

EMAIL ALERT

The Colorado Department of Regulatory Agencies (“DORA”) is conducting a sunset review of the Colorado statute regulating Pharmaceuticals and Pharmacists (C.R.S. § 12-22-101 *et seq.*, the “Pharmacy Act”), which is scheduled to sunset on July 1, 2012. In conducting its sunset review, DORA must determine whether any changes should be made to the Pharmacy Act. DORA is currently considering making a recommendation that ASCs be added to the Pharmacy Act’s definition of “Other Outlet,” which would require an ASC to register with the State Board of Pharmacy if it dispenses prescription drugs or controlled substances to its patients. There is a \$100 fee for registration, which would need to be renewed every other year in order for an ASC to continue dispensing drugs.

Other Outlet Registration

ASCs currently are not regulated by the State Board of Pharmacy, so any drugs provided to ASC patients are obtained under the DEA license of one of the ASC’s physicians. If ASCs were required to register with DORA, they would directly obtain any drugs provided to their patients, but would also have to comply with requirements applicable to Other Outlets. Although Other Outlet regulations are less stringent than those applied to retail pharmacies, Other Outlets are subject to a variety of requirements with respect to consultant pharmacists, written protocols, record-keeping, and inspections, among others.

Consultant Pharmacist Requirements

Registration as an Other Outlet would require an ASC to engage a consultant pharmacist who would be available to the ASC for consultation, and be responsible for providing written protocols for dispensing by non-pharmacists (“Protocols”). The consultant pharmacist would be required to review the Protocols on an annual basis and perform quarterly inspections of the ASC to assure its compliance with the Protocols.

Written Protocols

Other Outlets are required to submit their proposed Protocols for approval by the State Board of Pharmacy prior to implementation. In addition to general information regarding the Other Outlet, the Protocols must include descriptions of:



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(1) the types of drugs that are stocked by the Other Outlet; (2) the Other Outlet's drug storage areas, including physical construction, nature of locks, and security of any outside windows; (3) the Other Outlet's procedures for outdated and recalled drugs; (4) the Other Outlet's drug labeling, dispensing records, and packaging if it packages its own drugs; (5) the Other Outlet's systems for drug receipt recordkeeping (locations of invoices, receipts, DEA-222 forms, controlled substance inventories, etc.), drug storage, and documentation of distribution policies; and (6) the consultant pharmacist's inspection and Protocol review procedures. Any subsequent changes to the Protocols must be approved by the State Board of Pharmacy prior to implementation.

Recordkeeping Requirements

The Other Outlet regulations include extensive recordkeeping requirements related to general records, inventory records, dispensing records, receipts (invoices for drugs received and drugs credited), and distribution, loss, surrender, and disposal records. The majority of the required records must be retained for at least 2 years and be readily available upon request by State Board of Pharmacy inspectors.

Inspections and Disciplinary Actions

Other Outlets are subject to inspections of the facility, drugs, and appropriate records. The State Board of Pharmacy also has statutory authority to discipline or fine a registrant, and/or to suspend or revoke registration for violation of the statutory requirements.

Additional information regarding regulation of Other Outlets, as well as links to the Pharmacy Act, Other Outlet regulations, and registration and Protocols forms, can be accessed through DORA's website at:

<http://www.dora.state.co.us/pharmacy/bus/otheroutlet.htm>

DORA has requested CASCA's feedback no later than Wednesday, June 22, 2011. Accordingly, CASCA is requesting input from its members regarding the impact that the proposed change would have on their facilities. If you have questions or would like to contribute your comments, please contact Rob Schwartz, Executive Director of CASCA, at 303.761.1048.