California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

To: Board Members

Subject: Agenda Item XII. Discussion and Possible Action Related to Proposed Amendment to California Code of Regulations, Title 16, Section 1711 Related to Quality Assurance Programs, Including Comments Received During the 45-Day Comment Period

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Background:

At the February 7, 2023, Board meeting, the Board approved the proposed regulation text to amend Section 1711 related to Quality Assurance Programs. This proposal amends the board's regulations regarding quality assurance programs.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on August 9, 2024, with the comment period ending on September 23, 2024. Several comments were received during the comment period.

Attached to this memo are:

- The proposed text that was released for the 45-day public comment period.
- Board staff prepared summarized comments with recommendations.
- Institute for Safe Medication Practices (ISMP) Medication Safety Self-Assessment for Community/Ambulatory Pharmacy
- Comments received during the 45-day comment period.

At this Meeting:

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

- Adopt the regulation text as noticed on August 9, 2024.
- Amend the regulation and notice the modified text for a 15-day comment period.

Possible Adoption Language:

Accept the Board staff's recommended comment responses, approve the recommended updated modified text [either as "recommended by staff" or "as directed by the board"] for a 15-day comment period. If the Board does not receive any comments providing objections or adverse recommendations specifically directed at the proposed action or to the procedures followed by the Board in proposing or adopting the action, authorize the executive officer to take all steps necessary to adopt the proposed regulation at Section 1711 and complete the rulemaking process. Finally, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Department of Consumer Affairs
Title 16. Board of Pharmacy

Proposed Regulation Text

Quality Assurance Programs

Proposed changes made to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Amend section 1711 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows**:**

§ 1711. Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program that documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in ~~S~~section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

(1) The date, location, and participants in the quality assurance review;

(2) The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c)~~;~~, including:

(A) The date and approximate time or date range when the error occurred if known or can be determined. If it cannot be determined, the pharmacy shall note “unknown” in the record.

(B) The names of staff involved in the error.

(C) The use of automation, if any, in the dispensing process.

(D) The type of error that occurred. To ensure standardization of error reporting, the pharmacies’ policies and procedures shall include the category the pharmacy uses for identifying the types of errors.

(E) The volume of workload completed by the pharmacy staff on the date of the error, including clinical functions. If the date of the error is unknown, the average volume of workload completed daily shall be documented. For errors that occur in a community pharmacy, at a minimum the volume of workload records shall include the number of new prescriptions dispensed, the number of refill prescriptions dispensed, the number of vaccines administered, number of patient consultations given, and any other mandatory activities required by the pharmacy employer. Prescriptions filled at a central fill location and dispensed at the pharmacy must be documented separately from other prescriptions filled at the pharmacy.

(3) The findings and determinations generated by the quality assurance review; and~~,~~

(4) Recommend changes to pharmacy policy, procedure, systems, or processes, if any. The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program. Documentation of the steps taken to prevent future errors shall be maintained as part of the quality assurance report.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least ~~one~~ three years from the date the record was created. Any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the ~~b~~Board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal of the facility license.

(g) The pharmacy's compliance with this section will be considered by the ~~b~~Board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

NOTE: Authority cited: Sections 4005 and 4125, Business and Professions Code~~; and Section 2 of Chapter 677, Statutes of 2000~~. Reference: Sections 4125 and 4427.7, Business and Professions Code.

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Proposed Regulation to Amend Title 16 CCR Section 1711, Quality Assurance Programs

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Summarized 45-day Comments Regarding Quality Assurance (QA) Programs with Board Staff Recommendations:

Written Comments from Daniel Luce, CLM Pharmacy Advisors

Comment 1: Commenter expressed concern that, as drafted, the proposed regulations will "increase the administrative burden on pharmacies and will result in pharmacies not reporting quality related events and medication errors." The commenter requests that the proposed regulation be replaced with the regulations adopted by the Ohio Board of Pharmacy. (Commenter provided a link to a pdf; however, the link appears incomplete or incorrect as Board staff could not retrieve the document.)

Response to Comment 1: Board staff does not recommend any changes to the text based upon the comment. Board staff acknowledge that the proposed language includes additional data elements not required in the Board's current quality assurance regulations. QA programs are designed to document and assess medication errors to determine the cause and appropriate response to improve pharmacy service quality and prevent future errors. Public comments provided to the Board revealed that pharmacists were identifying additional contributing factors, but were prevented from including such factors at the direction of the licensee owner. Such an approach undermines the value of the QA process. To address, the Board determined it necessary to mandate additional reporting elements.

Further, Board staff note that prior Board discussions included discussions on implementing Just Culture by other Boards of Pharmacy, including Idaho and New Jersey. The Board's QA program is generally consistent with Just Culture, which encourages a systematic review of a medication error, including environmental factors, workflow, use of devices, and staffing patterns. Additionally, Board staff note that the Board previously discussed this issue in detail in prior Medication Error Reduction and Workforce Committee Meetings (information available on the Board's website: https://www.pharmacy.ca.gov/about/meetings_med_error.shtml).

Written Comments from Scott Young, Animal Policy Group

Comment 2: Commenter expressed concern that closed-door, mail-order veterinary pharmacies would find it challenging to comply with the requirements of 1711 due to the nature of the business practice. The commenter requests that the QA requirements be limited to human patients by adding "for a human patient" to subdivision (b).

Response to Comment 2: Board staff does not recommend any changes to the text based upon the comment. Board staff note that veterinary pharmacies are already required to comply with the requirements of section 1711.

Written Comments from Santa Clara Valley Medical Center

Comment 3: Commenter recommends removing the requirement to list the names of staff involved in the error. A requirement to report the names of staff involved in medication errors is inconsistent with other quality assurance (QA) reviews in the inpatient and outpatient setting. The commenter indicates QA reviews are intended to identify any systemic issues that need to be addressed. In contrast, other processes already exist to determine whether specific staff require discipline or other action. In addition, reporting of the names of staff involved in a medication error does not align with just culture.

Response to Comment 3: Board staff does not recommend any changes to the text based upon the comment. Board staff note that prior Board policy discussions have been clear that disclosing the names of the staff involved in the error is not intended to be punitive or assign blame but is intended to encourage an environment of learning for the individuals, and assist in improving processes/procedures and preventing the error from recurring. Further, Board staff notes that knowing the staff involved provides a full picture of what was happening within the pharmacy and why the error occurred. Additionally, Just Culture is not a "non-punitive or blame-free culture" but is focused on a system that evaluates what occurred in an error and what actions can be taken to prevent such errors in the future. According to ISMP, part of Just Culture is coaching the staff involved in the error, the decision made, and why that decision was made. The Board's QA program is generally consistent with Just Culture, which encourages a systematic review of a medication error, including environmental factors, workflow, use of devices, and staffing patterns. Board staff note that the Board previously discussed this issue in detail in prior Medication Error Reduction and Workforce Committee Meetings (information available on the Board's website: https://www.pharmacy.ca.gov/about/meetings_med_error.shtml).

Written Comments from Sheree Lowe, California Hospital Association

Comment 4: Commenter indicates that "hospital and community pharmacies are very different, with hospitals operating in a clinical environment and community

pharmacies operating in a retail, non-clinical environment." Concerning subdivision 1711(e)(2)(E) related to workload volume, the commenter indicates, "There is little to no evidence to support the need for a new costly and time-consuming requirement to gather workload statistics as part of every hospital's error reporting system."

Response to Comment 4: Board staff have reviewed the comment and recommend a change to the proposed language to provide that the requirements established in paragraph E should only apply to outpatient pharmacies.

Comment 5: Concerning subdivision 1711(f), which requires records to be retained for three years, the commenter indicates that they disagree that extending the time for record retention from one year to three years will advance error prevention and will increase the cost of health care.

Response to Comment 5: Board staff does not recommend any changes to the text based upon the comment. Board staff note that prior Board policy discussions have been clear it is necessary to maintain the records for a longer period because having the pharmacies retain the records for a longer period will help in determining and examining patterns that can assist in error reduction and prevention, both for the individual facility and industry wide. Board staff note that records can be stored electronically and can be electronically archived or purged following the end of the retention period. Additionally, Board staff note that the Board previous discussed this issue in detail in prior Medication Error Reduction and Workforce Committee Meetings (information available on the Board's website: https://www.pharmacy.ca.gov/about/meetings_med_error.shtml).

Comment 6: Commenter indicated that hospital pharmacies function very differently than community pharmacies. Commenter recommends that the Board consider the variation in the scope of services and responsibilities between the two types of pharmacies, especially given multiple state and federal regulators' extensive regulatory oversight of hospitals.

Response to Comment 6: Board staff does not recommend any changes to the text based upon this specific comment that is very general in nature; however, Board staff do recommend a change in (e)(2)(E) specifically related to the requirement to include the volume of work and suggest that the requirements apply only to outpatient pharmacies.

Written Comments from Valley Children's Hospital

Comment 7: Commenter indicated that hospital pharmacies have very different workloads and volumes compared to community pharmacies. Additionally, hospital pharmacies must comply with the QA requirements within Title 22, specifically: *(1) Evaluate, assess, and include a method to address each of the procedures and systems listed under subdivision (d) to identify weaknesses or deficiencies that could contribute to errors in the administration of medication. (2) Include an annual review to assess the effectiveness of the implementation of each of the procedures and systems listed under subdivision (d). (3) Be modified as warranted when weaknesses or deficiencies are noted to achieve the reduction of medication errors. (4) Describe the technology to be implemented and how it is expected to reduce medication-related errors as described in paragraph (1) of subdivision (a). (5) Include a system or process to proactively identify actual or potential medication-related errors. The system or process shall include concurrent and retrospective review of clinical care. (6) Include a multidisciplinary process, including health care professionals responsible for pharmaceuticals, nursing, medical, and administration, to regularly analyze all identified actual or potential medication-related errors and describe how the analysis will be utilized to change current procedures and systems to reduce medication-related errors. (7) Include a process to incorporate external medication-related error alerts to modify current processes and systems as appropriate. Failure to meet this criterion shall not cause disapproval of the initial plan submitted.*

The commenter recommends that facilities that must comply with Title 22 be excluded from subdivision (e).

Response to Comment 7: : Board staff have reviewed the comment and recommend a change to the proposed language to provide that the requirements established in paragraph E should only apply to outpatient pharmacies.

Written Comments from Sarah Pollo, California Retailers Association

Comment 8: Commenter indicates that its members will be unable to comply with the requirements of subdivision (e). The commenter stated that some of the requirements are vague and broad, the data elements are not measured, and making the required information available for Board inspections or submitting it to the Board could be an inappropriate disclosure of Patient Safety Work Product (PSWP) under the Patient Safety and Quality Improvement Act of 2005. Additionally, the commenter believes that the language does not provide sufficient details on what "mandatory activity" means. The commenter states that collecting the required information would be an administrative burden.

Response to Comment 8: Board staff have reviewed the comment and recommend a change to the text to remove the requirement for the report to

include documentation of "other mandatory activities" referenced in paragraph E.
The Patient Safety and Quality Improvement Act of 2005 does not limit sharing such information with a government agency for "public health surveillance, investigation, or other public health purposes or health oversight purposes". (42 U.S.C. section 299b-21.)

Comment 9: Commenter indicated that it is impossible to track central fill prescriptions separately as the workload is a shared responsibility across a single prescription. The commenter requests that the requirement be removed.

Response to Comment 9: Board staff does not recommend any changes to the text based upon the comment. Board staff note that the commenter appears to be misinterpreting the regulation text. The regulation text requires that prescriptions filled by a central fill location be documented separately from prescriptions volume filled at the pharmacy when documenting the total volume of prescriptions dispensed at the pharmacy on the day of the error, where applicable. The regulation does not require that the documentation be split into two documents.

Comment 10: Commenter recommends that the phrase "involved in the error" in subdivision (e)(2)(B) be replaced with "performing the step(s) in the dispensing process where the error originated and was not caught" because "involved" is overly broad.

Response to Comment 10: Board staff have considered the comment and recommend a change to the text to remove the requirement to document the name of staff involved in the error.

Comment 11: Commenter requests that the term "automation" be defined because automation is involved in nearly every prescription.

Response to Comment 11: Board staff does not recommend any changes to the text based upon the comment. Board staff note that the term "automation" is specific to the dispensing process, and staff do not believe a definition is required as in the text, the term is specifically linked to its use in dispensing.

Comment 12: Commenter requests that the requirement to include the pharmacy's categories for identifying the types of errors in the pharmacies' policies and procedures (subdivision (e)(2)(D)) be removed because they are proprietary and could jeopardize confidentiality.

Response to Comment 12: Board staff does not recommend any changes to the text based upon the comment. Board staff notes that QA reports are confidential

and would not be discoverable.

Comment 13: Commenter requests that the documentation requirement added to subdivision (e)(4) be removed as changes may be made to systems, workflow, and policies and procedures that may not be reported back to the specific individual in the field and stores cannot make changes in isolation from other stores.

Response to Comment 13: Board staff does not recommend any changes to the text based upon the comment. Board staff note that individuals in the field and stores must be aware of the steps taken to prevent future errors; otherwise, there will be no opportunity to learn from the error, which is the point of the QA process.

Comment 14: Commenter requests that the QA record retention period remain at one year instead of three because the change would require significant system updates.

Response to Comment 14: Board staff does not recommend any changes to the text based upon the comment. Board staff note that prior Board policy discussions have been clear it is necessary to maintain the records for a longer period because having the pharmacies retain the records for a longer period will help in determining and examining patterns that can assist in error reduction and prevention, both for the individual facility and industry wide. Further, Board staff notes that records can be stored electronically and can be electronically archived or purged following the end of the retention period. Additionally, the Board previous discussed this issue in detail in prior Medication Error Reduction and Workforce Committee Meetings (information available on the Board's website: https://www.pharmacy.ca.gov/about/meetings_med_error.shtml).

Comment 15: The commenter requests a one-year delayed implementation period to allow pharmacies to update their policies and procedures and systems.

Response to Comment 15: Board staff recommend that the Board establish a January 1, 2026 effective date.

Written Comments from Katrina Derry, University of California

Comment 16: Commenter recommends that subdivision (e)(2)(B), "The names of staff involved in the error" be removed from the regulation text. The commenter indicates that documenting the name may decrease voluntary reporting of errors due to fear of disciplinary action from the Board.

Response to Comment 16: Board staff have reviewed the comment and recommend a change to the proposed text based on the comment. Board staff recommend removing "The names of staff involved in the error." from subdivision

(e)(2)(B) of the proposed text.

Comment 17: Commenter indicates that hospitals and health-system operations are dynamic and challenging to quantify; as such, it will be difficult to determine the workload volume required via subdivision (e). The commenter recommends that health systems be excluded from subdivision (e) requirements.

Response to Comment 17: Board staff recommend a change to the proposed text based on the comment. Specifically, Board staff recommend removal of the requirement in (e)(2)(B) to record the names.

Written Comments from John Gray, Kaiser Permanente

Comment 18: The commenter recommends amending subdivision (d) to require medication error investigations to be completed using Just Culture principles, which were presented to the Board in 2023.

Response to Comment 18: Board staff does not recommend any changes to the text based upon the comment. Board staff note that prior Board policy discussions have been clear that the disclosure of the names of the staff involved in the error is not intended to be punitive or assign blame, and assist in improving processes/procedures and preventing the error from recurring, which is consistent with Just Culture. The Board's QA program is generally consistent with Just Culture, which encourages a systematic review of a medication error, including environmental factors, workflow, use of devices, and staffing patterns.

Comment 19: The commenter indicates that "the proposed requirement to include information about the use of automation and pharmacy workload volumes in pharmacies' QA reports" implies that two contributing factors, "technology/equipment" and "staffing and scheduling", are more important than others. Additionally, the commenter states that documentation of "the findings and determinations generated by the quality assurance review" is already required, which would already include contributing factors, such as the two mentioned. Finally, the commenter indicates they are unaware of medication error reporting systems with specific fields to document workload. They indicate systems would require costly and time-consuming updates to capture the workload. Commenter recommends that subdivisions (e)(2)(C) and (e)(2)(E) be removed.

Response to Comment 19: Board staff does not recommend any changes to the text based upon the comment. Board staff note that prior Board policy discussions have been clear it is necessary to understand the workload of the pharmacy, regardless of setting, on the day of the error in order to conduct a detailed analysis into the error and possible fatigue of the individuals involved. Additionally, Just

Culture is not a "non-punitive or blame-free culture" but is focused on a system that evaluates what occurred in an error and what actions can be taken to prevent such errors in the future. According to ISMP, part of Just Culture is coaching the staff involved in the error, the decision made, and why that decision was made. The Board's QA program is generally consistent with Just Culture, which encourages a systematic review of a medication error, including environmental factors, workflow, use of devices, and staffing patterns. As the commenter indicates documenting the findings and determinations is already required, maintaining the information with the QA report should not pose an issue. Further, Board staff note that the requirements are specific; however, licensees can determine how to collect the data based on their business practice. Board staff note that the Board previously discussed this issue in detail in prior Medication Error Reduction and Workforce Committee Meetings (information available on the Board's website: https://www.pharmacy.ca.gov/about/meetings_med_error.shtml).

Comment 20: The commenter indicates that the requirement to report medication errors with an ADDS device was added to provide the Board with data to prepare a report to the legislature as required by Business and Professions Code section 4427.8 and there is no statutory reason to continue requiring this kind of reporting. Additionally, the commenter indicates all community pharmacy medication errors will soon be reported to the Board via a Patient Safety Organization; therefore, to eliminate redundant error reporting requirements, the commenter requests that the Board eliminate the requirement to report errors related to the use of ADDS devices to the Board.

Response to Comment 20: Board staff does not recommend any changes to the text based upon the comment. Board staff notes that the proposed change is outside the scope of this regulatory action. As noted in public discussion in public meetings, the Board has noted that not all environments are required to comply with medication error reporting under the provisions of Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023).

Comment 21: The commenter disagrees with the increase in the records retention period from one year to three years as the increase will cause space issues within the pharmacy to store these records and will create additional administrative burdens for pharmacy staff. The commenter recommends that one-year records retention be maintained.

Response to Comment 21: Board staff does not recommend any changes to the text based upon the comment. Board staff note that prior Board policy discussions have been clear it is necessary to maintain the records for a longer period because having the pharmacies retain the records for a longer period will help in determining and examining patterns that can assist in error reduction and

prevention, both for the individual facility and industry wide. Board staff note that records can be stored electronically and can be electronically archived or purged following the end of the retention period. Additionally, Board staff note that the Board previous discussed this issue in detail in prior Medication Error Reduction and Workforce Committee Meetings (information available on the Board's website: https://www.pharmacy.ca.gov/about/meetings_med_error.shtml).

Written Comments from André Pieterse, Scripps Health

Comment 22: The commenter expressed concern about the requirement to include the names of the staff involved in the error, as required by subdivision (e)(2)(B). The commenter indicates that quality assurance programs are considered peer review and requiring the names of staff involved in the error causes concern that the Board and its staff will use the information during routine inspections and complaint investigations for disciplinary action against licensees. Additionally, the commenter indicated that requiring the names of the individuals involved in the error implies that blame will be placed on the individuals instead of shared accountability. The commenter believes this will cause error reduction efforts to be hampered and will lead to staff reporting fewer errors and recommends this requirement be removed from the regulation.

Response to Comment 22: Board staff have reviewed the comment and recommend removal of the requirement in (e)(2)(B) to record the names.

Comment 23: The commenter expressed concern about the workload documentation requirements of subdivision (e)(2)(E) as it could increase administrative burdens, strain resources, and may divert focus from patient care, reduce efficiency, and place additional stress on pharmacy staff. The commenter indicates that clinical workload in hospitals and other healthcare settings can vary significantly and documenting this in a standardized, consistent manner could be tremendously challenging. As acute care hospitals already have a statutory requirement (Health and Safety Code 1339.63) in place that requires medication error reduction programs (MERP), it is recommended that acute care hospitals and those institutions already mandated to follow HSC 1339.63 be exempt from the requirements of CCR 1711.

Response to Comment 23: Board staff have reviewed the comment and recommend a change to the proposed language to provide that the requirements established in paragraph E should only apply to outpatient pharmacies.

Comment 24: The commenter believes that the regulation will have minimal impact on reducing medication errors. The regulation considers errors as a "one-off event" and does not consider potential or near-miss errors. The commenter recommends that the Board consider a "well-rounded" strategy and provided the following language to replace the existing subdivision (e):

(e) Every pharmacy shall adopt a formal plan to eliminate or substantially reduce medication-related errors.
(f) Each pharmacy's plan shall do the following:
(1) Evaluate, assess, and include a method to address each of the procedures and systems listed under the categories of prescribing, prescription order communications, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, and technology to identify weaknesses or deficiencies that could contribute to errors in the dispensing and administration of medication.
(2) Include an annual review to assess the effectiveness of the implementation of each of the procedures and systems listed under subdivision (1).
(3) Be modified as warranted when weaknesses or deficiencies are noted to achieve the reduction of medication errors.
(4) Describe the technology to be implemented and how it is expected to reduce medication-related errors as described in paragraph (1) of subdivision (a).
(5) Include a system or process to proactively identify actual or potential medication-related errors. The system or process shall include concurrent and retrospective review.
(6) Include a process to regularly analyze all identified actual or potential medication-related errors and describe how the analysis will be utilized to change current procedures and systems to reduce medication-related errors.
(7) Include a process to incorporate external medication-related error alerts to modify current processes and systems as appropriate.
(~~f~~g) The ~~record~~ plan ~~of the quality assurance review,~~ as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least ~~one~~ three years ~~from the date the record was created~~. Any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the ~~b~~Board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal of the facility license.

Response to Comment 24: Board staff does not recommend any changes to the text based upon the comment. Staff note that the Board's regulation establish minimum requirements for compliance. Staff noted that there is nothing in the Board's regulations that would prevent an entity from implementing additional quality assurance provisions.

Board staff notes that QA programs are designed to document and assess medication errors to determine the cause and appropriate response to improve pharmacy service quality and prevent future errors. Further, Board staff note that prior Board discussions included discussion on implementing Just Culture by other

Boards of Pharmacy, including Idaho and New Jersey. The Board's QA program is generally consistent with Just Culture, which encourages a systematic review of a medication error, including environmental factors, workflow, use of devices, and staffing patterns. Additionally, Board staff note that the Board previously discussed this issue in detail in prior Medication Error Reduction and Workforce Committee Meetings (information available on the Board's website: https://www.pharmacy.ca.gov/about/meetings_med_error.shtml).

Written Comments from Steven Anderson, National Association of Chain Drug Stores

Comment 25: The commenter expressed concern that the proposed regulation "could potentially put pharmacies who are members of Patient Safety Organizations (PSOs) at odds with the requirements set forth in the Patient Safety and Quality Improvement Act of 2005 (PSQIA)." The comment states that "reports made to a PSO are designated as Patient Safety Work Product (PSWP). While each PSO participant can designate which elements of a report are PSWP, they typically include contributing factors, root cause analysis, and corrective action recommendations." Additionally, the commenter states that PSO members cannot share items designated as PSWP, and inappropriate disclosure could result in fines. Requiring pharmacies to make PSWP available for inspection or requiring pharmacies to submit PSWP to the Board could be considered an inappropriate disclosure.

Response to Comment 25: Board staff does not recommend any changes to the text based upon the comment. The Patient Safety and Quality Improvement Act of 2005 does not limit sharing such information with a government agency for "public health surveillance, investigation, or other public health purposes or health oversight purposes". (42 U.S.C. section 299b-21.)

Comment 26: Concerning subdivision (e)(2)(B), the commenter recommends that the word "involved" be replaced with the word "responsible" because "involved" is too broad. Additionally, the commenter recommends that the Board review this requirement to determine if it conflicts with the federal Patient Safety Act of 2005, in which a reported incident and the protected information should not be tied back to a healthcare provider to ensure the provider feels comfortable reporting incidents in the future.

Response to Comment 26: Board staff have consider the comment and recommend removal of the requirement established in (e)(2)(B).

Comment 27: Concerning subdivision (e)(2)(C), the commenter recommends that the Board define the "use of automation" as this term could be interpreted as ambiguous.

Response to Comment 27: Board staff does not recommend any changes to the text based upon the comment. Board staff note that the term "automation" is specific to the dispensing process and staff do not believe a definition is required as in the text, the term is specifically linked to its use in dispensing.

Comment 28: Concerning subdivision (e)(2)(D), the commenter indicates that the requirement that pharmacies' policies and procedures include the category the pharmacy uses for identifying the types of errors could jeopardize the pharmacies' confidentiality. The commenter indicates that the categories pharmacies use for identifying the types of errors are proprietary and specific to each company, so they request that this requirement be removed.

Response to Comment 28: Board staff does not recommend any changes to the text based upon the comment. Board staff notes that QA reports are confidential and would not be discoverable.

Comment 29: Concerning subdivision (e)(2)(E), the commenter indicates that pharmacies may be unable to comply because it is broad, and pharmacies do not specifically measure all activities conducted within the pharmacy. The commenter indicates that the increased administrative burden of collecting the additional data is counterintuitive and requests that this section be removed.

Response to Comment 29: Board staff does not recommend any changes to the text based upon the comment. Board staff note that prior Board policy discussions have been clear it is necessary to understand the workload of the pharmacy, regardless of setting, on the day of the error in order to conduct a detailed analysis into the error and possible fatigue of the individuals involved. Additionally, Just Culture is not a "non-punitive or blame-free culture" but is focused on a system that evaluates what occurred in an error and what actions can be taken to prevent such errors in the future. According to ISMP, part of Just Culture is coaching the staff involved in the error, the decision made, and why that decision was made. The Board's QA program is generally consistent with Just Culture, which encourages a systematic review of a medication error, including environmental factors, workflow, use of devices, and staffing patterns. Board staff note that the Board previously discussed this issue in detail in prior Medication Error Reduction and Workforce Committee Meetings (information available on the Board's website: https://www.pharmacy.ca.gov/about/meetings_med_error.shtml).

Comment 30: Concerning subdivision (e)(4), the commenter recommends that the Board review this amendment to determine if it conflicts with the federal Patient Safety Act of 2005, as the documentation may be designated as PSWP.

Response to Comment 30: Board staff does not recommend any changes to the

text based upon the comment. Board staff note that the proposed changes do not conflict with the Patient Safety and Quality Improvement Act of 2005, as the Act is not intended to limit sharing information with a government agency for "public health surveillance, investigation, or other public health purposes or health oversight purposes". (42 U.S.C. section 299b-21.)

Comment 31: Concerning subdivision (f), the commenter indicates that requiring the record of the quality assurance review to be immediately retrievable in the pharmacy for at least three years would require pharmacies to invest in significant system updates. Additionally, the commenter recommends the Board review this requirement to determine if it conflicts with the federal Patient Safety Act of 2005, specifically PSOs.

Response to Comment 31: Board staff does not recommend any changes to the text based upon the comment. Board staff note that prior Board policy discussions have been clear it is necessary to maintain the records for a longer period because having the pharmacies retain the records for a longer period will help in determining and examining patterns that can assist in error reduction and prevention, both for the individual facility and industry wide. Board staff note that records can be stored electronically and can be electronically archived or purged following the end of the retention period. Additionally, Board staff note that the Board previous discussed this issue in detail in prior Medication Error Reduction and Workforce Committee Meetings (information available on the Board's website: https://www.pharmacy.ca.gov/about/meetings_med_error.shtml). Finally, the proposed changes do not conflict with the Patient Safety and Quality Improvement Act of 2005, as the Act is not intended to limit sharing information with a government agency for "public health surveillance, investigation, or other public health purposes or health oversight purposes". (42 U.S.C. section 299b-21.)

Comment 32: The commenter requests a one-year delayed implementation period to allow pharmacies to update their policies and procedures and systems.

Response to Comment 32: Board staff have reviewed the comment and recommend that the Board establish a January 1, 2026 effective date.

Department of Consumer Affairs
Title 16. Board of Pharmacy

Proposed Modifications to Regulation Text
Quality Assurance Programs

Proposed changes made to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Modified regulation text to the proposed regulation text is indicated with a ~~double strikethrough~~ for deletions and a double underline for additions.

Amend section 1711 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows**:**

§ 1711. Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program that documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.
(b) For purposes of this section, “medication error” means any variation from a prescription or drug order not authorized by the prescriber, as described in ~~S~~section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.
(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.
(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:
(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.
(B) Communicate to the prescriber the fact that a medication error has occurred.
(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.
(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.
(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.
(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:
(1) The date, location, and participants in the quality assurance review;

(2) The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c)~~;~~, including:

(A) The date and approximate time or date range when the error occurred if known or can be determined. If it cannot be determined, the pharmacy shall note "unknown" in the record.

~~(B) The names of staff involved in the error.~~

(~~C~~B) The use of automation, if any, in the dispensing process.

(~~D~~C) The type of error that occurred. To ensure standardization of error reporting, the pharmacies' policies and procedures shall include the category the pharmacy uses for identifying the types of errors.

(~~E~~D) An outpatient pharmacy report must also document the ~~The~~ volume of workload completed by the pharmacy staff on the date of the error, if known, including clinical functions. If the date of the error is unknown, the average volume of workload completed daily shall be documented. For errors that occur in a community pharmacy, at a minimum the volume of workload records shall include the number of new prescriptions dispensed, the number of refill prescriptions dispensed, the number of vaccines administered, and number of patient consultations given~~, and any other mandatory activities required by the pharmacy employer~~. Prescriptions filled at a central fill location and dispensed at the pharmacy must be documented separately from other prescriptions filled at the pharmacy.

(3) The findings and determinations generated by the quality assurance review; and~~,~~

(4) Recommend changes to pharmacy policy, procedure, systems, or processes, if any. The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program. Documentation of the steps taken to prevent future errors shall be maintained as part of the quality assurance report.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least ~~one~~ three years from the date the record was created. Any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the ~~b~~Board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal of the facility license.

(g) The pharmacy's compliance with this section will be considered by the ~~b~~Board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

NOTE: Authority cited: Sections 4005 and 4125, Business and Professions Code~~; and Section 2 of Chapter 677, Statutes of 2000~~. Reference: Sections 4125 and 4427.7, Business and Professions Code.

2017

ISMP Medication Safety Self Assessment® for Community/Ambulatory Pharmacy

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

Dear Pharmacist, Pharmacy Technician, Manager, Owner, Executive:

The Institute for Safe Medication Practices (ISMP) is pleased to provide the nation's community pharmacies with a newly updated version of the ISMP Medication Safety Self Assessment® for Community/Ambulatory Pharmacy. This 2017 tool is designed to help organizations assess the safety of current medication practices and proactively identify opportunities for improvement.

In preparation for the release of this assessment tool, we selected and updated many items from the 2001 self assessment and added additional items as well. These changes represent new practices and processes that have evolved over the last 15 years that are known to impact medication safety, including new research findings about error prevention, as well as new technologies not widely adopted in 2001 when the previous self assessment was published. To incorporate these new items into the 2017 assessment, while keeping the assessment a manageable size, we have eliminated several items from the 2001 assessment that the majority of pharmacies previously indicated had been fully implemented either in some or all areas of their organization.

We encourage you to complete this self assessment as part of your ongoing quality improvement activities. Because medication use is a complex, multidisciplinary process, many characteristics of your pharmacy system are best assessed from the perspective of varying practitioners. Therefore, to accurately evaluate your system and maximize the value of the self assessment, we strongly encourage you to follow the process outlined on page 6.

We welcome the opportunity to work with you as you assess medication safety in your organization. While there is still much work to do, we are confident of success as we continue to work together to make America's community pharmacies even safer and more efficient.

Warm regards,

Michael R. Cohen, RPh, MS, ScD (hon.), DPS (hon.), FASHP
President
Institute for Safe Medication Practices

About the Institute for Safe Medication Practices (ISMP)

The Institute for Safe Medication Practices (ISMP) is the nation's only nonprofit, charitable organization devoted entirely to medication error prevention and safe medication use. ISMP is known and respected worldwide as the leading resource for independent and effective medication safety recommendations.

The Institute's recommended strategies for error prevention and risk identification are based on up-to-the minute information gained from analysis of reports to the voluntary ISMP National Medication Errors Reporting Program, onsite visits to individual healthcare organizations, and advice from outside advisory experts.

ISMP's initiatives, which are built upon system-based solutions, include: five medication safety newsletters for healthcare professionals and consumers that reach more than three million total readers; educational programs, including conferences on medication use issues; confidential consultation services to healthcare systems to proactively evaluate medication systems or analyze medication related sentinel events; advocacy for the adoption of safe medication standards by accrediting bodies, manufacturers, policy makers, and regulatory agencies; independent research to identify and describe evidence-based safe medication practices; and a consumer website (www.consumermedsafety.org) that provides patients with access to free medication safety information and alerts.

ISMP works with healthcare practitioners and institutions, regulatory and accrediting agencies, consumers, professional organizations, the pharmaceutical industry, and others to accomplish its mission. It is a federally certified patient safety organization (PSO), providing legal protection and confidentiality for patient safety data and error reports it receives.

As an independent nonprofit organization, ISMP receives no advertising revenue and depends entirely on charitable donations, educational grants, newsletter subscriptions, and volunteer efforts to pursue its lifesaving work. For more information that will make a difference to patient safety, please visit ISMP online at: www.ismp.org.

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES
www.ismp.org

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Advisory Panel

ISMP would like to thank the following members of our volunteer Advisory Panel, who helped inform the content of the 2017 ISMP Medication Safety Self Assessment® for Community/Ambulatory Pharmacy.

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We would also like to acknowledge the ISMP staff and fellows whose tireless efforts supported the completion of this assessment tool.

ISMP Medication Safety Self Assessment® for Community/Ambulatory Pharmacy

The 2017 ISMP Medication Safety Self Assessment® for Community/Ambulatory Pharmacy is designed to heighten awareness of the distinguishing characteristics of safe pharmacy systems.

The self assessment is divided into ten key elements that most significantly influence safe medication use. Each element is defined by one or more core characteristics of a safe pharmacy system that further define a safe medication use system. Each core characteristic contains individual self-assessment items to help you evaluate your success with achieving each core characteristic.

ISMP is not a regulatory or standards setting organization. As such, the self-assessment characteristics represent ideal practices and are not purported to represent a minimum standard of practice. Some of the self-assessment criteria represent innovative practices and system enhancements that are not widely available in pharmacies today. However, the value of these practices in reducing errors is grounded in expert analysis of medication errors, scientific research, or strong evidence of their ability to reduce errors.

Instructions for Conducting the Self Assessment

1. **Establish a team.** Establish a team of owners/managers, staff pharmacists, pharmacy technicians, and pharmacy students to collaboratively assess your pharmacy system by thoroughly investigating the level of implementation for each self-assessment item.

   Because medication use is a complex, interdisciplinary process, the value and accuracy of the self assessment is reduced if a single person involved in medication use completes the assessment.

   IMPORTANT! The self assessment should be completed in its entirety by staff and managers who work within the pharmacy, not by off-site managers on behalf of the pharmacy.

2. **Read and review the self assessment in its entirety before beginning the assessment process.** The team leader should provide each team member with either a hardcopy or electronic version of the self assessment (including the definitions) and the Frequently Asked Questions (FAQs), which can be accessed at: http://www.ismp.org/selfassessments/Community/2017. Staff should be encouraged to read the assessment prior to the first meeting.

   If a self-assessment item has an FAQ associated with it, "FAQ" will be noted next to the item. Defined terms are designated throughout the text in **BOLD, CAPITAL LETTERS** and can be found on pages 34-35.

3. **Convene the team.** Ensure that each team member can view either a hardcopy or electronic version of the self assessment during the evaluation process. There are two options for completing the assessment.

   - ***Option 1:*** Print a hard copy of the self assessment, fill in your choice (A through E, or Not Applicable) for each self-assessment item, and enter your responses into the online self-assessment form. (See ***Step 5*** for how to access the online form.)
   - ***Option 2:*** Use the online self-assessment form to view at team meetings and enter your choice (A through E, or Not Applicable) for each self-assessment item, while saving your entered information between meetings. (See ***Step 5*** for how to access the online form.)

     NOTE: By entering your pharmacy's responses into the online self-assessment form, you will receive a score for each Key Element and Core Characteristic and for the entire self assessment.

   Teams should be provided with sufficient time to complete the self assessment and be charged with the responsibility to evaluate, accurately and honestly, the current status of practices in your pharmacy.

   Based on participant feedback from our prior self assessments, we anticipate that it may take three team meetings of approximately 1 to 2 hours each to complete this self assessment. The purpose of the initial meeting is to allow discussion of the self-assessment items and identification of items that require some further research or input. The purpose of the subsequent meetings is to allow the team to reconvene to complete the assessment.

4. **Discuss each Core Characteristic and evaluate the pharmacy's current success with implementing the self-assessment items within that Core.** As necessary, investigate and verify the level of implementation with others. When a consensus on the level of implementation for each self-assessment item has been reached, select the appropriate column using a 5-point letter scale with:

   A. There has been no activity to implement this item in the pharmacy for any patient, prescription, drug, or staff.
   B. This item has been discussed for possible implementation in the pharmacy, but is not implemented at this time.
   C. This item has been partially implemented in the pharmacy for some or all patients, prescriptions, drugs, or staff.
   D. This item has been fully implemented in the pharmacy for some patients, prescriptions, drugs, or staff.
   E. This item has been fully implemented in the pharmacy for all patients, prescriptions, drugs, or staff.

For self-assessment items with multiple components, full implementation is evidenced only if all components are present.

A few self-assessment items may require evaluation using only column A (no activity) or column E (fully implemented), as partial implementation is not applicable.

Some of the self-assessment items offer the option of "Not Applicable." For these items, "Not Applicable" can only be selected if your pharmacy meets the listed scoring guideline. For example, if your pharmacy does not provide immunization services, then you can answer "Not Applicable" to item number 17.

Pharmacies may want to consider assigning an individual to record any discussion generated around each self-assessment item and the rationale behind the selected choice. This information, meant for internal use only, can assist the team when reviewing their responses to individual items or reassessing their pharmacy at a later date. This will provide insight into why the choice selected for each self-assessment item had been chosen at that point in time.

5. **Enter your responses in the online self-assessment form.** This step will be done simultaneously with ***Step 4*** if ***Option 2*** is used by the team to complete the assessment. To access the online form, go to: https://surveys.ismp.org/s3/Community-Self-Assessment. ***PLEASE NOTE: ISMP will not be collecting or aggregating data received through the online form.***

   - **If you do NOT enter all of your responses during the same session** and need to return to your entered information at a later time: Immediately prior to closing out of your session, save your entered information by clicking the "Save and continue later" link (located on the red bar at the top of each webpage), entering your email address, and pressing "Save." An email (from SurveyGizmo) will then be sent to the provided email address with a link that can be used to return to your saved information. If you do not receive an email, please check your spam, junk, or clutter email folder or quarantined messages.

     IMPORTANT! Only save your information once per session. This should be done immediately prior to exiting out of the online assessment. Your entered information is only saved when you are prompted to enter your email address and to press "Save."

   - **If you DO enter all of your pharmacy's responses during the same session**, but want the ability to return to your pharmacy's results at a later time: Prior to completing Key Element X (Quality Processes and Risk Management), click on the "Save and continue later" link (located on the red bar at the top of the webpage), enter your email address, and press "Save." An email (from SurveyGizmo) will then be sent to the provided email address with a link that can be used to view your pharmacy's results. If you do not receive an email, please check your spam, junk, or clutter email folder or quarantined messages.

     IMPORTANT! This must occur prior to clicking "Next" on the Key Element Ten (X) webpage.

6. **Obtain your pharmacy's results.** To receive your results, click "Next" on the Key Element Ten (X) webpage if you have finished answering all of the assessment items. You will then be prompted to print two reports. The first report is how your pharmacy answered each self-assessment item. The second report contains your pharmacy's score, the maximum score, and your pharmacy's score as a percentage of the maximum score for each Key Element and Core Characteristic and for the entire self assessment.

   IMPORTANT! If you did not save your pharmacy's assessment by providing an email address as described in ***Step 5***, this will be your last opportunity to print these two reports. If you did save your pharmacy's assessment by providing an email address, you can use the link that was emailed to the provided address at any point to retrieve your pharmacy's reports.

IF YOU HAVE QUESTIONS, please refer to the FAQs available on our website: **http://www.ismp.org/selfassessments/Community/2017**. Contact ISMP at **selfassess@ismp.org** or call **(215) 947-7797** during usual business hours (Eastern Time) if you need additional assistance.

Identifying and Prioritizing Opportunities for Improvement

1. **Identify areas of weakness.** Identify the Key Elements and Core Characteristics with the greatest opportunities for improvement (those with the lowest scores as a percentage of the maximum score), as well as the individual self-assessment items with a response of A-D.

2. **Prioritize your work.** Prioritize the above identified opportunities for improvement.

   - Start with items that you know you can achieve without considerable delay. Including these types of items at the top of your prioritized list can help ensure early success and establish momentum for ongoing improvements.
   - An item that scored C or D suggests that the risk-reduction strategy has been implemented in part with some success or in full in the pharmacy for some patients, prescriptions, drugs, or staff. Building upon these early successes is a natural progression of effort.
   - Do not hesitate to include a resource-intensive strategy high on your priority list. Items that require extensive time and financial outlays to implement also require extensive planning. Making a resource-intensive strategy a priority helps to ensure that the planning work begins immediately, even if implementation is a year or more away.
   - Successful change begins with acquiring staffs' buy-in to the change process. Strategies that incite enthusiasm strengthen the commitment to achieving a shared goal.

3. **Develop an action plan.** Develop your medication safety action plan with the goal of obtaining an E (full implementation) for each of your identified priorities.

4. **Monitor progress.** Monitor your pharmacy's progress with implementing the self-assessment items and continue to work toward the goals that your pharmacy outlined in its action plan. Plan to perform the self assessment again at a later date to track your pharmacy's improvement in medication safety.

A	No activity to implement
B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
D	Fully implemented for some patients, prescriptions, drugs, or staff
E	Fully implemented for all patients, prescriptions, drugs, or staff

I. PATIENT INFORMATION

Core Characteristic #1

Essential patient information is obtained, readily available in useful form, and considered when dispensing, administering, and monitoring the effects of medications.

		A	B	C	D	E
1	Patient information (patient's full name [including suffix], address, home telephone number, alternate means of contact [e.g., email address or cell phone number], gender, date of birth, and allergies) is obtained and entered into the pharmacy computer system before dispensing prescriptions, and is updated at each encounter.					
FAQ 2	The pharmacy has implemented policies and procedures and system enhancements to ensure that only one profile per person exists in its system.					
3	The pharmacy assesses and documents patients' preferred language for communication, health literacy, cultural influences relevant to medication therapy, and any hearing and/or visual impairments that may affect compliance with medication therapy.					
4	A current medication list, including prescription and over-the-counter (OTC) medications (with dose, frequency, and route) and immunizations (with vaccination dates), is obtained, entered into the pharmacy computer system, and updated at each encounter.					
5	A list of vitamins, herbal products, dietary supplements, homeopathic medications, and alternative medicines currently used by the patient is obtained, entered into the pharmacy computer system, and updated at each encounter.					
6	Basic information about comorbid and/or chronic conditions (e.g., diabetes, hypertension, renal or liver impairment, pregnancy, lactation) is obtained, entered into the pharmacy computer system, and updated at each encounter.					
7	The pharmacy takes steps to obtain patient weight when dispensing weight-based drugs, such as those used in chemotherapy treatment or pediatrics.					
8	When taking orders over the telephone, the prescriber (or authorized agent) is specifically queried about comorbid conditions, allergies, date of birth, patient weight (if applicable), and indication.					
9	Recent clinical data such as blood glucose levels, liver enzymes, renal function, blood pressure, and cholesterol levels are available to pharmacists to support clinical drug monitoring of patient-specific drug regimens.					

A	No activity to implement
B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
D	Fully implemented for some patients, prescriptions, drugs, or staff
E	Fully implemented for all patients, prescriptions, drugs, or staff

I. PATIENT INFORMATION (continued)

		A	B	C	D	E
10	Pharmacists verify any critical clinical information about the patient that is necessary to confirm the appropriateness of the medication and dose (e.g., allergies and reactions, weight, opioid tolerance, laboratory values, indication for drug).					
11	Prescription orders cannot be entered into the pharmacy computer system until the patient's allergies (or "no known allergies") have been properly entered and coded (patient allergies is a required field).					
12	Allergy information (including reaction information) is clearly visible on pharmacy computer system screens and accessible during order entry.					
13	There is a defined process that specifies how to modify patient allergies and reactions in the pharmacy computer system and who is permitted to make such changes.					
14	The pharmacy system incorporates special prompts for selected **HIGH-ALERT MEDICATIONS** to obtain or verify critical information about the patient (e.g., past opioid use for patients receiving transdermal fenta**NYL** patches, concentrated morphine solutions, long-acting opioids) necessary to confirm the appropriateness of the prescribed medication, dose, dosage form, and directions for use.					
15	Pharmacists consider the need for dose adjustments for medications based upon specific recent clinical data available (e.g., patient with renal impairment is identified when prescribed a potentially toxic drug that is excreted by the kidney).					
16	At the point of sale, pharmacy staff ask the patient (or person picking up the prescription) to state the patient's name and date of birth, and these two identifiers are verified against the patient's profile to help ensure that medications are being dispensed for the proper patient.					
17	All administered vaccines are fully documented in the patient's profile including: vaccine name, dose, national drug code (NDC) number, date of administration, vaccine manufacturer, vaccine lot number, the name and title of the person who administered the vaccine, and the address of the facility where the permanent record will reside. *Scoring guideline: Choose NOT APPLICABLE if immunization services are not provided at the pharmacy.*					
		NOT APPLICABLE				
18	Vaccine registries are checked before vaccines are administered to avoid duplication. *Scoring guideline: Choose NOT APPLICABLE if immunization services are not provided at the pharmacy.*					
		NOT APPLICABLE				

A	No activity to implement
B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
D	Fully implemented for some patients, prescriptions, drugs, or staff
E	Fully implemented for all patients, prescriptions, drugs, or staff

II. DRUG INFORMATION

Core Characteristic #2

Essential drug information is readily available in useful form and considered when dispensing, administering, and monitoring the effects of medications.

		A	B	C	D	E
19	Online drug information references are easily accessible in all dispensing areas and include user-friendly, up-to-date information on prescription, OTC, herbal, and alternative medicines.					
20	Online or other current veterinary references are easily accessible and used as needed when dispensing to nonhumans.					
21	The pharmacy computer system is periodically evaluated for clinically insignificant and false positive alerts, and action is taken to minimize alert fatigue.					
22	The pharmacy computer system performs dose range checks and warns pharmacy staff about overdoses and under-doses for narrow therapeutic index and **HIGH-ALERT MEDICATIONS**.					
23	The pharmacy computer system is tested and updated at least twice annually to ensure that critical alerts are present for narrow therapeutic index and **HIGH-ALERT MEDICATIONS**.					
24	The pharmacy computer system requires pharmacists to document rationale when overriding a serious alert (e.g., exceeding a **MAXIMUM DOSE**, a serious drug interaction).					
25	The pharmacy computer system defaults to a weekly dosage regimen for oral methotrexate, and if overridden to daily dosing, a **HARD STOP** verification of an appropriate oncologic indication is required.					
26	The pharmacy computer system automatically screens and detects medications to which patients may be allergic (including cross allergies), provides a clear warning to staff during order entry, and requires pharmacists to enter an explanation to override the warning.					
27	Pharmacists review all clinically significant pharmacy computer system warnings, even when a pharmacy technician initially enters prescriptions into the pharmacy computer system.					
28	The pharmacist ascertains the clinical purpose of each prescription before the medication is dispensed to ensure that the prescribed therapy is appropriate for the patient's condition.					

A	No activity to implement
B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
D	Fully implemented for some patients, prescriptions, drugs, or staff
E	Fully implemented for all patients, prescriptions, drugs, or staff

II. DRUG INFORMATION (continued)

		A	B	C	D	E
29	At least weekly, an updated interactive database, supplied by a drug database provider for the pharmacy computer system, is loaded into the system.					
FAQ 30	The pharmacy computer system alerts staff when safety screening does not occur due to data not being available.					
31	A designated pharmacist routinely reviews, for quality improvement purposes, reports of the documented rationale for selected pharmacy computer system warnings (e.g., **MAXIMUM DOSE** alerts, serious drug interactions, allergy alerts) that have been overridden to ensure justification and appropriateness.					

Core Characteristic #3

Medications added to the inventory are reviewed for their error potential, and strategies are undertaken to minimize the possibility of errors.

32	If sig codes are used by pharmacy staff during order entry, the codes are standardized within the pharmacy (and throughout a chain with multiple stores) and reviewed regularly to evaluate error potential.					
FAQ 33	A defined process exists for **PHARMACY LEADERSHIP** to create standardized **MNEMONICS**, sig codes, and speed codes.					
34	When a new item is added to the pharmacy inventory, the potential for error with that medication (e.g., sound-alike names, look-alike packaging, complex instructions for patients, confusing dosing parameters, clinical monitoring requirements) is evaluated.					
35	Before a new product is added to the pharmacy inventory, an evaluation assessing the potential for error includes a review of the literature for published errors related to that product.					
36	When new medications with heightened error potential are identified, the pharmacy establishes safety enhancement(s) (e.g., check systems, alert labels, reminders, limitations on use, sequestered storage and location) before initial use.					
37	After a medication has been on the market for several months, a staff or corporate level pharmacist is assigned responsibility to determine if medication errors or adverse reactions have been reported internally or externally since product launch, and safety enhancements are established in the pharmacy as necessary.					

A	No activity to implement
B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
D	Fully implemented for some patients, prescriptions, drugs, or staff
E	Fully implemented for all patients, prescriptions, drugs, or staff

III. COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION

Core Characteristic #4

Methods of communicating prescription orders and other drug information are standardized and automated to minimize the risk for error.

		A	B	C	D	E
38	The pharmacy computer system is able to receive electronic prescriptions with minimal data entry/transcription required.					
39	If the prescription is received on paper, prescription scanning is used to show an image of the original prescription on the pharmacy computer screen.					
FAQ 40	A process is in place to verify that the scanned image accurately represents the original prescription. *Scoring guideline: Choose NOT APPLICABLE if scanning is not utilized at the pharmacy.*					NOT APPLICABLE
41	A list of **ERROR-PRONE ABBREVIATIONS** (e.g., "U" for units) and dose designations (e.g., using trailing zeros for whole number doses, lack of using a leading zero for doses less than one) is established and used for internal communication and documentation of drug information on prescription orders, pharmacy labels, and in pharmacy computer systems.					
42	Feedback is provided to prescribers about quality and/or safety issues of electronic prescriptions generated by their prescribing systems (e.g., missing or mismatched quantities [1 for 10 mL insulin vial], mismatches between drug dosage form ordered and dosage units ordered [solution ordered, dose indicated in tablets], wrong drug selected, sig field contradicts instructions in the notes field).					
43	The pharmacy does not accept telephone orders for chemotherapeutic agents.					
44	Telephone or voice mail prescription orders received by a pharmacist, pharmacy intern, or certified technician (where allowed by regulation) are written down immediately on a pharmacy prescription blank.					
45	For telephone prescription orders, the pharmacy uses prescription pads that prompt the receiver to ask the caller for indication, allergies, date of birth, and, if needed, comorbid conditions and patient weight.					
FAQ 46	When telephone orders must be taken, the order is **READ BACK** to the prescriber or authorized agent for confirmation.					
47	The pharmacy uses an integrated voice response (IVR) system that includes prompts that require the prescriber or agent to stop and spell all names (prescriber, patient, and drug) and sound out numbers (e.g., 60 is emphasized as "six zero," 15 as "one five") when leaving a spoken prescription order.					

A	No activity to implement
B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
D	Fully implemented for some patients, prescriptions, drugs, or staff
E	Fully implemented for all patients, prescriptions, drugs, or staff

III. COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION (continued)

		A	B	C	D	E
48	The pharmacy has a formal policy to assess and clarify any unusual doses or uses of medications before dispensing.					
49	Pharmacists have a written policy to follow, to easily and effectively resolve conflicts when prescribers do not agree with their expressed concerns about the safety of an order.					
50	The pharmacist who clarifies an atypical order documents the problem identified, actions taken, and result or outcome through pharmacy computer systemized notes in the patient's profile or as an annotated note on the scanned prescription.					

A	No activity to implement
B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
D	Fully implemented for some patients, prescriptions, drugs, or staff
E	Fully implemented for all patients, prescriptions, drugs, or staff

IV. DRUG LABELING, PACKAGING, AND NOMENCLATURE

Core Characteristic #5

Strategies are undertaken to minimize the possibility of errors with drug products that have similar or confusing manufacturer labeling/packaging and/or drug names that look and/or sound alike.

		A	B	C	D	E
51	The *ISMP Medication Safety Alert!*® and/or other current literature is regularly reviewed to identify drug labeling, packaging, and nomenclature problems, and action is taken to prevent errors with these drugs.					
52	Different manufacturers are sought for products with labels/packages that look similar to other products to help differentiate the labels/packages.					
53	Alerts are built into the pharmacy computer system to remind practitioners about problematic drug names, including drugs with multiple suffixes such as XL, SR, ER, CD, and LA.					
54	Shelf tags or label enhancements (e.g., **TALL MAN LETTERS**) are used on packages and storage bins of drugs with problematic names, packages, and labels.					
55	Products with look-alike drug names and packaging that are known by the staff to be problematic are segregated and not stored next to one another, and a system clearly redirects staff to where the products have been relocated.					
56	Look-alike drug names do not appear on the same pharmacy computer system screen when selecting a drug during order entry, or look-alike drug names are clearly distinguished in a way that differentiates them (e.g., use of **TALL MAN LETTERS**) if they appear sequentially on the same pharmacy computer system screen.					

Core Characteristic #6

Prescription labels clearly identify the patient, product, directions for use, the dispensing pharmacy, and any other important information that the patient may need to take the medication accurately and safely.

		A	B	C	D	E
FAQ 57	Pharmacy prescription labels are easy for patients to read, have adequate "white" space, have a font size that is legible (i.e., 12-point font for patient name, drug name, strength, directions for use, and indication, if known), and contain the proper information for safe self-administration.					
FAQ 58	When appropriate and within regulatory boundaries, the pharmacy provides directions on the patient's label using the Universal Medication Schedule and simplified language (e.g., "for blood pressure" instead of "for hypertension").					

A	No activity to implement
B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
D	Fully implemented for some patients, prescriptions, drugs, or staff
E	Fully implemented for all patients, prescriptions, drugs, or staff

IV. DRUG LABELING, PACKAGING, AND NOMENCLATURE (continued)

		A	B	C	D	E
59	The pharmacy computer system produces clear and distinguishable prescription container labels that are free of **ERROR-PRONE ABBREVIATIONS** (e.g., "U" for units) or dose designations.					
60	When dispensing unit-of-use packaging to patients, staff avoid placing the pharmacy label on top of pertinent information on the manufacturer's label (e.g., drug name, strength, NDC).					
61	The pharmacy uses appropriate foreign language labels for patients who need them.					
FAQ 62	Appropriate labels are used for the visually impaired (e.g., larger font, Braille, talking).					
63A	The pharmacy computer system automatically prints appropriate auxiliary labels (e.g., for the ear, for the eye, take with food) when prescription labels are generated.					
OR	**OR** *(Respond to #63A or #63B only)*					
63B	During prescription order entry, the pharmacy computer system suggests appropriate auxiliary labels to be affixed manually prior to dispensing.					
64	If the prescriber provides the purpose of the medication on the prescription, the indication is included on the patient's prescription container label unless inclusion on the label is not desired by the patient.					
65	A description of the product (e.g., shape, imprints, color, scent) appears on the pharmacy label.					

A	No activity to implement
B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
D	Fully implemented for some patients, prescriptions, drugs, or staff
E	Fully implemented for all patients, prescriptions, drugs, or staff

V. DRUG STANDARDIZATION, STORAGE, AND DISTRIBUTION

Core Characteristic #7

Prescribed medications are accessible to patients and dispensed in a safe and secure manner.

		A	B	C	D	E
66	When patients have a legitimate need for prescription medications, but have exhausted their supply while traveling, lost their medications, or there is a statewide emergency, all pharmacists are empowered, as state law permits, to take appropriate action to ensure that critical doses are not missed.					
67	There is an efficient and timely process in place to obtain critically needed medications or notify providers when they are not immediately available (e.g., due to a drug shortage).					
68	A mechanism exists to identify the reasons that prescriptions have not been picked up after being prepared.					
69	A timely and efficient process is in place to identify medications that have been recalled by manufacturers and notify patients as appropriate.					

Core Characteristic #8

Medications and other necessary medication supplies are stored, dispensed, and returned to stock in a manner that reduces the likelihood of an error.

		A	B	C	D	E
70	Electronic systems that document temperature ranges around the clock and provide problem notification are used for refrigerators and freezers that store temperature-sensitive medications, and written procedures regarding how to handle any breach of a safe temperature range have been developed and are followed.					
71	Refrigerators of sufficient size or alternatively, separate refrigerators, are used for stock and prepared prescriptions waiting to be picked up, to ensure refrigerated medications are stored in an organized manner.					
72	The pharmacy has adequate space to safely organize and separate the storage of medications and drug supplies, and utilizes dividers on stock shelves, in narcotic cabinets, and in refrigerators, as needed.					
FAQ 73	There is a process in place to keep two-component (i.e., two vial) vaccines together and to keep diluents and their corresponding vaccines together if storage requirements do not differ. *Scoring guideline: Choose NOT APPLICABLE if vaccines are never stored in the pharmacy.*					**NOT APPLICABLE**
74	The pharmacy separates pediatric and adult vaccine formulations. *Scoring guideline: Choose NOT APPLICABLE if vaccines are never stored in the pharmacy.*					**NOT APPLICABLE**

A	No activity to implement
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C	Partially implemented for some or all patients, prescriptions, drugs, or staff
D	Fully implemented for some patients, prescriptions, drugs, or staff
E	Fully implemented for all patients, prescriptions, drugs, or staff

V. DRUG STANDARDIZATION, STORAGE, AND DISTRIBUTION (continued)

		A	B	C	D	E
75	The pharmacy does not stock sound-alike or look-alike drugs in the "fast mover" section (unless automation is employed).					
76	When stocking shelves, staff ensure that stickers (e.g., wholesale price labels) or cross-out lines do not obliterate key information on any part of the stock bottle label.					
77	To verify proper selection, the pharmacy system has implemented tablet/product imaging (or description) on the final verification screen.					
78	If completed prescriptions are not ultimately dispensed to patients, the return-to-stock (RTS) vials are labeled with the medication name, strength, expiration date, and NDC number or barcode (RTS medications are not returned to stock bottles).					

Core Characteristic #9

Hazardous drugs and chemicals are safely sequestered and not accessible in drug preparation areas.

79	An appropriately segregated and secured area of the pharmacy has been established to temporarily place returned, outdated, and recalled medications until they are destroyed or removed from the pharmacy.					
80	Active pharmaceutical ingredients and bulk chemicals used in the pharmacy for compounding are assessed at least quarterly, and those that are not regularly used are eliminated from stock.					
81	Active pharmaceutical ingredients and bulk chemicals used in the pharmacy for compounding are clearly labeled with their contents, the date the product was first opened, and the manufacturer's expiration date (if applicable). (If an expiration date is unavailable from the manufacturer, a 1-year expiration date from the date the product was first opened is assigned.)					
82	The pharmacy stores chemicals used in compounding in a separate area according to current USP <795> and <797> standards.					
83	The pharmacy does not store chemical substances (e.g., formalin, methanol) for distribution to a laboratory, doctor's office, or hospital.					
84	All caustic or hazardous chemicals and other non-drug substances are clearly labeled and stored on low shelves separate from all other medications and supplies in the pharmacy's drug inventory.					
85	Pharmacy prescription bottles and labels are not used to re-package non-drug substances (e.g., liquid chemicals, cleaning compounds, insecticides, soaps).					

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C	Partially implemented for some or all patients, prescriptions, drugs, or staff
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E	Fully implemented for all patients, prescriptions, drugs, or staff

VI. USE OF DEVICES

Core Characteristic #10

Sanitary practices are followed when using devices and equipment to store and prepare medications.

		A	B	C	D	E
86	Staff members use gloves and proper hand washing when handling individual loose oral solid products.					
87	All pharmacists follow standards for hand washing, wearing gloves, and equipment disposal to minimize the risks of disease transmission during the administration of vaccines. *Scoring guideline: Choose NOT APPLICABLE if immunization services are not provided at the pharmacy.*					
		NOT APPLICABLE				
88	Staff members follow appropriate hand washing procedures prior to compounding any prescription product.					
89	Dispensing devices (e.g., counting trays, Fillmaster®) are appropriately cleaned after being used to prepare chemotherapy, penicillin, sulfonamides, opioids, and medications that may leave a residue.					

Core Characteristic #11

The potential for **HUMAN ERROR** is mitigated through careful procurement, maintenance, use, and standardization of devices used to prepare prescription medications.

		A	B	C	D	E
90	The pharmacy performs maintenance, calibration, and cleaning on all counting devices, automated dispensing devices, and compounding equipment according to compendia or manufacturers' standards.					
91	The pharmacy performs manufacturers' suggested maintenance and cleaning schedules for all fax machines, scanners, and printers.					
92	Privileges to make modifications, adjustments, or changes in the bin contents of automated dispensing systems (e.g., robotics) are restricted to staff members who are well-trained in both the theory and the mechanics of the software system.					
93	Barcode scanning or a checklist/sign-off sheet is used to verify the drug name, strength, NDC, lot number, and expiration date of each stock bottle before the contents are added to an automated dispensing system (e.g., robotics).					
94	When adding new products, making changes in strength or dosage form, or when making other modifications to automated dispensing systems (e.g., robotics), two individuals independently verify the change with the use of a checklist/sign-off sheet.					
95	Barcoding is used to verify drug selection.					

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B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
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VII. ENVIRONMENTAL FACTORS, WORKFLOW, AND STAFFING PATTERNS

Core Characteristic #12

Medications are transcribed, prepared, dispensed, and administered within an efficient and safe workflow, and in a physical environment that offers adequate space and lighting and allows pharmacy staff to remain focused on medication use without distractions.

		A	B	C	D	E
96	Lighting is adequate (i.e., illumination levels at least 100 foot-candles) to clearly read labels and other important drug and patient information.					
97	A lighted magnifying lens is in a fixed location and is used to facilitate readability of prescriptions and labels.					
98	The temperature and humidity in the pharmacy conform to drug storage requirements.					
99	The pharmacy has implemented integrated voice response (IVR) systems that are integrated with the pharmacy computer system, to triage incoming calls.					
100	Areas where medication orders are transcribed and/or entered into the pharmacy computer system are isolated and free of distractions and interruptions.					
101	Areas where medication orders are verified are isolated and free of distractions and interruptions.					
102	Areas where point-of-care testing and/or immunization services are provided are private and free of distractions and interruptions. *Scoring guideline: Choose NOT APPLICABLE if point-of-care testing and immunization services are not provided.*					
		NOT APPLICABLE				
FAQ 103	The pharmacy has a dedicated, exclusive area for general, nonsterile compounding that meets current USP <795> standards.					
104	The pharmacy has an area for aseptic compounding of sterile preparations that meets current USP <797> standards. *Scoring guideline: Choose NOT APPLICABLE if sterile compounding is not offered.*					
		NOT APPLICABLE				
105	The pharmacy avoids using storage space that requires staff to reach over their heads or to climb to retrieve products.					
106	Workspaces where medications are prepared are clean, orderly, and free of clutter.					
107	Baskets, bins, or other containers are used during preparation and verification to separate different patients' orders.					

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VII. ENVIRONMENTAL FACTORS, WORKFLOW, AND STAFFING PATTERNS (continued)

		A	B	C	D	E
108	The pharmacy maintains a prescription pick-up/will-call area that is free from clutter and contains enough space to prevent "spillage" into the next basket or bin.					
109	Plans for new and/or expanded services are well communicated to all affected personnel, and appropriate consideration of resources is addressed prior to implementation.					
110	The pharmacy uses an automated, off-site, centralized dispensing operation to help reduce workload in the pharmacy.					
111	When preparing prescriptions, pharmacy staff work with one drug product at a time and affix the label to the patient's prescription container before working on the next prescription.					
112	All prescription orders (either the hard copy or a scanned image) are displayed at eye level during order entry.					

Core Characteristic #13

The complement of qualified, well-rested pharmacy staff matches the workload without compromising patient safety.

113	An employee assistance program is available, and participation is encouraged to help staff who are experiencing stress or issues that may affect work performance.					
114	Pharmacy staff undergo an annual physical examination, including vision and hearing screenings.					
115	Pharmacy staff work no more than 12 consecutive hours. Exception: isolated situations outside of usual operations.					
116	Pharmacy staff have at least 8 hours of rest between shifts worked. Exception: isolated situations outside of usual operations.					
117	Schedules and workload permit pharmacy staff to take at least one 15-minute break and one 30-minute break (for a meal) per 8 hours of work each day. Exception: isolated situations outside of usual operations.					
118	An effective back-up plan has been established for days when staffing is short due to illness, vacation, educational absences, and fluctuations in workload.					

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B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
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VII. ENVIRONMENTAL FACTORS, WORKFLOW, AND STAFFING PATTERNS (continued)

		A	B	C	D	E
119	Staffing patterns in the pharmacy are adequate to provide safe patient care services, including during times of anticipated higher workload (e.g., beginning of the month, prior to or immediately following holidays).					
120	When temporary agency staff are used, they have been properly oriented and trained in the particular pharmacy environment in which they will be working.					
121	When creating the work schedule, consideration is given to the use of supportive automated dispensing technology, prescription volume, and pharmacist/technician ratios.					
122	Prescription volume data is examined periodically to determine appropriate staffing levels, even during peak times when demand is highest.					
123	Metrics used to ascertain staff productivity and turnaround time are reasonable and do not impede the quality or safety of patient care services.					
124	The pharmacy does not ask pharmacists to meet a specific quota for prescription dispensing, including vaccine administrations if provided.					

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B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
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VIII. STAFF COMPETENCY AND EDUCATION

Core Characteristic #14

Pharmacy staff receive sufficient orientation to medication use and undergo baseline and annual proficiency evaluation of knowledge and skills related to safe medication practices.

		A	B	C	D	E
125	All new staff, including agency staff, undergo a baseline proficiency evaluation before working independently.					
126	All pharmacy staff, including float and agency staff, are educated about the specific pharmacy equipment available at each site (e.g., barcode scanner, automated dispensing equipment) and associated protocols/guidelines, and competency with equipment use is verified before staff are permitted to operate the equipment.					
127	All pharmacists, including float and agency staff, are educated about the specific patient self-administration and monitoring devices available at each site (e.g., glucose monitors, inhalation devices, pen devices, home diagnostic tests), and competency is verified before staff are permitted to educate a patient about the device.					
128	All compounding personnel receive ongoing education and competency assessment, including knowledge and training on standard operating procedures (SOP) in accordance with current USP <795> and <797> standards.					
129	Staff who administer immunizations are educated about the potential adverse effects of vaccines (e.g., anaphylaxis, syncope) and are prepared to respond appropriately. *Scoring guideline: Choose NOT APPLICABLE if immunization services are not provided at the pharmacy.*					
		NOT APPLICABLE				
130	Protocols are available and reviewed with staff on how to treat an emergency during patient care services, emergency supplies are on-hand, and staff know where to find the protocols and supplies.					
131	Those who train new staff have a reduced workload to accomplish the goals of orientation safely and thoroughly.					
132	The length of time for orienting new pharmacists, technicians, and management staff is individualized and based on an ongoing assessment of their needs.					
133	During orientation, pharmacy staff receive information about the pharmacy's actual error experiences, as well as published errors that occurred in other facilities.					

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E	Fully implemented for all patients, prescriptions, drugs, or staff

VIII. STAFF COMPETENCY AND EDUCATION (continued)

		A	B	C	D	E
134	Pharmacy preceptors review key medication-related policies and procedures, and specific error-prone conditions, at the start of each pharmacy student's rotation. *Scoring guideline: Choose NOT APPLICABLE if your organization does not serve as a site for pharmacy students.*					
		NOT APPLICABLE				
135	Pharmacy staff are educated about system-based strategies to reduce the risk of errors.					
136	Current policies and procedures are readily available, updated on a regular basis, and followed by pharmacy staff.					
137	As part of the overall performance evaluation process, a supervisor assesses each pharmacy staff member's skills and knowledge related to safe medication practices.					

Core Characteristic #15

Pharmacy staff are provided with ongoing education about medication error prevention and the safe use of drugs and devices that have the greatest potential to cause harm if misused.

138	Pharmacy staff are educated about new drugs added to the pharmacy inventory, including OTC medications, and any associated guidelines, restrictions, or special precautions are understood before the medications are dispensed or administered (e.g., vaccines).					
139	Medication errors and ways to avoid them are routinely discussed at staff meetings and in conversations between pharmacists, technicians, and managers.					
140	**HUMAN FACTORS** and the principles of error reduction (e.g., standardization, use of constraints, and redundancy for critical functions) are introduced during staff orientation.					
FAQ 141	Management and frontline staff receive training in identifying risk within the system and in incorporating high-leverage, error-reduction strategies to help eliminate the risk.					
142	Management and frontline staff are trained and skilled in the principles and applications of **CONTINUOUS QUALITY IMPROVEMENT (CQI)**.					
143	At least annually, pharmacy staff must complete an educational program on ways to avoid errors with **HIGH-ALERT MEDICATIONS**, narrow therapeutic index medications, and other error-prone medications or devices.					

A	No activity to implement
B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
D	Fully implemented for some patients, prescriptions, drugs, or staff
E	Fully implemented for all patients, prescriptions, drugs, or staff

VIII. STAFF COMPETENCY AND EDUCATION (continued)

		A	B	C	D	E
144	When errors occur, educational efforts are widespread among all pharmacy staff rather than remedial and directed at only those who were involved in an error.					
145	Pharmacy staff are provided with the necessary support and time to attend internal and external educational programs related to new medications and/or important medication safety issues.					

A	No activity to implement
B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
D	Fully implemented for some patients, prescriptions, drugs, or staff
E	Fully implemented for all patients, prescriptions, drugs, or staff

IX. PATIENT EDUCATION

Core Characteristic #16

Patients are included as active partners in their care through education about their medications and ways to avert errors.

		A	B	C	D	E
146	Pharmacists are allotted time by management for patient education activities.					
147	Confidential areas for patient counseling and medication therapy management (MTM) services are provided and are free of distractions and interruptions.					
148	Patients are encouraged to ask questions about the medications they are receiving.					
149	Patients are offered an opportunity for counseling. The offer includes a clear explanation of what counseling consists of (e.g., how to take and store the medication, possible side effects, interactions with other medications) and how it would benefit them.					
150	Criteria have been established for selected **HIGH-ALERT MEDICATIONS** or high-risk patient populations to trigger required medication counseling, and a system is in place to alert the pharmacist of this need when the patient comes in to pick up the prescription (e.g., bold alert on the bag, pharmacy computer system alert).					
151	Electronic **HARD STOPS** are in place at the point of sale to restrict completion of the sale until patient education has occurred for selected **HIGH-ALERT MEDICATIONS** or high-risk patient populations.					
FAQ 152	The pharmacist discusses important safety concerns (e.g., those found in Medication Guides, ISMP High-Alert Medication Safety Leaflets for consumers) during patient counseling with the patient/caregiver.					
153	The patient's prescription container is opened with the patient/caregiver to verify the medication.					
154	Pharmacists fully investigate all patient/caregiver concerns and questions about a medication (e.g., affordability, inability to swallow, difficulty adhering to directions, change in product appearance) prior to dispensing.					
155	Cultural issues that may affect compliance with prescribed therapy are identified and considered when counseling patients about their medications.					
156	The pharmacy takes steps to effectively communicate with patients who are visually or hearing impaired.					
157	Patients are instructed to call the pharmacy for any concerns or questions about their medication therapy.					

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B	Discussed, but not implemented
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D	Fully implemented for some patients, prescriptions, drugs, or staff
E	Fully implemented for all patients, prescriptions, drugs, or staff

IX. PATIENT EDUCATION (continued)

		A	B	C	D	E
158	Patients are provided with a telephone number at which a pharmacist can be reached 24 hours a day for any concerns or questions about their medication therapy.					
FAQ 159	When dispensing oral liquid medications, a proper metric-only measuring device is provided or suggested (e.g., oral syringe), and patients'/caregivers' ability to correctly measure the dose is verified by using the teach-back method.					
160	The patient or caregiver is asked to verify that the vaccine vial and syringe or the prefilled syringe is what is intended prior to vaccine administration. *Scoring guideline: Choose NOT APPLICABLE if immunization services are not provided at the pharmacy.*					
		NOT APPLICABLE				
161	Doses that require splitting tablets are dispensed only to patients who have demonstrated their ability to manipulate the dose properly, and devices for tablet splitting are available from the pharmacy.					
162	Patients are instructed on the proper use and maintenance of any devices dispensed from the pharmacy (e.g., glucose monitors, injectable pens, spacers used with inhalers).					
163	The pharmacy obtains sample devices from manufacturers to be used for patient education/demonstration.					
164	If someone other than the patient or caregiver picks up the prescription, a reasonable effort is made to contact the patient directly to provide medication counseling (e.g., call the patient at home, written suggestion placed in or on the bag for the patient to call the pharmacy for counseling).					
165	Patients are provided with up-to-date, useful, written information in their primary language about the medications that they are receiving, or a trained translator or language line is utilized to provide important oral and/or written information.					
166	The pharmacy provides an updated medication list when therapy changes and reviews it with the patient/caregiver.					
FAQ 167	The pharmacy provides a comprehensive appointment-based medication synchronization (ABMS) program that includes a complete medication review and monthly contact from a pharmacist to the patient, to discuss their medication therapy and any changes before dispensing to optimize medication use.					
168	The pharmacy provides consumers with information about proper disposal of medications and refers them to available community take-back programs.					

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IX. PATIENT EDUCATION (continued)

Core Characteristic #17

Pharmacists establish and participate in community-based disease prevention and monitoring programs to promote health and ensure appropriate therapy and outcomes of medication use.

		A	B	C	D	E
169	The pharmacy offers MTM services, delivered by a pharmacist, focused on improving patients' therapeutic outcomes.					
170	The pharmacy provides clinical disease management programs for conditions such as asthma, hypertension, diabetes, or hypercholesterolemia.					
171	In the past year, the pharmacy has provided at least one screening clinic to promote early detection of disease.					
172	The pharmacy develops and conducts at least one annual educational program or other proactive public health effort designed to improve safe use of medications in the community.					
173	The pharmacy transmits patient immunization administration records to the state or local immunization registry. *Scoring guideline: Choose NOT APPLICABLE if immunization services are not provided or if there is no state or local immunization registry.*					
						NOT APPLICABLE

A	No activity to implement
B	Discussed, but not implemented
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E	Fully implemented for all patients, prescriptions, drugs, or staff

X. QUALITY PROCESSES AND RISK MANAGEMENT

Core Characteristic #18

A safety-supportive **JUST CULTURE** and model of shared accountability for safe **SYSTEM DESIGN** and making safe **BEHAVIORAL CHOICES** is in place and supported by **PHARMACY LEADERSHIP** and immediate supervisors.

		A	B	C	D	E
174	Error-prevention strategies in the pharmacy target **SYSTEM DESIGN** and the management of safe **BEHAVIORAL CHOICES** of all staff.					
175	Pharmacy staff openly discuss errors without embarrassment or fear of reprisal from **PHARMACY LEADERSHIP** or immediate supervisors.					
176	Pharmacy staff are trained in clinical and administrative procedures for responding to medication errors.					
177	All medication errors that reach the patient, regardless of the level of harm that results, are honestly disclosed to patients/caregivers/families in a timely manner.					
178	If a medication error occurs and the patient takes the medication, regardless of the resulting level of harm, the error is honestly disclosed to the prescriber in a timely manner.					
179	**PHARMACY LEADERSHIP** and immediate supervisors have received formal education on establishing and/or maintaining a fair and just safety culture (e.g., **JUST CULTURE**).					
180	No disciplinary action is taken against pharmacy staff for making a **HUMAN ERROR**.					
181	**PHARMACY LEADERSHIP** and immediate supervisors receive formal training on ways to effectively evaluate pharmacy staff competency and performance, supervise and mentor staff on clinical skills, **COACH AT-RISK BEHAVIORS**, and handle difficult pharmacy staff behavior without allowing the presence or absence of medication errors to be a factor.					
182	Job descriptions and performance evaluations include specific accountability standards related to patient/medication safety (e.g., accountability for **BEHAVIORAL CHOICES** in response to the risks seen; willingness to speak up about safety issues and ask for help when needed; to follow the safety literature) that do not include the absence of errors or a numeric error threshold.					
183	The organization anticipates **AT-RISK BEHAVIORS** and proactively takes steps to encourage safe **BEHAVIORAL CHOICES** and discourage **AT-RISK BEHAVIORS**.					

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X. QUALITY PROCESSES AND RISK MANAGEMENT (continued)

		A	B	C	D	E
184	Immediate supervisors **COACH** staff who engage in **AT-RISK BEHAVIORS** involving patient safety, to assist them in making safer **BEHAVIORAL CHOICES** in the future.					
185	Error rates are not determined or calculated from error reports and are not used for internal (pharmacist-to-pharmacist) or external (pharmacy-to-pharmacy) comparisons.					
186	During event investigation (e.g., **ROOT CAUSE ANALYSIS [RCA]**), once risks have been identified, the focus of the initial analysis of the event is widened to analyze the same or similar risks throughout the organization and among other processes, and interventions extend beyond addressing the immediate risks involved in the event.					
187	When an event involves staff who cut corners, breached a policy, and/or did not follow a procedure, the conditions that led to these **AT-RISK BEHAVIORS** are investigated to uncover system-based incentives that encourage the behavior and/or system-based disincentives that discourage safe behaviors.					
188	When an event involves **HUMAN ERROR**, an investigation is undertaken to uncover any preexisting performance shaping factors (e.g., task complexity, workflow, time availability/urgency, experience, training, fatigue, stress) and other environmental conditions, **SYSTEM DESIGN** attributes, **BEHAVIORAL CHOICES**, or equipment design flaws that allowed the error to happen and reach the patient.					
FAQ 189	**PHARMACY LEADERSHIP** and immediate supervisors provide positive incentives for individuals to report errors.					
190	Pharmacy staff are anonymously surveyed at least annually to assess the organization's safety culture.					
191	Pharmacy staff involved in serious errors that cause patient harm are emotionally supported by **PHARMACY LEADERSHIP**, immediate supervisors, and colleagues, and are provided with ongoing support through an employee assistance program or other crisis intervention strategies.					
192	**PHARMACY LEADERSHIP** actively demonstrates its commitment to patient safety (and safe medication practices) by approving a safety plan, encouraging pharmacy staff to report errors, and approving **SYSTEM DESIGN** enhancements, including technology, that are likely to reduce errors.					

A	No activity to implement
B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
D	Fully implemented for some patients, prescriptions, drugs, or staff
E	Fully implemented for all patients, prescriptions, drugs, or staff

X. QUALITY PROCESSES AND RISK MANAGEMENT (continued)

		A	B	C	D	E
193	Specific medication safety objectives (e.g., reduce harm from errors with **HIGH-ALERT MEDICATIONS**; improve medication error detection, reporting, and use of the information) are included in the organization's strategic plans, directly communicated to all staff, and celebrated (acknowledged in a positive manner) when met.					
194	Patient safety is articulated in the organization's mission and/or vision statements.					

Core Characteristic #19

Pharmacy staff are expected to detect and report adverse events, errors (including **CLOSE CALLS**), hazards, and observed **AT-RISK BEHAVIORS**, and to regularly analyze these reports, as well as reports of errors that have occurred in other organizations, to mitigate future risks.

195	A clear definition and examples of medication errors and hazardous situations that should be reported have been established and disseminated to staff.					
196	A formal process has been established to report both hazardous situations that could lead to an error and actual errors, including **CLOSE CALLS**.					
197	One or more pharmacists in an individual pharmacy are assigned the responsibility of enhancing detection of medication errors, overseeing analysis of their causes, and coordinating an effective error-reduction plan (with corporate support as applicable).					
198	The pharmacy staff utilize a tool (e.g., Assess-ERR™) to document and analyze errors.					
199	A trusted pharmacist or manager facilitates periodic, announced focus groups for "off the record" discussions to learn about perceived problems with the dispensing system.					
200	The pharmacy operates a **CONTINUOUS QUALITY IMPROVEMENT (CQI)** program to enhance patient safety.					
201	The pharmacy periodically conducts patient satisfaction surveys regarding patient care services, with the intent of improving services and outcomes of care.					
202	The dispensing process is proactively analyzed at least annually (e.g., using a **PROACTIVE RISK ASSESSMENT** tool) to identify potential risk factors for medication errors.					

A	No activity to implement
B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
D	Fully implemented for some patients, prescriptions, drugs, or staff
E	Fully implemented for all patients, prescriptions, drugs, or staff

X. QUALITY PROCESSES AND RISK MANAGEMENT (continued)

		A	B	C	D	E
203	Practitioners who have been directly involved in a serious or potentially serious medication error participate in a **RCA** analyzing those failures in the system that allowed the error to happen, and assist with the development of **SYSTEM DESIGN** enhancements to reduce the potential for future errors.					
204	**CLOSE CALLS** and hazardous situations that have the potential to cause patient harm are given the same high priority for analysis and error-prevention strategies as errors that actually cause patient harm.					
205	Management and pharmacy staff routinely read and use published error experiences from other organizations to proactively target improvements in the dispensing process.					
206	Management routinely evaluates the literature for new technologies and successful evidence-based practices that have been effective in reducing errors in other organizations, to determine if the new technology and/or practice should be implemented in their organization.					
207	Pharmacy staff are provided with regular feedback about errors reported in the pharmacy, hazardous situations, and error-reduction strategies that are being implemented.					
208	**PHARMACY LEADERSHIP** and immediate supervisors support practitioner reporting to external error reporting programs such as the ISMP National Medication Errors Reporting Program and the ISMP National Vaccine Errors Reporting Program.					

Core Characteristic #20

Redundancies that support a system of **INDEPENDENT DOUBLE CHECKS** or an automated verification process are used for vulnerable parts of the medication system, to detect and correct serious errors before they reach patients.

209	For selected patient groups (e.g., pediatric patients and patients receiving medications dosed according to age or weight), a double check of the prescriber's calculated dose is made before preparing and dispensing the medication.					
210	The original prescription (or image of the original prescription) is used by the pharmacist while conducting data entry verification and when performing medication utilization review.					
FAQ 211	Both the medication base product and the mixing solution/diluent used for reconstituted products are **INDEPENDENTLY DOUBLE CHECKED** by a pharmacist. *Scoring guideline: Pharmacists who work alone should answer A or B.*					

A	No activity to implement
B	Discussed, but not implemented
C	Partially implemented for some or all patients, prescriptions, drugs, or staff
D	Fully implemented for some patients, prescriptions, drugs, or staff
E	Fully implemented for all patients, prescriptions, drugs, or staff

X. QUALITY PROCESSES AND RISK MANAGEMENT (continued)

		A	B	C	D	E
212	A pharmacist verifies the formulation of all OTC insulin with the patient/caregiver before the product is dispensed.					
213	Pharmacists periodically perform quality control checks by reviewing completed prescriptions in the will-call area, examining pharmacy labels, computer entries, and the location of stock bottles replaced in inventory, and conducting other forms of random checks that promote detection of errors.					
214	Medication selection, preparation, and labeling errors identified during routine checking processes are reported and collected for the purpose of identifying **SYSTEM DESIGN** issues and developing error-prevention strategies.					
215	Pharmacists who administer vaccines prepare and/or select one patient's vaccine at a time. *Scoring guideline: Choose NOT APPLICABLE if immunization services are not provided at the pharmacy.*					
		NOT APPLICABLE				
216	The pharmacy has established a process to include an **INDEPENDENT DOUBLE CHECK** of prescriptions for selected **HIGH-ALERT MEDICATIONS** before they are dispensed.					

Definitions *(For purposes of this self assessment)*

Defined terms in this document are designated throughout the text in **BOLD CAPITAL LETTERS**.

AT-RISK BEHAVIOR
A **BEHAVIORAL CHOICE** that increases risk where risk is not recognized or is mistakenly believed to be justified. Examples of common **AT-RISK BEHAVIORS** include: bypassing a duplicate therapy alert during order entry without due consideration; technology work-arounds such as bypassing barcoding during product selection.

BEHAVIORAL CHOICE
Refers to intentional acts that are undertaken by the free exercise of one's judgment. Unlike **HUMAN ERROR**, which is unintentional behavior, **BEHAVIORAL CHOICE** represents the purposeful behavior we intentionally employ while engaging in our day-to-day activities.

CLOSE CALL
An error that took place but was captured before reaching the patient. For example, penicillin was ordered for a patient allergic to the drug; however, the pharmacist was alerted to the allergy during computer order entry, the prescriber was called, and the penicillin was not dispensed to the patient.

COACH
A supportive discussion among staff (peer-to-peer or manager-to-workers) intended to: 1) help staff see the risks associated with their **BEHAVIORAL CHOICES** that were not seen or were misread as being insignificant or justifiable, 2) learn the incentives that encourage these **AT-RISK BEHAVIORS**, and 3) help staff make safer **BEHAVIORAL CHOICES** in the future.

CONTINUOUS QUALITY IMPROVEMENT
A system of standards and procedures to identify and evaluate quality-related events, and to constantly enhance the efficiency and effectiveness of the structures and processes of a pharmacy system that determine the outcomes of medication use. All information, communications, or data maintained as a component of such a system shall be privileged and confidential, and not subject to discovery in civil litigation.

ERROR-PRONE ABBREVIATIONS
Certain medical abbreviations, symbols, and dose designations that are considered "dangerous" and have often contributed to serious medication errors.

A complete list can be found at: www.ismp.org/Tools/errorproneabbreviations.pdf.

HARD STOP
An alert that halts the progress of prescribing, dispensing, or administering a medication that would likely be dangerous to a patient. The alert cannot be overridden until appropriate action occurs.

HIGH-ALERT MEDICATIONS
Medications that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are more devastating to patients. Examples of **HIGH-ALERT MEDICATIONS** include heparin, warfarin, insulin, and opioids. A complete list can be found at: http://www.ismp.org/communityRx/tools/ambulatoryhighalert.asp.

HUMAN ERROR
Inadvertently doing other than what should have been done; a mental slip, lapse, or mistake such as miscalculating a dose, forgetting to add water to an antibiotic powder for suspension, or transposing the labels on two prescription vials during production. **HUMAN ERRORS** are unintentional acts, not a **BEHAVIORAL CHOICE**.

HUMAN FACTORS
The study of the interrelationships between humans, the tools they use, and the environment in which they work and live.

INDEPENDENT DOUBLE CHECK
A procedure in which two individuals separately check each component of the work process. An example would be one person calculating a medication dose for a specific patient and a second individual independently performing the same calculation (not just verifying the calculation) and matching results.

JUST CULTURE
Refers to a safety-supportive model of shared accountability where healthcare institutions are accountable for the systems they design, for supporting the safe behavior choices of patients and staff, and for responding to staff behaviors in a fair and just manner. In turn, staff are accountable for the quality of their **BEHAVIORAL CHOICES (HUMAN ERROR** is not a **BEHAVIORAL CHOICE**) and for reporting their errors and system vulnerabilities.

For more information on **JUST CULTURE**, go to: http://www.ismp.org/NEWSLETTERS/ACUTECARE/articles/20060921.asp

MAXIMUM DOSE
The dose of a medication that represents the upper limit that is normally found in the literature and/or manufacturer recommendations. **MAXIMUM DOSES** may vary according to age, weight, or diagnosis.

MNEMONICS
A limited number of letters and/or numbers that are used typically in electronic systems as a shortcut to represent a specific medication (e.g., AMO250 may represent amoxicillin 250 mg capsules).

PHARMACY LEADERSHIP
Store owners or regional/corporate administrators.

PROACTIVE RISK ASSESSMENT
The process of identifying and systematically analyzing the risk and hazards embedded in the process and structure of care to prevent adverse events from occurring. Knowing the risk and hazards helps to inform the design, planning, and development of appropriate interventions that will eliminate or minimize risk and hazards before patient injury can occur.

READ BACK
A redundant safeguard in which an oral (verbal) prescription is transcribed (e.g., onto a pharmacy prescription pad) and then read back to the prescriber or prescriber's agent to verify accuracy of the prescription, including the patient's date of birth and the indication for the prescribed medication. **READ BACK** differs from repeat back or echoing the prescription from memory.

ROOT CAUSE ANALYSIS (RCA)
A retrospective process for identifying the most basic or causal factor(s) that underlies the occurrence or possible occurrence of an adverse event.

SYSTEM DESIGN
Refers to the design/redesign of processes, procedures, equipment, interfaces, overall structure, and the environment or conditions under which staff work, for the purpose of satisfying specific requirements, such as patient safety. The design of a system dictates how reliable it is in terms of satisfying specific requirements.

TALL MAN LETTERS
Refers to the use of mixed case bolded letters to help draw attention to the dissimilarities of certain look-alike drug name pairs. A list of look-alike drug names with recommended **TALL MAN LETTERS** can be found at: http://www.ismp.org/Tools/tallmanletters.pdf.

Funding Source

ISMP would like to gratefully acknowledge the Cardinal Health Foundation for its continued support of our efforts to improve medication safety in America's pharmacies.

Institute for Safe Medication Practices (ISMP)
200 Lakeside Drive, Suite 200, Horsham, PA 19044
Phone: (215) 947-7797 Fax: (215) 914-1492

www.ismp.org

Catizone, Luce, Menighan
300 W. Central Road
Mount Prospect, IL. 60005

September 22, 2024

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

Via Email: PharmacyRulemaking@dca.ca.gov

Re: Quality Assurance Program Proposed Regulation

Dear Ms. Martinez,

I write on behalf of clients represented by CLM Pharmacy Advisors (CLM), who are registered to practice pharmacy in California and have concerns with the proposed requirements related to Quality Assurance (QA) programs.

CLM commends the California State Board of Pharmacy's (Board) efforts to protect pharmacy patients and its responsibility to ensure quality care. Continuous Quality Improvement (CQI) and QA programs are critical components of pharmacy practice that focus on continually and systematically evaluating the pharmacy's prescription and patient care processes. Boards of Pharmacy recognize this importance and work to include and implement QA requirements in state practice acts and regulations. In fact, about twenty states require CQI programs to monitor and address quality-related events (QREs).

However, as imperative as these programs are to the evaluation and improvement of pharmacy practices, successful implementation and oversight are not without significant challenges. Among the challenges identified by studies, the more notable ones include having the time to report, involving all pharmacy staff in QRE reporting, objective and accurate reporting, and maintaining such processes.

The primary and most significant concern CLM wishes to express to the Board is that the proposed regulations will increase the administrative burdens on pharmacies and ultimately cause pharmacies to not report QRE's and medication errors. An outcome that is not beneficial to patient care and contrary to the intentions of the Board to positively affect patient care.

CLM respectfully asks that the Board consider replacing the proposed regulations with QA regulations adopted by the Ohio Board of Pharmacy. The Ohio regulations (4729$5-3-22_PH_FF_N_RU_20240906_1157.pdf(state.oh.us) accomplish the oversight and improvement provisions inherent to QA programs, establish reasonable and realistic requirements, and encourage the reporting, operation, and maintenance of QA programs.

If CLM can provide additional information or answer any questions related to our stated concerns, please do not hesitate to contact me. Thank you for your consideration.

Respectfully yours,

Daniel Luce
President
CLM Pharmacy Advisors

Animal Policy Group

September 23, 2024

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

Board of Pharmacy,

We recognize the importance of patient safety, including for our pets. However, the nature of closed-door, mail-order veterinary pharmacies makes it difficult to comply with section 1711.

We would like to ask the Board to limit this to human health, for the time being.
(b) For purposes of this section, "medication error" means any variation from a prescription or drug order for a human patient not authorized by the prescriber, as described in ~~S~~section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

We appreciate the Board's time. Please let us know if you have any questions.

Sincerely,

Scott Young
Senior Director, Pharmacy and Pharmaceutical Policy
scott@animalpolicygroup.com

SANTA CLARA VALLEY HEALTHCARE

Department of Pharmacy Services
777 Turner Dr. Suite 330
San Jose, CA 95128
(408) 885-2300

September 23, 2024
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear Lori Martinez,

We are submitting our comments related to Quality Assurance Programs. Please see below:

Board of Pharmacy - Quality Assurance Programs Proposed Text	**Recommendations**	**Comments/Rationale**
(B) The names of staff involved in the error.	Recommend to remove	A requirement to report the names of staff involved in medication errors is inconsistent with other quality assurance (QA) reviews in the inpatient and outpatient setting. QA reviews are intended to identify any systemic issues that need to be addressed, whereas other processes already exist to identify whether specific staff require discipline or other action. In addition, reporting of the names of staff involved in a medication error does not align with just culture.

If you have any questions, please contact us at (408) 885-2300 or via email at pharmacyadmin@hhs.sccgov.org.

Sincerely,

Department of Pharmacy Services
Santa Clara Valley Medical Center
777 Turner Dr, Suite 330
San Jose, CA 95128
Phone: (408) 885-2300
Fax: (408) 885-5822
Email: PharmacyAdmin@hhs.sccgov.org

September 20, 2024

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

Submitted via electronic mail to, Lori.Martinez@dca.ca.gov

SUBJECT: Board of Pharmacy Proposed Regulations: Amend Title 16, California Code of Regulations section 1711.

Dear Ms. Martinez:

On behalf of more than 400 hospitals and health systems, the California Hospital Association (CHA) appreciates the opportunity to comment on the Board of Pharmacy's (BoP) proposed regulations updating the requirements for each pharmacy to participate in an established quality assurance (QA) program to assess and document medication errors.

The BoP is a key partner with hospitals and their pharmacies to promote quality and safety for patients. The BoP's efforts to update these 20-year-old regulations to ensure they are consistent with modern pharmacy practices and to reduce medication errors are commendable. Ensuring the safe distribution of medication to patients is a core function of pharmacy practice, and pharmacists are integral in preventing medication errors, ensuring safe drug interactions, and helping avert other adverse medication events for patients.

Hospitals are deeply committed to patient safety and regulatory compliance and offer the following feedback for your consideration and action:

Section 1771 (e) (E) The volume of workload completed by the pharmacy staff on the date of the error, including clinical functions.

In the BoP's Initial Statement of Reason, the rationale for this requirement is based on a BoP survey "focused on the community pharmacy setting." Hospital and community pharmacies are very different, with hospitals operating in a clinical environment and community pharmacies operating in a retail, non-clinical environment. There is little to no evidence to support the need for a new costly and time-consuming requirement to gather workload statistics as part of every hospital's error reporting system.

Section 1771 (f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least three years from the date the record was created.

In the BoP's Initial Statement of Reason, it indicates that a 3-year retention period for QA records would "reduce confusion" and "provide more clarity to the ... public since records of drug acquisition and disposition must be maintained for a period of three years." There does not appear to be a correlation between record retention and reduction of confusion, and this change is not necessary. There is no evidence this time extension will advance error prevention and in fact would only add to the cost of health care in California at a time when all providers are working to reduce cost growth.

The California Legislature and the California Department of Health Care Access and Information are working diligently to lower health care costs. Every additional requirement a hospital must fulfill raises costs, which runs counter to this shared goal. These competing considerations must be balanced when updating regulations. Additionally, hospital pharmacies function very differently than community pharmacies, with hospitals serving much higher acuity patients. The BoP should consider the variation in the scope of services and responsibilities between the two types of pharmacies, especially given the extensive regulatory oversight of hospitals by multiple state and federal regulators.

CHA appreciates the opportunity to discuss these perspectives. If you have questions, please contact me at slowe@calhospital.org or 916-240-8277.

Sincerely,

Sheree Lowe

Sheree Lowe
Vice President, State Policy

Institution:	Valley Children's Hospital 9300 Valley Children's Place Madera, CA 93636	
Amended Sections	**Proposed/Modified Text**	**Comments/Recommendations**
16 CCR 1711 Page 1-2	(2) The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c), including: (A) The date and approximate time or date range when the error occurred if known or can be determined. If it cannot be determined, the pharmacy shall note "unknown" in the record. (B) The names of staff involved in the error. (C) The use of automation, if any, in the dispensing process. (D) The type of error that occurred. To ensure standardization of error reporting, the pharmacies' policies and procedures shall include the category the pharmacy uses for identifying the types of errors. (E) The volume of workload completed by the pharmacy staff on the date of the error, including clinical functions. If the date of the error is unknown, the average volume of workload completed daily shall be documented. For errors that occur in a community pharmacy, at a minimum the volume of workload records shall include the number of new prescriptions dispensed, the number of refill prescriptions dispensed, the number of vaccines administered, number of patient	**Comments:** As indicated in the Initial Statement of Reasons published for the proposed changes to CCR 1711, the Board's evaluation of medication errors and workforce survey was focused on community pharmacy settings, not in acute care hospitals. The volume of workload in a community pharmacy (i.e., number of prescriptions) is very different than the volume and type of workload in a hospital (i.e., IV compounding, automated dispensing cabinet refill, repackaging). Title 22 California Code of Regulations, Chapter 1 and Health and Safety Code (HSC) section 1339.63 requires that as a condition of licensure each hospital adopt a formal plan to eliminate or substantially reduce medication-related errors. Each facility's plan shall do the following: (1) Evaluate, assess, and include a method to address each of the procedures and systems listed under subdivision (d) to identify weaknesses or deficiencies that could contribute to errors in the administration of medication. (2) Include an annual review to assess the effectiveness of the implementation of each of the procedures and systems listed under subdivision (d). (3) Be modified as warranted when weaknesses or deficiencies are noted to achieve the reduction of medication errors. (4) Describe the technology to be implemented and how it is expected to reduce medication-related errors as described in paragraph (1) of subdivision (a). (5) Include a system or process to proactively identify actual or potential medication-related errors. The system or process shall include concurrent and retrospective review of clinical care. (6) Include a multidisciplinary process, including health care professionals responsible for pharmaceuticals, nursing, medical, and administration, to regularly

	consultations given, and any other mandatory activities required by the pharmacy employer. Prescriptions filled at a central fill location and dispensed at the pharmacy must be documented separately from other prescriptions filled at the pharmacy.	analyze all identified actual or potential medication-related errors and describe how the analysis will be utilized to change current procedures and systems to reduce medication-related errors. (7) Include a process to incorporate external medication-related error alerts to modify current processes and systems as appropriate. Failure to meet this criterion shall not cause disapproval of the initial plan submitted. Since the proposed language is clearly intended for outpatient pharmacies and hospitals already have requirements for quality assurance, please consider excluding facilities following Title 22 regulations.

September 20, 2024

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

Via Email: PharmacyRulemaking@dca.ca.gov

Re: Quality Assurance Program Proposed Regulation

Dear Ms. Martinez,

On behalf of the California Community Pharmacy Coalition (CCPC), I write to register the following comments and suggested modifications to the Board of Pharmacy's proposed regulation related to quality assurance programs.

The CCPC recognizes the Board's mission to protect pharmacy consumers. CCPC members have implemented Quality Assurance (QA) programs as required by the Board to help prevent medication errors and improve pharmacy services for Californians. We understand that the goal of the proposed QA program regulation is to "ensure a more robust review of the circumstances surrounding each error and identification of possible contributing factors, including workload, to help prevent future medication errors." While we appreciate this goal, we are concerned about the ability of our members to comply with many of the proposed requirements, some of which are vague and overly broad, and the impact to the workforce upon which our members rely for delivering care to the citizens of California.

In addition, passage of these amendments could potentially put pharmacies who are members of Patient Safety Organizations (PSOs) at odds with the requirements set forth in the Patient Safety and Quality Improvement Act of 2005 (PSQIA). PSOs have been established to achieve many of the same goals as the Board is trying to accomplish with these amendments. Reports made to a PSO are designated as Patient Safety Work Product (PSWP), and while each PSO participant can designate which elements of a report are PSWP, they typically include contributing factors, root cause analysis, and corrective action recommendations. Items designated as PSWP cannot be shared by PSO members and inappropriate disclosure could result in fines. Requiring pharmacies to make PSWP available for inspection or submitted to the Board could be considered an inappropriate disclosure.

Our primary and most significant concern relates to new Section 1711(e)(2)(E), which reads as follows:

> (E) The volume of workload completed by the pharmacy staff on the date of the error, including clinical functions. If the date of the error is unknown, the average volume of workload completed daily shall be documented. For errors that occur in a community pharmacy, at a minimum the volume of workload records shall include the number of new prescriptions dispensed, the number of refill prescriptions dispensed, the number of vaccines administered, number of patient consultations given, and any other mandatory activities required by the pharmacy employer. Prescriptions filled at a central fill location and dispensed at the pharmacy must be documented separately from other prescriptions filled at the pharmacy.

As written, our members would be unable to comply with this requirement. It is incredibly broad, and our member pharmacies do not specifically measure all data elements that are ascertainable in the provision as drafted. Further, it does not provide sufficient notice as to what the Board considers a "mandatory activity". For example, it could capture a task such as taking out the garbage since that is a "mandatory" activity. Collection of this data would also result in an increased administrative burden which is counterintuitive to the goal of this proposal.

Additionally, the separate tracking of central fill prescriptions is not possible. The split processing based on the shared nature of the work does not make local sense; the local community pharmacy and the central fill pharmacy both have shared responsibility and tasks that will be completed on a single prescription. We respectfully request that this section be removed.

The CCPC has additional concerns/suggestions with the proposed regulation as follows:

> Section 1711(e): analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:
>
> (1) The date, location, and participants in the quality assurance review;
>
> (2) The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c), <u>including</u>
> <u>(A) The date and approximate time or date range when the error occurred if known or can be determined. If it cannot be determined, the pharmacy shall note "unknown" in the record.</u>
> <u>(B) The names of staff involved in the error.</u>
> <u>(C) The use of automation, if any, in the dispensing process.</u>
> <u>(D) The type of error that occurred. To ensure standardization of error reporting, the pharmacies' policies and procedures shall include the category the pharmacy uses for identifying the types of errors.</u>

We recommend replacing the phrase "involved in the error" in (B) to "performing the step(s) in the dispensing process where the error originated and was not caught" because "involved" is overly broad. We also request that the word "automation" in (C) be defined because nearly every prescription has automation involved. Further, the requirement in (D) that the pharmacies' policies and procedures include the category the pharmacy uses for identifying the types of errors could jeopardize pharmacies' confidentiality. The categories pharmacies use for identifying the types of errors are proprietary and specific to each company, so we request that this requirement be removed.

> Section 1711(e)(4): Recommend changes to pharmacy policy, procedure, systems, or processes, if any.
> The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program. <u>Documentation of the steps taken to prevent future</u> errors <u>shall be maintained as part of the quality assurance report.</u>

Although many of our members contract with Patient Safety Organizations and make changes to systems, workflow, policies and processes, they do not necessarily communicate all steps specifically back to the specific individual in the field. This would be very costly to implement and if the stores were to make process changes in isolation, it could lead to destandardization. Where standardized workflows have built-in safeguards that drive patient safety, de-standardization could actually pose risks to patient safety. For this reason, we request that the documentation requirement be removed.

> Section 1711(f): The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least ~~one~~ <u>three</u> years from the date the record was created. Any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the ~~b~~Board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal of the facility license.

Requiring the record of the quality assurance review to be immediately retrievable in the pharmacy for at least three years would require our members to invest in significant system updates. We request that the timeframe remain one year.

In addition to the concerns and suggested revisions outlined above, we request a one-year delayed implementation of this regulation to allow pharmacies sufficient time to update their policies - and their systems - to comply.

The California Community Pharmacy Coalition is a project of the California Retailers Association and was formed to promote the positive impacts community pharmacies have within California's healthcare system by working on legislation and regulations that will expand access opportunities for community pharmacy services including in hard to reach, under-served areas where Californians often have very limited options for healthcare.

Thank you for taking our comments into consideration. Please do not hesitate to contact me at sarah@calretailers.com or Lindsay Gullahorn with Capitol Advocacy at lgullahorn@capitoladvocacy.com if you have any questions.

Sincerely,

Sarah Pollo
Policy Advocate
California Retailers Association

cc: Seung Oh, President, Board of Pharmacy
Anne Sodergren, Executive Officer, Board of Pharmacy
Julia Ansel, Deputy Executive Officer, Board of Pharmacy

From: Katrina Derry <Katrina.Derry@ucop.edu>
Sent: Monday, September 23, 2024 5:07 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Proposed Text Changes on Quality Assurance Programs

Hello,
I am writing to submit comments on Proposed Action to amend Section 1711, of Article 2 of Title 16, Division 17, of the California Code of Regulations related to the Quality Assurance Programs.

To: California Board of Pharmacy
RE: Proposed Text Changes to Quality Assurance Programs

The Medication Safety Officers at UCSF and UCI Health support promoting a culture of safety which prioritizes patient safety and engrains in its culture an environment where preventing, identifying, and reducing potential for harm from medication errors is of utmost importance. One of the key characteristics of a culture of safety is an environment that supports a reporting culture and a learning culture. In order to have visibility of potential and actual medication errors, the organization must provide psychological safety for its staff to communicate such risks. This is an environment where individuals will not be afraid of punitive action when involved in or reporting on actual or potential medication errors. There are several state and federal protections in place to provide health-systems with a quality improvement process that considers error reports to be protected and privileged and confidential. This supports front line staff in sharing errors so that medication use systems can be evaluated and improved and that staff can be educated and supported to provide safe patient care. Many organizations use a just culture model in which medication use systems and human actions and choices are evaluated in their role of contributing to medication errors and acted upon accordingly.

As such, the new addition of bullet B "(B) The names of staff involved in the error. " is in opposition to this tenet of safety culture, if the name of the individual involved in an error must be provided to the Board of Pharmacy. The unintended consequence of this requirement may likely be decreased voluntary reporting of errors due to fear of possible punitive action from the Board. The net effect of this will be fewer opportunities to learn from errors and make improvements to medication use systems and processes, and may unintentionally lead to increased patient harm over time.

Additionally, bullet E "The volume of workload completed by the pharmacy staff on the date of the error, including clinical functions. If the date of the error is unknown, the average volume of workload completed daily shall be documented. For errors that occur in a community pharmacy, at a minimum the volume of workload records shall include the number of new prescriptions dispensed, the number of refill prescriptions dispensed, the number of vaccines administered, number of patient consultations given, and any other mandatory activities required by the pharmacy employer. Prescriptions filled at a central fill location and dispensed at the pharmacy must be documented separately from other prescriptions filled at the pharmacy." has some challenges for health-system settings. This volume may be easier to quantify in a community pharmacy setting. However, hospital and health-system patient care delivery and operations are dynamic, diverse, and more challenging to quantify in a meaningful manner.

Health-system pharmacies currently have robust systems to improve safe use of medications and support quality assurance assessments, but recommend striking bullet B from the Quality Assurance Program requirements and excluding bullet E from health-system settings where a discreet volume of clinical and operational workload is more difficult to quantify.

Kind regards,

Katrina Derry, Kathy Ghomeshi, and Martin Torres

KAISER PERMANENTE®

September 20, 2024

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

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

RE: ***Proposal to amend section 1711 of Article 2 of Division 17 of Title 16 of the California Code of Regulations***

Dear Ms. Martinez:

Kaiser Permanente appreciates the opportunity to respond to the California Board of Pharmacy's request for comments on the proposed amendments to the Board's regulations pertaining to quality assurance programs. 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.

Kaiser Permanente commends the Board for its efforts to modernize its Quality Assurance (QA) program regulation. As discussed in the Initial Statement of Reasons, the regulation has gone unchanged for 20 years and would benefit from amendments to ensure that it is more consistent with modern pharmacy practice. We recommend a handful of modifications to the proposed regulation to ensure that the regulation is consistent with contemporary medication safety principles and to eliminate redundant event reporting requirements.

During the June 7, 2023 Medication Error Reduction and Workforce committee meeting, the committee received a presentation on Just Culture from the Institute for Safe Medication Practices.[1] During the discussion, the committee recommended that Board staff "look for opportunities to incorporate [Just Culture] concepts into [Board] investigations." Kaiser Permanente commends the Board for recognizing the importance of applying Just Culture principles to medication error investigations. We encourage the Board to amend the regulation as below to specify that licensees are expected to conduct medication error investigations using Just Culture principles. During its June 2023 meeting, the committee also discussed the Board's approach to medication errors, specifically that licensees are generally held accountable using administrative action such a citation with or without a fine. While we recognize that these instruments are not disciplinary action in the formal sense, we encourage the Board to consider whether this approach is consistent with Just Culture principles and the extent to which it might have a chilling effect on medication error reporting.

> (d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is

[1] California Board of Pharmacy, *August 2023 Meeting Materials*, https://www.pharmacy.ca.gov/meetings/agendas/2023/23_aug_bd_mat_xii.pdf (last visited Sept. 18, 2024).

discovered and shall be conducted in a manner consistent with Just Culture principles. All medication errors discovered shall be subject to a quality assurance review.

During its November 16, 2022 meeting, the Medication Error Reduction and Workforce committee reviewed several medication error reporting taxonomies, including the AHRQ common format for event reporting.[2] The AHRQ common format for event reporting for community pharmacies includes nine categories of contributing factors of which "technology/equipment" and "staffing and scheduling" account for two of the nine.[3] The proposed requirement to include information about the use of automation and pharmacy workload volumes in pharmacies' QA reports appears to presuppose that those two factors are more important contributing factors than any others. Furthermore, the regulation already requires the QA report to include documentation of "the findings and determinations generated by the quality assurance review," which should include information about the contributing factors identified. The purpose of the QA report is to provide documentation of the licensee's investigation and quality assurance review; if the licensee determines that the use of technology and/or staffing/workload were contributing factors to the error, then they will be documented in the QA report. However, if the use of technology and/or staffing/workload were not contributing factors, then we believe that information is superfluous and should not be included in the QA report. Finally, we know of no medication error reporting systems that provide discrete fields for documenting the pharmacy workload statistics identified in CCR 1711(e)(2)(E). If the regulation is finalized as written, we expect that organizations would be required to make costly and time-consuming updates to their error reporting systems to capture workload statistics in a discrete field. For the reasons outlined above, we recommend amending the proposed regulation as follows:

~~(e)(2)(C) The use of automation, if any, in the dispensing process.~~

…

~~(e)(2)(E) The volume of workload completed by the pharmacy staff on the date of the error,~~

~~including clinical functions. If the date of the error is unknown, the average volume of workload completed daily shall be documented. For errors that occur in a community pharmacy, at a minimum the volume of workload records shall include the number of new prescriptions dispensed, the number of refill prescriptions dispensed, the number of vaccines administered, number of patient consultations given, and any other mandatory activities required by the pharmacy employer. Prescriptions filled at a central fill location and dispensed at the pharmacy must be documented separately from other prescriptions filled at the pharmacy.~~

The requirement to report medication errors involving the use of an ADDS device in CCR 1711(f) was added to the regulation to provide the Board with the data it required to prepare a report to the legislature as required by Business and Professions Code section 4427.8. The Board is in the process of preparing the report to the legislature as evidenced by the Enforcement and Compounding committee's discussion of the report during its July 17, 2024 meeting. By the time this rulemaking is completed, we anticipate that the Board will have delivered the report to the legislature, thus fulfilling its obligation under BPC 4427.8. There is no statutory reason to require this kind of reporting to continue in perpetuity. Furthermore, with the enactment of Business and Professions Code section 4113.1, all community pharmacy medication errors will soon be reported to the Board via a Patient Safety Organization to be designated by the Board. Therefore, to eliminate redundant error reporting requirements in the Pharmacy Law, we request that the

[2] California Board of Pharmacy, *November 2022 Medication Error Reduction and Workforce Meeting Materials*, https://www.pharmacy.ca.gov/meetings/agendas/2022/22_nov_med_mat.pdf (last visited Sept. 18, 2024).
[3] PSO Privacy Protection Center, *Common Formats for Event Reporting - Community Pharmacy Version 1.0*, https://www.psoppc.org/psoppc_web/publicpages/commonFormatsCPV1.0 (last visited Sept. 18, 2024).

Board amends CCR 1711(f) to eliminate the requirement to report errors related to the use of ADDS devices to the Board.

In the Initial Statement of Reasons, the Board indicates that a three-year retention period for QA records would "reduce confusion" and "provide more clarity to the regulated public" since records of drug acquisition and disposition must be maintained for a period of three years.[4] Kaiser Permanente does not perceive any confusion over the various record retention periods and, as such, we do not believe that this change is necessary. Furthermore, requiring pharmacies to maintain QA records in the pharmacy for a period of three years will lead to greater difficulty in finding space within the pharmacy to store these records and will create additional administrative burdens for pharmacy staff to store and cull the records at the appropriate times. Therefore, we recommend continuing to require pharmacies to maintain QA records for a period of one year.

> (f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least ~~three~~ one year~~s~~ from the date the record was created. ~~Any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the Board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal of the facility license.~~

Kaiser Permanente appreciates the opportunity to provide feedback in response to the proposed amendments to the Board's regulations pertaining to quality assurance programs. 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

[4] California Board of Pharmacy, *Initial Statement of Reasons Quality Assurance Programs*, https://www.pharmacy.ca.gov/laws_regs/1711_isor.pdf (last visited Sept. 18, 2024).

September 23, 2024

Lori Martinez

2720 Gateway Oaks Drive Ste. 100
Sacramento, CA 95833
Email: PharmacyRulemaking@dca.ca.gov

RE: Proposed Draft Regulations – Quality Assurance Programs

Ms. Martinez:
On behalf of the Scripps Health we are submitting comments and recommendations below regarding the above mentioned proposed draft regulations.

Sincerely,

André Pieterse RPH, MBA, BCSCP, HACP, PRS

Director Pharmacy Services – Regulatory, Compliance & Medication Safety

Scripps Health

10010 Campus Point Dr.

San Diego, CA 92121

pieterse.andries@scrippshealth.org

scripps.org

Institution/Contact Name: André Pieterse – Scripps Health		
Section, Subdivision	**Proposed Language**	**Recommendation / Comment**
CCR 1711(e)	(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following: (1) The date, location, and participants in the quality assurance review; (2) The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c); including: (A) The date and approximate time or date range when the error occurred if known or can be determined. If it cannot be determined, the pharmacy shall note "unknown" in the record. ~~(B) The names of staff involved in the error.~~ (C) The use of automation, if any, in the dispensing process. (D) The type of error that occurred. To ensure standardization of error reporting, the pharmacies' policies and procedures	In reference to section B: It must be noted that Business and Professions Code 4125(b) gives protection of quality assurance programs in that it is considered peer review documents. The fact that this regulation will require the names of staff involved in the error gives concern that the Board and its staff will be using this information discovered during routine inspections and complaint investigations in proceedings involving disciplinary action against licensees. Additionally, under the 'Just Culture' model, creating an open, fair and Just Culture relies on developing managerial competencies that appropriately hold individuals accountable for their behaviors, and investigates the behavior that led to the error. Regarding human error, managers console the individual, then consider changes in processes, procedures, training and design. At-risk behavior suggests the need for coaching and managing through removing incentives for at-risk behavior; creating incentives for healthy behaviors; and increasing situational awareness. With reckless behavior, it is necessary to manage through remedial action and/or punitive action. By requiring the names of the individuals involved in the error, this requirement implies that blame will be placed for errors on individuals while there should be a system in place of shared accountability in which organizations are accountable for the systems and processes they have designed and for responding to the behaviors of their employees in a fair and just manner. By obtaining the names of those purportedly involved in an error and assigning blame, error reduction efforts will be severely hampered and will lead to staff reporting fewer errors. This will in turn lead to more errors being made. It is recommended to remove this requirement from the regulation.

	shall include the category the pharmacy uses for identifying the types of errors. (E) The volume of workload completed by the pharmacy staff on the date of the error,including clinical functions. If the date of the error is unknown, the average volume of workload completed daily shall be documented. For errors that occur in a community pharmacy, at a minimum the volume of workload records shall include the number of new prescriptions dispensed, the number of refill prescriptions dispensed, the number of vaccines administered, number of patient consultations given, and any other mandatory activities required by the pharmacy employer. Prescriptions filled at a central fill location and dispensed at the pharmacy must be documented separately from other prescriptions filled at the pharmacy. (F) *Exempt from these requirement are health facilities, as defined in Section 1250 of the Health and Safety Code, that follows the requirements of section 1339.63 of the Health and Safety Code.* (3) The findings and determinations generated by the quality assurance review; and, (4) Recommend changes to pharmacy policy, procedure, systems, or processes, if any. The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program. Documentation of the steps taken to	In reference to section E: The regulation change requiring documentation of pharmacy workload as it applies to clinical functions could negatively impact hospitals and hospital pharmacies by increasing administrative burdens, straining resources, and potentially disrupting work. This added responsibility may divert focus from patient care, reduce efficiency, and place additional stress on pharmacy staff. Clinical workload in hospital and other healthcare settings can vary significantly based on high variability in workload. Patient volume and patient complexity and acuity as it relates to errors is difficult to define when comparing less complex and greater workload to more complex and less workload and many other variables. Documenting this dynamic workload in a standardized, consistent manner could be tremendously challenging and may not accurately reflect the intensity and complexity of a staff member's clinical and operational duties. Inpatient workload can vary dependent the number of emergencies that present during a given day, which then can take away of routine direct patient care job functions. Reprioritization and pivoting are a constant presence within acute care pharmacists' job function and does not allow for consistent metrics to be obtained. Pharmacists are heavily involved in direct patient care including but not limited to: medication reconciliation, dosing adjustments and monitoring for adverse events. However, to set a standard and determine what is "clinical workload volume" across a realm of different staffing areas and specialties are not realistic metrics to obtain since they are so variable. While tracking workload is important, the specific documentation of clinical workload may not directly correlate with medication errors in an acute care hospital setting. Errors in these environments are often linked to factors such as communication breakdowns, system failures, or complex clinical scenarios, rather than the sheer volume of tasks. Therefore, focusing on workload documentation may not effectively address the root causes of errors in acute care hospitals.

	prevent future errors shall be maintained as part of the quality assurance report.	While retail pharmacy settings lend itself to simplified prescription volume metrics, the proposed regulation is an outdated model that is out of touch with the growth of clinical pharmacy in both the acute care and ambulatory settings. This regulation appears to assume that pharmacy is a profession practiced only in the retail setting and does not account for the shift that is seen towards clinical pharmacy where a pharmacist is highly involved in the clinical care of a patient as part of a team. In summary, requiring acute care hospital pharmacists and pharmacists practicing in clinical settings to document workload under CCR 1711 will not be practical or useful. The nature of their work is highly variable, fast-paced, complex and critically focused on patient care. This will make detailed workload documentation both burdensome and potentially detrimental to patient safety and care efficiency. Acute care hospitals already have a statutory requirement (Health and Safety Code 1339.63) in place that requires medication error reduction programs (MERP). These programs provide a vastly superior framework that effectively accomplishes the reduction of medication errors in hospitals. This has been recognized by board inspectors on a regular basis during licensing inspections in hospitals. Adding another layer of documentation will be redundant and place unnecessary strain on hospital and institutional pharmacies while offering no additional value. It is recommended that acute care hospitals and those institutions already mandated to follow HSC 1339.63 be exempt from the requirements of CCR 1711.
	~~(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality~~	As an alternative to the modifications requested above, it is recommended that, as a matter of policy, the board give consideration for a completely different approach regarding quality assurance in pharmacy settings. On the surface, the approach of specifying what items may be considered during a QA review seems like the logical approach. However, for those with careers and experience in performance and quality improvement in healthcare, the attempt by the board to solve very complex issues with a few lines of regulations

	~~assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:~~ ~~(1) The date, location, and participants in the quality assurance review;~~ ~~(2) The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);~~ ~~including:~~ ~~(A) The date and approximate time or date range when the error occurred if known or can be determined. If it cannot be determined, the pharmacy shall note "unknown" in the record.~~ ~~(B) The names of staff involved in the error.~~ ~~(C) The use of automation, if any, in the dispensing process.~~ ~~(D) The type of error that occurred. To ensure standardization of error reporting, the pharmacies' policies and procedures shall include the category the pharmacy uses for identifying the types of errors.~~ ~~(E) The volume of workload completed by the pharmacy staff on the date of the error,including clinical functions. If the date of the error is unknown, the average volume of workload completed daily shall be documented. For errors that occur in a community pharmacy, at a minimum the volume of workload records shall include the number of new prescriptions dispensed, the number of refill prescriptions dispensed, the number of vaccines administered, number of patient consultations given, and any other~~	falls short and is predicted to have minimal impact in reducing medication errors. Patient safety is a complex interface of systems and processes with human behaviors. Generally accepted principles in quality and performance improvement are multifaceted and data driven. What the board proposes incorporates only one facet of quality improvement which is known by many terms but most commonly 'root cause analysis'(RCA) is used. While the RCA has its uses, it usually is a one-off event and for those with limited experience in performing this specialized analysis it will be done superficially and it likely will not achieve the desired result of ensuring lasting success. Proof of this can be seen in the fact that the board has not seen a drop in reported errors and complaints as an outcome metric since the institution of statutes and regulation requirements for a Quality Assurance Program for pharmacies. Experience has shown that data specific to the practice setting is needed for any improvement methodology. To this effect, there is reliance on data and methods such as, proactive reviews, retrospective reviews, internal alerts, external alerts, rapid cycle improvements and measuring the outcomes of improvement experiments. There are well developed improvement models such a LEAN Methodology, Six Sigma and many others that have proven success and track records at companies such as Toyota who have proven themselves masters of defect (error) reduction. The biggest omission in this regulation is that no credence is given for potential/near miss errors. These are the biggest opportunities to learn from since a reduction in potential errors translate to a reduction in actual serious errors. Instead, there is sole reliance on retrospective review and analysis of a single error. It is also recommended, as an alternative to the above recommendations, that consideration be given to a well-rounded strategy in creating rules for a holistic error prevention program. The Board should explore the CDPH developed Medication Error Reduction Program (MERP) legislation for hospitals (HSC1339.63) almost 20 years ago and how this could be applied to ALL pharmacy practice settings. The proposed regulation adapted from HSC 1339.63 is an example of what a medication error reduction program should look like in

	~~mandatory activities required by the pharmacy employer.~~ ~~Prescriptions filled at a central fill location and dispensed at the pharmacy must be documented separately from other prescriptions filled at the pharmacy.~~ ~~(3) The findings and determinations generated by the quality assurance review; and,~~ ~~(4) Recommend changes to pharmacy policy, procedure, systems, or processes, if any. The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.~~ ~~Documentation of the steps taken to prevent future errors shall be maintained as part of the quality assurance report.~~ (e) Every pharmacy shall adopt a formal plan to eliminate or substantially reduce medication-related errors. (f) Each pharmacy's plan shall do the following: (1) Evaluate, assess, and include a method to address each of the procedures and systems listed under the categories of prescribing, prescription order communications, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, and technology to identify weaknesses or deficiencies that could contribute to errors in the dispensing and administration of medication.	the context of quality assurance. It must be noted that this error reduction system has been yielding impressive results in medication error reduction in hospitals since its inception.

	(2) Include an annual review to assess the effectiveness of the implementation of each of the procedures and systems listed under subdivision (1). (3) Be modified as warranted when weaknesses or deficiencies are noted to achieve the reduction of medication errors. (4) Describe the technology to be implemented and how it is expected to reduce medication-related errors as described in paragraph (1) of subdivision (a). (5) Include a system or process to proactively identify actual or potential medication-related errors. The system or process shall include concurrent and retrospective review. (6) Include a process to regularly analyze all identified actual or potential medication-related errors and describe how the analysis will be utilized to change current procedures and systems to reduce medication-related errors. (7) Include a process to incorporate external medication-related error alerts to modify current processes and systems as appropriate. (~~f~~g) The ~~record~~ plan ~~of the quality assurance review,~~ as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one three years ~~from the date the record was created~~. Any quality assurance record related to the use of a licensed automated drug delivery system must	

	also be submitted to the ~~b~~Board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal of the facility license. (h~~g~~) The pharmacy's compliance with this section will be considered by the ~~b~~Board as a mitigating factor in the investigation and evaluation of a medication error. (i~~h~~) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.	

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

September 23, 2024

Lori Martinez
Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833

Via email: PharmacyRulemaking@dca.ca.gov

Re: Quality Assurance Programs – Amending section 1711 of Title 16, Division 17, Article 2 of the California Code of Regulations

Dear Ms. Martinez,

On behalf of our members operating chain pharmacies in the state of California, NACDS thanks the Board of Pharmacy for the opportunity to submit comments on the Quality Assurance Programs proposed regulations amending section 1711 of Title 16, Division 17, Article 2 of the California Code of Regulations. Although NACDS appreciates the Board of Pharmacy's commitment to improving patient safety through pharmacy quality assurance programs designed to reduce medication errors, NACDS has a number of concerns with the proposed regulations.

Adoption of these amendments could potentially put pharmacies who are members of Patient Safety Organizations (PSOs) at odds with the requirements set forth in the Patient Safety and Quality Improvement Act of 2005 (PSQIA). PSOs have been established to achieve many of the same goals as the Board is trying to accomplish with these amendments. Reports made to a PSO are designated as Patient Safety Work Product (PSWP), and while each PSO participant can designate which elements of a report are PSWP, they typically include contributing factors, root cause analysis, and corrective action recommendations. Items designated as PSWP cannot be shared by PSO members and inappropriate disclosure could result in fines. Requiring pharmacies to make PSWP available for inspection or requiring pharmacies to submit PSWP to the Board could be considered an inappropriate disclosure.

Comments and Proposed Changes

We offer the following comments and proposed changes to the proposed regulation:

Proposed changes made to the current regulation language are shown by strikethrough for deleted language and underline for added language. Amend section 1711 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows: § 1711.

Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program that documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c) (1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

(1) The date, location, and participants in the quality assurance review;

(2) The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision

(c)~~;~~, including: Board of Pharmacy Proposed Text Page 2 of 2 16 CCR § 1711 Quality Assurance Programs 4/6/2024

(A) The date and approximate time or date range when the error occurred if known or can be determined. If it cannot be determined, the pharmacy shall note “unknown” in the record.

(B) The names of staff involved in the error.

We recommend replacing the word “involved” with the word “responsible” because “involved” is too broad. Also, we recommend the Board further analyze this amendment to determine whether or not it may conflict the federal Patient Safety Act of 2005 which is built on the premise that a reported incident and the protected information should not be tied back to a healthcare provider to ensure the provider feels comfortable reporting incidents in the future.

(C) The use of automation, if any, in the dispensing process.

We recommend the Board define the “use of automation” as this term count be interpreted to be ambiguous.

(D) The type of error that occurred. To ensure standardization of error reporting, the pharmacies’ policies and procedures shall include the category the pharmacy uses for identifying the types of errors.

This requirement that the pharmacies' policies and procedures include the category the pharmacy uses for identifying the types of errors could jeopardize pharmacies' confidentiality. The categories pharmacies use for identifying the types of errors are proprietary and specific to each company, so we request that this requirement be removed.

> (E) The volume of workload completed by the pharmacy staff on the date of the error, including clinical functions. If the date of the error is unknown, the average volume of workload completed daily shall be documented. For errors that occur in a community pharmacy, at a minimum the volume of workload records shall include the number of new prescriptions dispensed, the number of refill prescriptions dispensed, the number of vaccines administered, number of patient consultations given, and any other mandatory activities required by the pharmacy employer. Prescriptions filled at a central fill location and dispensed at the pharmacy must be documented separately from other prescriptions filled at the pharmacy.

As written, pharmacies may be unable to comply with this requirement. It is incredibly broad, and pharmacies do not specifically measure all activities conducted within the pharmacy. The increased administrative burden of collecting these additional data points to measure all activities conducted within the pharmacy is counterintuitive to the objective. We respectfully request that this section be removed.

(3) The findings and determinations generated by the quality assurance review; and,

(4) Recommend changes to pharmacy policy, procedure, systems, or processes, if any. The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program. Documentation of the steps taken to prevent future errors shall be maintained as part of the quality assurance report.

We recommend the Board further analyze this amendment to determine whether or not it may conflict the federal Patient Safety Act of 2005. The "documentation" may be designated as Patient Safety Work Product (PSWP).

(f) The record of the quality assurance review, as provided in subdivision

(e) shall be immediately retrievable in the pharmacy for at least three years from the date the record was created. Any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal of the facility license.

Requiring the record of the quality assurance review to be immediately retrievable in the pharmacy for at least three years would require pharmacies to invest in significant system updates. Also, we recommend the Board further analyze this amendment to determine whether or not it may conflict with the federal Patient Safety Act of 2005, specifically the role of the Patient Safety Organization (PSO).

g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section. NOTE: Authority cited: Sections 4005 and 4125, Business and Professions Code; and Section 2 of Chapter 677, Statutes of 2000. Reference: Sections 4125 and 4427.7, Business and Professions Code.

We support the Board's efforts to protect patient safety and encourage the Board to consider our comments in support of quality assurance efforts by licensees through patient safety organizations. In addition to the concerns and recommendations outlined above, we request a one-year delayed implementation of this regulation to allow pharmacies sufficient time to update their policies and system to comply. If you have any questions or need additional information, please contact Sandra Guckian, RPh, MS, IOM, Vice President, State Pharmacy & Advocacy, at sguckian@nacds.org or 703-774-4801.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

CC: Seung Oh, President, Board of Pharmacy
Anne Sodergren, Executive Officer, Board of Pharmacy
Julie Ansel, Assistant Executive Officer, Board of Pharmacy

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NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.