H.B. 276*
136th General Assembly

Occupational Regulation Report

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Primary Sponsors: Reps. John and Holmes

Impacted Profession: Dangerous drug manufacturers and their agents and affiliates

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LSC is required by law to issue a report for each introduced bill that substantially changes or enacts an occupational regulation. The report must: (1) explain the bill's regulatory framework in the context of Ohio's statutory policy of using the least restrictive regulation necessary to protect consumers, (2) compare the regulatory schemes governing the same occupation in other states, and (3) examine the bill's potential impact on employment, consumer choice, market competition, and cost to government.[1]

LEAST RESTRICTIVE REGULATION COMPARISON

Ohio's general regulatory policy

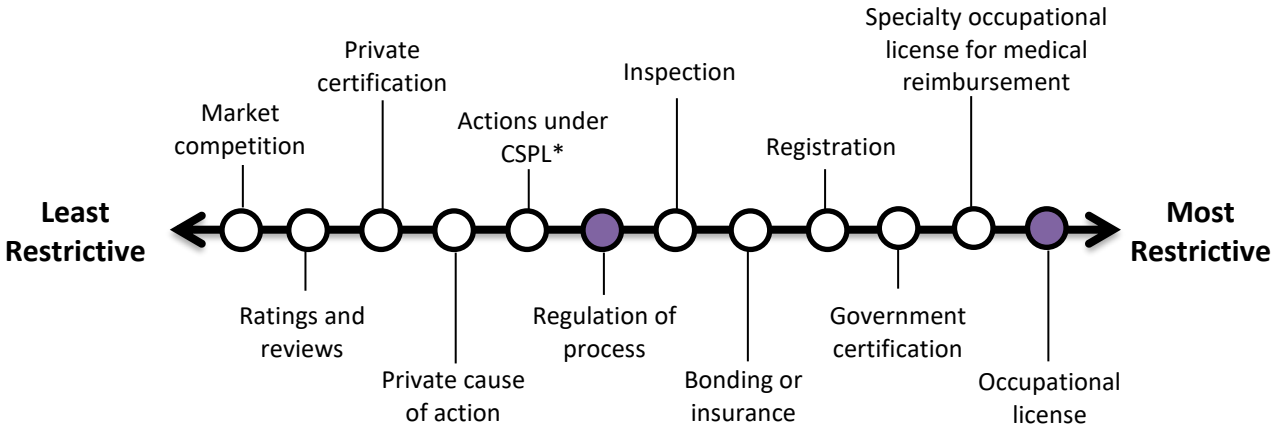
The general policy of the state is reliance on market competition and private remedies to protect the interests of consumers in commercial transactions involving the sale of goods or services. For circumstances in which the General Assembly determines that additional safeguards are necessary to protect consumers from "present, significant, and substantiated harms that threaten health, safety, or welfare," the state's expressed intent is to enact the "least restrictive regulation that will adequately protect consumers from such harms."[2]

The degree of "restrictiveness" of an occupational regulation is prescribed by statute. The following graphic identifies each type of occupational regulation expressly mentioned in the state's policy by least to most restrictive:

* This report addresses the "As Introduced" version of H.B. 276. It does not account for changes that may have been adopted after the bill's introduction.

[1] R.C. 103.26, not in the bill.

[2] R.C. 4798.01 and 4798.02, neither in the bill.



*CSPL – The Consumer Sales Practices Law

H.B. 276 prohibits a manufacturer of dangerous drugs or its agent or affiliate from limiting the acquisition of an outpatient "340B drug" by an entity that provides care to the medically underserved and that is eligible under the federal 340B Drug Pricing Program to obtain the drug at a reduced price.[3] Under the bill, violators are subject to various potential consequences, such as imposition of civil penalties or revocation of the dangerous drug manufacturer's license.[4]

In accordance with the law governing occupational regulation reports, this report discusses only the bill's occupational impact on the following: (1) individuals and (2) businesses that must obtain a license for which the applicant must satisfy a personal qualification.[5] Because continuing law requires a manufacturer of dangerous drugs to obtain a license (from the State Board of Pharmacy),[6] and because a license applicant must pass a criminal records check[7] (i.e., a personal qualification), this report will cover such manufacturers as well as their agents and affiliates.

Necessity of regulations

The bill's primary sponsors, Representative Marilyn John and Representative Adam Holmes, testified that the bill aims to ensure that certain safety net providers eligible for reduced drug prices under the federal 340B Drug Pricing Program are able to participate in that program as intended. They explained that this federal program requires drug manufacturers to enter into an agreement with the U.S. Secretary of Health and Human Services via which they commit, in exchange for having their drugs covered by Medicare and Medicaid, to provide front-end discounts on covered outpatient drugs purchased by "covered entities."

[3] R.C. 3902.72(B).

[4] R.C. 3901.22, not in the bill; R.C. 3902.72(C) and (D); and R.C. 4729.56(A), not in the bill.

[5] R.C. 103.26 and 103.27, not in the bill.

[6] R.C. 4729.52(B), not in the bill.

[7] R.C. 4729.53(A), not in the bill.

Representatives John and Holmes further elaborated that these covered entities include Federally Qualified Health Centers (FQHCs) that: (1) are located in areas of high need and serve vulnerable populations, (2) are open to all, regardless of insurance status or ability to pay, and (3) provide comprehensive primary and preventative medical, dental, vision, and mental health care; substance abuse disorder treatment; and affordable pharmacy services. They stated that FQHCs serve nearly a million patients from over 550 locations in 76 of Ohio's 88 counties. Representatives John and Holmes asserted that some FQHCs have struggled to receive the full benefits of the 340B Drug Pricing Program, and they said that, due to slim operating margins, many FQHCs report that they need the savings from that program to support core services for their patients.

Representatives John and Holmes indicated that covered entities other than FQHCs, such as community health centers, also are experiencing a reduced ability to use 340B drug cost savings to support health care programs. The sponsors explained that, because Ohio has not developed state-specific 340B distribution guidelines, some drug manufacturers have limited their distribution and delivery of drugs to the contracted pharmacy networks that support FQHC patients. Representatives John and Holmes stated that, as a result, patients are forced to travel to obtain their medications, and some who do not have the means to travel must go without. They said that, in addition to patients not getting the care they need, this leads to heightened utilization of emergency rooms as well as increased costs and stress to the entire healthcare system.

Representatives John and Holmes testified that the bill will prohibit drug manufacturers from refusing to ship medically necessary medications to a 340B covered entity or its pharmacy partners. They explained that, by establishing specific guidelines for delivery and distribution of 340B drugs in Ohio, their goal is to ensure that the program works as intended, to allow FQHCs to receive all the benefits of 340B drug discount pricing, and to provide health care access to those most in need.[8]

Restrictiveness of regulations

Licensure

Licensure is the most restrictive of all regulatory options identified within the state's continuum of regulations. Accordingly, the state's policy prescribes a narrow range of situations in which required licensure is appropriate; specifically, when all of the following circumstances are present:

- The occupation involves providing a service regulated by both state and federal law;
- The licensing framework allows individuals licensed in other states and territories to practice in Ohio; and

[8] See Representatives Marilyn John and Adam Holmes, H.B. 276 Sponsor Testimony (PDF), House Insurance Committee, June 10, 2025, which is available on the General Assembly's website, legislature.ohio.gov, by searching for "H.B. 276" and looking under the "Committee Activity" tab.

- The licensing requirement is based on uniform national laws, practices, and examinations that have been adopted by at least 50 U.S. states and territories.[9]

It appears that both continuing law and the bill satisfy the state policy's first criterion because aspects of distributing and pricing 340B drugs are regulated by both Ohio and federal law. The 340B Drug Pricing Program is established in federal law, and Ohio law regulates contracts between a terminal distributor of dangerous drugs and a 340B covered entity.[10]

As for the state policy's second criterion, it appears that licensing dangerous drugs manufacturers satisfies it. Continuing law authorizes the Board to issue a dangerous drugs manufacturer license to an out-of-state applicant who holds an analogous license issued by another state with similar licensure requirements and who pays the required licensure fee.[11]

Regarding the third criterion, neither current law nor the bill satisfies it because licensure of dangerous drugs manufacturers is not based on uniform national laws.

Discipline for violating bill

Under continuing law, manufacturers of dangerous drugs must by licensed by the State Pharmacy Board.[12] Under the bill, a licensed manufacturer that violates the bill's prohibitions (see "**Prohibitions involving 340B drugs**," below) may be subject to license denial, limitation, restriction, probation, suspension, or revocation. (The bill authorizes the Superintendent of Insurance to refer a complaint of such a violation to the Board for the consideration of such sanctions.)[13] In this way, the bill appears to increase restrictiveness for the licensees.

Process regulations

The state's policy does not provide specific guidance as to when a regulation of process is the best means of protecting the health, safety, and welfare of consumers. However, the policy as a whole suggests that regulations of process are the most preferred method of regulation when market competition, ratings and reviews, private certifications, private causes of action, and actions under the state's Consumer Sales Practices Law do not provide sufficient protection.[14]

Whether these mechanisms are a sufficient means of protecting consumers is a policy decision. However, continuing Ohio law establishes numerous process regulations that govern the distribution of dangerous drugs. For example, continuing law authorizes a manufacturer of

[9] R.C. 4798.02, not in the bill.

[10] 42 United States Code 256b and R.C. 4729.49.

[11] R.C. 4729.52(D), not in the bill.

[12] R.C. 4729.52(B), not in the bill.

[13] R.C. 3902.70(C); R.C. 4729.56(A), not in the bill.

[14] R.C. 4798.01, not in the bill.

dangerous drugs to furnish a sample drug to a charitable pharmacy if certain conditions are met.[15]

Prohibitions involving 340B drugs

The bill appears to increase restrictiveness by prohibiting a dangerous drugs manufacturer or its agent or affiliate from doing either of the following (unless the U.S. Department of Health and Human Services specifies otherwise):

- Limiting a 340B covered entity's acquisition of a 340B drug; or
- Requiring a 340B covered entity to submit any claims or utilization data as a condition of acquiring a 340B drug.[16]

The bill further increases restrictiveness by establishing consequences for these violations. One such consequence is a mandatory cease and desist order. Notably, another consequence includes a potential civil penalty of $50,000 for each violation, up to $10 million annually, and each package of drugs determined to be a violation constitutes a separate violation. In addition, a violator may be required to return payments received as a result of the violation and to pay attorney fees and other costs of investigating the violation.[17]

IMPACT STATEMENT

Opportunities for employment

The bill has no direct employment effects. Under H.B. 276, terminal distributors, manufacturers, or repackagers of dangerous drugs, along with third-party logistics providers, are prohibited from limiting the acquisition of a 340B drug or requiring a 340B grantee to submit any claims or utilization data, except when required to do so by U.S. law. Violators may be referred by the Superintendent to the Board for consideration of one or more of the sanctions specified in continuing law. These sanctions include suspension, revocation, restriction, limitation, and refusal to grant or renew a license, reprimand, and imposition of a fine.

While a noncomplying party could lose a state-issued license and thus be barred from employment in this field, it is unlikely that H.B. 276 will result in any changes in the labor market. No new licensing procedures or requirements are created. All parties currently working in this field or seeking to enter it would be free to continue with only a restriction of behavior, not a requirement for new action.

Consumer choice

The bill has no direct effects on the choices of citizen consumers. Under H.B. 276, consumers can freely trade with any healthcare provider, and those providers in turn can trade with any drug distributor in compliance. Consumers may face indirect effects if applying new

[15] R.C. 3719.811(B), not in the bill.

[16] R.C. 3902.72(B).

[17] R.C. 3902.72(C) and (D), and R.C. 3901.22 and 4729.56(A), not in the bill.

restrictions induce the marginal distributor, manufacturer, repackager, or logistics provider to leave the field. In an unregulated market, this reduction of competition would increase the market power of remaining parties, and this would be experienced by the consumer as increased prices. However, provision of prescription drugs is a highly regulated market, so manufacturers' opportunities to exploit market power are curtailed.

The current binding constraint on consumers is the effect of the behavior H.B. 276 seeks to prohibit. When a manufacturer limits 340B grantees ability to purchase drugs, these grantees either pay the market rate and pass the higher price on to the consumer or they decrease the scope of their operations to save costs, creating higher costs for the consumer in distance traveled or waiting times. The marginal patient faced with higher drug costs – either direct money costs or indirect opportunity costs – will forego using the drug, experiencing negative health outcomes. H.B. 276 seeks to increase consumer choice by shielding 340B entities from these market forces. As explained below, reliance on a purely unregulated drug market has offsetting suboptimalities.

Market competition

In a free market, professionals offer arrays of services to best serve potential customers. Some drug manufacturers and distributors would voluntarily refrain from the practices prohibited by the bill, while others would refrain from only some and still others from none at all. Their trading partners, 340B grantees, would choose the party who offered the combination of cost and services desired. Parties who best met the desires of more 340B grantees would have stronger reputations and would receive more business, while those disappointing 340B grantees would have worse reputations and would see their business prospects dwindle. In turn, 340B grantees engaging in a free market with citizen consumers would also provide an array of service and price options, and consumers would be free to trade with any desirable firm.

The market for healthcare in the U.S. is missing many key components of a free market that allow it to operate efficiently as just described. Drug manufacturers may hold patents that protect them from competition. Entities such as 340B grantees face high fixed costs, leading them to have larger facilities that are less numerous and farther apart. The final consumer of healthcare services, the citizen consumers receiving medical treatment, often face limited choices dependent on the healthcare provider available through their medical insurance. Each departure from the free-market ideal provides another opportunity for a party to use its market power to influence the terms of trade. In the case of 340B drugs, suppliers might choose to limit services to 340B grantees in an effort to require the drugs be procured through a different, more lucrative process. The economic term for when a party attempts to increase income through nonproductive bureaucratic limitations is rent-seeking. The same services are provided with the same efficiency, only profit is increased. Federal and state commerce laws have long supported the reduction of rents and opportunities for rent-seeking, thus keeping costs low for consumers. The rent-seeking restrictions of H.B. 276 are in that spirit. By keeping drug distributors and manufacturers from rent-seeking, the bill will allow 340B covered entities to face lower costs. This, in turn, will enable these entities to reduce costs for the consumer, so the marginal consumer will not be dissuaded from using medicines prescribed for better health.

Cost to government

For costs to government, please see the LSC fiscal note (PDF).

SUMMARY OF PROPOSED REGULATIONS

The bill authorizes the Superintendent to adopt rules or delegate rulemaking authority to the Board to implement the bill's requirements.[18]

In addition, the bill specifies that its provisions are not to be construed to conflict with or be less restrictive than applicable existing federal or state law or regulations.[19]

For a more detailed explanation of the bill, please see the LSC bill analysis (PDF).

[18] R.C. 3902.72(C) and (D).

[19] R.C. 3902.72(E).

COMPARISON TO OTHER STATES

Of the states surrounding Ohio, only West Virginia prohibits drug manufacturers from limiting specified entities' acquisition of a 340B drug. Several other states, such as Arkansas, Maryland, Minnesota, and Missouri, also have enacted such prohibitions. The table below summarizes those laws and related penalties.

State	Manufacturer Prohibitions Involving 340B Drugs	Potential Related Penalties
Ohio (under the bill)	Prohibits dangerous drugs manufacturers from: (1) limiting a 340B covered entity's acquisition of a 340B drug, or (2) requiring a 340B covered entity to submit any claims or utilization data as a condition for acquiring a 340B drug *(R.C. 3902.72(B))*	▪ License denial, limitation, restriction, probation, suspension, or revocation; ▪ Return of payments received as a result of the violation; ▪ Civil penalty of $50,000 for each package of drugs involved in the violation, up to $10 million annually; and ▪ Payment of attorneys and other costs of investigating the violation. (In addition, mandatory cease and desist order) *(R.C. 3902.72(C) and (D) and R.C. 3901.22 and 4729.56(A), not in the bill)*
Arkansas	Prohibits a pharmaceutical manufacturer from: (1) denying access to its drugs by a pharmacy that contracts or participates with a 340B covered entity; or (2) denying or prohibiting 340B drug pricing for Arkansas-based community pharmacies that receive drugs purchased under an arrangement with a 340B covered entity *(Ark. Code Ann. § 23-92-604(c))*	▪ Monetary penalty in an amount up to $1,000 for each violation, not to exceed $10,000, unless the violator knew or should have known it was in violation, in which case the penalty is in an amount up to $5,000 for each violation, not to exceed $50,000 in any six-month period; and ▪ License suspension or revocation if the licensee knew it was in violation. *(Ark. Code Ann. § 23-66-210; 23 Ark. Code Ann. R. 152-105)*

State	Manufacturer Prohibitions Involving 340B Drugs	Potential Related Penalties
Maryland	Generally prohibits a manufacturer that has signed a 340B pricing agreement from denying or limiting acquisition of a 340B drug by, or delivery of such a drug to, a pharmacy authorized to receive the drug on a 340B covered entity's behalf *(Md. Health Occ. Code § 12-6C-09.1(c))*	▪ $5,000 civil fine per package of 340B drugs involved in the violation; ▪ License discipline, suspension, or revocation; ▪ Injunction; ▪ Recovery of costs in Attorney General action; and ▪ Fine in an amount up to $1,000 or imprisonment up to one year or both. (In addition, mandatory cease and desist order) *(Md. Comm. Code §§ 13-403, 13-408, 13-409, and 13-411; Md. Health Occ. Code §§ 12-6C-09.1)*
Minnesota	Prohibits a drug manufacturer from restricting, prohibiting, or interfering with the delivery of a 340B drug to a pharmacy under contract with a 340B covered entity to receive and dispense the drugs on the entity's behalf *(Minn. Stat.§ 62J.96)*	None
Missouri	Prohibits a pharmaceutical manufacturer from denying, restricting, or prohibiting acquisition of a 340B drug by, or delivery of such a drug to, a pharmacy authorized to receive the drug on a covered entity's behalf *(Mo. Rev. Stat.§ 376.414)*	▪ If the violation is willful, knowing, and involves the intent to defraud: up to four years imprisonment plus a fine in an amount up to $10,000 or double the amount of financial gain from the violation; ▪ Award of actual and punitive damages, attorney fees, and equitable relief in a private lawsuit (including a class action); ▪ Injunction (and civil penalty of up to $5,000 for each violation of the injunction);

State	Manufacturer Prohibitions Involving 340B Drugs	Potential Related Penalties
		▪ Order of restitution to a person who has suffered a loss due to the violation; ▪ Civil penalty in an amount up to $1,000 per violation; ▪ Assessment of court costs; and ▪ License discipline, suspension, or revocation. *(Mo. Rev. Stat. §§ 376.414, 407.020(3), 407.025, 407.095, 407.100, 407.110, 407.130, 558.011, and 558.002)*
West Virginia	Generally prohibits a manufacturer of drugs or biological products or the manufacturer's agent or affiliate from: (1) denying, restricting, or prohibiting acquisition of a 340B drug by, or delivery of such a drug to, a location that a 340B entity has authorized to receive the drug , or (2) requiring a 340B entity to submit claims or utilization data as a condition for allowing acquisition of a 340B drug by, or delivery of such a drug to, the entity *(W. Va. Code § 60A-8-6a)*	▪ Civil penalty of up to $50,000 for each violation; ▪ Injunction; ▪ Temporary relief or restraining order; ▪ Order of restitution for actual damages (and noneconomic damages up to $10,000) to claimant who suffered a loss due to the violation; and ▪ If the manufacturer knew or reasonably should have known it was in violation: license suspension or revocation. Each package of 340B drugs subjected to a prohibited act is a separate violation. (In addition, mandatory cease and desist order) *(W. Va. Code §§ 33-11-6(c), 46A-7-108, 46A-7-110, and 60A-8-6a)*

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