OHIO LEGISLATIVE SERVICE COMMISSION

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Office of Research and Drafting

Legislative Budget Office

H.B. 652*
134th General Assembly

Occupational Regulation Report

Click here for H.B. 652's Bill Analysis / Fiscal Note

Primary Sponsors: Reps. Plummer and T. Young

Impacted Professions: Pharmacists and prescribers

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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

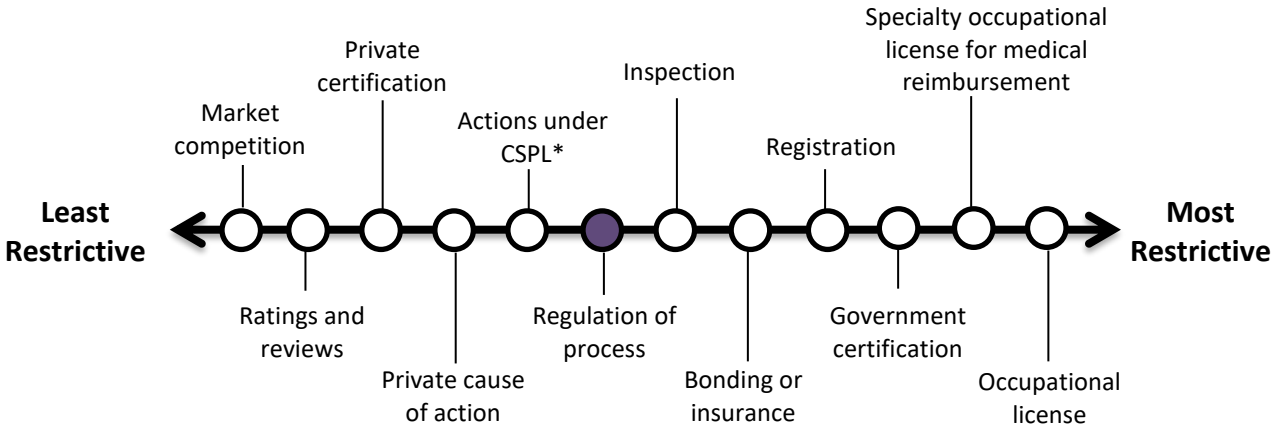
The general policy of the state is reliance on market competition and private remedies to protect the interests of consumers in commercial transactions involving the sale of goods or services. For circumstances in which the General Assembly determines that additional safeguards are necessary to protect 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. 652. 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

The bill prescribes new, and revises existing, process regulations for licensed pharmacists and prescribers (physicians, physician assistants, advanced practice registered nurses (APRNs), and dentists). These regulations supplement or modify extensive regulatory systems that apply to these professions under continuing law. The changes proposed by the bill do not appear to increase significantly the restrictiveness of those regulatory systems.

Necessity of regulations

The bill's sponsors, Representatives Plummer and T. Young, testified that the bill addresses a current gap regarding the State Board of Pharmacy's Ohio Automated Rx Reporting System (OARRS) and that the bill's goal is to strengthen OARRS and help fight against the current opioid epidemic.[3]

Restrictiveness of regulations

The state's general policy does not provide specific guidance regarding 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. It is difficult to project the extent to which the bill will curb the abuse of opioid analgesics or reduce the potentially harmful effects of misuse or overuse. It does not appear that the new and revised process regulations significantly increase the restrictiveness of the regulatory systems that apply to pharmacists and prescribers under continuing law.

The bill creates new, and revises existing, administrative burdens for licensed pharmacists and prescribers. It requires a pharmacist to:

[3] See Representatives Phil Plummer and Tom Young, House Bill 652 Sponsor Testimony, May 24, 2022, which is available on the General Assembly's website, legislature.ohio.gov, by searching for "H.B. 652" and navigating to the Committee Activity tab.

- Discuss with patients the risks of opioid addiction when dispensing an opioid analgesic; and
- Affix warning labels or stickers to opioid containers.

The bill requires a prescriber to:

- Review patient information from OARRS potentially more frequently than under current law when prescribing an opioid analgesic or benzodiazepine by eliminating the exception from checking OARRS if the drug is prescribed or personally furnished in an amount indicated for a period of seven days or less; and
- Provide patient counseling and education when prescribing an opioid analgesic.

Current law requires pharmacists to affix labels to a container containing controlled substances and, as part of the practice of pharmacy, to offer counseling when dispensing any prescription drug.[4] It also requires prescribers to review patient information from OARRS.[5] While the proposed changes to those requirements under the bill increase an existing administrative burden on pharmacists and prescribers, the proposed new and expanded requirements appear to be relatively minor. They mirror requirements that exist under current law in other contexts, do not appear to be particularly time consuming, and apply to a limited range of circumstances.

Other regulatory policies

As noted above, the bill modifies established regulatory frameworks that apply to specified health care professionals who practice in Ohio. With respect to physician assistants and dentists, Ohio law does not include a general policy statement explaining the state's intent in regulating those professions. However, it includes policy statements with respect to pharmacists, physicians, and APRNs.

Pharmacists

Ohio law declares a pharmacist's or other person's violation of Ohio or federal law governing the distribution of a drug of abuse, or commission of certain other unlawful acts, to be inimical, harmful, and adverse to the public welfare of Ohio citizens and to constitute a public nuisance. The remedy prescribed in Ohio law for a violation is for the Attorney General or the State Board of Pharmacy to sue to prevent the violation or for the Pharmacy Board to take disciplinary action.[6]

The bill's requirements that pharmacists discuss with patients the risks of opioid addiction when dispensing opioids and affix warning labels or stickers to opioid containers appear to govern the distribution of a drug of abuse. Thus, consistent with this policy declaration, a

[4] R.C. 3719.08, not in the bill, and Ohio Administrative Code (O.A.C.) 4729:5-5-09.

[5] R.C. 4715.302, 4723.487, 4730.53, and 4731.055.

[6] R.C. 4729.35 and 4729.16, not in the bill.

violation of those proposed requirements may be considered harmful to the public welfare and constitute a public nuisance.

Physicians and APRNs

Ohio law declares the practice of medicine in all of its branches, or the treatment of human ailments without the use of drugs or medicines and without operative surgery, by any person not holding a valid and current license or certificate issued under the Nurses Law, the Optometrists and Dispensing Opticians Law, or the Physicians and Limited Practitioners Law,[7] to be inimical to the public welfare and to constitute a public nuisance.[8] The bill's regulations applicable to physicians and APRNs do not appear to interfere or conflict with this policy declaration.

Separately, with respect to APRNs, the Nurse Licensure Compact that takes effect January 1, 2023, and to which Ohio is a party, includes the following findings:

- The health and safety of the public are affected by the degree of compliance with and the effectiveness of enforcement activities related to state nurse licensure laws.
- Violations of nurse licensure and other laws regulating the practice of nursing may result in injury or harm to the public.[9]

The bill's regulations applicable to APRNs appear to be consistent with the findings described above. It is possible that compliance with the bill's requirements that APRNs review OARRS information potentially more frequently than under current law and provide patient counseling and education when prescribing an opioid, or violations of those requirements, affect public health and safety. For example, according to the federal Centers for Disease Control and Prevention guidelines for prescribing opioids, prescribers who review a database for a patient's prescription drug history before prescribing opioids are better able to determine whether a patient might be at higher risk for an opioid overdose or use disorder.[10]

IMPACT STATEMENT

Opportunities for employment

As a result of the new requirements related to pharmacist dispensing of opioid analgesics established by H.B. 652, it is possible that pharmacists could see an increase in workload to discuss with patients or patient's representatives the risks of opioid addiction, as well as affixing warning labels or stickers to the container in which the drug is dispensed. If this occurs, it is

[7] R.C. Chapters 4723, 4725, and 4731, respectively.

[8] R.C. 4731.341, not in the bill.

[9] R.C. 4723.11, not in the bill.

[10] See CDC Guideline for Prescribing Opioids for Chronic Pain, which may be accessed by conducting a keyword "guidelines for prescribing opioids" search on the federal Centers for Disease Control and Prevention website: cdc.gov.

possible that pharmacies may need to hire additional staff, which would increase opportunities for employment for pharmacists.

The bill also eliminates the exception that prescribers required to request patient information from OARRS that covers at least the previous 12 months when first prescribing or personally furnishing an opioid analgesic or benzodiazepine for a patient if the drug is prescribed or furnished for use over a period of seven days or less. This will increase the workload for prescribers. However, it is unlikely that this increase in workload will be significant, and therefore should not affect opportunities for employment for prescribers.

Consumer choice and cost

It is unlikely that H.B. 652 will affect consumer choice. While pharmacies may require additional staff to discuss the risks of opioid addiction, the number of overall pharmacies in the state is unlikely to be affected by this bill. However, the bill allows pharmacists to charge a fee for each discussion, which could increase the cost for patients.

The elimination of the exception on prescribers requesting patient information from OARRS should not affect consumer choice or cost.

Market competition and wages

If H.B. 652 results in pharmacies hiring additional pharmacists, it could increase market competition for pharmacists, which may in turn increase wages.

Cost to government

For any potential cost to government, see the LBO fiscal note.

SUMMARY OF PROPOSED REGULATIONS

Pharmacists

Patient discussions

The bill's required patient discussions for pharmacists described above must include an explanation that opioid addiction risk increases substantially after taking the drug for five or more days.[11]

Warning labels or stickers

The Pharmacy Board must adopt standards and procedures regarding the bill's required warning labels and stickers, described above, for the following:

- The location on the container where it must be affixed; and

[11] R.C. 3719.065(B).

- The font and format of the included language, which must at least indicate the drug is an opioid analgesic and carries an addiction or overdose risk.[12]

Prescribers

OARRS reviews

The bill eliminates an exemption that allows a prescriber to not review patient information from OARRS if prescribing or furnishing an opioid analgesic or benzodiazepine for use over a period of seven days or less. Thus, it requires the review regardless of how long the drug is prescribed or furnished.[13]

Patient counseling and education

Each health-related licensing board must adopt guidelines regarding patient counseling and education for a provider prescribing an opioid analgesic in an amount indicated for five or more days. A health-related licensing board is a state board that issues a license to practice as a licensed health professional authorized to prescribe drugs.[14]

For more information regarding the bill's proposed regulations, see LSC's H.B. 652 As Introduced Analysis (PDF), which is available on the General Assembly's website: legislature.ohio.gov.

COMPARISON TO OTHER STATES

Pharmacists

Patient discussions

It does not appear that Indiana, Kentucky, Michigan, Pennsylvania, or West Virginia specifically require pharmacists to discuss with patients the risks associated with opioid analgesics, including the risk of addiction. Due to terminology variances, it is difficult to ascertain. These discussions may occur in practice, even if not specifically required, under general counseling requirements as part of the practice of pharmacy.[15]

Warning labels or stickers

Federal law requires pharmacists dispensing an opioid prescription to affix to the package a label showing certain information, including any cautionary statements. Federal regulations require that the label include the following statement: "Caution: Federal law prohibits the

[12] R.C. 3719.081.

[13] R.C. 4715.302, 4723.487, 4730.53, and 4731.055.

[14] R.C. 3719.065(C), by reference to R.C. 3719.062, not in the bill.

[15] See, e.g., O.A.C. 4729:5-5-09 and 49 Pa. Code 27.19 (requiring pharmacists to offer counsel to patients regarding prescriptions).

transfer of this drug to any person other than the patient for whom it was prescribed," but does not provide any other specific language for other cautionary statements.[16]

It does not appear that Indiana, Kentucky, Michigan, Pennsylvania, or West Virginia require pharmacists to affix a warning label or sticker to the container in which an opioid analgesic is dispensed describing the risk associated with opioids. While Indiana does not require this warning label, it does require that a pharmacist affix to an opioid container a label with a statement that the drug is an opioid.[17] Several other jurisdictions, including the states identified in the table below, require such a warning label for opioid containers.

Requirements Regarding Warning Labels or Stickers for Opioid Containers	
State	**Relevant Provisions**
Ohio	Under the bill, a pharmacist, when dispensing an opioid analgesic for use outside of a hospital, must affix to the container a red warning label or sticker that describes the risks associated with opioid analgesics and follow the standards and procedures the State Board of Pharmacy adopts for the warning label or sticker *(R.C. 3719.081)*.
Arizona	When dispensing an opioid, a pharmacist must place the drug in a container that has a red cap and warning label stating "CAUTION: OPIOID, Risk of Overdose and Addiction" or other similarly clear language indicating the possibility of overdose and addiction *(Ariz. Rev. Stat. 36-2525(L) and Ariz. Admin. Code R4-23-407)*.
California	Whenever a prescription drug containing an opioid is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug must prominently display on the label or container, by means of a flag or other notification mechanism, a notice that states: "Caution: Opioid. Risk of overdose and addiction" *(Cal. Bus. & Prof. Code 4076.7)*.
Colorado	When a pharmacist dispenses a prescription drug to a patient for outpatient use that contains an opioid not prescribed for the treatment of a substance use disorder or is a partial opioid antagonist, the label or container must bear a notification that states, or is substantially equivalent to: "Caution: Opioids carry a risk of overdose and addiction" *(Colo. Rev. Stat. 12-280-124 and 3 Colo. Code. Reg. 719-1:3.00.00)*.
Hawaii	A pharmacist who dispenses any opioid drug must include on the drug's package a warning label that contains wording substantially similar to the following warning: "Caution: Opioid. Risk of overdose and addiction" *(Hawaii Rev. Stat. 329-39.5)*.

[16] 21 Code of Federal Regulations 290.5 and 1306.14 and see page 54 of Pharmacist's Manual (PDF), which may be accessed by conducting a keyword "pharmacist's manual" search on the U.S. Drug Enforcement Agency's Diversion Control Division website: deadiversion.usdoj.gov.

[17] Ind. Code 16-42-19-11.

Requirements Regarding Warning Labels or Stickers for Opioid Containers	
State	**Relevant Provisions**
Minnesota	Whenever a prescription drug containing an opiate is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug must prominently display on the label or container a notice that states "Caution: Opioid. Risk of overdose and addiction" *(Minn. Stat. 151.212)*.
New Jersey	When a pharmacist dispenses a prescription for an opioid medication, the pharmacist must affix, to the container, a red, orange, or yellow warning label or sticker that contains the warning: "Opioid Risk of Addiction and Overdose." New Jersey administrative rules prescribe the required formatting for the warning label or sticker. *(N.J. Stat. 24:21-17 and N.J. Admin. Code 13:39-7.12.)*

Prescribers

OARRS reviews

In Ohio, OARRS is the electronic drug database maintained by the State Board of Pharmacy to monitor the misuse and diversion of controlled substances.[18] The states bordering Ohio have similar prescription drug monitoring databases that collect and track prescriptions for controlled substances. As described in the table below, these states generally require a prescriber to review patient information from the state database before prescribing certain drugs. Except for Michigan, a prescriber's duty to review patient information does not depend on the duration for which the drug is prescribed.

Prescription Drug Monitoring Database Review Requirements	
State	**Relevant Provisions**
Ohio	Under the bill, before first prescribing or furnishing an opioid analgesic or benzodiazepine, a prescriber must review patient information from OARRS if prescribing or furnishing the drug for use over any length of time (current law exempts a prescriber from reviewing that information if prescribing or furnishing for a period of seven days or less) *(R.C. 4715.302, 4723.487, 4730.53, and 4731.055)*.
Indiana	A practitioner (including a physician, physician assistant, nurse practitioner, and dentist) generally must obtain information about a patient from Indiana's prescription drug monitoring database before prescribing an opioid or benzodiazepine *(Ind. Code 25-26-24-11 and 25-26-24-19(k) and (q) and 844 Ind. Admin. Code 2.2-3-7 and 5-6-7 and 848 Ind. Admin. Code 5-4-7)*.

[18] R.C. 4729.75, not in the bill.

Prescription Drug Monitoring Database Review Requirements	
State	**Relevant Provisions**
Kentucky	A practitioner (including a physician, physician assistant, APRN, and dentist) may access information from Kentucky's prescription drug monitoring database for purposes of providing medical or pharmaceutical treatment to a patient. Before prescribing controlled substances for pain, the practitioner generally must review information from the database for the 12-month period immediately preceding the patient encounter. *(Ky. Rev. Stat. 218A.010 (40) and 218A.202 and 201 Ky. Admin. Reg. 8:540, 9:260, and 20:057.)*
Michigan	Before prescribing or dispensing to a patient a controlled substance in a quantity that exceeds a three-day supply, a prescriber (including a physician, physician assistant, APRN, and dentist) generally must obtain and review a report from Michigan's prescription drug monitoring database *(Mich. Comp. Laws 333.7109, 333.7303a, and 333.17708)*.
Pennsylvania	A prescriber (a person licensed to distribute, dispense, or administer controlled substances) generally must search Pennsylvania's prescription drug monitoring database each time the prescriber prescribes an opioid drug product or benzodiazepine *(35 Pa. Stat. 872.3 and 872.8)*.
West Virginia	A prescriber (including a physician, physician assistant, APRN, and dentist), on initially prescribing or dispensing an opioid or benzodiazepine to a patient who is not suffering from a terminal illness, must access West Virginia's prescription drug monitoring database for information regarding the patient. After that, the practitioner must do so at least annually if the practitioner continues to treat the patient with a controlled substance. *(W. Va. Code 60A-9-5a.)*

Patient counseling and education

The bill requires each health-related licensing board to adopt guidelines regarding patient counseling and education to be provided by a prescriber when prescribing an opioid in an amount indicated for a period of five or more days.[19] While neighboring states do not appear to have an equivalent provision, Ohio and several of those states require prescribers to have a discussion with a patient regarding the risks associated with opioid use before prescribing an opioid, depending on whether the patient is a minor. The table below describes those requirements.

[19] R.C. 3719.065(C).

Patient Counseling and Education Requirements When Prescribing Opioids	
State	**Relevant Provisions**
Ohio	Currently, before issuing to a minor an opioid prescription, a prescriber generally must discuss with the minor and minor's parent or guardian the risks of addiction and overdose and the dangers of taking opioids with other drugs or alcohol *(R.C. 3719.01, 3719.061(B), and 4729.01(I), not in the bill)*.
Indiana	Before prescribing, requires a physician, physician assistant, dentist, or advance practice nurse to discuss with the patient the potential risks and benefits of opioid treatment, the risk of dependency and addiction, and other treatments available *(828 Ind. Admin. Code 1-1-25, 844 Ind. Admin. Code 2.2-3-5 and 5-6-5, and 848 Ind. Admin. Code 5-4-5)*.
Kentucky	No clear equivalent.
Michigan	Before prescribing an opioid , a prescriber (including a physician, physician assistant, APRN, and dentist) generally must discuss with the patient or patient's representative the risks of addiction and overdose and the dangers of taking opioids with other drugs or alcohol *(Mich. Comp. Laws 333.7109, 333.7303b, 333.7303c, and 333.17708)*.
Pennsylvania	Before issuing to an individual an opioid prescription, the prescriber (a person licensed to distribute, dispense, or administer a controlled substance) generally must discuss with the individual the risks of addiction and overdose, the dangers of taking opioids with other drugs or alcohol, and the nonopioid pain treatment options available *(35 Pa. Cons. Stat. 52B01 and 52B02 and 35 Pa. Stat. 872.3)*.
West Virginia	A health care practitioner (including a physician, physician assistant, APRN, and dentist), when issuing an initial opioid prescription to a minor, must discuss with the minor's parent or guardian the risks associated with opioid use and the reasons why the prescription is necessary. If issuing a subsequent opioid prescription to any patient, the practitioner must discuss the risks of addiction and overdose, the dangers of taking opioids with other drugs or alcohol, and the alternative treatments available. If issuing a third prescription, the practitioner must discuss the benefits of seeking treatment through a pain clinic or specialist and the risks associated with choosing not to pursue those options. *(W. Va. Code 16-54-1, 16-54-4, 16-54-5, and 16-54-6.)*

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