



# Ohio Legislative Service Commission

## Final Analysis

Audra Tidball

### **Am. Sub. H.B. 188** 131st General Assembly (As Passed by the General Assembly)

- 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, Beagle, Burke, Coley, Eklund, Faber, Gardner, Hite, Hughes, Jones, Jordan, LaRose, Lehner, Patton, Seitz, Uecker

**Effective date:** March 23, 2016

---

## ACT SUMMARY

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

- Authorizes one or more pharmacists practicing under a consult agreement with one or more physicians 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 separate processes that were based on whether the patient's drug therapy was 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 who is at a location remote from the physician and has never been physically examined by the physician.

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

- Establishes September 15 as the deadline for submitting a timely application for biennial renewal of certain licenses and certificates issued by the Board of Nursing and November 1 as the date a license or certificate lapses if not renewed.

---

## 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 continuing law to manage an individual's drug therapy under specified conditions. The act modifies the activities that may be included in a pharmacist's practice under a consult agreement and the process used to enter into and implement consult agreements.

#### Entering into a consult agreement

The act authorizes one or more pharmacists to enter into a consult agreement with one or more physicians. Previously, a consult agreement was between a single pharmacist and single physician.

Under the act, a consult agreement must meet all of the following conditions:

**(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>

---

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

The act establishes a single process for entering into and implementing a consult agreement. This is in place of the separate processes that applied under prior law depending on whether the individual whose drug therapy was being managed was (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>

### **Contents of a consult agreement**

The act continues the requirement that a consult agreement be in writing. It 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) Practice protocols;
- (3) A description of the drug therapy management protocols.<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 act 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, 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>

---

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

<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) and 4729.01.

The act specifies that a consult agreement does not permit a pharmacist to manage drug therapy prescribed by a physician who is not a party to the agreement.<sup>6</sup>

### **Blood and urine tests**

The act authorizes a pharmacist practicing under a consult agreement, to the extent specified in the agreement and permitted in rules to be adopted under the act, to order blood and urine tests. In accordance with practice protocols that are part of the consult agreement, the pharmacist may evaluate the results of those tests that are related to the drug therapy being managed. The act 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 prior law and in addition to the requirements described above, the act 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**

Under the act, 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

---

<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).

relationship and the drug therapy remains within the scope of the physician's practice and the pharmacist's training and experience.<sup>11</sup>

### **Termination of a consult agreement**

The act modifies termination provisions applicable to consult agreements to account for the fact that one or more pharmacists or physicians may enter into a consult agreement under the act. 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 replaces prior law provisions that authorized 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 act eliminates the following provisions that applied under prior law according to whether the patient being treated was in an institutional setting:

#### **Outside 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 limiting a consult agreement to the particular diagnosis for which a physician prescribed an individual's drug therapy;

---

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

<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 prohibition on implementing a consult agreement until it was signed by the pharmacist, physician, and the patient or another person authorized to provide consent to treatment;
- A specification that a pharmacist's management of drug therapy could include monitoring and modifying a prescription, but could not include dispensing a drug that had not been prescribed;
- 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 an alternate physician or pharmacist to be designated if the primary physician or pharmacist was unavailable to consult directly with the other party.

**Within 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 could be entered into or implemented;
- A provision specifying that the consult agreement policy must require an alternate pharmacist or physician to be available when the parties who entered into a consult agreement were not physically present and available at the hospital or long-term care facility;
- A provision specifying that a consult agreement did not permit a pharmacist to act under the agreement in a hospital or long-term care facility where the pharmacist was not authorized to practice.

**Immunity from civil liability**

The act adds certain immunities for pharmacists and physicians with regard to the actions of other parties to a consult agreement. Under the act, a pharmacist is not liable in a civil action for injury or loss to a person or property that allegedly arises from a physician's change in a drug for a patient whose drug therapy the pharmacist is managing under a consult agreement.<sup>16</sup> Similarly, a physician is not liable for injury or

---

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

<sup>16</sup> R.C. 4729.39(D)(1)(a).

loss allegedly arising from a pharmacist's change in a drug under a consult agreement, unless the physician authorized the specific change.<sup>17</sup>

The act 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>18</sup>

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

For a patient who is on a consistent drug therapy with a drug that is not a controlled substance, the act increases the amount of a drug that a pharmacist is authorized to dispense or sell without a prescription. Under continuing law, a pharmacist may dispense or sell up to a 72-hour supply of a dangerous drug, other than a schedule II controlled substance, without a prescription if the following conditions are met: (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 another health 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>19</sup>

The act provides that, 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. If a standard unit of dispensing for the drug exceeds a 30-day supply, the pharmacist may sell or dispense the standard unit.<sup>20</sup> Under the act, a particular drug cannot be dispensed or sold to the same patient more than once in any 12-month period.<sup>21</sup>

### **Prescribing to a patient at a remote location**

The act requires the State Medical Board to adopt rules governing the requirements for a physician to prescribe or personally furnish a prescription drug to a

---

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

<sup>18</sup> R.C. 4729.39(D)(2).

<sup>19</sup> R.C. 4729.281(A)(1) through (4).

<sup>20</sup> R.C. 4729.281(A)(4)(b)(i).

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

patient who is at a location remote from the physician and on whom the physician has never conducted a physical examination.<sup>22</sup> The act specifies different requirements for the rules governing drugs that are controlled substances and those that are not.

Regarding prescription drugs that are controlled substances, the act requires the rules to establish standards that are consistent with federal law.<sup>23</sup> The act 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 law unchanged by the act.<sup>24</sup>

Regarding prescription drugs that are not controlled substances, the act 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>25</sup>

The act requires that the initial rules be adopted not later than one year after the act's effective date. The rules must be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119).<sup>26</sup>

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

The act makes changes to the Board of Nursing's procedures for renewing 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>27</sup> In each case, the act establishes the following:

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

---

<sup>22</sup> R.C. 4731.74(B).

<sup>23</sup> R.C. 4731.74(B)(2).

<sup>24</sup> R.C. 4731.74(A)(1), referencing R.C. 3719.01, not in the act.

<sup>25</sup> R.C. 4731.74(B)(1).

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

<sup>27</sup> R.C. 4723.06, 4723.063, 4723.08, 4723.091, 4723.24, 4723.42, and 4723.47.

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

Prior to the act, a license or certificate issued by the Board was renewed according to a schedule the Board established in rules. The act does not change that process 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 act, 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 September 15 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 November 1 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>28</sup>

Prior to the act, the Board's rules required completed renewal applications to be postmarked, renewed online, or otherwise received by the Board before July 1 in odd numbered years for registered nurses and even numbered years for licensed practical nurses; otherwise, a late processing fee was required. If the license renewal fee and late processing fee, if applicable, were not paid prior to September 1, the license lapsed.<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 act 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> Prior to the act, the Board's rules required the application to be postmarked, renewed online, or otherwise received by the Board before July 1 in odd numbered years; otherwise, a late processing fee was required.<sup>31</sup>

---

<sup>28</sup> R.C. 4723.24.

<sup>29</sup> Ohio Administrative Code (O.A.C.) 4723-7-09.

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

<sup>31</sup> O.A.C. 4723-8-08.



## Inactive status and conforming changes

Prior law required that the Board classify as inactive a license to practice nursing as a registered or licensed practical nurse if the holder provided to the Board, on or before the license renewal date, written notice of intent not to practice in Ohio. Under the act, this notice is to be provided on or before the date the license lapses.<sup>32</sup>

The act extends to a certificate of authority the requirement that the Board classify the certificate as inactive upon written notice. Under the act, a notice of intent not to practice under the certificate may be submitted on or before the date the certificate lapses.<sup>33</sup>

The act makes conforming changes to other provisions of law that reference the Board's renewal procedures.<sup>34</sup>

---

## 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
Passed Senate (33-0)	12-09-15
House concurred in Senate amendments (92-0)	12-09-15

15-HB188-131.docx/emr

---

<sup>32</sup> R.C. 4723.24.

<sup>33</sup> R.C. 4723.42.

<sup>34</sup> R.C. 4723.06, 4723.063, 4723.08, 4723.091, and 4723.47.

