South Carolina Department of Labor, Licensing and Regulation

South Carolina Board of Pharmacy

GUIDANCE DOCUMENT

Health System Non-Dispensing Drug Outlet Permits

This Guidance Document is issued by the South Carolina Board of Pharmacy pursuant to the authority delegated to the Board in the South Carolina Pharmacy Practice Act, including S.C. Code Ann. Regs. 99-43(K) and S.C. Code Ann. §§ 40-43-10; 40-43-30(27), (28); 40-43-86(B), (C); and 40-43-60(D).

The South Carolina Board of Pharmacy ("Board") offers a Health System Non-Dispensing Drug Outlet Permit ("HSND") that allows certain facilities within a hospital or health system that do not dispense drugs or devices to patients to operate under a distinct regulatory structure. The HSND permit classification was developed to streamline the regulatory permitting process for health systems by allowing consolidation of certain qualifying non-dispensing facilities under a single permit rather than requiring each facility to obtain its own non-dispensing drug outlet permit. This guidance document outlines key requirements, limitations, and structuring options for health systems seeking to ensure regulatory compliance when utilizing this permitting model.

Background of the HSND Permitting Classification

On May 15, 2023, Board of Pharmacy Regulation, S.C. Code Ann. Regs. 99-43, *Facility Permit Classifications*, was revised to create Subsection K, creating a Hospital-Owned Health System – Non-Dispensing Drug Outlet Permit ("Health System Non-Dispensing Drug Outlet Permit"). Implementation of Subsection K was delayed until the March 2024 Board Meeting at which point the Board addressed questions from various health systems regarding the permit. Following additional questions raised in early 2025 by the Board's Health System Committee, the Board provided further guidance during the March 2025 Board meeting.

Overview – Health-System Non-Dispensing Drug Outlet Permit v. Non-Dispensing Drug Outlet Permit

The table below is intended to provide a quick reference of the differences between the HSND and NDDO permits. Health systems are encouraged to consult with their legal counsel to determine the best permitting structure for their operational needs.

	Health System Non-Dispensing Permit (HSND)	**Non-Dispensing Drug Outlet Permit (NDDO)**
Permit Structure	Must be associated with a permitted hospital pharmacy (*institutional pharmacy practice setting ONLY*); a hospital institutional pharmacy may have two permits for one physical pharmacy location if one of those pharmacy permits is solely affiliated with the HSND permit	For any clinic/practice that stores and/or administers legend drugs or devices that a health system chooses not to roll under a HSND permit, each facility must be permitted as a NDDO absent an exception to the permitting requirement
PIC/Consultant Pharmacist	PIC of associated pharmacy is responsible for all clinics/practices rostered under the HSND permit; a consultant pharmacist is not required for each rostered facility	Must have a consultant pharmacist for each NDDO permit
	PIC may serve on both the pharmacy permit and HSND without coming before the Board for approval to serve as a PIC for two facilities; a second PIC may be named to cover the rostered sites only if a second pharmacy permit is sought and obtained to be solely affiliated with the HSND permit	Consultant pharmacist is responsible for all duties of a consultant pharmacist
Inspection Requirements	Monthly inspections of each rostered site must be conducted and available at the HSND permit site for review by the Board upon request; PIC is responsible for determining who completes the monthly inspection (does not have to be RPh)	Monthly inspections of the permitted facility must be conducted, and these inspections available on-site at the permitted facility
	Any rostered sites may be inspected during an inspection of the institutional pharmacy holding the HSND permit	Facility is inspected as a standalone NDDO site by the Board
Controlled Substances	If a facility stores or administers controlled substances, it may not be rostered underneath an HSND	Controlled substances storage and administration acceptable, assuming compliance with all other relevant law