



# Ohio Legislative Service Commission

## Bill Analysis

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### Sub. H.B. 188

131st General Assembly

(As Reported by S. Health and Human Services)

**Reps.** Manning and Huffman, Maag, Rezabek, Gonzales, Amstutz, Anielski, Antonio, Baker, Blessing, Boyce, Boyd, Buchy, Burkley, Conditt, Craig, Derickson, Dever, Dovilla, Gerberry, Ginter, Green, Hackett, Hall, Hambley, Hayes, Howse, Kraus, Kuhns, Leland, McClain, M. O'Brien, Patterson, Pelanda, Perales, Ramos, Reece, Retherford, Rogers, Ryan, Schaffer, Scherer, Sears, Sheehy, Slaby, R. Smith, Stinziano, Strahorn, Terhar, Young, Rosenberger

**Sens.** Manning, Brown, Tavares

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## BILL SUMMARY

### Consult agreements for management of drug therapy by pharmacists

- Authorizes a pharmacist practicing under a consult agreement with a physician to (1) manage a patient's drug therapy for specified diagnoses or diseases and (2) order and evaluate blood and urine tests.
- Creates a single process for establishing a consult agreement, in place of the separate processes that are based on whether a patient's drug therapy is being managed within or outside a hospital or long-term care facility.
- Grants certain immunities from civil liability to pharmacists and physicians practicing under consult agreements.

### Drug refills without a prescription

- Increases to a 30-day supply (from a 72-hour supply) the amount of a drug that a pharmacist may dispense or sell without a prescription for a patient who is on a consistent therapy with a drug that is not a controlled substance.

### Prescribing based on a remote examination

- Requires the State Medical Board to adopt rules governing the requirements for a physician to prescribe or personally furnish a prescription drug to a person on

whom the physician has never conducted a clinical assessment, and who is at a location remote from the physician.

## **Renewal of licenses and certificates issued by the Board of Nursing**

- Makes changes to the law governing procedures for the renewal of certain licenses and certificates issued by the Ohio Board of Nursing.

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## **CONTENT AND OPERATION**

### **Consult agreements for management of drug therapy by pharmacists**

A pharmacist practicing under a consult agreement with a physician is authorized by current law to manage an individual's drug therapy under specified conditions. The bill modifies the activities that may be included in a pharmacist's practice under a consult agreement and the process that is used to enter into and implement a consult agreement.

#### **Entering into a consult agreement**

The bill expands current law, which provides that a consult agreement is between a single pharmacist and single physician, to authorize one or more pharmacists to enter into a consult agreement with one or more physicians. Under the bill, all of the following conditions must be met:

**(1) Ongoing patient relationship** – Each physician must have an ongoing physician-patient relationship with each patient whose drug therapy is being managed;

**(2) Scope of physician practice** – The diagnosis for which each patient has been prescribed drug therapy must be within the scope of each physician's practice;

**(3) Pharmacist training and experience** – Each pharmacist must have training and experience related to the particular diagnosis for which drug therapy is prescribed.<sup>1</sup>

The bill establishes a single process for entering into and implementing a consult agreement. This is in place of the separate processes that apply under current law and are distinguished by whether the pharmacist is managing the drug therapy of an individual who is (1) a hospital patient or long-term care facility resident or (2) someone other than a hospital patient or long-term care facility resident.<sup>2</sup>

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<sup>1</sup> R.C. 4729.39(A).

<sup>2</sup> R.C. 4729.39.



## **Contents of a consult agreement**

As under current law, a consult agreement must be in writing. The bill requires the agreement to include all of the following:

(1) The diagnoses and diseases being managed under the agreement, including whether each disease is primary or comorbid;

(2) A description of the drugs or drug categories the agreement involves;

(3) A description of the procedures, decision criteria, and plan the pharmacist is to follow in acting under a consult agreement;

(4) A description of how the pharmacist is to comply with requirements for recordkeeping and communication with a consulting physician, as specified in current law and under the bill.<sup>3</sup>

## **Management of drug therapy**

Subject to the terms of the consult agreement and rules to be adopted by the State Board of Pharmacy, the bill authorizes a pharmacist to manage drug therapy for treatment of specified diagnoses or diseases for each patient subject to the agreement.<sup>4</sup> Managing drug therapy includes:

--Changing the duration of treatment for the current drug therapy;

--Adjusting a drug's strength, dose, dosage form, frequency of administration, or route of administration;

--Discontinuing use of a drug;

--Administering a drug;

--Adding a drug to the patient's drug therapy, notwithstanding that pharmacists are not licensed health professionals authorized to prescribe drugs under Ohio law.<sup>5</sup>

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<sup>3</sup> R.C. 4729.39(B)(3).

<sup>4</sup> R.C. 4729.39(B)(1)(a).

<sup>5</sup> R.C. 4729.39(B)(1)(a)(v) and 4729.01.



The bill prohibits a pharmacist from managing drug therapy prescribed by a physician who is not a party to the agreement.<sup>6</sup>

### **Ordering blood and urine tests**

The bill authorizes a pharmacist practicing under a consult agreement, to the extent specified in the agreement and permitted in rules to be adopted under the bill, to order blood and urine tests and to evaluate the results of those tests that are related to the drug therapy being managed. The bill specifies, however, that the authority to evaluate the tests does not authorize a pharmacist to make a diagnosis.<sup>7</sup>

### **Other provisions of consult agreements**

Similar to existing law and in addition to the requirements described above, the bill provides that all of the following apply to its single process for establishing and using consult agreements:

--The content of a consult agreement must be communicated to each patient whose drug therapy is managed under the agreement.<sup>8</sup>

--The pharmacist must maintain a record of each action taken for each individual whose drug therapy is managed.<sup>9</sup>

--Regular communication must occur between the pharmacist and a physician acting under a consult agreement, at intervals specified by the primary physician. The agreement may include a requirement that the pharmacist send a consult report to each consulting physician.<sup>10</sup>

### **Duration of a consult agreement**

A consult agreement is effective for two years. The agreement may be renewed so long as the physician continues to maintain an ongoing physician-patient relationship, and the drug therapy remains within the scope of the physician's practice and the pharmacist's training and experience.<sup>11</sup>

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<sup>6</sup> R.C. 4729.39(B)(8).

<sup>7</sup> R.C. 4729.39(B)(1)(b).

<sup>8</sup> R.C. 4729.39(B)(4).

<sup>9</sup> R.C. 4729.39(B)(5).

<sup>10</sup> R.C. 4729.39(B)(6).

<sup>11</sup> R.C. 4729.39(A) and (B)(7).

## Termination of a consult agreement

The bill modifies termination provisions in current law to account for the fact that one or more pharmacists or physicians may enter into a consult agreement under the bill. A consult agreement, or the portion of the agreement that applies to a particular patient, may be terminated by a pharmacist or physician who entered into the agreement. A patient whose drug therapy is being managed or an individual who consented to the treatment or is authorized to act on behalf of the patient also may terminate the agreement by providing notice of termination. This is in place of provisions in current law permitting termination by the patient or the patient's representative by withdrawing consent.<sup>12</sup>

A pharmacist or physician who receives notice of the patient's termination must provide written notice to every other pharmacist or physician who is a party to the agreement. A pharmacist or physician who terminates a consult agreement with regard to one or more patients must provide written notice to all other parties to the agreement. The termination must be recorded by the pharmacist and physician in the medical records of each patient to whom the termination applies.<sup>13</sup>

## Eliminated provisions

In creating a single process for a pharmacist's practice under a consult agreement, the bill eliminates the following provisions of current law that apply according to whether the patient being treated is or is not in an institutional setting:

### When the patient is not in a hospital or long-term care facility<sup>14</sup>

- A requirement that a separate consult agreement be entered into for each individual whose drug therapy is to be managed;
- A provision that limits a consult agreement to the particular diagnosis for which a physician prescribed an individual's drug therapy;
- A prohibition on implementing a consult agreement until it has been signed by the pharmacist, physician, and the patient or another person authorized to provide consent to treatment;

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<sup>12</sup> R.C. 4729.39(B)(2)(a).

<sup>13</sup> R.C. 4729.39(B)(2)(b).

<sup>14</sup> R.C. 4729.39(B).



- A specification that a pharmacist's management of drug therapy may include monitoring and modifying a prescription that has been issued, but may not include dispensing a drug that has not been prescribed by a physician;
- A requirement that a pharmacist make reasonable attempts to contact and confer with the consulting physician before commencing any action to manage an individual's drug therapy;
- A provision authorizing the designation of an alternate physician or pharmacist if the primary physician or pharmacist is unavailable to consult directly with the other party.

**When the patient is in a hospital or long-term care facility<sup>15</sup>**

- A requirement that a hospital or long-term care facility adopt a policy for consult agreements before a consult agreement may be entered into or implemented;
- A provision specifying that the policy adopted for consult agreements must require an alternate pharmacist or physician to be available when the parties who entered into a consult agreement are not physically present and available at the hospital or long-term care facility;
- A provision specifying that a consult agreement does not permit a pharmacist to act under the agreement in a hospital or long-term care facility at which the pharmacist is not authorized to practice.

**Rules**

The bill maintains a provision in current law that requires the State Board of Pharmacy and the State Medical Board, in consultation with each other, to adopt rules that establish standards and procedures for entering into a consult agreement and managing a patient's drug therapy under the agreement. The rules are to specify any categories of drugs or types of diseases for which a consult agreement may not be established. The rules are to be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119.).<sup>16</sup>

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<sup>15</sup> R.C. 4729.39(C).

<sup>16</sup> R.C. 4729.39(C).

## **Immunity from civil liability**

The bill adds certain immunities for pharmacists and physicians with regard to the actions of other parties to a consult agreement. Under the bill, a pharmacist who acts in accordance with a consult agreement regarding a physician's change in a drug for a patient whose drug therapy the pharmacist is managing under the agreement is not liable in a civil action for injury or loss to a person or property that allegedly arises from the change.<sup>17</sup> Similarly, a physician acting in accordance with a consult agreement regarding a pharmacist's change in a drug for a patient whose drug therapy the pharmacist is managing under a consult agreement is not liable for injury or loss allegedly arising from the change, unless the physician authorized the specific change.<sup>18</sup>

The bill specifies that its immunity provisions do not limit a physician's or pharmacist's civil liability for damages arising from actions that are not related to a change in a drug for a patient under a consult agreement.<sup>19</sup>

## **Dispensing certain dangerous drugs without a prescription**

For a patient who is on a consistent drug therapy with a noncontrolled substance, the bill increases the amount of a drug that current law authorizes a pharmacist to dispense or sell without a prescription. Current law permits a pharmacist to dispense or sell up to a 72-hour supply of a dangerous drug, other than a schedule II controlled substance, without a prescription in circumstances where (1) the pharmacy has a record of a prescription for the patient, but the prescription does not provide for a refill or the time permitted by rules adopted by the State Board of Pharmacy for providing refills has elapsed, (2) the pharmacist is unable to obtain authorization to refill from the original prescriber or a health care professional responsible for the patient's care, and (3) in the pharmacist's professional judgment, the drug is essential to sustaining the patient's life or continuing drug therapy for a chronic condition and failure to supply the drug could result in harm to the patient's health.<sup>20</sup>

Under the bill, if the drug to be supplied is not a controlled substance and the pharmacy's records demonstrate that the patient has been on a consistent drug therapy, the pharmacist may sell or dispense up to a 30-day supply as provided in the prescription, unless a standard unit of dispensing for the drug exceeds a 30-day supply, in which case the pharmacist may sell or dispense a standard unit. The bill requires the

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<sup>17</sup> R.C. 4729.39(D)(1)(a).

<sup>18</sup> R.C. 4729.39(D)(1)(b).

<sup>19</sup> R.C. 4729.39(D)(2).

<sup>20</sup> R.C. 4729.281(A)(1) to (4)(a).



pharmacist to exercise professional judgment in determining the amount of the drug to dispense or sell.<sup>21</sup> However, the bill prohibits a pharmacist from supplying a drug in an amount authorized by the bill to the same patient more than once in any 12-month period.<sup>22</sup>

### **Prescribing based on a remote examination**

The bill requires the State Medical Board to adopt rules governing the requirements for a physician to prescribe or personally furnish a prescription drug to a patient on whom the physician has never conducted a clinical assessment, and who is at a location remote from the physician.<sup>23</sup> The bill specifies different requirements for the rules governing controlled and noncontrolled substances.

Regarding prescription drugs that are controlled substances, the bill requires the rules to establish standards that are consistent with federal law.<sup>24</sup> The bill defines "controlled substance" as a drug, compound, mixture, preparation, or substance in schedule I, II, III, IV, or V of the controlled substance schedules established under existing law.<sup>25</sup>

Regarding prescription drugs that are not controlled substances, the bill requires the rules to authorize a physician to establish a physician-patient relationship by the use of appropriate technology that permits a medical evaluation and the collection of relevant clinical history as needed to establish a diagnosis, identify any underlying conditions, and identify any contraindications to the treatment that is being recommended. The technology must permit the required medical evaluation and collection of clinical history in a manner that is consistent with the minimal standard of care for in-person care by a physician.<sup>26</sup>

The bill requires that the initial rules be adopted not later than one year after the bill's effective date. The rules must be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119.).<sup>27</sup>

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<sup>21</sup> R.C. 4729.281(A)(4)(b)(i).

<sup>22</sup> R.C. 4729.281(A)(4)(b)(ii).

<sup>23</sup> R.C. 4731.74(B).

<sup>24</sup> R.C. 4731.74(B)(2).

<sup>25</sup> R.C. 4731.74(A)(1), referencing R.C. 3719.01, not in the bill.

<sup>26</sup> R.C. 4731.74(B)(1).

<sup>27</sup> R.C. 4731.74(C).





## **Board of Nursing license renewal procedures**

The bill makes changes to the law governing the Ohio Board of Nursing and its procedures for the renewal of a license to practice nursing as a registered nurse or licensed practical nurse or a certificate of authority held by an advanced practice registered nurse.<sup>28</sup> In each case, the bill establishes the following:

(1) The dates by which an application for renewal and a late application are to be submitted;

(2) The date by which an active license or certificate lapses if not renewed or classified as inactive.

Under existing law, a license or certificate issued by the Board of Nursing may be renewed according to a schedule established by the Board in rules. The bill maintains this law for any license or certificate other than a license to practice nursing as a registered or licensed practical nurse or a certificate of authority held by an advanced practice registered nurse.

### **Licensed practical nurse and registered nurse licenses**

Under the bill, an active license to practice nursing is subject to renewal in odd-numbered years for a registered nurse and in even-numbered years for a licensed practical nurse. An application for renewal is due on the fifteenth day of September of the renewal year; however, a late application may be submitted before the license lapses. If a license is not renewed or classified as inactive, the license lapses on the first day of November of the renewal year. A license holder who submits a renewal application after September 15, but before November 1, must include the fee for processing a late application.<sup>29</sup>

### **Certificates of authority**

With respect to a certificate of authority that authorizes a registered nurse to practice in an advanced practice registered nursing specialty, the bill specifies that the certificate lapses and may be renewed, including by late application, according to the same schedule established for a registered nurse license.<sup>30</sup>

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<sup>28</sup> R.C. 4723.06, 4723.063, 4723.08, 4723.091, 4723.24, 4723.42, and 4723.47.

<sup>29</sup> R.C. 4723.24.

<sup>30</sup> R.C. 4723.42.



## Inactive status and conforming changes

Existing law requires that the Board classify as inactive a license to practice nursing as a registered or licensed practical nurse if the holder provides to the Board, on or before the license renewal date, written notice of his or her intent not to practice in Ohio. Under the bill, this notice is to be provided on or before the date the license lapses.<sup>31</sup>

The bill extends to a certificate of authority the requirement that the Board classify the certificate as inactive upon written notice. Under the bill, a notice of intent not to practice under the certificate may be submitted on or before the date the certificate lapses.<sup>32</sup>

The bill also makes conforming changes to other provisions of law that reference Board of Nursing renewal procedures.<sup>33</sup>

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## HISTORY

ACTION	DATE
Introduced	05-05-15
Reported, H. Health & Aging	06-24-15
Passed House (92-0)	06-30-15
Reported, S. Health & Human Services	11-18-15

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<sup>31</sup> R.C. 4723.24.

<sup>32</sup> R.C. 4723.42.

<sup>33</sup> R.C. 4723.06, 4723.063, 4723.08, 4723.091, and 4723.47.

