



# Ohio Legislative Service Commission

## Bill Analysis

Nick Thomas

### Sub. H.B. 341\*

130th General Assembly

(As Reported by S. Insurance & Financial Institutions)

**Reps.** Smith, Wachtmann, Antonio, Barnes, Boyd, Brown, Johnson, Sears, R. Adams, Amstutz, Anielski, Ashford, Baker, Beck, Bishoff, Blair, Blessing, Boose, Boyce, Buchy, Burkley, Butler, Carney, Celebrezze, Conditt, Curtin, Damschroder, Derickson, DeVitis, Dovilla, Driehaus, Duffey, Fedor, Foley, Gerberry, Green, Grossman, Hackett, C. Hagan, Hall, Hayes, Henne, Hill, Hottinger, Huffman, Landis, Letson, Lundy, Mallory, McClain, McGregor, Patmon, Patterson, Pelanda, Perales, Phillips, Pillich, Ramos, Rogers, Rosenberger, Ruhl, Scherer, Schuring, Slaby, Slesnick, Sprague, Stebelton, Stinziano, Strahorn, Sykes, Terhar, Thompson, Williams, Winburn, Young, Batchelder

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## BILL SUMMARY

- Beginning April 1, 2015, establishes several conditions related to the State Board of Pharmacy's Ohio Automated Rx Reporting System (OARRS) that apply to a prescriber when prescribing or personally furnishing certain drugs, including the following:
  - That the prescriber, before initially prescribing or personally furnishing an opioid analgesic or a benzodiazepine, request patient information from OARRS that covers at least the previous 12 months;
  - That the prescriber make periodic requests for patient information from OARRS if the course of treatment continues for more than 90 days.
- Establishes several exceptions from the required review of an OARRS report, including drugs prescribed to hospice or cancer patients, drugs to be administered in hospitals or long-term facilities, drugs to treat acute pain from surgery or a delivery, and drug amounts for use in seven days or less.

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\* This analysis was prepared before the report of the Senate Insurance and Financial Institutions Committee appeared in the Senate Journal. Note that the list of co-sponsors and the legislative history may be incomplete.

- Beginning January 1, 2015, requires that certain prescribers, as well as pharmacists, when renewing their professional licenses, certify to their licensing boards that they have access to OARRS and subjects the licensees to possible disciplinary action for false certifications.
- Authorizes the State Board of Pharmacy to restrict a person from obtaining further information from OARRS if the person creates, by clear and convincing evidence, a threat to the security of information contained in OARRS.
- Requires, rather than permits as under current law, the State Board of Pharmacy to provide information from OARRS to prescribers, pharmacists, and the Administrator of Workers' Compensation if certain criteria are met.
- Requires a managed care organization (MCO) to have entered into a contract with the Department of Medicaid before information from OARRS can be provided to the MCO.
- Requires the State Board of Pharmacy to provide information from OARRS to a Workers' Compensation managed care organization if certain criteria are met.

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## CONTENT AND OPERATION

### Review of patient information in OARRS

Beginning April 1, 2015, the bill establishes several conditions related to a prescriber's use of information available from the Ohio Automated Rx Reporting System (OARRS) (see "**OARRS and current law**," below). The conditions apply to a prescriber when prescribing or personally furnishing a drug that is either an opioid analgesic or a benzodiazepine as part of a patient's course of treatment for a particular condition.<sup>1</sup> The bill does not define opioid analgesic or benzodiazepine.<sup>2</sup>

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<sup>1</sup> R.C. 4715.302(B), 4723.487(B), 4725.092(B), 4730.53(B), and 4731.055(B) and Section 4.

<sup>2</sup> An opioid is a medication that relieves pain. It reduces the intensity of pain signals reaching the brain and affects those brain areas controlling emotion. See National Institute of Drug Abuse, *Prescription Drug Abuse, What are opioids?* (last visited April 17, 2014), available at <<http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/what-are-opioids>>. A benzodiazepine is a depressant prescribed to relieve anxiety and sleep problems. Valium and Xanax are among the most widely prescribed benzodiazepines. See National Institute of Drug Abuse, *Prescription Drug Abuse, Glossary* (last visited April 17, 2014), available at <<http://www.drugabuse.gov/publications/research-reports/prescription-drugs/glossary>>. Note: advanced practice registered nurses and physicians assistants do not have the authority to personally furnish these types of drugs (R.C. 4723.481(E)(3) and 4730.43(A)(3), not in the bill).

The bill requires a prescriber, before initially prescribing or personally furnishing the opioid analgesic or benzodiazepine, to request, or have a delegate request, patient information from OARRS that covers at least the previous 12 months.<sup>3</sup> If the patient's course of treatment for the condition continues for more than 90 days, the bill requires the prescriber to make periodic requests for patient information from OARRS until the course of treatment ends. Such requests must be made at intervals not exceeding 90 days.<sup>4</sup>

The bill also requires the prescriber to assess the information in the OARRS report on receipt of the report and to document in the patient's record that the report was received and assessed.<sup>5</sup>

### **Prescribers subject to the bill**

The bill applies to the following prescribers: dentists, advanced practice registered nurses holding certificates to prescribe, optometrists holding therapeutic pharmaceutical agents certificates, physician assistants holding certificates to prescribe, and physicians authorized to practice medicine, osteopathic medicine, or podiatry.<sup>6</sup>

### **Prescriptions issued in other states**

The bill requires a prescriber who practices primarily in an Ohio county that adjoins another state to request information available in OARRS pertaining to prescriptions issued or drugs furnished to the patient in the state adjoining that county.<sup>7</sup> The bill does not define the phrase "practices primarily."

### **Exceptions to OARRS review**

The bill provides for several exceptions from the required review of an OARRS report. These include all of the following:

(1) The OARRS report is not available (all prescribers);

(2) The drug is prescribed or personally furnished to a hospice patient or to any other patient who has been diagnosed as terminally ill (dentists, advanced practice registered nurses, physician assistants, and physicians but not optometrists);

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<sup>3</sup> R.C. 4715.302(B)(1), 4723.487(B)(1), 4725.092(B)(1), 4730.53(B)(1), and 4731.055(B)(1).

<sup>4</sup> R.C. 4715.302(B)(2), 4723.487(B)(2), 4725.092(B)(2), 4730.53(B)(2), and 4731.055(B)(2).

<sup>5</sup> R.C. 4715.302(B)(3), 4723.487(B)(3), 4725.092(B)(3), 4730.53(B)(3), and 4731.055(B)(3).

<sup>6</sup> R.C. 4715.302, 4723.487, 4725.092, 4730.53, and 4731.055.

<sup>7</sup> R.C. 4715.302(B)(1), 4723.487(B)(1), 4725.092(B)(1), 4730.53(B)(1), and 4731.055(B)(1).



(3) The drug is prescribed or personally furnished in an amount indicated for a period not to exceed seven days (all prescribers);

(4) The drug is prescribed or personally furnished for the treatment of cancer or another condition associated with cancer (advanced practice registered nurses, physician assistants, and physicians but not dentists and optometrists);

(5) The drug is prescribed or personally furnished for administration in a hospital, nursing home, or residential care facility (advanced practice registered nurses, physician assistants, and physicians but not dentists and optometrists);

(6) The drug is prescribed or personally furnished to treat acute pain resulting from a surgical or other invasive procedure or a delivery (physicians only).<sup>8</sup>

### **Disciplinary action**

Beginning April 1, 2015, the bill authorizes the following boards to discipline prescribers for failure to request patient information in OARRS as required by the bill: the State Dental Board, the Board of Nursing, the State Board of Optometry, and the State Medical Board.<sup>9</sup>

### **Required access to OARRS**

The bill requires that each prescriber who prescribes or personally furnishes opioid analgesics or benzodiazepines as part of the prescriber's regular practice, as well as pharmacists, obtain access to OARRS not later than January 1, 2015. The bill does not define the phrase "regular practice." Failure to obtain access to OARRS by January 1, 2015, constitutes grounds for license or certificate suspension.

The bill's requirement does not apply if the State Board of Pharmacy has restricted the professional from obtaining information from OARRS.<sup>10</sup>

### **License renewals**

Beginning January 1, 2015, the bill requires that each prescriber who prescribes or personally furnishes opioid analgesics or benzodiazepines, as well as pharmacists, when renewing a license or certificate, certify to the board responsible for licensure or certification that the professional has been granted access to OARRS.

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<sup>8</sup> R.C. 4715.302(C), 4723.487(C), 4725.092(C), 4730.53(C), and 4731.055(C).

<sup>9</sup> R.C. 4715.30, 4723.28, 4725.19, 4730.25, and 4731.22. The State Medical Board is responsible for the licensure of both physician assistants and physicians.

<sup>10</sup> R.C. 4729.80(A)(5); Section 5.

The bill's requirement regarding license renewals does not apply if the State Board of Pharmacy has notified the relevant board that the professional has been restricted from obtaining further information from OARRS (see "**State Board of Pharmacy notification**," below).<sup>11</sup>

The bill authorizes a licensing board to take a disciplinary action against a licensee if the licensee certifies to the board that the licensee has been granted access to OARRS and the board later determines that the licensee in fact does *not* have that access.<sup>12</sup>

## **Mandatory provision of information from OARRS**

### **Prescribers, pharmacists, and the Administrator of Workers' Compensation**

The bill requires, rather than permits as under current law, the State Board of Pharmacy, on receipt of a request from a prescriber or the prescriber's delegate approved by the Board, to provide to the prescriber a report of information from OARRS relating to a patient who is either (1) a current patient of the prescriber or (2) a potential patient of the prescriber based on a referral of the patient to the prescriber.<sup>13</sup> It does not appear that this mandatory provision of information is limited to the prescriber of an opioid analgesic or a benzodiazepine.

Similarly, the bill requires, rather than permits as under current law, the Board, on receipt of a request from a pharmacist or the pharmacist's delegate approved by the Board, to provide to the pharmacist information from OARRS relating to a current patient of the pharmacist.<sup>14</sup>

The bill requires, rather than permits as under current law, the Board to provide to the Administrator of Workers' Compensation information from OARRS that the Administrator requests relating to a workers' compensation claimant, including information in OARRS related to prescriptions for the claimant that were not covered or reimbursed under the Workers' Compensation Law.<sup>15</sup>

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<sup>11</sup> R.C. 4715.14(A), 4723.486(B), 4725.16(A), 4729.12, 4730.48(A), and 4731.281(B) and Sections 3 and 5.

<sup>12</sup> R.C. 4715.14(A)(3), 4715.30, 4723.486(C)(3), 4723.28, 4725.16(A)(3), 4725.19, 4730.48(A)(4)(c), 4730.25, 4731.281(B)(6)(c), and 4731.22.

<sup>13</sup> R.C. 4729.80(A)(5).

<sup>14</sup> R.C. 4729.80(A)(6).

<sup>15</sup> R.C. 4729.80(A)(11).



## Managed care organizations

Continuing law requires the State Board of Pharmacy, on receipt of a request from the medical director of a managed care organization (MCO) that has entered into a data security agreement with the Board to provide to the medical director information from OARRS relating to a Medicaid recipient enrolled in the MCO. The bill adds the requirement that the medical director must have entered into a contract with the Department of Medicaid.<sup>16</sup>

The bill also requires that the State Board of Pharmacy provide to the medical director of an MCO that has entered into a contract with the Administrator of Workers' Compensation information from OARRS relating to a workers' compensation or other claimant assigned to the MCO. The report must include information in OARRS related to prescriptions for the claimant that were not covered or reimbursed under the Workers' Compensation Law. If the Board requests, the Administrator must confirm whether the claimant has been assigned to the MCO. The bill also directs that a contract between the Administrator and an MCO include a requirement that the MCO enter into a data security agreement with the State Board of Pharmacy governing the MCO's use of OARRS.<sup>17</sup>

## Restricting access to OARRS

The bill authorizes the State Board of Pharmacy to restrict a person from obtaining further information from OARRS if the person creates, by clear and convincing evidence, a threat to the security of information contained in OARRS.<sup>18</sup> Current law permits the Board to restrict a person from obtaining further information under certain circumstances, including the following: (1) when providing false information to OARRS with the intent to obtain or alter information and (2) when using information obtained from OARRS as evidence in any civil or administrative proceeding.<sup>19</sup>

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<sup>16</sup> R.C. 4729.80(A)(8).

<sup>17</sup> R.C. 4121.443 and 4729.80(A)(10).

<sup>18</sup> R.C. 4729.86(C)(1)(d).

<sup>19</sup> R.C. 4729.86(C).



## **Notice and hearing**

The bill also specifies that the Board may restrict a person from obtaining information from OARRS after providing notice and affording an opportunity for hearing in accordance with the Administrative Procedure Act (R.C. Chapter 119.).<sup>20</sup>

## **Summary restriction**

The bill does permit the Board, if it determines that the allegations regarding a person's actions warrant restricting the person from obtaining further information from OARRS without a prior hearing, to summarily impose the restriction. The bill specifies that a telephone conference call may be used by the Board for reviewing the allegations and taking a vote on the summary restriction. The bill also provides that a summary restriction remains in effect, unless removed by the Board, until the Board's final adjudication order becomes effective.<sup>21</sup>

## **State Board of Pharmacy notification**

The bill requires the State Board of Pharmacy to notify the government entity responsible for licensing a prescriber if the Board restricts the prescriber from obtaining further information from OARRS.<sup>22</sup>

## **OARRS and opioid dependent infants**

The bill requires that the State Board of Pharmacy provide to a prescriber, or delegate of a prescriber, treating a newborn or infant patient diagnosed as opioid dependent an OARRS report relating to the patient's mother.<sup>23</sup>

## **OARRS and current law**

OARRS is the drug database established and maintained under current law by the State Board of Pharmacy.<sup>24</sup> Rules adopted by the Board require that when a reported drug (controlled substance, carisoprodol, or tramadol)<sup>25</sup> is dispensed by a pharmacy or

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<sup>20</sup> R.C. 4729.86(C)(1).

<sup>21</sup> R.C. 4729.86(C)(2).

<sup>22</sup> R.C. 4729.861.

<sup>23</sup> R.C. 4729.80(A)(12).

<sup>24</sup> R.C. 4729.75, not in the bill.

<sup>25</sup> Carisoprodol is a muscle relaxant used to relieve pain and discomfort caused by strains, sprains, and other muscle injuries. See <<http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682578.html>>.



personally furnished by a dentist, optometrist, or physician<sup>26</sup> to an outpatient, this information must be reported to OARRS on a weekly basis.<sup>27</sup> Prescribers and pharmacists may request patient information from the database, including information from ten other states: Arizona, Connecticut, Indiana, Kansas, Kentucky, Michigan, Minnesota, South Carolina, South Dakota, and Virginia.<sup>28</sup>

Under existing law, the State Dental Board, Board of Nursing, State Board of Optometry, and State Medical Board must adopt rules that establish standards and procedures to be followed by the prescribers whom the board regulates regarding the review of patient information available through OARRS.<sup>29</sup> These rules vary by profession.

### **Dentists, nurses, and physicians**

Under rules adopted by their respective boards, if a dentist, advanced practice registered nurse, or physician believes or has reason to believe that a patient may be abusing or diverting drugs, he or she must use sound clinical judgment in determining whether or not the reported drug should be prescribed or furnished under the circumstances.<sup>30</sup> The rules specify the extent to which patient information available from OARRS is to be accessed for assistance in making this determination if certain signs of drug abuse or diversion are exhibited.<sup>31</sup> A dentist is required to consider whether to access OARRS.<sup>32</sup> An advanced practice registered nurse cannot prescribe a reported drug without first reviewing a patient's OARRS report.<sup>33</sup> A physician is

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Tramadol is an opiate analgesic used to relieve moderate to moderately severe pain. *See* <<http://www.nlm.nih.gov/medlineplus/druginfo/meds/a695011.html>>.

<sup>26</sup> Current law does not permit advanced practice registered nurses or physician assistants holding certificates to prescribe to personally furnish controlled substances. *See* R.C. 4723.481(E)(3) and 4730.43(A)(3), not in the bill.

<sup>27</sup> O.A.C. 4729-37-03 and 4729-37-07.

<sup>28</sup> R.C. 4729.80. *See also* written testimony provided by the State Board of Pharmacy to the House Health and Aging Opiate Addiction Treatment and Reform Subcommittee, January 21, 2014.

<sup>29</sup> R.C. 4715.302, 4723.487, 4725.092, 4730.53, and 4731.055.

<sup>30</sup> O.A.C. 4715-6-01(B), 4723-9-12(B), and 4731-11-11(B).

<sup>31</sup> Some of the signs of drug abuse or diversion specified in the rules are having a history of drug-related criminal activity, refusing to participate in a drug screen, and having a family member express concern related to the patient's drug use. O.A.C. 4715-6-01(B), 4723-9-12(B), and 4731-11-11(B).

<sup>32</sup> O.A.C. 4715-6-01(B).

<sup>33</sup> O.A.C. 4723-9-12(B)(1).



required to access OARRS.<sup>34</sup> When a dentist, advanced practice registered nurse, or physician accesses OARRS, the receipt and assessment of patient information must be documented.<sup>35</sup>

Regarding advanced practice nurses and physicians, current rules also provide that other signs of possible abuse or diversion may necessitate review of the patient's OARRS report.<sup>36</sup>

### **Optometrists and physician assistants**

Although the State Board of Optometry and the State Medical Board have yet to adopt rules regarding the review of patient information available through OARRS, such rules have been proposed and are currently under consideration.<sup>37</sup>

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## **HISTORY**

<b>ACTION</b>	<b>DATE</b>
Introduced	11-07-13
Reported, H. Health & Aging	02-25-14
Passed House (96-0)	03-12-14
Reported, S. Insurance & Financial Institutions	---

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<sup>34</sup> O.A.C. 4731-11-11(B)(1).

<sup>35</sup> O.A.C. 4715-6-01(B), 4723-9-12(B), and 4731-11-11(B).

<sup>36</sup> O.A.C. 4723-9-12(B)(2) and 4731-11-11(B)(2). Other signs of abuse or diversion may include frequently requesting early refills of reported drugs, recurring emergency department visits to obtain reported drugs, and appearing impaired or sedated during an office visit or examination.

<sup>37</sup> Telephone conversation with representatives of the Ohio State Board of Optometry, December 10, 2013. E-mail correspondence with representatives of the State Medical Board of Ohio, December 11, 2013.

