



Idaho State Board of Pharmacy

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Background:

- What led to the revision of the rule? Was there any directive from the Idaho legislature or was it prompted internally by the Board? **Idaho Code 54-1735 was amended in 2015, this rule change returns the language.**

Scope:

- Does the reporting requirement apply to the sale of both legend drugs and controlled substances? **Yes**
- Does the reporting requirement apply to direct sales of vaccines to Idaho practitioners? **No, vaccines are administered by the provider and not required to be reported.**
- Does the rule apply to the provision of free goods pursuant to Patient Assistance Programs? Product in these programs is earmarked for a specific patient, but ultimately shipped to a practitioner for administration (e.g., in the case of vaccines and specialty products). **Yes, as they are dispensed by the practitioner.**
- Please confirm that if an entity does not ship (or otherwise provide products) to Idaho practitioners, the entity does not need to submit a report, but it must inform the Board and provide its facility name, license number, and note that it does not ship to practitioners. **Correct**
- Is this notification required monthly or is a single notification sufficient? **If you do not ship to practitioners, one notification is enough. If you do ship to practitioners monthly reporting is required.**

Samples:

- Does the reporting requirement apply to the provision of both legend drug samples and samples of controlled substances? **Controlled substance are required to be reported, though legend drug samples are not.**
- Does the reporting requirement include reporting of samples that are hand delivered by Sales Professionals? **If they are controlled substances, yes.**
- Does the reporting requirement include reporting of samples that are shipped to Idaho practitioners? **If they are controlled substances, yes.**
- Does the reporting requirement apply if a manufacturer uses a 3PL to ship samples to practitioners but does not directly distribute the samples itself? **If they are controlled substances, yes.**
- If an HCP has an Idaho license but also practices in another state, does the reporting requirement apply only to the samples distributed in the state of Idaho or to all samples? **The reporting requirement is only for samples distributed to an Idaho practice address.**

Reports:

- Does Idaho Board of Pharmacy want one file submission from a company with direct sales and samples combined on one worksheet or separate trade sales and samples worksheets and/or files? **One worksheet is fine.**

Identification Numbers

- In reviewing the data requirements, Idaho is requesting that companies report the DEA number associated with the physician practice that purchased a prescription product from the company. As part of the customer onboarding process, many companies add customer identifiers that are associated with the shipping address of the customer. This requirement is aligned to the Drug Supply Chain Security Act (DSCSA) track and trace customer linking and sales reporting process. In many cases, a doctor's DEA is associated with their home address and not the practice location. In these instances, many companies do not add the DEA number to the customer record but instead add a Health Industry Number (HIN) number that is specifically assigned to that location. The HIN number is established by the Health Industry Business Communications Council (HIBCC.org). This number is a standard industry number utilized by both manufactures and wholesaler/distributors to identify a customer. Can you please confirm that a DEA number is not required for direct sales by the state of Idaho and in the monthly report can we substitute a HIN number for the DEA? **The DEA number must be reported for any controlled substance medications. The practitioner's professional license number should be listed for legend drug sales.**
- In addition, many companies providing products to Public Health Service (PHS) covered entities only store the PHS ID associated with these shiptos. This ID is utilized universally as a means to validate eligibility with the PHS program. These shiptos would also not have a DEA. Should companies instead report the PHS number? **The DEA number must be reported for any controlled substance medications. The practitioner's professional license number should be listed for legend drug sales.**
- A DEA number is not required for sample distribution unless it is a controlled substance. If a company does not sample controlled substances its sample disbursement records and reporting system may not have this information readily available. It may be able to be found through research. Is the company obligated to research and provide the DEA number in the Idaho submission? **Not for legend medications, but for controlled substances, yes.**
- Many companies contract and sell to Idaho physician practices comprised of multiple physicians. When a company, for example, receives a vaccine order from a practice, in most cases it is place by the Office Manager for the location and the product is dispensed by multiple physicians. As part of the customer onboarding process, the company obtains a Idaho HCP State License for that practice and documents in the system the proxy name associated with that license. For the Board of Pharmacy's report, the company may only be able to provide the Idaho State License and proxy name associated with that sale. In many cases this will not be the physician who dispensed the vaccine. Does the reporting requirement apply to these situations? **The Board will exempt Vaccines from the reporting requirement. are not required to be reported.**
- Is providing the Idaho State License and Proxy Name associated with the sale meeting the reporting requirements? **No, it does not.**
- The company likely does not have visibility to all licensed physicians within a practice or the products that they dispense. **The wholesaler should list the practitioner's name and professional license number.**

