

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** PCS for HB 1373 Medication Administration  
**SPONSOR(S):** Children, Families & Seniors Subcommittee  
**TIED BILLS:** **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Children, Families & Seniors Subcommittee		Gilani	Brazzell

### SUMMARY ANALYSIS

The Agency for Persons with Disabilities (APD) is responsible for providing services to persons with developmental disabilities. A developmental disability is defined as a disorder or syndrome that is attributable to intellectual disability, cerebral palsy, autism, spina bifida, Down syndrome, Phelan-McDermid syndrome, or Prader-Willi syndrome; that manifests before the age of 18; and that constitutes a substantial handicap that can reasonably be expected to continue indefinitely.

Persons with developmental disabilities reside in various types of residential settings, including community-based residential facilities licensed and regulated by APD. Medication services are an important element of care for individuals with developmental disabilities in APD facilities and are often provided by unlicensed direct service providers (DSPs).

Medication assistance or administration typically involves observation of the client to ensure correct self-administration of medication, or directly giving or applying the medication as prescribed, respectively. Medication administration is generally a nurse's responsibility; however, a majority of states will allow trained unlicensed personnel to perform these tasks to meet the demand. Similarly, APD serves more than 50,000 clients and must rely on unlicensed personnel such as DSPs for these functions, provided they have undergone the appropriate training. Currently, unlicensed personnel can administer or supervise at least eight routes of administration (enteral, inhaled, ophthalmic, oral, otic, rectal, topical, and transdermal).

Currently, unlicensed personnel must complete a 4-hour initial training course in medication administration and have their skills assessed and validated by a licensed nurse or physician in each route of administration they intend to use. This assessment includes onsite observation of the administration of medication to or supervision of self-administration by a client. A nurse or physician must validate these skills each year in the same manner.

The PCS for HB 1373 revises the training requirements for unlicensed personnel to administer medication to or supervise self-administration of medication by clients in APD's facilities. Specifically, the bill:

- Increases the length of the initial training course on medication administration from four to eight hours;
- Adds an annual requirement for successful completion of two hours of continuing education in medication administration and error prevention;
- Eliminates the requirement of annual revalidation for various routes of medication administration (inhaled, ophthalmic, rectal); and
- Permits initial validation by simulation during the initial training course rather than on an actual client for various routes of medication administration (otic, transdermal, or topical).

The bill will have an insignificant impact on state government.

The bill provides an effective date of July 1, 2018.

## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

##### **Present Situation**

###### Agency for Person with Disabilities

The Agency for Persons with Disabilities (APD) is responsible for providing services to persons with developmental disabilities. A developmental disability is defined as a disorder or syndrome that is attributable to intellectual disability, cerebral palsy, autism, spina bifida, Down syndrome, Phelan-McDermid syndrome, or Prader-Willi syndrome; that manifests before the age of 18; and that constitutes a substantial handicap that can reasonably be expected to continue indefinitely.<sup>1</sup> The overarching goal for APD is to prevent or reduce the severity of the developmental disability and implement community-based services that will help individuals with developmental disabilities achieve their greatest potential for independent and productive living in the least restrictive means.<sup>2</sup>

Persons with developmental disabilities reside in various types of residential settings. Some individuals with developmental disabilities live with family, some live in their own homes, while others may live in community-based residential facilities.<sup>3</sup> Pursuant to s. 393.067, F.S., APD is charged with licensing community-based residential facilities that serve and assist individuals with developmental disabilities; these include foster care facilities, group home facilities, residential habilitation centers, and comprehensive transitional education programs (CTEPs).<sup>4</sup>

Individuals who meet Medicaid eligibility requirements may choose to receive services in the community through the state's Medicaid Home and Community-Based Services (HCBS) waiver for individuals with developmental disabilities administered by APD or in an Intermediate Care Facility for the Developmentally Disabled (ICF/DD).<sup>5</sup>

While the majority of individuals served by APD live in the community, a small number live in Intermediate Care Facilities for the Developmentally Disabled (ICF/DD). ICF/DD's are defined in s. 393.063(25), F.S., as a residential facility licensed and certified by the Agency for Health Care Administration pursuant to part VIII of ch. 400, F.S. ICF/DD's are considered institutional placements.

###### Medication Administration

Medication services are an important element of care for individuals with developmental disabilities in residential facilities. A direct service provider (DSP)<sup>6</sup> has face-to-face contact with APD clients and provides a variety of services to clients in residential facilities, including medication assistance or administration.

Medication assistance generally includes being aware of clients' medications, reminding them to take the medication as directed, helping with containers, providing water if necessary, and supervising<sup>7</sup>

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<sup>1</sup> s. 393.063(9), F.S.

<sup>2</sup> s. 393.062, F.S.

<sup>3</sup> s. 393.063(28), F.S., defines residential facility as a facility providing room and board and personal care for persons who have developmental disabilities.

<sup>4</sup> AGENCY FOR PERSONS WITH DISABILITIES, *Planning Resources*, <http://apd.myflorida.com/planning-resources/> (last visited Jan. 21, 2018).

<sup>5</sup> s. 393.0662, F.S.

<sup>6</sup> A "direct service provider" is an adult who has direct face-to-face contact with an APD client while providing services to the client or has access to a client's living areas, funds, or personal property, s. 393.063(13), F.S.

<sup>7</sup> Supervised self-administered medication means direct, face-to-face observation of a client during the client's self-administration of medication and includes instruction or other assistance necessary to ensure correct self-administration of medication, Rule 65G-7.001(26), F.A.C.

them while they take the medication on their own to ensure they do so safely and appropriately.<sup>8</sup> Medication administration is more involved and can include removing the correct dosage, handing the client the medication or inserting or applying the medication for the client as prescribed.<sup>9</sup>

Medication administration is generally a nurse’s responsibility; however, a majority of states, including Florida, allow trained unlicensed personnel to perform these tasks.<sup>10</sup> Training to administer medication can either be through direct training and delegation from a nurse or through classroom-based training and certification.<sup>11</sup> The latter method of training generally involves an initial training course, continuing education, and verification of skills through simulations or directly on a patient or client.<sup>12</sup> The 24 states that use classroom-based training for unlicensed personnel require them to either pass an examination or complete continuing education, and in some instances require both.<sup>13</sup>

APD serves more than 50,000 persons with developmental disabilities in the state<sup>14</sup> and does not have enough licensed nurses to meet the needs of its clients.<sup>15</sup> Section 393.506, F.S., allows unlicensed personnel such as DSPs to administer medication to or supervise self-administration of medication by APD clients, provided they have undergone the appropriate training.<sup>16</sup>

Training Requirements for Unlicensed Personnel s. 393.506, F.S.		
	Initial Requirements	Recurring Requirements
<b>Training Course</b> <sup>17</sup>	Minimum of 4-hour course in medication administration.	None.
<b>Competency Determination</b> <sup>18</sup>	A nurse or physician must assess the unlicensed personnel and find them competent to administer or supervise self-administration of medication on an actual client.	A nurse or physician must revalidate competency of all routes of administration at least annually in an onsite setting which includes personally observing the unlicensed personnel properly administer and supervise self-administration of medication to an actual client.
<b>Informed Consent</b> <sup>19</sup>	The client, or the client’s guardian or legal representative, must give informed consent to the unlicensed personnel administering or supervising self-administration of medication.	Annually, and at any point the patient’s conditions or routes of administration change.

<sup>8</sup> *Compendium of Residential Care and Assisted Living Regulations and Policy: 2015 Edition*, US DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF DISABILITY, AGING AND LONG-TERM CARE POLICY, June 15, 2015, at 21, available at <https://aspe.hhs.gov/system/files/pdf/110391/15alcom.pdf> (last visited Jan. 25, 2018). See also Rule 65G-7.001

<sup>9</sup> *Id.* at 21. See also Rule 65G-7.001(1), F.A.C.

<sup>10</sup> *Id.* at 22-23. Approximately 36 states allow trained unlicensed personnel to administer medication and 18 states allow unlicensed trained personnel to assist with medication.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.* at 21.

<sup>13</sup> *Id.* at 24.

<sup>14</sup> AGENCY FOR PERSONS WITH DISABILITIES, *About Us*, <http://apdcares.org/about/> (last visited Jan. 24, 2018).

<sup>15</sup> Agency for Persons with Disabilities, *2018 Agency Legislative Bill Analysis for HB 1373*, at 3, Jan. 10, 2018 (on file with Children, Families, and Seniors Subcommittee staff).

<sup>16</sup> S. 400.9685, F.S. relates to administration of medication by unlicensed personnel in ICF/DDs. These facilities are regulated by the Agency for Health Care Administration and have their own requirements for trained unlicensed personnel and delegation of tasks. Rule 65G-7.002

<sup>17</sup> S. 393.506(2), F.S.

<sup>18</sup> Ss. 393.506(2), 393.506(4), F.S.

<sup>19</sup> S. 393.506(3), F.S. Informed consent includes a description of the medication routes and procedures the unlicensed personnel is authorized to supervise or administer. See also Rule 65G-7.002, F.A.C.

## Routes of Administration

There are various ways that medication can be administered to a person. Some require skilled nursing and can only be administered by a licensed practitioner.<sup>20</sup> However, trained unlicensed personnel may use the following routes to administer medication to an APD client:

Route of Administration	Definition
<b>Enteral</b>	Medication delivered by tube via the body's gastrointestinal system (e.g. nasal passage tubes, feeding tubes). <sup>21</sup>
<b>Inhaled</b>	Delivery of medication droplets or moisture suspended in a gas, such as oxygen, by inhalation through the nose or mouth (e.g. inhalers, nebulizers). <sup>22</sup>
<b>Ophthalmic</b>	A solution or ointment to be instilled into the eye or applied on or around the eyelid (e.g. eye drops). <sup>23</sup>
<b>Oral</b>	Any medication in tablet, capsule, or liquid form introduced into the gastrointestinal tract by mouth. <sup>24</sup>
<b>Otic</b>	Solutions or ointments to be placed in the outer ear canal or applied around the outer ear (e.g. ear drops, ear cream). <sup>25</sup>
<b>Rectal</b>	Any prescribed medication, capsule, enema or suppository to be administered via the rectum. <sup>26</sup>
<b>Topical</b>	A salve, lotion, ointment, cream, shampoo or solution applied locally to a body part. <sup>27</sup>
<b>Transdermal</b>	An adhesive patch containing a pre-measured amount of topical medication that is absorbed into the body via the epidermis (outer layer of skin) at a fixed rate (e.g. nicotine patches). <sup>28</sup>

## Medication Errors

A medication error is a preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of a healthcare professional, the patient, or consumer.<sup>29</sup> Medication errors such as administering the wrong medication or dosage can have serious health consequences on an individual. Educational interventions are one method to reduce medication errors.<sup>30</sup> Health professionals are required to take continuing education courses in prevention of medical errors in order to renew their licenses.<sup>31</sup> Many states require their trained unlicensed personnel to take similar courses as well; however, Florida has no such statutory requirement for trained unlicensed personnel in APD-licensed facilities.<sup>32</sup> Medication errors are generally reported by the providers within 24 hours,<sup>33</sup> or found during monthly or annual APD quality improvement reviews.<sup>34</sup>

<sup>20</sup> Only licensed practitioners may administer medication that requires injection or is administered on an as-needed basis in the practitioner's professional judgment and assessment of the client. See generally Rules 64B9-12, 64B9-14, and F.A.C.

<sup>21</sup> Rule 65G-7.001(8), F.A.C.

<sup>22</sup> Rule 65G-7.001(10), F.A.C.

<sup>23</sup> Rule 65G-7.001(16), F.A.C.

<sup>24</sup> Rule 65G-7.001(17), F.A.C.

<sup>25</sup> Rule 65G-7.001(18), F.A.C.

<sup>26</sup> Rule 65G-7.001(28), F.A.C.

<sup>27</sup> Rule 65G-7.001(28), F.A.C.

<sup>28</sup> Rule 65G-7.001(28), F.A.C.

<sup>29</sup> NATIONAL COORDINATING COUNCIL FOR MEDICATION ERROR REPORTING AND PREVENTION, *About Medication Errors*, <http://www.nccmerp.org/about-medication-errors> (last visited Jan. 28, 2018). See also 65G-7.006, F.A.C.

<sup>30</sup> *Medication Errors: Technical Series on Safer Primary Care*, WORLD HEALTH ORGANIZATION (2016), at 10, available at <http://apps.who.int/iris/bitstream/10665/252274/1/9789241511643-eng.pdf> (last visited Jan. 28, 2018).

<sup>31</sup> 456.013(7), F.S.

<sup>32</sup> *Supra* fn. 8, at 24.

<sup>33</sup> Rule 64G-7.006(3), F.A.C.

<sup>34</sup> Email from Rebecca Grissom, Deputy Director of Legislative Affairs, Agency for Persons with Disabilities, RE: Medical Errors Data (Jan. 25, 2018)(on file with the Children, Family, and Seniors Subcommittee).

APD has reported an overall upward trend of medication errors, with 98% occurring in licensed group homes.<sup>35</sup>

Medication Errors in APD Facilities <sup>36</sup>				
	2011	2012	2013	2014
Wrong Medication	137	802	527	610
Wrong Dosage	1,022	2,133	2,389	1,462
Wrong Person	81	82	170	166
Medication Not Given	4,076	7,995	8,099	6,371
Documentation Error	2,263	3,481	4,088	4,059
Non-Validated Staff	--	26,464	10,318	8,528
Medication Not Given	4,076	7,995	8,099	6,371

### Effect of the Bill

The PCS for HB 1373 revises the training requirements for unlicensed personnel to administer medication to or supervise self-administration of medication by clients in APD's residential facilities.

Unlicensed personnel are currently required to take a 4-hour initial training course on medication administration. The bill increases the length of this course from 4 to 8 hours. Currently, initial competency assessments and revalidations require that the unlicensed personnel administer or supervise self-administration on an actual client. The bill does not require this for competency assessments of otic, transdermal, or topical routes of medication administration; in those instances, the unlicensed personnel only needs to satisfactorily simulate the administration, and furthermore can do so during the initial training course. This will streamline the validation process for these routes by not requiring a second visit from a nurse or physician.

The bill adds the requirement that unlicensed personnel successfully complete a 2-hour course in medication administration and error prevention every year.

The bill only requires annual revalidation of unlicensed personnel if a residential facility performs oral and enteral routes of medication administration. Annual revalidation is not required for ophthalmic, rectal, or inhaled routes of medication.

The bill provides an effective date of July 1, 2018.

#### B. SECTION DIRECTORY:

**Section 1:** Amends s. 393.506, F.S., relating to administration of medication.

**Section 2:** Provides an effective date.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

#### A. FISCAL IMPACT ON STATE GOVERNMENT:

##### 1. Revenues:

None.

<sup>35</sup> Id.

<sup>36</sup> Id.

2. Expenditures:

The bill will have an insignificant impact on state government. APD will experience minimal costs associated with updating forms and rule promulgation to implement the changes of the bill, but states that it will be able to absorb these costs within existing resources.<sup>37</sup>

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill will have an indeterminate impact on providers at residential facilities who allow unlicensed personnel to administer medication. Competency validations require the provider to pay a nurse or physician to assess the facility's unlicensed personnel.<sup>38</sup> The bill reduces the number of nurse or physician validations required. To the extent that providers pay for fewer validations, they will see a positive impact. However, the bill increases the number of hours required for the initial course and also adds a recurring 2-year continuing education course requirement for revalidations. To the extent that providers pay increased costs for this continuing education for their unlicensed personnel, they will see a negative impact. It is unknown what the net effect of these two changes will be on providers.

D. FISCAL COMMENTS:

Compliance with clients' prescribed medication regimens may avoid the need for medical care for clients resulting from noncompliance with such regimens. APD clients who are enrolled on iBudget Florida waiver receive fee-for-service state plan Medicaid benefits unless they opt into Managed Medical Assistance.

### III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill does not specify if revalidation is required for otic, transdermal, or topical routes of medication administration.

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<sup>37</sup> *Supra* fn. 15, at 5.

<sup>38</sup> *Id.*

#### IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES