leads to a positive and swift resolution to this important issue.

Respectfully Yours,

Chad Baker
Senior Vice President, Government Relations
FLAVORx, Inc.
cbaker@flavorx.com

Institution/Contact Name	FLAVORx/Chad Baker	
Section, Subdivision	**Proposed Language**	**Recommendation/Comment**
1735.1, Introduction & Scope.	(i) A facility that limits compounding to combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13.	Recommendation: "A facility that compounds using flavoring agents combined with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient or patient's agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13." Dropping the word "limits" clears up the confusion around whether sections 1735.2-1725.13 would apply to all flavorings should a facility also perform occasional compounding of Tamiflu, amoxicillin, magic mouthwash, etc.
1735.15. Flavoring Agents.	(a) In addition to the standards in USP Chapter 795 and the Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) a facility that limits its compounding as described in Section 1735.1(i) shall establish the following SOPs:	The underlined text infers facilities would need to comply with USP 795 standards in order to flavor medications. If that is the Board's intention, then the exemptions spelled out in 1735.1 (i) will not bring flavoring back to California's pharmacies. The application of USP 795 standards to the practice of flavoring is what drove pharmacies away from providing the service. If that is not the Board's intention, then one possible solution is to remove that reference and go with: "(a) a facility that limits its compounding as described in Section 1735.1(i) shall establish the following SOPs:"

CSPS
CALIFORNIA SOCIETY of PLASTIC SURGEONS

January 27, 2025

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

re: Proposed Regulations on Compounded Drug Preparations, Hazardous Drugs and Radiopharmaceuticals

Dear Ms. Martinez,

The California Society of Plastic Surgeons (CSPS) appreciates the opportunity to provide additional comments on the proposed regulations on compounded drug products. Plastic surgeons provide highly skilled surgical services that improve both the functional capacity and quality of life of patients. These services include the treatment of congenital deformities, burn injuries, traumatic injuries, hand conditions, and cancer.

We appreciate the Board reviewing our previous comments on December 9th. We have reviewed the staff responses to our comments and continue to be concerned with the applicability of the proposed regulations on physicians and their ability to "compound" medications in their offices. Although physicians may not be under the enforcement jurisdiction of the Board of Pharmacy, we believe the proposed regulations would change the standard of care for physicians who compound medications. This is also mentioned in the letter referenced in the staff comments from Reji Varghese of the Medical Board of California and quoted below.

> *It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine).*

We believe the proposed regulations change the standard of care and will not allow physicians to buffer certain medications such as lidocaine in-office. As you may know, buffered lidocaine is created when sodium bicarbonate is added to lidocaine with or without epinephrine using aseptic technique to neutralize the pH of the preparation. The buffering of lidocaine significantly decreases the subjective pain of the injection and increases the onset of the local anesthesia for the patient. After the anesthetic takes effect, a surgeon can perform procedures in the least-expensive place of service – the office.

We believe it is important to note there are no existing issues that we are aware of related to physicians buffering medications such as lidocaine or marcaine. We have not heard of any patient harm coming as a result of this type of compounding.

We would like to propose the Board of Pharmacy amend the proposed regulations to include the language below which is being proposed by the California Medical Association.

> **§ 1735.1:** In addition to the standards in USP Chapter 795 and, Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the compounding of a CNSP shall meet the following requirements of this article. **This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.**
>
> **§ 1736.1:** In addition to the standards set forth in USP Chapter 797 and Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the following requirements apply throughout this article. **This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.**
>
> **§ 1737.1:** In addition to the requirements in USP Chapter 800 and Food Drug Cosmetic Act (FDCA) section 503a (21 U.S.C. §353a) the following requirements apply to the compounding of Hazardous Drugs. **This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.**
>
> **§ 1738.1:** In addition to the standards in the USP Chapter 825, the processing of Radiopharmaceuticals shall meet the requirements of this section. **This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.**

We believe these changes will allow for physicians to continue buffering medications in the manner they have been for years benefiting patients. We appreciate your consideration of our requested changes.

Respectfully,

Gordon K. Lee, MD
President, California Society of Plastic Surgery

CALIFORNIA MEDICAL ASSOCIATION

January 27, 2025

Lori Martinez
Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
PharmacyRulemaking@dca.ca.gov

Sent via e-mail

RE: Compounded Drug Products Regulations, Second Modified Text Jan. 10, 2025

Dear Ms. Martinez:

On behalf of our over 50,000 medical student and physician members, the California Medical Association (CMA) submits the following comments on the second modified text of the Board of Pharmacy's (Board) proposed Compounded Drug Products regulations. The Board proposes to amend, repeal, and replace existing regulations, and to adopt new regulations relating to drug compounding.

1. **Language of Proposed Text Conflicts with Board's Description of Its Effect (throughout all sections)**

CMA is disappointed by the Board's refusal to revise its proposed language to clarify that the regulations do not apply to physicians. In its response to public comment requesting clarification on whether the regulations apply to physicians and other licensed practitioners, the Board effectively stated the regulations do not apply to licensees of other healing arts boards, noting: "[…] [the] Board's regulations apply to licensees within the Board's jurisdiction. The Board's jurisdiction is limited to those businesses and individuals within its practice act."[1]

The language of the proposed regulations, however, is written in a manner that could be construed to apply to compounding in any setting and by any individual,[2] because their scope is not expressly limited to pharmacists and pharmacies, unlike the current regulation[3]. Thus, the Board's proposed regulations continue to violate the clarity standard of the

[1] Board Jan. 8, 2025 Meeting Materials, Staff Recommended Responses: General Comments, p. 13, https://www.pharmacy.ca.gov/meetings/agendas/2025/25_jan_bd_mat_gen_comm.pdf.
[2] The proposed regulations are generally drafted to apply to the act of compounding, and are not expressly limited to licensees of the Board of Pharmacy. See, e.g., proposed regulation text at § 1735.1 ("[…] the compounding of a CNSP shall meet the following requirements of this article."); § 1735.2 ("[…] the compounding of CNSP shall meet the following requirements of this article."); §§ 1735.3-1735.12 & 1735.14 ("[…] the following requirements apply to nonsterile compounding."); §§ 1736.2-1736.9, 1736.11-1736.20 ("[…] the following requirements apply to sterile compounding."); § 1736.21 ("[…] the following requirements apply to allergenic extracts.").
[3] 16 CCR § 1735(a) (defining "compounding" to mean "activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription").

Administrative Procedure Act because the language of the regulations plainly conflicts with the Board's description of the effect of the regulations.[4]

CMA reiterates its request from CMA's prior comment letter dated December 9, 2024, to revise the proposed regulations to clarify they do not apply to compounding performed by physicians outside of a pharmacy setting, so that the proposed language of the regulations aligns with the Board's description of the effect of the regulations.

2. **Requirement to Verify a Preparation Produces a Clinically Significant Difference Interferes with Exercise of Professional Judgment and Exceeds Federal Law (§§ 1735(d), 1735.1(e)(1)(B), 1736(d), 1736.1(e)(1)(B))**

CMA is concerned that the Board's proposed modified text establishes a new requirement for pharmacists to "verify" that a prescribed compounded drug product produces a clinically significant difference for the medical need of an identified individual patient under specific conditions. The changes to proposed Sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) mandate that pharmacists "verify" that each prescription for a compounded preparation, which would otherwise be essentially a copy of a commercially available drug, produces a clinically significant difference for the medical need of an identified individual patient, particularly when the product is not listed in the American Society of Health-System Pharmacists (ASHP) or Food and Drug Administration (FDA) Drug Shortages Database.

In its first modified text, the Board proposed requiring pharmacists "determine" that a compounded preparation meets this standard. However, following comments from the Outsourcing Facilities Association, the Board replaced "determine" with "verify." In its response, the Board stated:

> *[…] the practice of pharmacy includes pharmacists verifying that a prescribed medication is clinically appropriate for a patient irrespective of whether it is a compounded medication.*[5]

Further, in response to a comment from the Alliance for Pharmacy Compounding advocating alignment with the "FDA's Essential Copies Guidance document," the Board explained:

> *[…] as written, the language provides flexibility for a pharmacist to use their professional judgment when determining if a compound is essentially a copy. Should the Board amend the language to include the recommended language, the Board would be limiting this flexibility and a pharmacist's professional judgment. Further, Board staff note that the commenter appears to suggest that a pharmacist does not have an obligation to exercise clinical judgment when compounding or dispensing a medication. The Board believes*

[4] Gov. Code §§ 11340(b) & 11349.1(a)(3); 1 CCR § 16 (a)(2).
[5] Board Jan. 8, 2025 Meeting Materials, Staff Recommended Responses: Section 1735 et seq (Nonsterile), pp. 1-2, https://www.pharmacy.ca.gov/meetings/agendas/2025/25_jan_bd_mat_non_ster.pdf.

> *it is important to underscore that pharmacists must exercise clinical judgment in all aspects of practice and not simple [sic] defer their judgment to another individual. This is [sic] obligation is memorialized throughout Pharmacy Law, including notably BPC Section 4306.5.*[6]

CMA acknowledges the role of pharmacists exercising professional judgment, as outlined in Business and Professions Code (BPC) section 4306.5. However, the proposed requirement to "verify" introduces unnecessary and unintended rigidity into the process. Contrary to the Board's assertion, mandating verification in every instance of compounding a drug that is otherwise commercially available and not on a shortage list sets a prescriptive standard for how pharmacists must exercise their professional judgment. The language of the regulations expressly requires pharmacists to verify the existence of a clinically significant difference for each compounded preparation in this situation, rather than allowing pharmacists to exercise their professional judgment as to when such verification may be warranted. This mandate impedes the flexibility the Board claims to seek to preserve and, as such, the language violates the clarity standard because it conflicts with the Board's description of the effect of the regulations in its response above.[7]

Pharmacists are already obligated to exercise judgment when dispensing dangerous drugs and are empowered by BPC section 733(b)(1) to refuse to dispense a prescription based on professional judgment, potential harm, or legal concerns. Eliminating the "verify" requirement from the proposed regulation would not abrogate pharmacists' statutory responsibilities but would instead maintain the flexibility pharmacists need to practice most effectively.

The verification requirement would also impose significant administrative burdens on both pharmacists and prescribing physicians. For each compounded medication, pharmacists would need to collect and document proof of verified clinical significance for the prescribed drug, while physicians may be required to provide additional supporting evidence. This process could lead to delays in dispensing compounded medications, creating barriers for patients who rely on these treatments. For some patients, such delays could limit timely access to necessary therapies, ultimately harming their care.

Finally, federal law, specifically 21 USC § 353a and 21 CFR Part 216, does not establish a documentation requirement, let alone a verification requirement for compounding. FDA guidance only recommends that "[…] the compounder should ensure that the determination is documented on the prescription."[8] The guidance also clarifies that the FDA "[…] generally does not intend to question prescriber determinations that are documented in a prescription

[6] Id. at 6.
[7] Gov. Code § 11349.1(a)(3); 1 CCR § 16 (a)(2).
[8] FDA, *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry*, p. 8, Section III.B.2, https://www.fda.gov/media/98973/download.

or notation."[9] Current state regulations require pharmacists to retain the documentation of the determination of clinical significance.[10]

The Board's proposal, however, goes beyond all of these standards by mandating that pharmacists both verify and document the prescriber's determination. This additional verification obligation introduces a new requirement, not a clarification of existing state or federal statute. By creating this new regulatory standard, the proposal could be interpreted to place an unprecedented burden on pharmacists, that of duplicating the evaluation already made by the prescriber. This shift in legal construction is unnecessary, given that pharmacists are already accountable for using their professional judgment to ensure compliance with established pharmacy laws.

For these reasons, CMA recommends deleting "verify and" from proposed sections 1735(d), 1735.1(e)(1)(B), 1736(d), and 1736.1(e)(1)(B) of the second modified text. This would maintain the documentation standard established in current regulation while ensuring pharmacists retain the flexibility to perform verifications as deemed appropriate based on their professional judgment, as intended by the Board.

Thank you for your consideration. Please feel free to contact me with any questions at (916) 444-5532 or asanchez@cmadocs.org.

Sincerely,

S. Alecia Sanchez
Chief Strategy Officer
California Medical Association

[9] Id. at 9.
[10] 16 CCR § 1735.2(d)(3).

Comments of Professional Compounding Centers of America, Inc. (PCCA) regarding the California Board of Pharmacy's proposed "Second Modified Text" to Title 16 CCR Sections 1735 et seq, 1736 et seq, 1737 et seq, and 1738 et seq related to Compounded Drug Preparations, Hazardous Drugs, and Radiopharmaceuticals. Submitted to Lori Martinez at PharmacyRulemaking@dca.ca.gov on January 27, 2025.		
Section, Subdivision	**Proposed Language**	**Recommendation/Comment**
Section 1735.7(c)(1)	The manufacturer, lot number, and expiration date for each component.	Recommend: We recommend that the clause in Section 1735.7(c)(1) be removed entirely. Rationale: **1. Protection of Corporate Proprietary Information**: The identity of the manufacturer of an API is corporate proprietary information and is considered a trade secret for entities such as PCCA. The information holds significant value because disclosing the identity of carefully sourced suppliers would grant competitors a substantial and unfair business advantage. PCCA and other similar businesses, have invested heavily in developing relationships with manufacturers, performing rigorous vetting processes, and ensuring compliance with stringent quality standards. Public disclosure of this information would undermine these efforts and expose suppliers' business models to harm. Suppliers' customarily treat the identity of manufacturers as confidential and provide this information directly to FDA under strict assurances of privacy. The FDA recognizes the sensitivity of this information and allows suppliers to designate it as "confidential" when submitted through the Drug Registration and Listing System. Importantly, the FDA does not release this information publicly in its otherwise comprehensive National Drug Code (NDC) Directory. Similarly, the FDA excludes this information from reports it makes public regarding compounded drug products manufactured by outsourcing facilities. These practices reflect a consistent understanding of the confidential and proprietary nature of this information at the federal level.

		2. California State Laws Protect Trade Secrets: California law explicitly protects proprietary information, including trade secrets relating to food, drugs, and cosmetics. Under the California Public Records Act, Cal. Gov. Code, §§ 6250 et seq., corporate records and trade secrets are exempt from public disclosure. Specifically, § 6254.15 shields "corporate proprietary information including trade secrets." Further, the California Health and Safety Code § 110165 precludes the state from disclosing any information acquired about trade secrets, emphasizing that such proprietary information are entitled to protection. **3. Alignment with Federal Standards:** The proposed requirement goes beyond existing federal regulatory standards, including USP Chapters 795 and 797, which do not mandate disclosure of the manufacturer in compounding records. Instead, USP standards require documentation of the lot number, expiration date, and supplier information, which ensures traceability and accountability without risking the exposure of trade secrets.
Section 1736.9(d)	When the COA is received from a supplier, it must provide the name and address of the manufacturer. An API provided with a COA without this data shall not be used in a CSP.	Recommend: Remove the language: "When the COA is received from a supplier, it must provide the name and address of the manufacturer. An API provided with a COA without this data shall not be used in a CSP." Rationale: See comment in response to Section 1735.7(c)(1). **1. No Legal or Regulatory Requirement for Manufacturer Information on COAs:** Neither the FDCA nor any FDA implementing regulation—or even a non-binding guidance document—includes a "requirement for the COA" from a supplier to disclose the manufacturer name or address. Under the FDCA the sole requirement for COAs is that compounded drugs must be accompanied by valid COAs for their bulk drug substances to qualify for exceptions to the FDCA.

		Specifically: - 21 U.S.C. § 353a(b)(1)(a)(iii) requires that compounded drugs must be accompanied by valid COAs to qualify under Section 503A exemptions. - 21 U.S.C. § 353b(a)(2)(D) similarly requires valid COAs for bulk drug substances under Section 503B exemptions. Neither the FDCA nor FDA regulations impose any obligation to include the manufacturer's information on a COA. Instead, the FDA has long accepted the practice of suppliers providing COAs that incorporate quality testing data from the suppliers themselves as well as data from the manufacturer's own quality testing. **2. FDA Guidance Does Not Impose Such a Requirement:** FDA guidance documents related to compounding further underscore the lack of any requirement to include manufacturer information on COAs. **The FDA Guidance for Industry: Pharmacy Compounding of Human Drug Products Under Section 503A** (June 2016) states only that compounded drug products must be accompanied by valid COAs for each bulk drug substance. There is no mention of manufacturer information being required on the COA. While the nonbinding **FDA Guidance for Industry: Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients** *recommends* including the manufacturer's name and address on COAs in the context of cGMP compliance for outsourcing facilities, it has no implication here as it applies solely to outsourcing facilities operating under Section 503B of the FDCA. It does not apply to compounding pharmacies operating under Section 503A, which are expressly exempt from cGMP requirements. See 21 U.S.C. § 353a(a) (exempting 503A compounded formulations from cGMP requirements imposed under 21 U.S.C. § 351(a)(2)(B)). This distinction is critical. cGMP compliance is irrelevant to Section 503A compounding pharmacies, and the FDA has recognized that requiring manufacturer

		information on COAs is not necessary to meet the requirements of Section 503. **3. Unintended Negative Impacts:** Mandating the inclusion of manufacturer information on COAs, as proposed by the California Board of Pharmacy, would impose unnecessary burdens on compounding pharmacies and suppliers alike. The harmful consequences of the proposed regulations include (1) exposing proprietary sourcing strategies—which are considered trade secrets—in violation of California law, and (2) a regulation that diverges from federal standards and guidance, creating unnecessary confusion and inconsistency for suppliers and compounding pharmacies operating across multiple jurisdictions.
Section 1736.11(c)(2)	The manufacturer, lot number, and expiration date for each component for the CSP.	Recommend: Remove the clause entirely. Rationale: See comment in response to Section 1735.7(c)(1).
Section 1738.11(b)	When the COA is received from a supplier, it must provide the name and address of the manufacturer.	Recommend: Remove the language: “When the COA is received from a supplier, it must provide the name and address of the manufacturer.” Rationale: See comment in response to Sections 1735.7(c)(1) and 1736.9(d).