



## American Society for Pharmacy Law

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### DISCIPLINE

#### Pharmacies in Washington state begin new self-inspection process

Effective March 1, the Washington State Pharmacy Quality Assurance Commission promulgated new rules regarding pharmacy inspections (WAC 246-869-190). Every year in March, the responsible pharmacy manager must complete a self-inspection using forms provided by the Commission and must sign the self-inspection report and retain it in the pharmacy's files for 2 years. In addition, if there is a change in the responsible manager, the new responsible manager must complete a self-inspection within 30 days, sign, and retain the work sheets for 2 years.

The worksheets contain 49 specific inspection components, plus specific audits of 10 patient profiles for compliance with required elements, and 5 profiles for compliance with DUR requirements. Also, an audit must be done of 5 patients who have requested non-child-resistant containers. Additional work sheet addenda are to be completed for hospital, nuclear, sterile-compounding, and long-term care pharmacies. Managers are responsible for noting any instance of noncompliance and recording the date when the noncompliance has been corrected and the actions taken.

Commission-initiated inspections at a random interval will include prior notification to the pharmacy that an inspection may be conducted within the next 6 months. At that point, the pharmacy has 14 days to specify up to 14 calendar-day "blackout dates," with justification as to why the pharmacy should be counted as unavailable for inspection. The inspection that results will itself be unannounced. At the end of the inspection, the Commission will prepare a report indicating areas of noncompliance and the pharmacy ("uncorrected deficiencies") and the pharmacy will have an opportunity to prepare a plan of correction for approval by the Commission. (PQAC Policy & Procedure No. 58, March 1, 2018)

The new rules replace the former "A," "Conditional," and "Unsatisfactory" ratings that were posted on an inspection certificate with the requirement that a pharmacy may not retain its license unless it has completed an inspection without deficiencies or is in the process of complying with an approved plan of correction. (WAC 246-869-040)

The Commission will continue to conduct unannounced inspections without any prior notice in response to complaints, upon a finding by a quorum of the Commission that an investigation should be opened. [Wash. Dept. of Health, PQAC. Pharmacy Inspections; 2018 Mar 1; <http://bit.ly/2otDym9>]