HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 1373 Persons with Developmental Disabilities
SPONSOR(S): Health & Human Services Committee; Children, Families & Seniors Subcommittee; Stevenson
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 1788

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Children, Families & Seniors Subcommittee	9 Y, 0 N, As CS	Gilani	Brazzell
2) Health & Human Services Committee	16 Y, 0 N, As CS	Gilani	Calamas

SUMMARY ANALYSIS

The Agency for Persons with Disabilities (APD) is responsible for providing services to persons with developmental disabilities. 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, including Florida, allows trained unlicensed personnel to perform these tasks to meet the demand. Currently, trained unlicensed personnel can provide or supervise eight routes of medication 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 registered 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 registered nurse or physician must revalidate these skills each year in the same manner.

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

- Increases the length of the initial training course on medication administration from 4 to 6 hours;
- Adds an annual requirement for successful completion of 2 hours of inservice training in medication administration and error prevention, which can count towards existing inservice training requirements;
- Eliminates the annual revalidation requirement for various routes of medication administration (otic, transdermal, or topical);
- Requires 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).
- Grandfathers certain unlicensed personnel already trained and validated to administer medication.
- Requires retraining for certain unlicensed personnel who lapse in their training requirements.

Additionally the bill allows a licensed practical nurse to train and validate unlicensed personnel and grants APD rulemaking authority to establish qualification requirements for trainers and to adopt rules for enforcing this section.

The bill has an insignificant, negative impact on APD.

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 in the state. 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.[1] APD's overarching goal 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.[2]

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.[3] Pursuant to s. 393.067, F.S., APD licenses and regulates 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.[4]

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).[5] While the majority of APD clients live in the community, a small number live in ICF/DDs. ICF/DDs are considered institutional placements and are licensed and certified by the Agency for Health Care Administration pursuant to part VIII of ch. 400, F.S.[6]

Medication Administration

Medication services are an important element of care for individuals with developmental disabilities in residential facilities. A direct service provider (DSP) has face-to-face contact with APD clients and provides a variety of services to clients in residential facilities, including medication assistance or administration.[7]

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[8] them

[1] S. 393.063(9), F.S.
[2] S. 393.062, F.S.
[3] A "residential facility" is a facility providing room and board and personal care for persons who have developmental disabilities, s. 393.063(28), F.S.
[4] AGENCY FOR PERSONS WITH DISABILITIES, *Planning Resources*, http://apd.myflorida.com/planning-resources/ (last visited Jan. 21, 2018).
[5] S. 393.0662, F.S.
[6] S. 393.063(25), F.S.
[7] 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.
[8] 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, Rules 65G-7.001(26) and 65G-7.005, F.A.C.

while they take the medication on their own to ensure they do so safely and appropriately.[9] 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.[10]

Medication administration is generally a nurse's responsibility; however, most states, including Florida, allow trained unlicensed personnel to perform these tasks.[11] Training to administer or supervise self-administration of medication can either be through direct training and delegation from a nurse or through classroom-based training and certification.[12] The latter training method generally involves an initial training course, continuing education, and verification of skills through simulations or directly on a client.[13] 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.[14]

APD serves more than 50,000 persons with developmental disabilities[15] and does not have enough licensed nurses to provide medication assistance and administration to all who need it.[16] 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 the unlicensed personnel have undergone the appropriate training.[17]

Training Requirements for Unlicensed Personnel, s. 393.506, F.S.		
	Initial Requirements	**Recurring Requirements**
Training Course[18]	Minimum of 4-hour course in medication administration.	None.
Competency Determination[19]	A registered 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 registered 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.
Informed Consent[20]	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 client's conditions or routes of administration change.

[9] *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).
[10] Id. *See also* Rule 65G-7.001(1), F.A.C.
[11] *Supra* note 9, at 22-23. Approximately 36 states allow trained unlicensed personnel to administer medication and 18 states allow unlicensed trained personnel to assist with medication.
[12] Id.
[13] Id. at 21.
[14] Id. at 24.
[15] AGENCY FOR PERSONS WITH DISABILITIES, *About Us*, http://apdcares.org/about/ (last visited Jan. 24, 2018).
[16] Agency for Persons with Disabilities, *Agency Analysis of 2018 House Bill 1373*, p. 3 (Jan. 10, 2018)(on file with Children, Families, and Seniors Subcommittee staff).
[17] S. 400.9685, F.S. relates to administration of medication by unlicensed personnel in ICF/DDs. Agency for Health Care Administration regulates these facilities and has its own requirements for trained unlicensed personnel and delegation of tasks, Rule 65G-7.002, F.A.C.
[18] S. 393.506(2), F.S.
[19] Ss. 393.506(2), 393.506(4), F.S.
[20] 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.[21] However, trained unlicensed personnel may use the following routes to administer medication to an APD client:[22]

Route of Administration	Definition
Enteral	Medication delivered by tube via the body's gastrointestinal system (*e.g.* nasal passage tubes, feeding tubes).[23]
Inhaled	Delivery of medication droplets or moisture suspended in a gas, such as oxygen, by inhalation through the nose or mouth (*e.g.* inhalers, nebulizers).[24]
Ophthalmic	A solution or ointment to be instilled into the eye or applied on or around the eyelid (*e.g.* eye drops).[25]
Oral	Any medication in tablet, capsule, or liquid form introduced into the gastrointestinal tract by mouth.[26]
Otic	Solutions or ointments to be placed in the outer ear canal or applied around the outer ear (*e.g.* ear drops, ear cream).[27]
Rectal	Any prescribed medication, capsule, enema or suppository to be administered via the rectum.[28]
Topical	A salve, lotion, ointment, cream, shampoo or solution applied locally to a body part.[29]
Transdermal	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).[30]

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.[31] 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.[32] Health professionals in Florida are required to take continuing education courses in prevention of medical errors in order to renew their licenses.[33] Many states also require their trained unlicensed personnel to take similar continuing education courses; however, Florida has no such statutory requirement for trained unlicensed personnel in APD-licensed facilities.[34]

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[21] Only licensed practitioners may administer medication that requires injection or administration on an as-needed basis in the practitioner's professional judgment and assessment of the client. *See generally* Rules 64B9-12, 64B9-14, and 65G-7.005 F.A.C.
[22] S. 393.506(1), F.S.
[23] Rule 65G-7.001(8), F.A.C.
[24] Rule 65G-7.001(10), F.A.C.
[25] Rule 65G-7.001(16), F.A.C.
[26] Rule 65G-7.001(17), F.A.C.
[27] Rule 65G-7.001(18), F.A.C.
[28] Rule 65G-7.001(24), F.A.C.
[29] Rule 65G-7.001(27), F.A.C.
[30] Rule 65G-7.001(28), F.A.C.
[31] 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 generally* 65G-7.006, F.A.C., medication errors can include but are not limited to administering the wrong medication, the wrong dose, via the wrong route, or to the wrong client; failing to administer or timely administer medication or timely fill or refill prescriptions; and administering expired or mislabeled medication.
[32] *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).
[33] S. 456.013(7), F.S.
[34] *Supra* note 9, at 24.

In APD facilities, providers must report medication errors within 24 hours.[35] Additionally, APD audits medication errors during its monthly and annual quality improvement reviews.[36] APD has reported an overall upward trend of medication errors in its facilities, with 98% occurring in licensed group homes.[37]

Medication Errors in APD Facilities[38]	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
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

CS/CS/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 6 hours. The bill grandfathers in unlicensed personnel who, on or before July 1, 2018, are already trained and validated for oral or enteral routes of medication administration.

Currently, initial competency assessments and revalidations require the unlicensed personnel to administer or supervise self-administration on an actual client. The bill revises the requirements for otic, transdermal, and topical routes of medication administration. For these three routes, the bill removes the revalidation requirement, and furthermore, requires the initial competency assessment to be conducted via simulation 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. Any unlicensed personnel that are grandfathered in under the bill but who have not been validated in these routes of medication administration must obtain validation prior to administering them. Since otic, transdermal, and topical routes of medication administration only require initial validation under the bill, this will eliminate the potential gap in validations.

The bill adds the requirement that trained unlicensed personnel successfully complete 2 hours of APD-approved inservice training in medication administration and error prevention each year. This may count towards any existing annual inservice training requirements but does not increase the total number of hours required by such annual inservice training.

The bill requires retraining for individuals who lapse in their annual revalidations for oral or enteral routes of medication administration or who do not complete the annual 2-hour inservice training. In those instances, the unlicensed personnel have to retake the initial 6-hour training course and obtain any validations necessary in their practice. This may help reduce medication errors by ensuring that training is up to date.

Currently, only a registered nurse or physician can train or validate unlicensed personnel in APD facilities. The bill allows a licensed practical nurse (LPN) to train and validate unlicensed personnel in addition to a registered nurse or physician. LPNs have a narrower scope of practice than registered

[35] Rule 64G-7.006(3), F.A.C.
[36] 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).
[37] Id.
[38] Id.

nurses do and they must practice under the direction of a registered nurse, physician, or dentist.[39] However, an LPN's scope of practice specifically includes the administration of treatments and medications.[40] This may give providers a cost-effective alternative to training and validations.

The bill grants APD rulemaking authority to address qualification requirements for trainers and to adopt rules to enforce this section.

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.

2. Expenditures:

   The bill will have an insignificant, negative 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.[41]

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.[42] The bill reduces the number of nurse or physician validations required and allows a licensed practical nurse to train and validate unlicensed personnel. To the extent that providers pay for fewer or less expensive validations, they will see a

[39] The practice of "practical nursing" means the performance of selected acts, including the administration of treatments and medications, in the care of the ill, injured, or infirm; the promotion of wellness, maintenance of health, and prevention of illness of others under the direction of a registered nurse, a licensed physician, a licensed osteopathic physician, a licensed podiatric physician, or a licensed dentist; and the teaching of general principles of health and wellness to the public and to students other than nursing students. In contrast, a registered nurse practices "professional nursing," which means the performance of those acts requiring substantial specialized knowledge, judgment, and nursing skill based upon applied principles of psychological, biological, physical, and social sciences. S. 464.003(16),(19),(20),(22), F.S.
[40] Id.
[41] *Supra* note 16, at 5.
[42] Id.

positive impact. The bill additionally increases the number of hours required for the initial training course and adds an annual 2-hour inservice training requirement for trained unlicensed personnel; however, this 2-hour inservice training can count towards existing inservice training requirements. To the extent that providers pay increased costs for initial training and continuing inservice training 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, resulting in some, nominal, cost avoidance to the Medicaid program.

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:

The bill provides APD sufficient rulemaking authority to address qualification requirements for individuals training unlicensed personnel and to adopt rules to enforce the provisions of this section.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 15, 2018, the Health and Human Services Committee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The strike-all amendment:

- Reduces the length of the initial training course from 8 hours to 6 hours.
- Requires annual revalidation for three additional routes of medication administration (ophthalmic, rectal, and inhaled).
- Grandfathers certain unlicensed personnel already trained and validated to administer medication.
- Allows the annual 2-hour inservice training course to count towards existing annual inservice training requirements.
- Requires retraining for certain unlicensed personnel who lapse in their training requirements.
- Allows a licensed practical nurse to train and validate unlicensed personnel.
- Provides APD rulemaking authority to establish qualification requirements for trainers and methods of enforcement.

The analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.