

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Military and Veterans Affairs, Space, and Domestic Security

BILL: SB 1028

INTRODUCER: Senator Cruz

SUBJECT: End-stage Renal Disease Facility Emergency Planning

DATE: January 18, 2022

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Caldwell	MS	Pre-meeting
2.			HP	
3.			RC	

I. Summary:

SB1028 modifies provisions addressing emergency management planning issues for individuals with special health care needs and incorporates end stage renal disease (ESRD) facilities into emergency management planning, including the following statutory changes:

- Adds end stage renal (ESRD) facilities to the list of facilities and organizations which must annually provide information to its clients regarding the registration process for special needs shelter requests during emergency and disaster declarations.
- Creates requirements for local emergency management agencies to identify and include in emergency preparedness and contingency operations plans health care facilities, which includes ESRD facilities.
- Requires local emergency management plans to prioritize the restoration of electric and water utilities to health care facilities, including ESRD facilities, within its jurisdiction during a declared state of emergency.
- Creates an emergency and contingency operations planning component for ESRD facilities with requirements for a written operations plan, patient communications, back-up site within 50 mile radius, continuity of care plans, and contingency plans.
- Provides rulemaking authority to the Agency for Health Care Administration (AHCA), in consultation with the Division of Emergency Management (DEM).

The bill is effective July 1, 2022 and has an indeterminate fiscal impact on both state and local government. Many of the activities are already required under federal law; however, SB 1028 may require additional workload as the implementation timelines are not identical.

II. Present Situation:

Chronic Kidney Disease

Chronic kidney disease (CKD) affects approximately 15 percent of American adults or 37 million people and is the progressive loss of renal function which leads to the potential total loss of kidney function.¹ Early interventions can slow the progression of CKD as can controlling blood pressure and blood glucose levels, reducing albuminuria,² eating a healthy diet, and maintaining a healthy lifestyle.³ Signs and symptoms of CKD include:

- Nausea;
- Vomiting;
- Loss of appetite;
- Fatigue and weakness;
- Changes in urination;
- Chest pain;
- Shortness of breath, if fluid builds up in the lungs;
- Swelling of feet and ankles;
- High blood pressure;
- Headaches;
- Difficulty sleeping;
- Decreased mental sharpness;
- Mental twitches and cramps;
- Persistent itching; and
- Metallic taste.⁴

End-Stage Renal Disease (ESRD)

End-Stage Renal Disease (ESRD) occurs when CKD reaches an advanced state and an individual's kidneys no longer function to keep an individual alive.⁵ Any person with ESRD has kidneys which function below 10 percent of their normal ability.⁶ Currently, more than 786,000 people in the United States live with end-stage renal disease.⁷

¹ Centers for Medicare and Medicaid Services, *Chronic Kidney Disease Disparities: Educational Guide for Primary Care* (April 2021), p.5, available at <https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf> (last visited January 7, 2022).

² Albuminuria is measurement of the amount of protein in the urine. If a person's kidneys are healthy, there should be very little to no protein in the person's urine. See National Kidney Foundation, *Albuminuria*, www.kidney.org (last visited January 7, 2022).

³ Centers for Medicare and Medicaid Services, *Chronic Kidney Disease Disparities: Educational Guide for Primary Care* (April 2021), p.7, available at <https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf> (last visited January 7, 2022).

⁴ Mayo Clinic, End stage renal disease, <https://www.mayoclinic.org/diseases-conditions/end-stage-renal-disease/symptoms-causes/syc-20354532> (last visited on January 7, 2022).

⁵ Mayo Clinic, *End stage renal disease*, <https://www.mayoclinic.org/diseases-conditions/end-stage-renal-disease/symptoms-causes/syc-20354532> (last visited on January 7, 2022).

⁶ Christine DiMaria, *What you need to know about End Stage Kidney Disease (ESRD)*(July 3, 2019) available at <https://www.healthline.com/health/end-stage-kidney-disease> (last visited on January 7, 2022).

⁷ United States Renal Data System, *2020 Annual Data Report*, <https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease> (last visited January 7, 2022).

As a progressive disease, each stage of the disease varies by the patient and from the time of diagnosis until the end stage, the duration of that initial diagnosis time to the end stage last anywhere from 10 to 20 years.⁸ Treatment options for those with ESRD may include different types of dialysis or kidney transplant surgery based on the patient's circumstances. Of those with ESRD, current data shows that 71 percent are on dialysis and 21 percent have had a kidney transplant.⁹

During different types of dialysis, a machine does the work of an individual's kidneys to filter harmful wastes, salts, and fluids.¹⁰ Depending on the procedure, this process can be conducted at home or a facility, including specialized ESRD facilities. Dialysis can be a time consuming multi-hour, several days a week commitment of which many patients can complete at home.¹¹

A kidney transplant is a surgical procedure which requires the removal, if required, of the individual's affected, non-functioning kidneys and the placement of donated, functioning kidney. An individual can function normally with one kidney.¹² For 2021, 1,385 kidney transplants were reported for Florida.¹³

End Stage Renal Disease Facilities

End stage renal disease dialysis facilities are not licensed by the State of Florida; however, federal law and regulations establish minimum guidelines for the reimbursement of dialysis and transplant services for qualified Medicaid and Medicare recipients with ESRD and those guidelines determine whether a facility is in compliance for federal reimbursement.¹⁴ A dialysis facility is defined by federal regulation as an entity that provides either outpatient maintenance services, or home dialysis training and support services, or both. The facility can be independent or associated with a hospital that includes a self-care unit that furnishes only self-dialysis services.¹⁵

To qualify for federal reimbursement, facilities and providers must operate and furnish services in compliance with applicable federal, state, and local laws and regulations relating to licensure

⁸ Christine DiMaria, What you need to know about End Stage Kidney Disease (ESRD)(July 3, 2019) available at <https://www.healthline.com/health/end-stage-kidney-disease> (last visited on January 7, 2022).

⁹ United States Renal Data System, 2020 Annual Data Report, <https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease> (last visited January 7, 2022).

¹⁰ Johns Hopkins Medicine, *End Stage Renal Disease (ESRD)*, <https://www.hopkinsmedicine.org/health/conditions-and-diseases/end-stage-renal-disease-esrd> (last visited January 7, 2022).

¹¹ Johns Hopkins Medicine, *End Stage Renal Disease (ESRD)*, <https://www.hopkinsmedicine.org/health/conditions-and-diseases/end-stage-renal-disease-esrd> (last visited January 7, 2022).

¹² Christine DiMaria, What you need to know about End Stage Kidney Disease (ESRD)(July 3, 2019) available at <https://www.healthline.com/health/end-stage-kidney-disease> (last visited on January 7, 2022).

¹³ U.S. Department of Health and Human Services, *Organ Procurement and Transplantation Network (report run on January 7, 2022)*, available at <https://optn.transplant.hrsa.gov/data/view-data-reports/state-data/> (last visited on January 7, 2022).

¹⁴ See Section 299I of the Social Security Act Amendments of 1972, Pub. L. 92-603 (original extension of Medicare coverage to insured individuals, their spouses, and dependent children with ESRD who require dialysis or transplantation; effective July 1, 1973); 42 CFR part 494, Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services, available at <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-494#toc=1> (last visited January 7, 2022).

¹⁵ 42 CFR §494.10, *Definitions, Conditions for Coverage of End-Stage Renal Disease Facilities* available at <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-494#page-top> (last visited January 7, 2022).

and other relevant health and safety requirements.¹⁶ Additionally, the regulations include specific patient safety requirements, infection control standards,¹⁷ water quality standards,¹⁸ standards for reuse of bloodlines and hemodialyzers,¹⁹ fire and building safety standards,²⁰ and emergency preparedness requirements.²¹

Each facility must have an emergency preparedness plan that complies with all federal, state, and local requirements and which must be updated every two years. The regulations provide specific elements which must be included in the plan including assessment of facility and community based hazards, strategies for cooperation and collaboration, and plans for patient continuity of care.²² The dialysis facility is also required to develop and implement emergency preparedness policies and procedures which address staffing, evacuations, back-up sites, and use of emergency equipment.²³ In addition to these components, the federal regulations address the development of patient care plans, the delivery of patient care at home, special purpose ESRD facilities, qualifications of personnel, and overall facility governance issues.²⁴

State of Florida Emergency Preparedness

The State Emergency Management Act (Act)²⁵ establishes the framework for how Florida prepares, responds, and recovers from emergencies and disasters. It confers upon the Governor, the Division of Emergency Management (DEM),²⁶ and the governing body of each county and municipality certain emergency powers in the event of emergencies²⁷ and disasters²⁸ resulting

¹⁶ 42 CFR §494.20 *Condition: Compliance with Federal, State, and local laws and regulations. Coverage of End-Stage Renal Disease Facilities* available at <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-494#page-top> (last visited January 7, 2022).

¹⁷ 42 CFR §494.30 *Condition: Infection control*, available at <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-494#page-top> (last visited January 7, 2022).

¹⁸ 42 CFR §494.40 *Condition: Water and dialysate quality*, available at <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-494#page-top> (last visited January 7, 2022).

¹⁹ 42 CFR §494.50 *Condition: Reuse of hemodialyzers and bloodlines*, available at <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-494#page-top> (last visited January 7, 2022).

²⁰ 42 CFR §494.60 *Condition: Physical environment*, available at <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-494#page-top> (last visited January 7, 2022).

²¹ 42 CFR §494.62 *Condition of participation: Emergency preparedness*, available at <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-494#page-top> (last visited January 7, 2022).

²² 42 CFR §494.62(a)1-4; *Emergency plan; Condition of participation: Emergency preparedness*, available at <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-494#page-top> (last visited January 7, 2022).

²³ 42 CFR §494.62(b)1-9

²⁴ 42 CFR part 494 *Conditions for Coverage of End-Stage Renal Disease Facilities*, available at <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-494#page-top>

²⁵ See ch. 252, F.S.

²⁶ The Division of Emergency Management is established within the Executive Office of the Governor as a separate budget entity. It is responsible for all professional, technical, and administrative support functions necessary to carry out its responsibilities under part I of ch. 252, F.S. The director of the division is appointed by and serves at the pleasure of the Governor, and is the head of the division.

²⁷ “Emergency” means any occurrence, or threat thereof, whether natural, technological, or manmade, in war or in peace, which results or may result in substantial harm to the population or substantial damage to or loss of property. See s. 252.34(4), F.S.

²⁸ “Disaster” means any natural, technological, or civil emergency that causes damage of sufficient severity and magnitude to result in a declaration of a state of emergency by a county, the Governor, or the President of the United States. See s. 252.34(2), F.S.

from natural,²⁹ technological,³⁰ or manmade causes³¹ to ensure preparations of the state will be adequate to deal with, reduce vulnerability to, and recover from such emergencies and disasters; to prepare for the common defense and to protect the public peace, health, and safety; and to preserve the lives and property of the state.

The Governor, the DEM, and the counties and municipalities have specific emergency powers and authority granted to them in the event of an emergency. The individual powers are broad, but also include specific parameters in which they may be executed. State law requires the development and maintenance of a state comprehensive emergency management plan under DEM's direction. The plan incorporates several components, including ensuring the adequacy of security and medical personnel, availability and accessibility of public shelter space, and accommodation of individuals with special needs through special needs shelters within social distancing standards.³² To ensure that adequate space has been identified should an emergency arise and to allow for pre-authorization for entry by emergency personnel, the DEM, along with several state agencies who provide health and human services, are required to conduct an annual registration process and maintain a registry for special needs clients and their caregivers.³³ Current state law requires all appropriate agencies and community-based caregivers to assist DEM with the registration of their special needs clients annually, including:

- Aging and disability resource centers;
- Memory disorder clinics;
- Home health care providers;
- Hospices;
- Nurse registries;
- Home medical providers;
- Department of Children and Families;
- Department of Health;
- Agency for Health Care Administration;
- Department of Education;
- Agency for Persons with Disabilities; and
- Department of Elderly Affairs.³⁴

Physicians licensed under chapter 458 or 459 are not required to assist with the registration process, but may elect to participate.³⁵

²⁹ "Natural emergency" means an emergency caused by a natural event, including, but not limited to, a hurricane, storm, a flood, severe wave action, a drought, or an earthquake. *See s. 252.34(8), F.S.*

³⁰ "Technological emergency" means an emergency caused by a technological failure or accident, including but not limited to, an explosion, transportation accident, radiological accident, or chemical or other hazardous material incident. *See s. 252.34(12), F.S.*

³¹ "Manmade emergency" means an emergency caused by an action against persons or society, including but not limited to, an enemy attack, sabotage, terrorism, civil unrest, or other action impairing the orderly administration of government. *See s. 252.34(7), F.S.*

³² Section 252.35, F.S.

³³ Section 252.355, F.S.

³⁴ Section 252.355, (2)(b), F.S.

³⁵ Section 252.355, (2)(b), F.S.

The state's special needs registry is administered by the Department of Health (DOH) and individuals register online.³⁶ Information is kept private and exempt from public release under Florida's Sunshine Laws.³⁷ Visitors to the website are put on notice that registration for the special needs registry does not automatically qualify someone for a special needs shelter and are directed to also visit their county's disaster preparedness websites.³⁸ The local county websites are listed on the DEM website and each county site has social media links, shelter information, links to the special needs shelter registry, and an emergency notification system.

The Agency for Health Care Administration (AHCA) is the agency designated as the state's chief health policy and planning entity and the department responsible for the licensure, inspection, and regulation of over 48,500 health care facilities in the state. During a state of emergency, the AHCA collaborates with other emergency coordination officers in the relevant state agencies, including tracking the relocation of patients or residents, and establishing and maintaining communications between various health care entities.³⁹ The AHCA has developed an emergency response website resource page for providers and facilities online.⁴⁰

III. Effect of Proposed Changes:

SB 1028 modifies several statutes to address emergency management planning issues for individuals with special health care needs and incorporates end stage renal disease (ESRD) facilities into emergency management planning, including the making the following modifications:

Section 1 amends paragraph (b) of subsection (2) of section 252.355, F.S., relating to emergency management planning to add ESRD facilities to the list of health care provider and social services entities that must provide information annually to their clients about the registry for special needs shelters and assist with the registration of those individuals with special needs. This modification would add ESRD facilities to this mandatory list of organizations and facilities that serve individuals who have unique health care needs, disabilities, impairments, and other health conditions who may need help with an evacuation, rescue, or shelter during an emergency or disaster.

Section 2 creates s. 252.3571, F.S., which requires every local county emergency management plan to identify the health care facilities, which would include ESRD facilities, in its jurisdiction for which water and electric utilities must prioritize the emergency return of such services during a declared state of emergency or disaster. Current state law provides general guidelines for

³⁶ Florida Department of Health, *Special Needs Registry*, <https://snr.flhealthresponse.com/> (last visited January 10, 2022).

³⁷ Normally, under Florida's open government laws, information collected by the state would be open for public inspection and review. Information provided by a person or a business to the DEM for purposes of emergency planning was granted an exemption from s. 119.01(1), F.S. and Art. I of the State Constitution in s. 252.905, F.S.

³⁸ Florida Department of Health, *Special Needs Registry*, <https://snr.flhealthresponse.com/> (last visited January 10, 2022).

³⁹ Agency for Health Care Administration, *Emergency Operations Plan*, available at: https://ahca.myflorida.com/MCHQ/Plans/pdfs/Emergency_Mobilization_Plan.pdf (last visited January 10, 2022).

⁴⁰ Agency for Health Care Administration, *Emergency Preparedness Resources*, https://ahca.myflorida.com/mchq/emergency_activities/index.shtml (last visited January 7, 2022).

performance management of the power generation capability of shelters⁴¹ and supplies of portable generators owned by the state and local government.⁴²

Section 3 creates s. 381.0305, F.S., which establishes the emergency preparedness and contingency operations guidelines for end stage renal disease (ESRD) facilities.

For this new section, definitions are provided for the following terms:

- “Agency” means the Agency for Health Care Administration;
- “Disaster” means the same as in s. 252.34, F.S.;
- “Emergency” means an incident likely to threaten the health, welfare, or safety of ESRD facility patients or staff or the public, including a fire, equipment failure, power outage, flood, interruption in utility service medical emergency, or natural or other disaster.
- “End stage renal disease facility” or “facility” means a facility certified by the Centers for Medicare and Medicaid Services which provides dialysis services under the supervision of a licensed physician.
- “Local emergency management agency” has the same meaning as in s. 252.34, F.S.

Emergency Preparedness and Contingency Operations Plans

In addition to federal regulatory requirements under 42 C.F.R. s. 494.62, each ESRD facility will be required to adopt a written emergency preparedness and contingency operations plan which addresses how to care for a patient during an emergency or disaster. The plan must be:

- Updated annually and have each update approved by the facility’s management.
- Include notification procedures for notice as soon as practicable regarding closure or reduction in hours due to an emergency or disaster for the following:
 - Each hospital with which the facility has a transfer agreement;
 - The local or regional trauma agency that serves the geographic area in which the ESRD facility is located; and
 - Each applicable local management agency.
- Unless the facility meets the exception, each ESRD facility must execute a contract with another ESRD facility within a 50-mile radius which stipulates that the other ESRD will provide dialysis treatment to facility patients who are unable to receive scheduled dialysis treatment due to facility’s closure or reduction in hours.
- Establish procedures and documented patient communication plan for when a patient’s dialysis treatment plan is interrupted.

The bill also requires that a copy of an ESRD facility’s emergency preparedness and contingency operations plan be provided upon request to:

- Each hospital with which the ESRD facility has a transfer agreement.
- The local or regional trauma agency that serves the geographic area where the facility is located.

⁴¹ Section 252.35(2)(a)2, F.S.

⁴² Section 252.35(2)(s) and (t), F.S.

Continuity of Care Requirements

SB 1028 requires continuity of care plans which have been approved by the facility's management and are a part of the facility's emergency management preparedness plans, be developed and provided to patients. The bill requires these continuity of care plans be provided to patients within 30 days before admission to the facility and should include the following:

1. Information on the procedures for distributing written materials to facility patients which specifically describe the facility's emergency preparedness and contingency operations plans.
2. Detailed procedures, based on the facility's patient population, regarding the facility's contingency plan, including transportation options, for patients to access each ESRD facility with which the facility has an agreement or has made advance preparations to receive dialysis treatment.

To receive an exception to contracting with another ESRD facility within a 50-mile radius, an ESRD facility must show that all of the following apply:

1. An ESRD facility is not located within a 50 mile radius of the facility.
2. The ESRD facility has received written approval from the AHCA granting the exemption.

Training and Coordination

The bill requires each ESRD facility to contact a representative from the local and state emergency management agencies, local emergency operations center, and local or regional trauma agency to receive feedback on its emergency preparedness plan, including whether modifications should be made, and to ensure all affected agencies and hospitals are aware of the anticipated number of patients, and the expected level of need its facility will generate during an emergency or disaster.

Each ESRD facility shall also be required to adopt an emergency contingency plan for the continuity of essential building systems during an emergency or disaster. As part of the continuity plan, each ESRD must contract with another facility within a 50-mile radius to provide emergency contingency services or seek an exception as described earlier in this section.

Rulemaking Authority

The bill directs AHCA, in consultation with DEM, to adopt rules to implement this section. At a minimum, the rules must require the medical director of emergency medical services provider licensed under ch. 401, F.S., approve protocols which give preference to the emergency transfer of a dialysis patient from the patient's location directly to an outpatient ESRD facility during a state of emergency declared by the Governor pursuant to ch. 252, F.S., or a disaster declared by the President pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42. U.S.C. ss 5121 et seq.

Section 4 establishes the effective date of the Act as July 1, 2022.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

End stage renal disease facilities which are privately owned would be impacted by the changes included in SB 1028 as any new provisions would be applicable to their emergency preparedness and contingency operations activities. As most ESRD facilities are subject to the licensing and regulation of the federal Centers for Medicare and Medicaid Services, many of the general requirements in SB 1028 can be found in federal regulation, 42 C.F.R. 494.62. However, SB 1028 does apply more specific timeframes on some provisions where the federal regulation does not provide a time frame or establishes a geographic limitation which would be more limiting or restrictive where the federal regulation provides no geographic goal (requirement for a backup facility within a designated radius). In other cases, the federal frequency level is below the amount included in SB 1028, such as the frequency of certain trainings or review of materials.

C. Government Sector Impact:

The AHCA and DEM will have increased regulatory review of emergency management and contingency operations plans for ESRD facilities in the same manner which they do for other health care and human service organizations who submit plans or participate in the special needs shelter registry process.

Neither AHCA nor DEM has submitted an agency review of SB 1028, so it is unclear if either agency would experience any fiscal impact.

The local emergency management agencies may also experience additional workload by the addition of the ESRD to the list of organizations on the special needs registry; however, given the special needs of these individuals, it is highly likely that many of these individuals were already registering or seeking special needs shelter assistance during an emergency or disaster. SB 1028 may add clarity to the registry process for both persons with needs and to the agencies and local emergency management agencies which must collaborate and coordinate the services during an emergency or disaster.

VI. Technical Deficiencies:

The bill requires each ESRD facility to provide a copy of its continuity of care plan to each patient within 30 days before admission to its facility (lines 56 through 159). However, if the patient is admitted on an emergency or urgent basis, the continuity plan cannot be provided 30 days or any days prior to admission. In those instances, the bill does not address how the facility can meet this standard or what the consequences may be for a facility which fails to meet this standard.

Secondly, the bill directs the AHCA, in consultation with the DEM to conduct rulemaking and provides specific direction relating to the emergency transfer of dialysis patients during a state of emergency or disaster as declared by the Governor or President of the United States. (lines 205-214). The directive to prioritize the transfer of dialysis patients does not appear to have a clear directive as it does not specify if the preference or priority for transport is only among other transfer patients being served by emergency medical services or for all emergency medical services transportation. The provision may be interpreted to direct emergency medical services providers to prioritize dialysis transfer patients over all other emergency transportation patients, including those which may require immediate transportation to an emergency medical facility for any condition or situation, rather than to prioritize dialysis patients among only those who were being transported via emergency medical services for *transfer purposes* from one facility to another during an emergency or disaster situation.

VII. Related Issues:

In several provisions, SB 1028 refers to the “local or regional trauma agency” which serves a general area; however, this term is not defined in this section. “Trauma agency” is defined under s. 395.4001(12), F.S., to mean a department-approved agency established by one or more counties, or a department-approved entity with which one more counties contract, for the purposes of administering an inclusive regional trauma system.⁴³

VIII. Statutes Affected:

This bill substantially amends section 252.355 of the Florida Statutes.

This bill creates the following sections of the Florida Statutes: 252.3571 and 381.0305.

⁴³ The department references in the definition is the Department of Health.

IX. Additional Information:

- A. **Committee Substitute – Statement of Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

- B. **Amendments:**

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
