OHIO LEGISLATIVE SERVICE COMMISSION

**Bill Analysis**

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# H.B. 642

132nd General Assembly
(As Introduced)

**Reps.** Gonzales, Brinkman

## BILL SUMMARY

- Classifies as adulterated a nonprescription diabetes test device (i.e., glucose meter or test strip) that was not purchased or acquired directly from the device's manufacturer or an authorized distributor.
- Requires a manufacturer to post on its website the names of its authorized distributors of diabetes test devices, and to report that information to the State Board of Pharmacy for inclusion on the Board's website.
- Establishes recordkeeping requirements for pharmacists related to the acquisition and sale of nonprescription diabetes test devices.
- Specifies that a pharmacist's failure to comply with the bill's requirements regarding nonprescription diabetes test devices constitutes unprofessional conduct in the practice of pharmacy.
- Declares an emergency.

## CONTENT AND OPERATION

### Nonprescription diabetes test devices

The bill contains several provisions relating to ensuring that nonprescription diabetes test devices are purchased directly from a manufacturer or authorized distributor. "Nonprescription diabetes test device" is defined by the bill as a glucose

meter or test strip for use in the treatment of individuals with diabetes or prediabetes, that may be sold without a prescription, and that is labeled for consumer use.[1]

### Adulterated nonprescription diabetes test devices

For purposes of Ohio's Pure Food and Drug Law, the bill specifies that a nonprescription diabetes test device is considered adulterated if it is not purchased or acquired either directly from the device's manufacturer or an authorized distributor.[2] Continuing law prohibits (1) manufacturing, selling, or delivering an adulterated device, (2) adulterating a device, and (3) receiving into commerce an adulterated device, or delivering or offering to deliver such a device.[3] A violation of those provisions is a fourth degree misdemeanor for the first offense and a second degree misdemeanor for each subsequent offense.[4]

### Publication of authorized distributors

The bill requires each manufacturer of nonprescription diabetes test devices to post on its website the names of its authorized distributors. Manufacturers also must report that information to the State Board of Pharmacy.[5] For existing manufacturers, both requirements must be met within 30 days of the bill's effective date.[6] Any changes to the information must be updated on the website and reported to the Board within 30 days after the change.

The Board is required to post on its website the names of each manufacturer's authorized distributors. The information must be updated within 30 days after receiving a report of a change from a manufacturer.[7]

### Recordkeeping

The bill requires pharmacists that dispense nonprescription diabetes test devices pursuant to prescriptions to maintain for three years complete and accurate records of

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[1] R.C. 3715.75.

[2] R.C. 3715.63(A)(8).

[3] R.C. 3715.52(A), not in the bill.

[4] R.C. 3715.99(D), not in the bill.

[5] R.C. 3715.75.

[6] Section 3.

[7] R.C. 3715.75.

the acquisition and sale of the devices. The records must be made available during business hours for inspection by proper officers of the law.[8]

The bill specifies that its recordkeeping requirements are in addition to existing recordkeeping requirements concerning records of original prescriptions.[9]

### Pharmacist discipline

Under current law, one reason the Board may impose professional disciplinary sanctions is for "unprofessional conduct in the practice of pharmacy." The bill adds the following to unprofessional conduct in the practice of pharmacy:

(1) Submitting a claim for payment for a nonprescription diabetes test device to a health insurer, government entity, pharmacy benefit manager, or any other third-party payer when the pharmacist or pharmacy intern knew or should have known that the dispensed device was adulterated;

(2) Knowingly failing to maintain and retain records of the acquisition and sale of nonprescription diabetes test devices.[10]

## HISTORY

| ACTION | DATE |
|---|---|
| Introduced | 05-09-18 |

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[8] R.C. 4729.371.

[9] R.C. 4729.37.

[10] R.C. 4729.16(A)(2)(b) and (C)(7) and (8).