

Economic Impact Statement

LSA Document #07-541

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

This proposed rule adds [856 IAC 4](#) to establish standards for pharmacists administering immunizations for influenza under a physician's approved protocol as is permitted by Indiana Code 25-26-13-31.2. Indiana's General Assembly mandated the Indiana Board of Pharmacy to adopt rules under [IC 4-22-2](#) concerning the qualifications, protocols, and record keeping requirements for a pharmacist to administer immunizations.

Pharmacists have always been allowed to immunize per a physician's prescription. The legislation allows for pharmacists to engage in the same practice under a physician's approved protocol.

The rule explicitly states the type of training that is necessary for a pharmacist to immunize in conjunction with a standing protocol and what must be included in said protocol.

Impact on Small Businesses**1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule:**

NAICS CODE 446	110 Pharmacies	400*
NAICS CODE 621	Ambulatory Health Care	160
NAICS CODE 622	Hospitals	125
NAICS CODE 623	Nursing and Residential Care Facilities	
	Comprehensive Care Facilities	518
	Residential Care Facilities	88

[IC 4-22-2.1-4](#) provides that "small business" means any person, firm, corporation, limited liability company, partnership, or association that:

- (1) is actively engaged in business in Indiana and maintains its principal place of business in Indiana;
- (2) is independently owned and operated;
- (3) employs one hundred (100) or fewer full-time employees; and
- (4) has gross annual receipts of five million dollars (\$5,000,000) or less.

Of the approximately 1,400 retail pharmacies in Indiana, staff of the Indiana Board of Pharmacy estimates that 1,000 are chain drug stores that do not meet the definition of a small business.

There are currently 9,100 holders of active Indiana pharmacist licenses. A NAICS code is not assigned to pharmacists. Of these 9,100 licensees, 6,463 have Indiana addresses and, of these, an unknown percentage do not actively practice pharmacy.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small business will incur to comply with the proposed rule.

- (a) The proposed rule does not mandate immunization by protocol.

The rule only serves as direction to pharmacists who choose to immunize under protocols. The rule requires standard training that a pharmacist should already have if he or she is administering, training that is now mandated by the General Assembly. If a pharmacy elects to immunize, the pharmacy/pharmacist will be required to comply with the rule. Since the rule does not mandate small businesses to train pharmacists to immunize, small businesses will incur reporting, record keeping, and other costs associated with immunization under a protocol only if they elect to provide this service.

- (b) The proposed rule requires only additional training for pharmacists who voluntarily choose to provide this service to their patients with no other cost to small business.

The cost of immunization under a protocol derives principally from the capital investment of training pharmacists in accordance with the rule's requirements. That capital investment may be no more than the paid time off allowing a pharmacist the opportunity to complete the training. Immunization training is available through free online continuing education programs. In lieu of free online training, the Indiana Pharmacists Alliance (IPA) provides training courses for \$215.

Those expenses are offset by the increase in vaccinations at pharmacies (30% increase by one retail chain estimate). Pharmacy vaccinations are also administered at lower cost to patients who pay almost three times as much for physician office vaccinations

- (c) The proposed rule requires additional record and reporting in very limited instances.

All pharmacies are already required to engage in record keeping related to drug dispensing and

administration by both state and federal law and that record keeping is not impacted by the rule.

The only additional record keeping/reporting required is in the event of an adverse event associated with the immunization. In the event of an adverse event, the pharmacist must report to the patient's physician and the physician that approved the protocol. In addition the adverse event must be reported to the Vaccine Adverse Events Reporting System (VAERS). There is no cost to report to VAERS, and the reporting can be done electronically.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

The costs of the rule derive principally from the capital investment of training pharmacists in immunization. Expenses are offset by the increase in vaccinations at pharmacies as the income associated therewith.

It should be recognized that the immunization training is available to pharmacists at no cost. The cost of training will be between a range of zero dollars (all pharmacists utilize the free training) to \$1,389,545 (all pharmacists within Indiana pay \$215 for the training). It is reasonable to assume that not all pharmacists will obtain the training and that, of those who do, an unknown but small percentage will elect to pay for training.

There will also be some cost associated with obtaining training in cardiopulmonary resuscitation (CPR). Training in CPR ranges from \$20 to \$40 and is available online or through certified instructors. Many pharmacists are already CPR certified, and, of those not trained, employers will save costs through training programs.

In addition, it is reasonable to assume that some pharmacies will contract with a physician to develop the protocols required by statute.

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; or any other state or federal law.

The training required by statute to be adopted by rule is to ensure that pharmacists who immunize have the proper skill set to provide this service to patients.

The General Assembly explicitly sought these requirements to be included in the rule. "The rules must include the following requirements: (1) The pharmacist must have completed an accredited training program. (2) The pharmacist must be certified in cardiopulmonary resuscitation (CPR)." [IC 25-26-13-31.5](#).

5. Regulatory flexibility analysis

Consideration of alternative methods of achieving the purpose of the proposed rule

There is no alternative as the General Assembly mandated the training requirements. Such training is not available without cost.

Conclusion

Pharmacists can play an important role in disease prevention by advocating and administering immunizations. Allowing pharmacists to administer immunizations under a physician's protocol can result in increasing immunization rates. Public safety is the primary Board responsibility. The requisite training in the rule ensures that pharmacists who immunize under a standing doctor's order will have the skill set necessary to properly administer vaccinations.

Supporting Data, Studies, or Analyses

Non-Traditional Settings for Influenza Vaccination of Adults: Costs and Cost Effectiveness.

Pharmacoeconomics. 26(2):163-178, 2008. Lisa A. Prosser; Megan A. O'Brien; Noelle-Angelique M. Molinari; Katherine H. Hohman; Kristin L. Nichol; Mark L. Messonnier; Tracy A. Lieu

Michael J. Simko R.Ph., Clinical Pharmacy Services, Walgreens

Tabitha Cross, Director of Professional Development, Indiana Pharmacists Alliance

Websites providing ACPE training for immunization:

http://www.pharmacist.com/AM/Template.cfm?Section=Quick_List_Search

http://www.neu.ceedutest.com/ce_im/

Posted: 05/28/2008 by Legislative Services Agency

An [html](#) version of this document.