



WA Pharmacy Quality Assurance Commission - Business Practices Committee

Issue Assessment – Draft: April 25, 2015

Name of Issue: Quality Control

Concerns	Patient safety is negatively impacted when pharmacies do not have a quality control program in place to identify, quantify, and address errors.
Evidence	<p>Virtually all industry activities related to public safety require QC, including airlines, rail transport, police and fire protection, food production and distribution, and drug manufacturing. Medicare Part D requires participating pharmacies to implement a continuous quality improvement (CQI) program, as do a growing number of third-party payers in the private sector and state pharmacy boards. A number of health care environments including hospitals have QI/QC requirements. Hundreds of studies have been published showing the benefits of CQI programs on public safety across a wide range of industries.</p> <p>The watershed 1999 Institutes of Medicine study, “To Err is Human,” concluded that most medical errors result from systems, process and conditions that lead people to make mistakes, more than “bad apples.” Major recommendations fell in these areas: (1) a national focus on safety; (2) public mandatory reporting of selected indicators of (hospital) errors, combined with voluntary reporting on broader measures in a confidential (QI) environment; (3) raising performance expectations for safety improvements through regulation, professional groups and purchasers; and (4) implementing safety systems and a “culture of safety,” with medication processes given as a major example requiring actions by multiple parties.</p> <p>A series of structured questions in the 2014 “Washington Pharmacy Survey” addressed quality improvement processes and response to errors. Among more than 3,000 respondents:</p> <ul style="list-style-type: none"> • 80% agree or strongly agree that when mistakes happen, there are efforts to identify why; but agreement falls to 68% when the question asks about learning from mistakes “rather than punishing them,” and only 62% say there mostly or always is discussion on how to prevent recurrence. Questions do not define “mistake.” • 77% agree that mistakes are documented when they reach the patient and could cause harm, but only 24% say documentation occurs if mistakes reach the patient/could not cause harm, or if they could cause harm but are corrected before dispensing. Nuances in these questions illustrate the importance of defining what is an error. • Response patterns suggest incomplete execution of QI approaches. • Committee discussion of the survey on 1/6/15 noted that (1) documentation takes time and for minor errors, this time may not be well spent; and (2) Discovery of errors (baseline for any response) is lower without universal counseling. • For more detail see slides 15-22 in the attached slide pack reporting results of the survey’s structured questions. <p>[Possible later addition: Should we address aspects of the ISMP “Medication Safety Self-Assessment for Community/Ambulatory Pharmacy, ”such as its “Quality Processes and Risk Manatement” domain, or the eight highlighted “self-assessment characteristics with the highest weight”?]</p>
Current Law	Only addressed in Washington <u>pharmacy</u> rules under:

<p>(Summary and References)</p>	<p>Hospital: WAC 246-873-110 (non-specific requirement for QA program) Sterile Compounding: WAC 246-871-080 (surveillance adverse reactions; incident reports on “drug errors”) Dialysis: WAC 246-905-050 (non-specific requirement for QA program) ADDD's: WAC 246-872-050 (general components for QA program)</p> <p>There are QI requirements in statute and WAC for some other licensed health care corporate entities including hospitals (RCW 70.41.200), ambulatory surgery facilities (RCW 70.230.080), and assisted living facilities (RCW 18.20.390).The hospital and ambulatory surgery provisions require disclosure to DOH as part of inspection and review. In addition RCW 43.70.510 allows voluntary formation of coordinated quality improvement programs by state licensed health care institutions and medical facilities (other than hospitals due to their separate law), or by groups of five or more providers. All of the above laws provide immunity from disclosure in civil suits.</p>
<p>Other States (Summary)</p>	<p>Arizona: R4-23-620 Rule is under "Professional Practices". Pertains to all types of pharmacies. Permit holder and PIC are accountable. Included in Pharmacy Policy and Procedures and reviewed biennially. CQA requires personnel training, error documentation and analysis, implementation of solutions, and annual review with pharmacy personnel. Record retention of review is two years. Regulatory oversight by BOP limited to inspection of CQA P&P and enforcing pharmacy's compliance with P&P. Limits state Board's regulatory oversight to compliance with policies, and requires consideration of compliance as a mitigating factor in investigating/evaluating medication error.</p> <p>California: 1711 Rule is under "Pharmacies". Pertains to all types of pharmacies. Permit holder is accountable. QA requires patient and provider notification. Error analysis and documented review required within two business days. Record retention of error review is one year. Compliance may mitigate error.</p> <p>Connecticut: 20-635-1 though 6 Rule is under "Quality Assurance Programs for Pharmacies". Pertains to all pharmacies. QA requires patient and provider notification. Error analysis and documented review required. Record retention of error review is three years and available for inspection within 48 hours.</p> <p>Florida: 64B16-27.300 Rule is under "Pharmacy Practice, Standards of Practice". Pertains to all types of pharmacies. PIC is accountable. Included in Pharmacy Policy and Procedures. CQI requires error documentation and analysis, including staffing levels, workflow and technology support, and implementation of solutions. Requires pharmacy staff CQI Committee that reviews errors every three months. A redacted Summarization of Quality Related Events required in P&P for BOP review. Record retention is two years. Identified records protected from discovery in civil or administrative actions.</p> <p>Iowa: 657-8.26 (155A) Rule is under "Universal Practice Standards". Pertains to all types of pharmacies. PIC is accountable. Requires patient and provider notification. CQI requires personnel training, error documentation and analysis, including staffing levels, workload,</p>

	<p>technology, training; and annual review with pharmacy personnel. Record retention is two years. Discovery protections.</p> <p>Indiana: IAC Rule 1/28.1-11 Rule is under "Institutional and Home Health Care". Pertains to institutional pharmacies. PIC is accountable. QI requires error documentation and analysis, including staffing levels, and implementation of solutions. Requires pharmacy staff QI Committee that reviews errors every three months. A redacted summary report of improvement efforts required semiannually. Record retention is two years. Discovery protections.</p> <p>Maryland: Chapter 26 Section .04 Rule is under "Patient Safety". Pertains to all pharmacies. Permit holder is accountable. Error analysis and documented review required every 3 months. Pharmacy required to maintain, document, and review a list of "high-alert" medications every 6 months. Record retention is two years. Discovery protections.</p>
<p>Action Options (Rule Making or Other)</p> <p>These are purely options of what we may or may not want to use.</p>	<ul style="list-style-type: none"> • Place rule under WAC 246-869-010, "Pharmacies' Responsibilities" or under a new rule, "Continuous Quality Assurance Program for Pharmacies" under Chapter 246-869, "Pharmacy Licensing". • Rule pertains to all types of pharmacies, including non-resident. Address under "Accountability" issue whether non-resident pharmacy's PIC should have WA pharmacist license. • Hold both the permit holder and/or PIC accountable. • Delineate QAC components: error identification--notification--analysis--plan of correction--documentation--report--review--retention. • Require patient notification and prescriber notification where warranted. Require personnel training, error documentation and analysis, and implementation of solutions. Define what errors subject to documentation: Only if reach patient? Only if cause harm? "Potentially serious" per ISMP (which includes "serious near-misses")? Broad discretion? • Require analysis to address work flow, staffing, technology, training. • Consider a deadline or time frame for analysis and documentation and implementation of solutions. • Require a Pharmacy QC Committee meeting at set intervals for error review and P&P recommendations if necessary. Require PIC and/or permit holder review. Require error/QC review with pharmacy personnel at set intervals or after each error. • Require a redacted summary report or QC reports to be kept on site for compliance inspection, both to review compliance with QA process, and for other inspection purposes such as level of errors. Require report(s) to be sent to permit holder. Set a time period for record retention. • Discovery protections in civil suits. • In order to avoid redundant, conflicting or inefficient requirements, align structure and process for any new mandatory pharmacy QI programs with those for any new Statement of Charges/Plan of Correction approach to pharmacy inspections that might result from the exploration of licensing procedures that was authorized by the Commission on March 12, 2015.

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Applicable WACs

WAC 246-873-110

Additional responsibilities of pharmacy service.

(1) General. The pharmacy service shall participate in other activities and committees within the hospital affecting pharmaceutical services, drugs and drug use.

(2) Quality assurance. The pharmaceutical service shall establish a pharmacy quality assurance program.

(3) Clinical activities. The director of pharmacy should develop clinically oriented programs, including but not limited to obtaining and recording comprehensive drug histories and participation in discharge planning to affect appropriate drug use, a formal drug information service, prescribing, and administration of drugs

WAC 246-871-080

Quality assurance.

There shall be a documented, ongoing quality assurance program that is reviewed at least annually.

(1) The quality assurance program shall include but not be limited to methods to document:

- (a) Medication errors;
- (b) Adverse drug reactions;
- (c) Patient satisfaction;
- (d) Product sterility.

There shall be written documentation that the end product has been tested on a sampling basis for microbial contamination by the employee responsible for compounding parenteral products. Documentation shall be on a quarterly basis at a minimum.

(2) Nonsterile compounding. If bulk compounding of parenteral solutions is performed utilizing nonsterile chemicals, extensive end product testing, as referenced in *Remington*, must be documented prior to the release of the product from quarantine. This process must include appropriate testing for particulate matter and testing for pyrogens.

(3) Expiration dates. There shall be written justification of the chosen expiration dates for compounded parenteral products.

WAC 246-905-050

Quality assurance.

Home dialysis programs involved in the distribution of legend drugs as permitted by RCW [18.64.257](#) and 69.41.032, shall develop a quality assurance program for drug distribution and shall maintain records of drug distribution errors and other problems, including loss due to damage or theft.

WAC 246-872-050

What are quality assurance and performance improvement requirements for the use of automated drug distribution devices?

Each facility shall establish and maintain a quality assurance and performance program that includes but is not limited to:

- (1) Accuracy of medication filling and removal;

- (2) Regular review of controlled substances discrepancies;
- (3) Use of the data collected to take action to insure quality of care and make improvements to the automated drug distribution device system;
- (4) Documentation of the outcomes of the quality assurance activities.