



# Ohio Legislative Service Commission

## Bill Analysis

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### Sub. H.B. 367

129th General Assembly

(As Reported by S. Health, Human Services and Aging)

**Reps.** Maag, Grossman, Murray, Fende, Antonio, Duffey, Hackett, Sears, Beck, Blair, Blessing, Bubb, Carney, Celebrezze, Celeste, Gardner, Garland, Hill, Johnson, Letson, Lundy, Mallory, Matheney, Milkovich, O'Brien, Phillips, Ramos, Stautberg, Stebelton, Stinziano, Terhar, Wachtmann, Winburn, Yuko, Batchelder

**Sen.** Tavares

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## BILL SUMMARY

### Pediatric respite care programs

- Requires the Department of Health to regulate pediatric respite care programs, which are programs that provide services to patients under age 27 who have been diagnosed before age 18 with life-threatening diseases or conditions that shorten life expectancy.
- Establishes a licensing process for pediatric respite care programs that is similar to the Department's existing licensure process for hospice care programs.
- Names the licensing provisions as "Sarah's Law."

### Non-self-injectable cancer drugs

- Generally prohibits pharmacists and pharmacy interns from dispensing a non-self-injectable cancer drug by delivering or causing it to be delivered directly to the patient, the patient's representative, or the patient's private residence.
- Specifies that the dispensing prohibition does not apply when the patient's private residence is an institutional or health care facility or, if certain notifications have been provided, when the patient is a hospice patient or home health agency client.

## **Methadone treatment programs**

- Modifies licensure requirements for methadone treatment programs to specify that treatment cannot be maintained within a 500-foot radius of a public or private school, licensed day-care center, or other child-serving agency.
- Relative to license applications pending on the date the 500-foot proximity requirement takes effect, requires the Ohio Department of Alcohol and Drug Addiction Services (ODADAS) to apply the requirement when determining whether to issue the license.
- Permits ODADAS to waive the proximity requirement if it receives, from each public or private school, licensed day-care center, or other child-serving agency within a 500-foot radius of the entity, a letter of support for the location that is satisfactory to ODADAS.
- Prohibits ODADAS from considering the proximity requirement when determining whether to renew, withdraw, or revoke a license issued before the effective date of the requirement.

## **Emergency clause and delayed effective dates**

- Declares an emergency.
- Specifies that the bill's provisions that pertain to methadone treatment programs take effect immediately, but the provisions that pertain to pediatric respite care programs and non-self-injectable cancer drugs take effect 90 days after the bill's effective date.

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## **CONTENT AND OPERATION**

### **PEDIATRIC RESPITE CARE PROGRAMS**

#### **Regulation and licensure**

The bill requires the Department of Health to regulate pediatric respite care programs through a licensing process that is similar to the Department's existing licensure of hospice care programs.<sup>1</sup> The bill specifies that its provisions regarding licensure of pediatric respite care programs are to be known as "Sarah's Law."<sup>2</sup>

As defined by the bill, a pediatric respite care program is a program that provides inpatient respite care and related services only to pediatric respite care patients and pediatric respite care patients' families in order to meet the physical, psychological, social, spiritual, and other special needs that are experienced during or leading up to the final stages of illness, dying, and bereavement. All of the following services may be provided by a pediatric respite care program:

- (1) Short-term inpatient care, including both palliative and respite care and procedures;
- (2) Nursing care by or under the supervision of a registered nurse;
- (3) Physician's services;
- (4) Medical social services by a social worker under the direction of a physician;

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<sup>1</sup> R.C. 3712.031(C).

<sup>2</sup> Section 7.

(5) Medical supplies, including drugs and biologicals, and the use of medical appliances;

(6) Counseling for pediatric respite care patients and pediatric respite care patients' families;

(7) Bereavement services for respite care patients' families.<sup>3</sup>

The bill defines "pediatric respite care patient" as a patient who (1) is less than 27 years old, (2) has been diagnosed before age 18 with a life-threatening disease or condition that is expected to shorten the patient's life expectancy, regardless of whether the patient is terminally ill, and (3) has voluntarily requested and is receiving care from a licensed pediatric respite care program.<sup>4</sup> The bill defines "pediatric respite care patient's family" as a patient's family members, including a spouse, brother, sister, child, or parent, and any other relative or individual who has significant personal ties to the patient and who is designated as a member of the patient's family by mutual agreement of the patient, the relative or individual, and the patient's interdisciplinary team.<sup>5</sup> A patient's interdisciplinary team is a working unit composed of professional and lay persons that includes at least a physician, a registered nurse, a social worker, a member of the clergy or a counselor, and a volunteer.<sup>6</sup>

### **Separate licensure**

The bill provides for separate licensure of pediatric respite care programs and hospice care programs. It specifies that the term "pediatric respite care program" does not include a hospice care program, and in a corresponding provision, it specifies that the term "hospice care program" does not include a pediatric respite care program. As a result, neither program is subject to the other program's licensing requirements.<sup>7</sup>

### **Required components**

Under the bill, any person or public agency licensed to provide a pediatric respite care program is required to do all of the following:

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<sup>3</sup> R.C. 3712.01(J).

<sup>4</sup> R.C. 3712.01(K).

<sup>5</sup> R.C. 3712.01(L).

<sup>6</sup> R.C. 3712.01(D).

<sup>7</sup> R.C. 3712.01(A), (B), and (J), 3712.03, and 3712.031.

(1) Provide a planned and continuous pediatric respite care program (the medical components must be under the direction of a physician);

(2) Ensure that care is available 24 hours a day, 7 days a week;

(3) Establish an interdisciplinary plan of care for each pediatric respite care patient and the patient's family that is coordinated by one designated individual who must ensure that all components of the plan of care are addressed and implemented, addresses maintenance of patient-family participation in decision making, and is reviewed by the patient's attending physician and by the patient's interdisciplinary team immediately prior to or on admission to each session of respite care;

(4) Have an interdisciplinary team or teams that provide or supervise the provision of pediatric respite care program services and establish the policies governing the provision of the services;

(5) Maintain central clinical records on all pediatric respite care patients under its care.<sup>8</sup>

### **Contracting for the provision of components**

A provider of a pediatric respite care program may arrange for another person or public agency to furnish one or more of the above components pursuant to a written contract. If the provider contracts with a home health agency for this purpose, the contract for the care must include all of the following terms:

(1) The provider must furnish a copy of the patient's interdisciplinary plan to the home health agency and must specify the care that is to be provided by the home health agency;

(2) The regimen described in the established plan of care must be continued while the patient receives care from the home health agency, subject to the patient's needs, and with approval of the coordinator of the interdisciplinary team;

(3) All care, treatment, and services furnished by the home health agency must be entered into the patient's medical record;

(4) The designated coordinator of the interdisciplinary team must ensure conformance with the established plan of care;

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<sup>8</sup> R.C. 3712.061(A).

(5) A copy of the home health agency's medical record and discharge summary must be retained as part of the patient's medical record.<sup>9</sup>

### **Prohibitions against unlicensed activities**

The bill prohibits a person or public agency from doing any of the following without a license:

--Holding itself out as providing a pediatric respite care program;

--Providing a pediatric respite care program;

--Using the term "pediatric respite care program" or any term containing "pediatric respite care" to describe or refer to a health program, facility, or agency.<sup>10</sup>

The Department must petition the court of common pleas of the county in which the prohibited activity is taking place for an order enjoining that person or public agency from conducting those activities without a license. Any person or public agency may request the Department to petition the court, and the Department must do so if it determines that the person or public agency named in the request is violating one or more of the prohibitions described above. The bill gives the court jurisdiction to grant injunctive relief upon a showing that the person or public agency named in the petition is conducting those activities without a license.<sup>11</sup>

A person who violates any of the prohibitions is guilty of a second degree misdemeanor on a first offense, and a first degree misdemeanor on each subsequent offense.<sup>12</sup>

### **Exemptions**

The bill specifies that the prohibitions against unlicensed activities described above do not apply to any of the following:

(1) A member of an interdisciplinary team or an employee of a licensed pediatric respite care program.<sup>13</sup>

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<sup>9</sup> R.C. 3712.061(B).

<sup>10</sup> R.C. 3712.051(A).

<sup>11</sup> R.C. 3712.051(C).

<sup>12</sup> R.C. 3712.99.

<sup>13</sup> R.C. 3712.051(A).

(2) A hospital.

(3) A nursing home or residential care facility.

(4) A home health agency, if it provides services under contract with a licensed pediatric respite care facility.

(5) A regional, state, or national nonprofit organization whose members are providers of pediatric respite care programs, individuals interested in pediatric respite care programs, or both, as long as the organization does not provide or represent that it provides pediatric respite care programs.<sup>14</sup>

(6) A person or government entity certified by the Ohio Department of Developmental Disabilities (ODODD) as a supported living provider. ("Supported living" means services provided for as long as 24 hours a day to an individual with mental retardation or other developmental disability through any public or private resources, including moneys from the individual, that enhance the individual's reputation in community life and advance the individual's quality of life by doing the following: (a) providing the support necessary to enable an individual to live in a residence of the individual's choice, with any number of individuals who are not disabled, or with not more than three individuals with mental retardation and developmental disabilities unless the individuals are related by blood or marriage, (b) encouraging the individual's participation in the community, (c) promoting the individual's rights and autonomy, and (d) assisting the individual in acquiring, retaining, and improving the skills and competence necessary to live successfully in the individual's residence.<sup>15</sup>)

(7) A residential facility licensed by ODODD. (A "residential facility" is a home or facility in which a mentally retarded or developmentally disabled person resides, except the home of a relative or legal guardian in which a mentally retarded or developmentally disabled person resides, a respite care home certified by a county board of developmental disabilities, a county home or district home, or a dwelling in which the only mentally retarded or developmentally disabled residents are in an independent living arrangement or are being provided supported living.<sup>16</sup>)

(8) A respite care home certified by a county board of developmental disabilities. (A "respite care home" is a facility that provides temporary, as opposed to permanent,

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<sup>14</sup> R.C. 3712.051(B).

<sup>15</sup> R.C. 5126.01(U)(1).

<sup>16</sup> R.C. 5123.19(A)(1)(a).

care for persons with mental retardation or developmental disabilities when their regular caretakers need a respite from providing care.<sup>17)</sup>

(9) A person providing respite care under a family support services program established by a county board of developmental disabilities. ("Respite care" is appropriate, short-term, temporary care that is provided to a mentally retarded or developmentally disabled person to sustain the family structure or to meet planned or emergency needs of the family.<sup>18)</sup>

(10) A person or government entity providing respite care under an ODODD-administered Medicaid waiver.<sup>19)</sup>

## **Licensure process**

Every person or public agency that proposes to provide a pediatric respite care program must apply to the Department for a license. An application for a license for a pediatric respite care program consists of both of the following:

(1) Application form – an applicant must provide required information on a form prescribed and provided by the Department.

(2) Fees – an applicant must pay the required license fee established by rules to be adopted by the Director of Health. This fee cannot exceed \$600 without Controlling Board approval. The maximum fee approved by the Controlling Board cannot exceed \$900.<sup>20)</sup>

The Department must grant a license to the applicant if the applicant is in compliance with the statutes and rules governing pediatric respite care programs. A license is valid for three years.<sup>21)</sup>

## **License renewal**

A licensed pediatric respite care program may renew its license by applying for renewal in the same manner as applying for initial licensure and providing a license renewal fee established in rules to be adopted by the Director of Health. This renewal

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<sup>17</sup> Telephone interview with Ohio Department of Developmental Disabilities representative (Feb. 6, 2009).

<sup>18</sup> R.C. 5126.11(A).

<sup>19</sup> R.C. 5111.871.

<sup>20</sup> R.C. 3721.031(A)(2).

<sup>21</sup> R.C. 3721.031(C)(1) and 3721.041(A) and (B).



fee cannot exceed \$600 without Controlling Board approval. The maximum fee approved by the Controlling Board cannot exceed \$900.<sup>22</sup> An application for renewal must be made at least 90 days prior to the expiration of the license. The Department must renew the license if the applicant is in compliance with the statutes and rules governing pediatric respite care programs.<sup>23</sup>

## **Inspections**

The Department is required to make inspections as necessary to determine whether pediatric respite care program facilities and services meet the requirements of the bill and the rules adopted under it.<sup>24</sup> An inspection fee must be established by the Director of Health in those rules. This fee cannot exceed \$1,750 without Controlling Board approval. The maximum fee approved by the Controlling Board cannot exceed \$2,625.<sup>25</sup>

## **Disciplinary actions**

The Department may suspend or revoke a license of a pediatric respite care program if the license holder made any material misrepresentation in the application for the license or no longer meets the requirements of the bill or the rules adopted under it. The Department must comply with the Administrative Procedure Act (R.C. Chapter 119.) when taking disciplinary actions.<sup>26</sup>

## **Rulemaking**

The Director of Health is required to adopt, and permitted to amend and rescind, rules in accordance with the Administrative Procedure Act that do all of the following:

(1) Provide for licensure of pediatric respite care programs and suspension and revocation of those licenses;

(2) Establish a license fee, license renewal fee, and inspection fee in accordance with the maximum amounts described above;

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<sup>22</sup> R.C. 3721.031(A)(2).

<sup>23</sup> R.C. 3712.041(B).

<sup>24</sup> R.C. 3712.031(C)(2).

<sup>25</sup> R.C. 3712.031(A)(3).

<sup>26</sup> R.C. 3712.031(C)(1) and 3712.041(C).

(3) Establish requirements for pediatric respite care program facilities and services;

(4) Provide for the granting of licenses to persons and public agencies that are accredited or certified to provide pediatric respite care programs by an entity whose standards for accreditation or certification equal or exceed those provided for by the bill and the rules adopted under it;

(5) Establish interpretive guidelines for the rules described above;<sup>27</sup>

(6) Implement criminal background check requirements for applicants for employment with a pediatric respite care program who will be providing direct care to pediatric respite care patients, including the circumstances under which a program may employ a person who has been convicted of or pleaded guilty to specified offenses (such as certain sex and drug offenses) but meets personal character standards set by the Director.<sup>28</sup>

### **Existing law extended to pediatric respite care programs**

The bill otherwise provides for pediatric respite care programs to be subject to the same requirements as hospice care programs. The issues addressed in the laws made applicable to pediatric respite care programs include the following:

--Required criminal background checks for applicants for employment with a pediatric respite care program who will be providing direct care to pediatric respite care patients;<sup>29</sup>

--Permission to request criminal background checks for applicants for employment with a pediatric respite care program who will not be providing direct care to pediatric respite care patients;<sup>30</sup>

--Requirements and responsibilities related to a patient's durable power of attorney for health care;<sup>31</sup>

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<sup>27</sup> R.C. 3712.031(A) and (B).

<sup>28</sup> R.C. 3712.09(F)(2).

<sup>29</sup> R.C. 3712.09.

<sup>30</sup> R.C. 109.57 and Sections 5, 6, 6A, 8, and 9.

<sup>31</sup> R.C. 1337.11.

--Requirements and responsibilities related to a patient's do-not-resuscitate order;<sup>32</sup>

--Provisions holding a pediatric respite care program liable for a physician's failure to obtain informed consent before a medical procedure only if the physician is an employee of the program;<sup>33</sup>

--Prohibitions related to assisted suicide.<sup>34</sup>

The bill also makes a number of changes to conform the licensing system of pediatric respite care programs to the licensing system of hospice care programs.<sup>35</sup>

## **NON-SELF-INJECTABLE CANCER DRUGS**

### **Prohibition on direct delivery**

The bill generally prohibits a pharmacist or pharmacy intern from dispensing a non-self-injectable cancer drug by delivering the drug directly to, or causing the drug to be directly delivered to, any of the following:<sup>36</sup>

- (1) The patient;
- (2) The patient's representative, which may include the patient's guardian or a family member or friend of the patient;
- (3) The patient's private residence.

### **Exceptions**

A pharmacist or pharmacy intern may dispense a non-self-injectable drug to the patient's private residence if one of the following three circumstances is the case:<sup>37</sup>

- (1) The patient's private residence is a nursing home, residential care facility, rehabilitation facility, or similar institutional facility or health care facility.

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<sup>32</sup> R.C. 2133.01.

<sup>33</sup> R.C. 2317.54.

<sup>34</sup> R.C. 3795.01.

<sup>35</sup> R.C. 3701.881, 3721.01, 3963.01, 4719.01, 4752.02, 5119.70, and 5119.71.

<sup>36</sup> R.C. 4729.43(B).

<sup>37</sup> R.C. 4729.43(B)(3).

(2) If the patient is an adult and a hospice patient or client of a home health agency, the patient, licensed health professional who prescribed the drug to the patient, or an employee or agent of the prescriber has notified the pharmacist or pharmacy intern that the patient is a hospice patient or client of a home health agency and an employee or agent of the hospice care program or home health agency will be administering the drug to the patient.

(3) If the patient is a minor and a hospice patient or client of a home health agency, either of the following has notified the pharmacist or pharmacy intern that the patient is a hospice patient or client of a home health agency and an employee or agent of the hospice care program or home health agency will be administering the drug to the patient: (a) the licensed health professional who prescribed the drug to the patient or an employee or agent of the prescriber, or (b) the parent, guardian, or other person who has care or charge of the patient and is authorized to consent to medical treatment on the patient's behalf.

## **Penalties**

A pharmacist or pharmacy intern who willfully violates, conspires to violate, attempts to violate, or aids and abets a violation of the dispensing prohibition may be subject to disciplinary action by the State Board of Pharmacy. The disciplinary sanctions the Board may take include revoking, suspending, or limiting the pharmacist's or intern's identification card; placing the pharmacist's or intern's identification card on probation; refusing to grant or renew the pharmacist's or intern's identification card; or imposing a monetary penalty or forfeiture not to exceed \$500.<sup>38</sup>

## **Definitions**

The bill defines "non-self-injectable cancer drug" as a dangerous drug indicated for the treatment of cancer or a cancer-related illness that must be administered intravenously or by subcutaneous injection that an individual cannot reasonably self-administer.<sup>39</sup> (A "dangerous drug" is generally classified as a drug that may be legally dispensed only on a prescription.<sup>40</sup>) The bill defines a "home health agency" as a person or government entity, other than a nursing home, residential care facility, or hospice care program, that has the primary function of providing any of the following services to a patient at a place of residence used as the patient's home: skilled nursing care, physical therapy, speech-language pathology, occupational therapy, medical social

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<sup>38</sup> R.C. 4729.16(A)(5).

<sup>39</sup> R.C. 4729.43(A)(2).

<sup>40</sup> See R.C. 4729.01(F).

services, or home health aide services.<sup>41</sup> The bill defines "hospice patient" and "hospice care program" consistent with the laws governing the licensure of hospice care programs.<sup>42</sup>

## METHADONE TREATMENT PROGRAMS

### Location requirements for licensure

The bill modifies the requirements an alcohol and drug addiction program must meet to be licensed by the Ohio Department of Alcohol and Drug Addiction Services (ODADAS) to maintain methadone treatment. Currently, five requirements must be met to obtain licensure of a methadone treatment program.<sup>43</sup> The bill adds a sixth requirement: the treatment cannot be maintained within a 500-foot radius of a public or private school, licensed day-care center, or other child-serving agency.<sup>44</sup>

In the case of a license application pending on the effective date of the bill's proximity requirement, the bill specifies that the proximity requirement described above must be applied by ODADAS in determining whether to issue the license. ODADAS may waive the proximity requirement in accordance with provisions specified by the bill (see "**Waiver**," below).<sup>45</sup>

In the case of a license issued prior to the effective date of the bill's proximity requirement, the bill prohibits ODADAS from considering the requirement in determining whether to renew, withdraw, or revoke the license.<sup>46</sup>

### **Waiver**

The bill specifies that ODADAS may waive the proximity requirement if it receives, from each public or private school, licensed day-care center, or other child-serving agency that is within the 500-foot radius of the location of the proposed methadone treatment program, a letter of support for the location. ODADAS must

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<sup>41</sup> R.C. 4729.43(A)(1), which references the definition of "home health agency" in law governing criminal records checks for prospective employees responsible for child care or direct care to older adults (R.C. 3701.881).

<sup>42</sup> R.C. 3712.01(A) and (B).

<sup>43</sup> R.C. 3793.11(C)(1) to (5).

<sup>44</sup> R.C. 3793.11(C)(6).

<sup>45</sup> Section 4.

<sup>46</sup> R.C. 3793.11(K).

determine whether a letter of support is satisfactory for purposes of waiving the requirement.<sup>47</sup>

## EMERGENCY CLAUSE AND DELAYED EFFECTIVE DATES

The bill declares that it is an emergency measure necessary for the immediate preservation of the public peace, health, and safety.<sup>48</sup> Therefore, it is not subject to the referendum under article II, section 1d of the Ohio Constitution.

The bill specifies that its provisions that pertain to the licensure of pediatric respite care programs and non-self-injectable cancer drugs go into effect 90 days after the bill's effective date.<sup>49</sup> The provisions pertaining to methadone treatment programs are to take effect immediately.

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## HISTORY

ACTION	DATE
Introduced	11-01-11
Reported, H. Health & Aging	03-14-12
Passed House (91-0)	03-27-12
Reported, S. Health, Human Services & Aging	11-21-12

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<sup>47</sup> R.C. 3793.11(D).

<sup>48</sup> Section 10.

<sup>49</sup> Section 3.

