#### HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 539 Hospice Care

SPONSOR(S): Health & Human Services Committee, Health Innovation Subcommittee; Harrell

TIED BILLS: IDEN./SIM. BILLS: SB 474

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	13 Y, 0 N, As CS	Langston	Poche
2) Health & Human Services Committee	16 Y, 1 N, As CS	Langston	Calamas

### **SUMMARY ANALYSIS**

Hospice is a program of care and support for terminally ill patients. A specially trained team of professionals and caregivers provide care for the patient's physical, emotional, social, and spiritual needs, and provides support to family caregivers. In Florida, the Agency for Health Care (AHCA) and the Department of Elder Affairs (DOEA) regulate hospices. A hospice is defined as a corporation or limited liability company that provides a continuum of palliative and supportive care for a terminally ill patient and his or her family members. As of April 17, 2017, there are 45 licensed hospice providers in the state.

AHCA and DOEA developed outcome measures to determine the quality and effectiveness of hospice care and annually report on such information. Currently, state reporting requirements for hospice data do not include national outcome measures based on federal regulations. The bill removes existing outcome measures related to pain. Instead, AHCA and DOEA must adopt federal quality outcome measures for hospice care by December 31, 2019. It also requires AHCA and DOEA to develop a system for annual public reporting of the new outcome measures.

Current law prohibits a hospice from releasing patient records or any portion of patient records, unless a patient or legal guardian has given express written informed consent or a court of competent jurisdiction has ordered the release. The bill allows access to hospice records if the person requesting the information provides to the hospice a patient authorization, proof of judicial appointment, or court order granting access.

Current law requires hospices to have policies and procedures for disposal of Class II drugs upon the patient's death. Similarly, federal Medicare standards require hospices to dispose of controlled drugs in accordance with state and federal law. The bill allows hospices to assist in the disposal of prescribed controlled substances following the death of a patient in the home if the hospice has clearly defined policies, procedures, and systems for acceptable disposal methods.

The bill has no fiscal impact on state or local governments.

The bill provides an effective date of July 1, 2017.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0539c.HHS

#### **FULL ANALYSIS**

#### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

## **Background**

## **Hospice**

Hospice is a program of care and support for terminally ill patients, which helps them to live comfortably. A specially trained team of professionals and caregivers provide care for the terminally ill patient's physical, emotional, social, and spiritual needs, and provide support to family caregivers. The team that provides hospice services includes physicians, nurses, medical social workers, spiritual and pastoral counselors, home health aides, therapists, bereavement counselors, and specially trained volunteers. Hospice care includes the following items and services:

- · Nursing care;
- Physical or occupational therapy, or speech-language pathology services;
- Medical social services:
- Home health aide and homemaker services;
- Medical supplies, including prescription drugs and biologicals, and the use of medical appliances;
- Physician services;
- · Short-term inpatient care; and
- Counseling.<sup>4</sup>

Hospice care may be provided to a patient in an inpatient hospice facility, with licensed beds;<sup>5</sup> it may also be provided to the patient in the patient's home or in another facility, such as a hospital or a nursing home. Hospices provide four levels of care:

- **Routine care** provides the patient with hospice services at home or in a home-like setting. The patient's family provides primary care, with the assistance of the hospice team.
- Continuous care provides the patient with skilled nursing services in his or her home during a medical crisis.
- **Inpatient care** is provided in a healthcare facility for symptoms of a medical crisis that cannot be managed in the patient's home. Inpatient care is provided on a temporary basis as determined by the patient's physician and the hospice team.
- Respite care is provided in a healthcare facility and is primarily to provide the patient's family members and caretakers with a period of relief.<sup>6</sup>

To be eligible for hospice services under Medicaid or Medicare, <sup>7</sup> a patient must have a prognosis of living six months or less and no longer be seeking curative care. <sup>8</sup> However, Medicare coverage does

<sup>8</sup> 42 U.S.C. § 1395d, 1395x. **STORAGE NAME**: h0539c.HHS

<sup>&</sup>lt;sup>1</sup> Centers for Medicare and Medicaid Services, *Medicare Hospice Benefits*, available at <a href="https://www.medicare.gov/Pubs/pdf/02154.pdf">https://www.medicare.gov/Pubs/pdf/02154.pdf</a> (last visited April 17, 2017).

<sup>2</sup> Id.

<sup>&</sup>lt;sup>3</sup> Florida Hospice and Palliative Care Association, *About Hospice*, <a href="http://www.floridahospices.org/hospice-palliative-care/about-hospice/">http://www.floridahospices.org/hospice-palliative-care/about-hospice/</a>, (last visited April 17, 2107).

 <sup>&</sup>lt;sup>4</sup> 42 U.S.C. § 1395x(dd).
 <sup>5</sup> A hospice must obtain a Certificate of Need (CON) to increase the number of licensed beds in an inpatient facility, see the discussion of CON below.
 <sup>6</sup> Id.

Medicare is the federal health insurance program for people who are 65 or older, certain younger people with disabilities, and people with end-stage renal disease. Medicare Part A covers hospice care.

not end if a patient lives beyond six months after admission; the patient can continue to receive services as long as a physician continues to document the patient's eliqibility.9

## Hospice Care in Florida

# Regulation of Hospices

In Florida, the Agency for Health Care Administration (AHCA) and the Department of Elder Affairs (DOEA) regulate hospices pursuant to part IV of Chapter 400, F.S., part II of Chapter 408, F.S., and Chapter 58A-2, F.A.C. A hospice is defined as a corporation or limited liability company that provides a continuum of palliative<sup>10</sup> and supportive care for a terminally ill<sup>11</sup> patient and his or her family members. 12 Section 400.601(6), F.S., defines "hospice services" as the items and services furnished to a patient and his or her family by a hospice and specifies where those services may be provided. 13

Hospices are subject to the Certificate of Need (CON) program.<sup>14</sup> A CON is a written statement issued by AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service. The Florida CON program has three levels of review: full, expedited, and exempt. 15 Unless a hospital project is exempt from the CON program, it must undergo a full comparative review. 16 Projects required to undergo full comparative review include building a hospice and establishing a hospice program or hospice inpatient facility. <sup>17</sup> Section 408.036(3), F.S., provides exemptions to CON review for certain projects, which includes adding hospice services or swing beds<sup>18</sup> in a rural hospital, the total of which does not exceed one-half of its licensed beds.

As of April 17, 2017, there are 45 licensed hospice providers in Florida, with 1,038 licensed beds. 19

## Hospice Outcome Measures

Current law requires AHCA and DOEA to develop outcome measures to determine the quality and effectiveness of hospice care in a licensed hospice and annually report on such information.<sup>20</sup> At a minimum, the outcome measures require that half of patients who report severe pain on a 0-to-10 scale report a reduction to "5" or less by the end of the 4th day of care on the hospice program.<sup>21</sup>

AHCA and DOEA must consider and adopt national initiatives, such as those developed by the National Hospice and Palliative Care Organization, to set benchmarks for measuring the quality of hospice care. 22 The current outcome measures are:

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<sup>&</sup>lt;sup>10</sup> Palliative care means services or interventions which are not curative but are provided for the reduction or abatement of pain and human suffering. S. 400.601(7), F.S.

Rule 59C-1.0355, F.A.C.; s. 400.601(10), F.S. In Florida, a "terminally ill" patient, for hospice purposes, is as a patient with a medical prognosis that his or her life expectancy is 1 year or less if the illness runs its normal course.

Hospice services may be provided in a place of temporary or permanent residence used as the patient's home for the purpose of maintaining the patient at home; or, if the patient needs short-term institutionalization, the services shall be furnished in cooperation with those contracted institutions or in the hospice inpatient facility.

CON programs are designed to restrain health care costs and provide for directed, measured planning for new services and facilities National Conference of State Legislators, CON-Certificate of Need State Laws, available at http://www.ncsl.org/research/health/concertificate-of-need-state-laws.aspx (last visited April 17, 2017). <sup>15</sup> S. 408.036, F.S.

<sup>&</sup>lt;sup>16</sup> ld.

<sup>&</sup>lt;sup>17</sup> ld.

<sup>18</sup> S. 395.602(2)(g), F.S., defines "swing bed" as a bed which can be used interchangeably as a hospital, skilled nursing facility, or intermediate care facility bed pursuant to 42 C.F.R. parts 405, 435, 440, 442, and 447.

AGENCY FOR HEALTH CARE ADMINISTRATION, Facility/Provider Search Results - Hospice, http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (last visited April 14, 2017).

S. 400.60501, F.S.; rule 58A-2.005(4), F.A.C.

<sup>&</sup>lt;sup>21</sup> S. 400.60501(1), F.S.

<sup>&</sup>lt;sup>22</sup> S. 400.60501(2), F.S.

- 50 percent or more of patients who reported severe pain on a 0-to-10 scale reported a reduction to five or less by the end of the fourth day of care in the hospice program;
- 50 percent or more of patients reported they received the right amount of medicine for their pain; and
- 50 percent or more of patients or family members recommended hospice services to others based on the care the patient received.<sup>23</sup>

In the most recent annual report, 97.8 percent of hospices met the standard for the first outcome measure,<sup>24</sup> and all hospices met the second and third measures.<sup>25</sup>

In addition to state requirements, hospices are required to report certain information to the federal government through the Hospice Quality Reporting Program.<sup>26</sup>

As a condition of participation for Medicare and Medicaid certification, 42 C.F.R. 418.54(e), requires that, as a part of a comprehensive assessment of each patient, the hospice must collect data elements that allow for measurement of outcomes for each patient. This program includes data submitted by hospices through the Hospice Item Set and the Hospice Consumer Assessment of Healthcare Providers and Systems.<sup>27</sup> Hospices must document and measure the data elements in the same way for each patient and the data must take into consideration all aspects of care related to hospice and palliation.<sup>28</sup> The measures include:

- Percentage of patient stays treated with an opioid that was offered or prescribed a bowel regimen or documentation of why this was not needed;
- Percentage of patient stays during which the patient was screened for pain during the initial nursing assessment;
- Percentage of patient stays during which the patient screened positive for pain and received a comprehensive assessment of pain within one day of the screening;
- Percentage of patient stays during which the patient was screened for dyspnea during the initial nursing assessment:
- Percentage of patient stays during which the patient screened positive for dyspnea and received treatment within one day of the screening;
- Percentage of patient stays with chart documentation that the hospice discussed or attempted to discuss preferences for life sustaining treatments;
- Percentage of patient stays with documentation of a discussion of spiritual or religious concerns or documentation that the patient or caregiver did not want to discuss them;
- Percentage of patients receiving at least one visit from registered nurses, physicians, nurse practitioners, or physician assistants in the last three days of life;
- Percentage of patients receiving at least two visits from medical social workers, chaplains or spiritual counselors, licensed practical nurses or hospice aides in the last seven days of life; and
- Percentage of patient stays during which the patient received all care processes captured by quality measures, as applicable.

Hospices must also document the data in a systematic and retrievable way for each patient and must be used in individual patient care planning, in coordination of services, and must be used for each

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Department of Elder Affairs, 2015 Report: Hospice Demographic and Outcome Measures, (Feb. 8, 2016) available at http://elderaffairs.state.fl.us/doea/Evaluation/2015\_Hospice\_Report\_Final.pdf (last visited April 17, 2017).

Only Samaritan Care Hospice of Osceola, Inc., did not meet the 50% standard for this measure.

<sup>&</sup>lt;sup>25</sup> Supra, note 23.

<sup>&</sup>lt;sup>26</sup> Department of Elder Affairs, *Agency Analysis of 2017 House Bill 539* (Jan. 27, 2017) (on file with Health Innovation Subcommittee

CENTERS FOR MEDICARE & MEDICARE & MEDICARD SERVICES, Hospice Quality Reporting, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/ (last visited April 17, 2017). <sup>28</sup> 42 C.F.R. 418.54(e).

<sup>&</sup>lt;sup>29</sup> CENTERS FOR MEDICARE & MEDICAID SERVICES, Current Measures, <a href="https://www.cms.gov/Medicare/Quality-Initiatives-Patient-">https://www.cms.gov/Medicare/Quality-Initiatives-Patient-</a> Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.html (last visited April 17, 2017).

hospice's quality assessment and performance improvement program.<sup>30</sup> The U.S. Department of Health and Human Services is required to establish procedures for making data available to the public; however, no date has been specified to begin public reporting of quality data.<sup>31</sup>

Currently, state reporting requirements for hospice data do not include national outcome measures based on federal regulations.<sup>32</sup>

#### Access to Records

A hospice must maintain an up-to-date interdisciplinary record of care it furnishes to its patients and their families.<sup>33</sup> These records must contain pertinent past and current medical, nursing, social, and other therapeutic information, and such other information that is necessary for the safe and adequate care of the patient.<sup>34</sup> Additionally, hospice personnel must make notations regarding all aspects of care for the patient and his or her family in the record.<sup>35</sup> These records of care are confidential.<sup>36</sup>

Section 400.611(3), F.S., prohibits a hospice from releasing any patient records or portion of patient records, unless:

- A patient or legal guardian has given express written informed consent;
- A court of competent jurisdiction has so ordered; or
- A state or federal agency, acting under its statutory authority, requires submission of aggregate statistical data.

Absent written informed consent, anyone wishing to obtain a deceased patient's interdisciplinary hospice record must obtain a court order.

## Disposal of Prescribed Controlled Substances

While there is no statutory provision related to hospice care that addresses the disposal of prescribed controlled substances in a hospice patient's home, rule 58A-2.005(3)(a)7, F.A.C., requires hospices to have policies and procedures in place for disposal of Class II drugs upon the patient's death. Similarly, federal Medicare standards require hospices to dispose of controlled drugs in accordance with state and federal law.<sup>37</sup>

Federal law authorizes a person lawfully entitled to dispose of a decedent's property to collect controlled substances from the decedent for destruction, if that decedent was an ultimate user<sup>38</sup> who died while in lawful possession of a controlled substance.<sup>39</sup>

<sup>39</sup> 21 C.F.R. s. 1317.30. **STORAGE NAME**: h0539c.HHS

<sup>&</sup>lt;sup>30</sup> 42 C.F.R. s. 418.58 requires hospices to develop, implement, and maintain an effective, ongoing, quality assessment and performance improvement program. Pursuant to 42 C.F.R. s. 418.312, hospices must submit this data to CMS.

<sup>31</sup> Supra note 26. DOEA expects that this data will be available around July 2017.

Agency for Health Care Administration, *Agency Analysis of 2017 House Bill 539* (Jan. 27, 2017) (on file with Health Innovation Subcommittee staff).

<sup>&</sup>lt;sup>33</sup> S. 400.611(1), F.S.

<sup>&</sup>lt;sup>34</sup> ld.

<sup>&</sup>lt;sup>35</sup> ld.

<sup>&</sup>lt;sup>36</sup> S. 400.611(3), F.S.

<sup>&</sup>lt;sup>37</sup> 42 C.F.R. s. 418.106; see 21 CFR s. 1317, for the federal regulations controlling the disposal of controlled substances.

<sup>&</sup>lt;sup>38</sup> 21 U.S.C. s. 802(27) defines "ultimate user" as a person who has lawfully obtained, and who possesses, a controlled substance for his or her use or for the use of a member of his or her household.

## **Effect of Proposed Changes**

### Access to Records

CS/CS/HB 539 allows access to a patient's interdisciplinary hospice records if the person requesting the records provides to the hospice:

- A patient authorization executed by the patient prior to death;
- In the case of an incapacitated patient, a patient authorization executed prior to the patient's death by the patient's then acting legal guardian, health care surrogate, health care proxy or agent under power of attorney;
- A court order appointing the person as the administrator, curator, executor or personal representative of the patient's estate with authority to obtain the patient's medical records;
- If a judicial appointment has not been made, a last will that is self-proved and designates the person to act as the patient's personal representative; or
- An order by a court of competent jurisdiction to release the interdisciplinary record to the person.

The bill also requires a hospice to release requested aggregate patient statistical data to a state or federal agency acting under its statutory authority.

The bill defines "patient authorization" as an unrevoked written statement by the patient, or an oral statement made by the patient that has been reduced to writing in the patient's interdisciplinary record of care. Additionally, in the case of an incapacitated patient, an unrevoked written or oral statement reduced to writing to release the interdisciplinary record to a person requesting the record made by the patient's then acting legal guardian, health care surrogate, agent under a power of attorney, or health care proxy.

# **Hospice Outcome Measures**

The bill removes existing outcome measures relating to pain management and reporting of a patient's level of pain following their entrance to a hospice program. Instead, AHCA and DOEA must adopt federal quality outcome measures for hospice care and develop a system for annually reporting to the public hospice compliance with the new outcome measures. Additionally, AHCA will revise Rule 58A-2.005(4) F.A.C., which currently defines outcome measure reporting procedures for hospices, to reflect the bill provisions.<sup>40</sup> AHCA and DOEA must adopt these measures by December 31, 2019.

# <u>Disposal of Prescribed Controlled Substances</u>

The bill authorizes a hospice physician, nurse, or social worker to assist in the disposal of prescribed controlled substances following the death of a patient in the home, pursuant to federal regulations, if the hospice has clearly defined policies, procedures, and systems for acceptable disposal methods. Hospice staff and volunteers are prohibited from removing prescribed controlled substances; disposal must occur in the patient's home. The bill does not require a hospice program to dispose of prescribed controlled substances.

The bill provides an effective date of July 1, 2017.

<sup>40</sup> Id.

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# **B. SECTION DIRECTORY:**

- Section 1: Amends s. 400.60501, F.S., relating to outcome measures; adoption of national initiatives; public reporting; annual report.
- Section 2: Creates s. 400.6096, F.S., relating to disposal of prescribed controlled substances following the death of a patient in the home

	<b>Section 3:</b> Amends s. 400.611, F.S., relating to interdisciplinary records of care; confidentiality; release of records.
	Section 4: Provides an effective date of July 1, 2017.
	II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT
A.	FISCAL IMPACT ON STATE GOVERNMENT:
	1. Revenues: None.
	2. Expenditures: None.
В.	FISCAL IMPACT ON LOCAL GOVERNMENTS:
	1. Revenues: None.
	2. Expenditures: None.
C.	DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR: None.
D.	FISCAL COMMENTS: None.
	III. COMMENTS
A.	CONSTITUTIONAL ISSUES:
	Applicability of Municipality/County Mandates Provision:     Not applicable. The bill does not appear to affect county or municipal governments.
	2. Other: None.
В.	RULE-MAKING AUTHORITY: None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

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#### IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 20, 2017, the Health Innovation Subcommittee adopted a strike-all amendment that:

- Allowed hospices to provide community palliative care services, either directly or through a
  contracted provider, to "seriously ill" patients, who have a life-threatening medical condition that
  may be irreversible and continue indefinitely that may be managed through palliative care, or as
  necessary to manage the side effects of treatment for a progressive disease or medical or surgical
  condition for seriously ill patients;
- Required hospices to report on federally approved outcome measures;
- Permitted hospice staff to assist a deceased patient's family with the disposal of prescribed controlled substances pursuant to federal guidelines; and
- Permitted a person seeking access to a deceased patient's hospice records to obtain those records by providing either patient authorization, a court order, or a self-proved will.

The bill was reported favorably as a committee substitute.

On April 20, 2017, the Health and Human Services Committee adopted two amendments that:

- Removed the portion of the bill that would have allowed hospices to provide community palliative care services to seriously ill patients;
- Specified the section of federal law for adopting and reporting national hospice outcome measures;
   and
- Revised the definition of "patient authorization", for the purpose of access to interdisciplinary
  hospice records, to permit an incapacitated patient's legal guardian, agent, surrogate, or proxy to
  provide such authorization through an oral statement reduced to writing.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as reported by the Health and Human Services Committee.

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