HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCS for HB 937 Nonemergent Patient Care
SPONSOR(S): Professions & Public Health Subcommittee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Professions & Public Health Subcommittee		Morris	McElroy

SUMMARY ANALYSIS

In November 2020, as a response to the COVID-19 pandemic, the federal Centers for Medicare and Medicaid Services began issuing waivers to eligible hospitals authorizing the practice of acute hospital care at home. The Acute Hospital Care at Home program (Program) allows eligible hospitals to treat eligible patients in their homes for more than 60 acute conditions, such as asthma, congestive heart failure, pneumonia, and chronic obstructive pulmonary disease. The Program treats patients who require acute inpatient admission to a hospital and at least daily checks by a physician and a medical team monitoring the patient's care needs on an ongoing basis. Patient participation in the Program is voluntary.

Participating hospitals must have screening protocols which assess both medical and non-medical factors, including working utilities, assessment of physical barriers, and screenings for domestic violence concerns. Eligible patients are admitted only from emergency departments and inpatient hospital beds. An in-person evaluation is required prior to starting care at home. Registered nurses must evaluate each patient once per day, either in person or remotely, and two in-person visits must occur daily by either a registered nurse or a paramedic.

Paramedics are regulated by the Department of Health (DOH) and are certified to provide basic life support (BLS) and advanced life support services (ALS). Paramedics are not authorized under current law to provide non-emergent BLS and ALS in a home care setting.

PCS for HB 937 authorizes paramedics to provide BLS and ALS services to acute hospital care at home patients as specified by a physician. A physician who supervises or provides medical direction to a paramedic for acute hospital care at home is liable for any act or omission of the paramedic when performing ALS or BLS services in such setting.

An institutional pharmacy is a pharmacy located within a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility locations where medicinal drugs are compounded, dispensed, stored, or sold. Class III institutional pharmacies are institutional pharmacies affiliated with a hospital which employ a registered pharmacist who consults with and dispenses medicinal drugs to patients on the premises of the hospital, for use on hospital premises. Class III institutional pharmacies also dispense, distribute, compound, and fill prescriptions for medicinal drugs for inpatient treatment only. It is unclear whether such a pharmacy is authorized to dispense to a patient receiving care under an acute care at home program.

The bill authorizes Class III institutional pharmacies to dispense, distribute, compound, and fill prescriptions for medicinal drugs for inpatient treatment and for acute hospital care at home program patients.

The bill has a significant, negative fiscal impact on DOH and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2022.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Emergency Medical Services

The Department of Health (DOH) regulates paramedics under part III of ch. 401, F.S. A paramedic is a person who is certified by DOH to perform basic life support (BLS) and advanced life support (ALS) services.[1]

BLS service refers to any emergency medical service that uses only basic life support techniques.[2] BLS includes basic non-invasive interventions to reduce morbidity and mortality associated with out-of-hospital medical and traumatic emergencies.[3] The services provided may include stabilization and maintenance of airway and breathing, pharmacological interventions, trauma care, and transportation to an appropriate medical facility.[4]

ALS service refers to any emergency medical or non-transport service that uses advanced life support techniques.[5] ALS includes the assessment or treatment of a person by a qualified individual, such as a paramedic, who is trained in the use of techniques such as the administration of drugs or intravenous fluid, endotracheal intubation, telemetry, cardiac monitoring, and cardiac defibrillation.[6]

Paramedics are not authorized under current law to provide non-emergent BLS and ALS in a home care setting.

Acute Hospital Care at Home

Hospitals are licensed and regulated pursuant to ch. 395, F.S., by the Agency for Health Care Administration (AHCA) in this state.

In November, 2020, as a response to the COVID-19 pandemic, the federal Centers for Medicare and Medicaid Services (CMS) began issuing waivers to eligible hospitals authorizing the practice of acute hospital care at home.[7] The Acute Hospital Care at Home program (Program) allows eligible hospitals to treat eligible patients in their homes. A patient's home is his or her permanent residence, which includes assisted living, but does not include nursing homes.[8]

Treatment for more than 60 acute conditions, such as asthma, congestive heart failure, pneumonia, and chronic obstructive pulmonary disease, may be provided through the Program.[9] The Program treats patients who require acute inpatient admission to a hospital and at least daily rounding by a physician and a medical team monitoring the patient's care needs on an ongoing basis.[10] Patient participation in the program is voluntary.[11]

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[1] S. 401.23(17), F.S.
[2] S. 401.23(8), F.S.
[3] S. 401.23(7), F.S., and U.S. Department of Transportation, National Highway Safety Administration, *National EMS Scope of Practice Model* 23-24, *available at* www.nhtsa.gov/people/injury/ems/pub/emtbnsc.pdf (last visited Jan. 29, 2022).
[4] Id.
[5] S. 401.23(2), F.S.
[6] S. 401.23(1), F.S.
[7] Centers for Medicare and Medicaid Services, Press Release – CMS Announces Comprehensive Strategy to Enhance Hospital Capacity Amid COVID-19 Surge, https://www.cms.gov/newsroom/press-releases/cms-announces-comprehensive-strategy-enhance-hospital-capacity-amid-covid-19-surge (last visited Jan. 29, 2022).
[8] Centers for Medicare and Medicaid Services, *Acute Hospital Care at Home Frequently Asked Questions,* https://qualitynet.cms.gov/acute-hospital-care-at-home/resources#tab2 (last visited Jan. 29, 2022).
[9] *Supra*, note 7.
[10] Id.
[11] *Supra*, note 8.

Participating hospitals are required to have screening protocols which assess both medical and non-medical factors, including working utilities, assessment of physical barriers, and screenings for domestic violence concerns. Eligible patients are admitted only from emergency departments and inpatient hospital beds. An in-person evaluation is required prior to starting care at home. Registered nurses must evaluate each patient once per day, either in person or remotely, and two in-person visits must occur daily by either a registered nurse or a paramedic.[12] Programs must obtain a waiver from AHCA rule requiring only registered nurses to conduct evaluations in order for paramedics to conduct such in-person visits.[13]

As of January, 2022, 90 hospital systems and 197 hospitals across 37 states are approved to participate in the Program.[14] Participants in Florida include Mayo Clinic, Cleveland Clinic, Health First hospitals,[15] Keralty Hospital,[16] and Tampa General Hospital.[17]

Pharmacy Regulation

A person must obtain a DOH-issued permit to operate one of five types of pharmacies:

- **Community pharmacy** – Where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.[18]
- **Institutional pharmacy** – Hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility locations where medicinal drugs are compounded, dispensed, stored, or sold.[19]
- **Nuclear pharmacy** – Where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold, other than hospitals.[20]
- **Special pharmacy** - Locations where medicinal drugs are compounded, dispensed, stored, or sold if these locations do not otherwise meet an applicable pharmacy definition in s. 465.003, F.S.[21]
- **Internet pharmacy** – Locations not otherwise licensed or issued a pharmacy permit within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state to fill or refill prescriptions or to dispense, distribute, or otherwise practice pharmacy in this state.[22]

All permitted pharmacies must pass an on-site inspection before DOH will issue an initial permit and any time a pharmacy changes its ownership or address.[23]

Institutional Pharmacies

An institutional pharmacy is a pharmacy within a healthcare institution, such as a hospital, nursing home, or clinic (as opposed to a community pharmacy, which dispenses drugs to the general public on an outpatient basis).[24] There are four types of institutional pharmacies:[25]

- Class I Institutional permits are issued to institutional pharmacies in which all medicinal drugs are administered from individual prescription containers to individual patients and in which

[12] *Supra*, note 8
[13] Programs must obtain an AHCA waiver for Rule 59A-3.243(4)(c) and (6), F.A.C., relating to nursing services.
[14] Centers for Medicare and Medicaid Services, *Approved Facilities/Systems for Acute Hospital Care at Home,* https://qualitynet.cms.gov/acute-hospital-care-at-home/resources#tab1 (last visited Jan. 29, 2022).
[15] Palm Bay Hospital, Holmes Regional Medical Center, Viera Hospital, and Cape Canaveral Hospital.
[16] Formerly Westchester Hospital.
[17] Id.
[18] Ss. 465.003(11)(a)1. and 465.018, F.S.
[19] Ss. 465.003(11)(a)2. and 465.019, F.S.
[20] Ss. 465.003(11)(a)3. and 465.0193, F.S.
[21] Ss. 465.003(11)(a)4. and 465.0196, F.S.
[22] Ss. 465.003(11)(a)5. and 465.0197, F.S.
[23] Rule 64B16-28(1)(d), F.A.C.
[24] S. 465.003(11), F.S.
[25] S. 465.019, F.S.

medicinal drugs are not dispensed on the premises, except that licensed nursing homes[26] may purchase medical oxygen for administration to residents.

- Class II Institutional permits are issued to institutional pharmacies that employ a registered pharmacist who consults with and dispenses medicinal drugs to patients on the premises of the institution, for use on the premises of the institution.
- Modified Class II Institutional permits are issued to institutional pharmacies in a short-term, primary care treatment center that meet all the requirements for a Class II permit, except space and equipment requirements.
- Class III Institutional permits are issued to institutional pharmacies, including central distribution facilities, affiliated with a hospital that provide the same services that are authorized by a Class II institutional pharmacy permit. Additionally, an Class III Institutional pharmacy may:
    - Dispense, distribute, compound, and fill prescriptions for medicinal drugs;
    - Prepare prepackaged drug products;
    - Conduct other pharmaceutical services for the affiliated hospital and for entities under common control that are appropriately permitted;
    - Provide the above-listed services to an entity under common control which holds an active health care clinic establishment permit.[27]

Class III Institutional pharmacies must also maintain policies and procedures which address:[28]

- Safe practices for the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products;
- Recordkeeping to monitor the movement, distribution, and transportation of medicinal drugs and prepackaged drug products;
- Recordkeeping of pharmacy staff responsible for each step in the preparation, dispensing, prepackaging, transportation, and distribution of medicinal drugs and prepackaged drug products; and
- Medicinal drugs and prepackaged drug products that may not be safely distributed among Class III institutional pharmacies.

All institutional pharmacies must designate a consultant pharmacist of record.[29] The consultant pharmacist's responsibilities include:[30]

- Maintaining all drug records required by law;
- Ordering and evaluating laboratory or clinical testing when necessary for the proper performance of the consultant pharmacist's responsibilities;[31]
- Conducting drug regimen reviews as required by state or federal law; and
- Inspecting the facility and preparing a written report to be filed at the permitted facility monthly.

Dispensing by Institutional Pharmacies

An institutional pharmacy must hold a community pharmacy permit to dispense medicinal drugs to outpatients.[32] However, hospitals that operate Class II or Class III institutional pharmacies may dispense a limited supply of medicinal drugs to emergency department patients and inpatients upon discharge when the prescriber determines the medicinal drug is warranted and community pharmacy services are unavailable. An authorized prescriber may prescribe and a hospital pharmacy may

[26] Nursing homes are licensed under part II, ch. 400, F.S.
[27] A health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned or operated by a business entity. See s. 499.01(2)(r), F.S.
[28] S. 465.019(1)(d), F.S.
[29] S. 465.019(5), F.S., and r. 64B16-28.501, F.A.C.
[30] S. 465.0125, F.S., and r. 64B16-28.501, F.A.C.
[31] A consultant pharmacist may only order these tests for patients under the care of a licensed home health agency and when authorized by a licensed allopathic physician, osteopathic physician, podiatric physician, or dentist. The consultant pharmacist must complete additional training and meet additional qualifications in the practice of institutional pharmacy, as required by the board. See s. 465.0125.
[32] S. 465.019(4), F.S.

dispense the greater of a 48-hour supply of a medicinal drug or a supply sufficient to last until the end of the next business day.[33] An authorized prescriber may prescribe a medicinal drug beyond the initial prescription period if the prescriber determines the medicinal drug is warranted.[34] Additionally, a hospital pharmacy may dispense a supply of a medicinal drug that will last up to 72 hours if the patient is located in an area of the state in which a state of emergency is declared.[35] Such dispensing must be in accordance with the hospital's procedures.

It is unclear whether a Class III institutional pharmacy is authorized to dispense to a patient receiving care under an acute care at home program.

Effect of the Bill

Acute Hospital Care at Home

HB 937 authorizes paramedics to provide BLS and ALS to acute hospital care at home patients as specified in a paramedic's supervisory relationship with a physician or a physician's standing orders. A physician who supervises or provides medical direction to a paramedic for acute hospital care at home is liable for any act or omission of the paramedic when performing ALS or BLS services in such setting.

Acute hospital care at home is acute and post-acute health care services provided in a qualified patient's permanent residence through a program approved by CMS and AHCA.

Institutional Pharmacies

The bill authorizes Class III institutional pharmacies to dispense, distribute, compound, and fill prescriptions for medicinal drugs for inpatient treatment and acute care at home patients.

The bill makes technical and conforming changes.

The bill provides an effective date of July 1, 2022.

B. SECTION DIRECTORY:

Section 1: Amends s. 401.23, F.S., relating to definitions.
Section 2: Amends s. 401.272, F.S., relating to emergency medical services community health care.
Section 3: Amends s. 465.003, F.S., relating to definitions.
Section 4: Amends s. 465.019, F.S., relating to institutional pharmacies.
Section 5: Amends s. 14.33, F.S., relating to Medal of Heroism.
Section 6: Amends s. 252.515, F.S., relating to Post Disaster Relief Assistance Act; immunity from civil liability.
Section 7: Amends s. 395.1027, F.S., relating to regional poison control centers.
Section 8: Amends s. 401.245, F.S., relating to Emergency Medical Services Advisory Council.
Section 9: Provides an effective date of July 1, 2022.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

[33] Id.
[34] Id.
[35] Id.

None.

B. 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:

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 and current law provide sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES