



# Legislative Summary: In-Office Dispensing State Regulations Overview

*The information contained in this document is for reference only and is not an endorsement or business advice from CSRO. Practices should consult an attorney regarding the laws governing their state and the impact on their particular circumstances.*

In response to the inquiries CSRO has received about in-office dispensing, CSRO has developed a reference tool outlining the legislative and regulatory landscape to help inform rheumatologists who want to learn more about in-office dispensing.

States vary widely in how they approach in-office dispensing: some allow it with few or no limitations, while others heavily regulate the process. A table is provided on page two of this document summarizing regulations by state with descriptions of the regulation categories below – if a state is not listed, no regulations of that type are known. Please note, this information is meant as a general overview; exceptions may exist. Practices who are considering incorporating in-office dispensing into the services they offer should consult with an attorney who has expertise related to state-level pharmacy regulation.

## IN-OFFICE DISPENSING REGULATION CATEGORIES:

- **Controlled Substances Regulation:** State does not allow physicians to dispense certain controlled substances or places supply limitations on those substances.
- **Demonstration of Need:** State requires a demonstration of need prior to a permit being issued to a practice. Practices may have to demonstrate difficulty obtaining a medication or lack of geographic pharmacy access for a specific patient or area.
- **Established Patient Limitation:** State limits the ability to dispense to patients who are under the physician's care.
- **License Requirement:** Physicians may be required to qualify for and maintain a license to operate an in-office dispensing operation. State licensure requirements will typically be more onerous than state registration requirements in terms of required documents, written policies and procedures, and inspections. Practices may need to pay a fee as part of the licensure process. If dispensing controlled substances, state may have additional requirements along with any federal requirements. *States that do not require a license may have requirements related to dispensing of controlled substances.*
- **Prohibited Dispensing:** Physician dispensing is generally prohibited with very limited exceptions.
- **Registration Requirement:** State requires dispensing physicians to register with a state regulatory agency or board. Requirements typically include submission of forms as well as record and inventory requirements, and a fee may be charged. If dispensing controlled substances, state may require registration in addition to any Federal registration requirements. *States that do not require registration may have requirements related to dispensing of controlled substances.*
- **Reimbursement Limitations:** State imposes reimbursement limitations for drugs dispensed by a practice.
- **Supply Limitations:** State applies limits to the supply a physician is able to dispense in-office. These limitations can make in-office dispensing economically prohibitive.

State	Controlled Substance Regulation	Demonstration of Need	Established Patient Limitation	License Requirement	Prohibited Dispensing	Registration Requirement	Reimbursement Limitations	Supply Limitations
Arizona						Yes		
Arkansas		Yes				Yes		
California			Yes					
Florida	Yes					Yes		
Georgia						Yes <sup>①</sup>		
Hawaii				Yes				
Idaho						Yes		
Iowa						Yes <sup>②</sup>		
Louisiana						Yes		
Maryland						Yes		
Massachusetts								Yes
Michigan				Yes				
Missouri			Yes					
Montana	Yes					Yes		
Nebraska				Yes				
Nevada				Yes				
New Hampshire	Yes							
New Jersey							Yes	Yes
New Mexico			Yes					
New York								Yes
North Carolina				Yes				
Ohio				Yes				
Oklahoma						Yes		
Pennsylvania	Yes							Yes
Rhode Island			Yes					
South Carolina			Yes	Yes <sup>③</sup>				
South Dakota			Yes			Yes		
Tennessee			Yes					
Texas					Yes <sup>④</sup>			
Utah					Yes			
Vermont			Yes					
Virginia				Yes				
West Virginia			Yes			Yes		
Wisconsin			Yes					
Wyoming					Yes			

Yes<sup>①</sup> - A letter of intent must be submitted to the Georgia Composite Medical Board | Yes<sup>②</sup> - Must notify state board of intent periodically

Yes<sup>③</sup> - Required for "non-owned" sites | Yes<sup>④</sup> - Geographic need exception