WRITTEN COMMENTS RELATED TO SELF-ASSESSMENTS

From: Alireza Alibanaei
To: McFall, Julie@DCA
Subject: Comment on Draft Self-Assessment Forms
Date: Thursday, April 16, 2026 1:51:31 PM

Dear Ms. McFall,

Thank you for the opportunity to provide comments on the draft self-assessment forms currently under consideration.

While self-assessments are an important tool for promoting compliance and patient safety, I respectfully recommend that the Board consider the operational realities faced by community pharmacies, particularly independent pharmacies. The increasing complexity and volume of documentation requirements can place significant administrative burdens on pharmacies already operating under staffing and reimbursement constraints.

To improve effectiveness, I suggest that the Board:

- Streamline self-assessment forms to focus on high-risk and patient safety–critical areas
- Avoid duplicative or overly burdensome documentation requirements
- Provide clear guidance and practical examples to assist pharmacies in completing the assessments accurately

Additionally, fair reimbursement for pharmacists' professional services remains a critical issue. Without addressing financial pressures—particularly those related to PBM reimbursement—pharmacies may struggle to allocate sufficient time and resources toward meaningful self-assessment and quality improvement activities.

A balanced approach that supports both compliance and operational sustainability will ultimately lead to better patient care and safer pharmacy practice.

Thank you for your consideration.

Sincerely,
Alireza Alibanaei, Pharm.D.
Pharmacy Owner

WRITTEN COMMENTS
RELATED TO
SURGICAL SELF-ASSESSMENT

From: Brian S. Chu
To: McFall, Julie@DCA
Subject: Self assessment comments.
Date: Friday, April 17, 2026 8:22:32 PM

Hello

Please see some comments for the self assessments.

Positives
1. Really like the format and the instructions for no and n/a
2. Really like the reference to bpc or code. That helps with finding more.
3. Like having the section on discharge meds on the hospital self assessment

Considerations
1. Remove the initials on each page
2. Keep the detailed specifics for each line. It is more general now and requires detailed review of each statute
3. Clarify why surgical clinic is highlighted and not other types of clinics.
Thank you.

From: Ma, SangSang
To: McFall, Julie@DCA
Subject: Public Comment: Draft Surgical Clinic Self-Assessment
Date: Tuesday, April 21, 2026 6:48:02 PM
Attachments: Outlook-prm0rmcd.png
Outlook-nega3cem.png
Outlook-0a4ssi0w.png
Outlook-bt2vd0hf.png

Dear Board Members,

Thank you for the opportunity to provide feedback on the draft Surgical Clinic Self‑Assessment. We appreciate your work on this important document. Please find our questions and comments outlined below. Thank you for your consideration.

Surgical Clinic Self-Assessent Change 2026

Section/Reference	Section/Topic	Comments
Page 1	Page 1	What is the goal of changing the self‑assessment format? Specifically, how does the new approach—using hyperlinks to reference guidelines rather than listing them in full—improve the process?
Page 2	Clinic Administrator; License #; Expiration Date:	Not all Administrators in our ASCs hold clinical licensure. We recommend removing the word *"Clinic"* from the title and adding *"(if applicable)"* next to *"License # and Expiration Date"* to accommodate those who do hold licenses.
Page 2	"Type of Sevices Provided" "ADDS License # (list):"	What is the requirement for an ASC that utilizes an ADDS? Based on the statement below, it appears that an ASC's ADDS would not require its own license, since the Board may only issue an ADDS license to a California‑located pharmacy with a current, valid, and active pharmacy license. Under this language, the ADDS must operate under the supervision of the pharmacy that holds the ADDS license, not the ASC. "The Board may issue an ADDS license to a California‑located pharmacy with a current, valid, and active pharmacy license. An ADDS shall only be operated under the supervision of the pharmacy holding the ADDS license." Could you please clarify whether an ASC is required to obtain any additional licensure or documentation when using an ADDS?
Section 1: Facility Requirements BPC 4013 BPC 4190	The clinic notifies the Board of any change in the clinic's address or email address.	The following language outlines the requirement for facilities to join and maintain the Board's email notification list: "(a) Any facility licensed by the board shall join the board's email notification list within 60 days of obtaining a license or at the time of license renewal. (b) Any facility licensed by the board shall update its email address with the board's email notification list within 30 days of a change in the facility's email address." **We recommend adding a clear timeline reference to section 1.2 verbiage so that the required timeframes (60 days and 30 days) are immediately visible and not overlooked.**

Best Regards,

SangSang Ma, PharmD, MBA
Director of Pharmacy

Sutter Surgery Center Division (SSCD)
Ambulatory Surgery Centers (ASCs) Service Line
Sutter Health System Office – Pharmacy Services

FTO Alert: April 9th & 10th, 2026

Sutter Health

Telephone/Text: (916)224-2291
Email: SangSang.Ma@SutterHealth.Org

SutterHealth.Org

From: Sandra Bardas
To: McFall, Julie@DCA
Subject: Comments for Surgical Clinic Self assessment
Date: Thursday, April 23, 2026 11:07:01 AM

I noticed that you added Clinic Administrator on p2. I am unclear as to what type of license is being referred to in this entry. Is there a specific clinic administrator license and if so, what agency is responsible for that licensure? Are you really referring to the Nurse Manager of the Clinic? If so, it would be better to make that clarification.

Sandra Bardas
Consultant Pharmacist RPH32539

WRITTEN COMMENTS RELATED TO WHOLESALER/THIRD-PARTY SELF-ASSESSMENT

From: Charles Martinson
To: McFall, Julie@DCA
Cc: Dale Schleich; Phuong-Ha Ngo
Subject: Re: Public Comment on Proposed Use of Wholesaler and Third-Party Logistics Provider Self-Assessment for Virtual Manufacturers
Date: Friday, April 17, 2026 7:00:02 PM

Dear Members of the Board and Julie McFall,

I am writing in response to the California State Board of Pharmacy's request for public comment regarding the proposed use of the Wholesaler and Third-Party Logistics Provider Self-Assessment (Form 17M-26, Draft dated April 16, 2026) as an inspection and compliance tool for virtual manufacturers.

Arcutis Biotherapeutics, like many modern pharmaceutical companies, operates as a virtual manufacturer. While we retain full regulatory responsibility for product quality, compliance, and oversight, we do not own or operate physical drug storage, distribution, or handling facilities. Those activities are performed by licensed and inspected third-party partners, such as contract manufacturers, third-party logistics providers, and wholesalers, that are already subject to oversight by the Board, FDA, and DEA under their respective licenses.

The current self-assessment checklist was developed for entities that physically possess, store, and distribute drugs. This is evident throughout the document in requirements related to premises, facility security systems, temperature and humidity monitoring, physical inventory storage, quarantine areas, receipt and delivery of drugs, and on-site inspections. Applying this checklist to virtual manufacturers introduces significant ambiguity, as many sections are structurally inapplicable by design rather than due to noncompliance.

As a result, virtual manufacturers are placed in a position where they must interpret applicability, thereby increasing the likelihood of inconsistent interpretation between inspectors and licensees, and it does not meaningfully enhance patient safety or supply

chain integrity.

Virtual manufacturers are not seeking reduced oversight. Rather, we support clear, enforceable, and role-appropriate regulatory expectations that reflect how accountability is exercised in modern pharmaceutical operating models. Virtual manufacturers meet their obligations through governance mechanisms such as quality agreements, partner qualification and auditing, supply chain security programs, Drug Supply Chain Security Act (DSCSA) compliance, deviation and complaint oversight, recall coordination, and regulatory reporting. These activities are core to compliance.

For these reasons, we respectfully request that the Board consider developing a separate inspection and self-assessment framework specifically tailored to virtual manufacturers, rather than extending a wholesaler or third-party logistics provider checklist to us. A virtual manufacturer-specific inspection list would reduce confusion, improve consistency, and enable inspectors to evaluate compliance against requirements that are directly relevant and objectively applicable.

Such a framework could focus on governance and accountability structures, oversight of licensed third-party partners, quality and technical agreements, supply chain security and DSCSA compliance, recall readiness, complaint management, change management, regulatory reporting, and documentation and auditability.

We appreciate the Board's willingness to solicit stakeholder input and its efforts to adapt regulatory oversight to evolving pharmaceutical business models. Arcutis welcomes the opportunity to participate in further discussions to support the development of a virtual manufacturer-specific inspection approach.

Thank you for your time.

My best,

Charles Martinson, *Designated Representative*

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cmartinson@arcutis.com ½ www.arcutis.com
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From: Laura M Dawly
To: McFall, Julie@DCA
Subject: Draft Wholesaler/Third-Party Logistics Provide Self-Assessment addendum request for dialysis
Date: Wednesday, April 22, 2026 1:42:58 PM
Attachments: Outlook-sns0oe5z.png

Good afternoon,
After reviewing the wholesaler self-assessment, I was hoping for possible clarification addendum for the dialysis Cal. Code Regs. Tit. 16, &1787- authorization to distribute Dialysis drugs and devices. I work for a Distribution Center that ship prescription and medical devices directly to home patients. I was hired here for the state of Nevada- BOP needing a license RPH for these products shipped to their state. California, however, I'm told that I am NOT needed due to this current existing regulation. I believe this regulation is decades old and possibly was under the original assumption that this was for physician and RN supervised dialysis clinics having access to dialysis medications.

There might be loopholes as currently written, possibly putting these patients in harm' s way for patients receiving home treatments. 16 CCR & 1787 (b) The drugs and devices specified in 1787(a) may be distributed on the basis of s written or oral order received from a licensed prescriber. The prescriber or his or her authorized employee may transmit orders directly to a pharmacist or a designated representative. I am told that I am NOT a pharmacy, thus a designated representative is replacing the use of a pharmacist to ensure accurate orders being shipped directly to patients, essentially warehouse workers with minimum high school education and no mandatory state exam for a designated representative license is meeting these guidelines for FDA mandated prescription dialysate and medical devices.

My concerns are:

1. Who is verifying a valid order/ prescription if no RPH has determined correct dosage?
2. Are warehouse workers qualified for final product verification for prescription home orders?
3. Possibly a more rigorous state testing for Designated Rep license to ensure qualified individuals
4. Specify RX label requirements for these "non-prescriptions"

For these reasons, I wanted to submit a request for a more detailed wholesaler self-assessment or addendum for dialysis under CCR Tit. 16, 1787.

Laura Michelle Dawly, Pharm.D.
Distribution Pharmacist in Charge
Manufacturing & Supply Chain Care Enablement

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From: Watson, Sara
To: McFall, Julie@DCA
Cc: Constable, Nathan
Subject: Cardinal Health - Feedback Re: Wholesaler/ Third-Party Logistic Provider Self-Assessment Form
Date: Thursday, April 23, 2026 1:43:23 PM
Attachments: image001.png
Cardinal Health_Wholesaler 3PL Self Assessment Feedback_04 2026.pdf

Good afternoon Ms. McFall,

Please find attached Cardinal Health's feedback in response to the recent draft Wholesaler/ Third-Party Logistic Provider Self-Assessment Form.

Thank you,

Sara Watson, CPhT
Manager, Regulatory Affairs
WIN SOUTH ERG Co-Chair
614.339.3134 - Direct Line
Remote – Texas
Adaptability | Harmony | Empathy | Consistency | Developer

Click here for resources on our Controlled Substance Monitoring Program.

Sara Watson, CPhT
Manager, Regulatory Affairs

Cardinal Health
7000 Cardinal Place
Dublin, OH 43017
614.339.3134 tel

cardinalhealth.com

VIA Email To: julie.mcfall@dca.ca.gov

April 23, 2026

Julie McFall
Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
(916) 701-2283

RE: Wholesaler/ Third-Party Logistic Provider Self-Assessment Feedback

Dear Ms. McFall:

I am writing regarding the revised Wholesaler/Third-Party Logistic Provider Self-Assessment draft on behalf of Cardinal Health, Inc. (NYSE: CAH) (Cardinal Health).

About Cardinal Health

Cardinal Health is a publicly traded distributor of pharmaceuticals, a global manufacturer and distributor of medical and laboratory products, and a provider of performance and data solutions for health care facilities. With more than 50 years in business, operations in more than 30 countries and approximately 46,500 employees globally with 3,572 living in California. Cardinal Health is essential to care. We serve:

- roughly 90 percent of U.S. hospitals;
- more than 29,000 U.S. pharmacies;
- more than 3.4 million U.S. patients with more than 46,000 home healthcare products;
- more than 6,200 U.S. labs with nearly 51,000 laboratory products;
- more than 10,000 specialty physician offices and clinics.

Cardinal Health also maintains 55 facilities located in California, including our pharmaceutical distribution centers located in Valencia, CA and Elk Grove, CA.

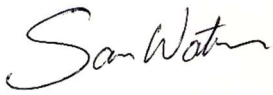
Specific Comments to the Draft

Cardinal Health appreciates the Board of Pharmacy's (Board) approach to simplify and consolidate the self-assessment form. Additionally, allowing for electronic signature is a welcome change.

Cardinal Health does request the Board update the recognized accrediting body listed on page 3 of the draft to reflect changes since the last revision. In 2020, the National Association of Boards of Pharmacy (NABP) transitioned its Verified-Accredited Wholesale Distributors (VAWD) program to NABP Drug Distributor Accreditation[1]. To reflect the change and prevent confusion, Cardinal Health requests replacing "VAWD Accreditation #" with "NABP Accreditation #."

Thank you for your consideration of Cardinal Health's comments. Should you have any questions, please feel free to contact me at sara.watson@cardinalhealth.com.

Sincerely,



Sara Watson, CPhT
Manager, Regulatory Affairs

[1] "Rebranding Continues with New Names, Logos for Accreditation Programs," February 20, 2020, https://nabp.pharmacy/news/blog/rebranding-continues-with-new-names-logos-for-accreditation-programs/#:~:text=The%20National%20Association%20of%20Boards%20of%20Pharmacy,(VAWD)**%20Transitions%20to%20NABP%20Drug%20Distributor%20Accreditation

From: Gunson, Frank
To: McFall, Julie@DCA
Cc: Gunson, Frank
Subject: Draft Wholesaler/Third-Party Logistics Provider Self-Assessment Request for Comments
Date: Monday, April 27, 2026 4:49:44 AM
Attachments: image001.png

Good morning-

McKesson appreciates the California Board of Pharmacy's continued engagement with stakeholders and the opportunity to provide comments on the wholesaler self-assessment form. We support the Board's objective of promoting compliance through self-examination and education and offer the following comments in a collaborative spirit, with a focus on alignment, efficiency, and risk-based oversight.

Primary Recommendation: Reciprocity for Accredited and Certified Facilities

As a priority, we respectfully request the Board consider formal reciprocity or regulatory deference for wholesale distributor and third-party logistics facilities that maintain:

- NABP Drug Distributor Accreditation; and/or
- ISO-certified quality management systems (e.g., ISO 9001), where applicable.

These programs provide rigorous, independent verification of licensure and regulatory standing, facility controls, personnel oversight, written policies and procedures, recordkeeping, and supply-chain safeguards.

Consideration: The Board may wish to consider whether facilities, upon furnishing evidence of current NABP Drug Distributor Accreditation and/or ISO-certified quality management systems, could be eligible for abbreviated self-assessment sections, reduced duplication, or streamlined affirmative responses for overlapping control areas, thereby meaningfully reducing administrative burden for both licensees and the Board while preserving strong regulatory assurance and public-health protections.

Opportunities to Reduce Duplication

Several sections of the self-assessment form appear to duplicate information already verified through licensure and renewal processes, routine inspections, and recognized third-party accreditation oversight. Examples include licensure status confirmations, DEA registration attestations, and broad statements of compliance with all applicable laws. These questions increase administrative effort without providing additional insight into compliance maturity or risk posture.

Consideration: The Board may wish to consider whether elements of the self-assessment that duplicate information already verified through licensure, inspections, or recognized third-party oversight could be streamlined or consolidated, allowing both licensees and the Board to focus efforts on areas of substantive compliance risk while maintaining effective regulatory oversight.

Scope and "N/A" Considerations

Although the form permits "N/A" responses, many wholesalers repeatedly select this option for activities not performed under their licensed scope, such as corporate-level changes or product destruction. These repetitive responses add administrative burden without enhancing risk identification or compliance oversight.

Consideration: Aligning the self-assessment more closely with risk-based principles—such as by tailoring sections to the activities conducted by the facility—could improve efficiency while maintaining strong regulatory protections.

Additional Observations and Suggestions

- Form Improvements: Overall, the revised checklist appears improved compared to the prior version, including a clearer layout and more explicit, succinct prompts.
- Change-Based Reporting Model: To further enhance efficiency, the Board could consider a change-based reporting approach whereby licensees certify that previously submitted information remains unchanged, with enhanced disclosure reserved for material operational, ownership, or quality-system changes occurring since the prior reporting period.
- Technical Corrections: McKesson noted that certain embedded links reference incorrect regulations (e.g., CCR sections 1780 and 1781 linking to natural resources regulations) and that the form refers to "VAWD" rather than the current "Drug Distributor Accreditation (DDA)" terminology. Correcting these items would further improve clarity and accuracy.

We offer these comments as a constructive effort to align California's self-assessment process with risk-based regulatory principles and nationally recognized oversight frameworks. We appreciate the Board's openness to stakeholder input and welcome continued dialogue on opportunities to enhance regulatory effectiveness while reducing unnecessary administrative burden.

Best regards,

Frank Gunson
Vice President, Regulatory Affairs & Patient Safety | *m* 610.412.9650