

No. 25-1097

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**IN THE UNITED STATES COURT OF APPEALS  
FOR THE EIGHTH CIRCUIT**

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STATE OF KANSAS, et al.

Plaintiffs-Appellants,

v.

ROBERT F. KENNEDY, JR., et al.

Defendants-Appellees.

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On Appeal from the United States District Court  
for the Northern District of Iowa

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**ADDENDUM**

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## 42 U.S.C. § 1395i-3

### § 1395i-3. Requirements for, and assuring quality of care in, skilled nursing facilities

#### (a) “Skilled nursing facility” defined

In this subchapter, the term “skilled nursing facility” means an institution (or a distinct part of an institution) which--

- (1) is primarily engaged in providing to residents--
  - (A) skilled nursing care and related services for residents who require medical or nursing care, or
  - (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons,

and is not primarily for the care and treatment of mental diseases;

- (2) has in effect a transfer agreement (meeting the requirements of section 1395x(l) of this title) with one or more hospitals having agreements in effect under section 1395cc of this title; and

- (3) meets the requirements for a skilled nursing facility described in subsections (b), (c), and (d) of this section.

#### (b) Requirements relating to provision of services

\* \* \*

- (4) Provision of services and activities

- (A) In general

To the extent needed to fulfill all plans of care described in paragraph (2), a skilled nursing facility must provide, directly or under arrangements (or, with respect to dental services, under agreements) with others for the provision of--

- (i) nursing services and specialized rehabilitative services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident;
    - (ii) medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident;
    - (iii) pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident;

(iv) dietary services that assure that the meals meet the daily nutritional and special dietary needs of each resident;

(v) an on-going program, directed by a qualified professional, of activities designed to meet the interests and the physical, mental, and psychosocial well-being of each resident;

(vi) routine and emergency dental services to meet the needs of each resident; and

(vii) treatment and services required by mentally ill and mentally retarded residents not otherwise provided or arranged for (or required to be provided or arranged for) by the State.

The services provided or arranged by the facility must meet professional standards of quality. Nothing in clause (vi) shall be construed as requiring a facility to provide or arrange for dental services described in that clause without additional charge.

(B) Qualified persons providing services

Services described in clauses (i), (ii), (iii), (iv), and (vi) of subparagraph (A) must be provided by qualified persons in accordance with each resident's written plan of care.

(C) Required nursing care

(i) In general

Except as provided in clause (ii), a skilled nursing facility must provide 24-hour licensed nursing service which is sufficient to meet nursing needs of its residents and must use the services of a registered professional nurse at least 8 consecutive hours a day, 7 days a week.

(ii) Exception

To the extent that clause (i) may be deemed to require that a skilled nursing facility engage the services of a registered professional nurse for more than 40 hours a week, the Secretary is authorized to waive such requirement if the Secretary finds that--

(I) the facility is located in a rural area and the supply of skilled nursing facility services in such area is not sufficient to meet the needs of individuals residing therein,

(II) the facility has one full-time registered professional nurse who is regularly on duty at such facility 40 hours a week,

(III) the facility either has only patients whose physicians have indicated (through physicians' orders or admission notes) that each such patient does not require the services of a registered nurse or a physician for a 48-hour period, or has made arrangements for a registered professional nurse or a physician to spend such time at such facility as may be indicated as necessary by the physician to provide necessary skilled nursing services on days when the regular full-time registered professional nurse is not on duty,

(IV) the Secretary provides notice of the waiver to the State long-term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965) and the protection and advocacy system in the State for the mentally ill and the mentally retarded, and

(V) the facility that is granted such a waiver notifies residents of the facility (or, where appropriate, the guardians or legal representatives of such residents) and members of their immediate families of the waiver.

A waiver under this subparagraph shall be subject to annual renewal.

\* \* \*

**(d) Requirements relating to administration and other matters**

\* \* \*

(4) Miscellaneous

(A) Compliance with Federal, State, and local laws and professional standards

A skilled nursing facility must operate and provide services in compliance with all applicable Federal, State, and local laws and regulations (including the requirements of section 1320a-3 of this title) and with accepted professional standards and principles which apply to professionals providing services in such a facility.

(B) Other

A skilled nursing facility must meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary.

\* \* \*

**(f) Responsibilities of Secretary relating to skilled nursing facility requirements**

(1) General responsibility

It is the duty and responsibility of the Secretary to assure that requirements which govern the provision of care in skilled nursing facilities under this subchapter, and the enforcement of such requirements, are adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys.

\* \* \*

## 42 U.S.C. § 1396r

### § 1396r. Requirements for nursing facilities

#### (a) “Nursing facility” defined

In this subchapter, the term “nursing facility” means an institution (or a distinct part of an institution) which--

- (1) is primarily engaged in providing to residents--
  - (A) skilled nursing care and related services for residents who require medical or nursing care,
  - (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons, or
  - (C) on a regular basis, health-related care and services to individuals who because of their mental or physical condition require care and services (above the level of room and board) which can be made available to them only through institutional facilities,

and is not primarily for the care and treatment of mental diseases;

- (2) has in effect a transfer agreement (meeting the requirements of section 1395x(l) of this title) with one or more hospitals having agreements in effect under section 1395cc of this title; and

- (3) meets the requirements for a nursing facility described in subsections (b), (c), and (d) of this section.

Such term also includes any facility which is located in a State on an Indian reservation and is certified by the Secretary as meeting the requirements of paragraph (1) and subsections (b), (c), and (d).

#### (b) Requirements relating to provision of services

\* \* \*

- (4) Provision of services and activities

- (A) In general

To the extent needed to fulfill all plans of care described in paragraph (2), a nursing facility must provide (or arrange for the provision of)--

- (i) nursing and related services and specialized rehabilitative services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident;

- (ii) medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident;
- (iii) pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident;
- (iv) dietary services that assure that the meals meet the daily nutritional and special dietary needs of each resident;
- (v) an on-going program, directed by a qualified professional, of activities designed to meet the interests and the physical, mental, and psychosocial well-being of each resident;
- (vi) routine dental services (to the extent covered under the State plan) and emergency dental services to meet the needs of each resident; and
- (vii) treatment and services required by mentally ill and mentally retarded residents not otherwise provided or arranged for (or required to be provided or arranged for) by the State.

The services provided or arranged by the facility must meet professional standards of quality.

(B) Qualified persons providing services

Services described in clauses (i), (ii), (iii), (iv), and (vi) of subparagraph (A) must be provided by qualified persons in accordance with each resident's written plan of care.

(C) Required nursing care; facility waivers

(i) General requirements

With respect to nursing facility services provided on or after October 1, 1990, a nursing facility--

(I) except as provided in clause (ii), must provide 24-hour licensed nursing services which are sufficient to meet the nursing needs of its residents, and

(II) except as provided in clause (ii), must use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week.

(ii) Waiver by State

To the extent that a facility is unable to meet the requirements of clause (i), a State may waive such requirements with respect to the facility if--



(I) the facility demonstrates to the satisfaction of the State that the facility has been unable, despite diligent efforts (including offering wages at the community prevailing rate for nursing facilities), to recruit appropriate personnel,

(II) the State determines that a waiver of the requirement will not endanger the health or safety of individuals staying in the facility,

(III) the State finds that, for any such periods in which licensed nursing services are not available, a registered professional nurse or a physician is obligated to respond immediately to telephone calls from the facility,

(IV) the State agency granting a waiver of such requirements provides notice of the waiver to the State long-term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965) and the protection and advocacy system in the State for the mentally ill and the mentally retarded, and

(V) the nursing facility that is granted such a waiver by a State notifies residents of the facility (or, where appropriate, the guardians or legal representatives of such residents) and members of their immediate families of the waiver.

A waiver under this clause shall be subject to annual review and to the review of the Secretary and subject to clause (iii) shall be accepted by the Secretary for purposes of this subchapter to the same extent as is the State's certification of the facility. In granting or renewing a waiver, a State may require the facility to use other qualified, licensed personnel.

(iii) Assumption of waiver authority by Secretary

If the Secretary determines that a State has shown a clear pattern and practice of allowing waivers in the absence of diligent efforts by facilities to meet the staffing requirements, the Secretary shall assume and exercise the authority of the State to grant waivers.

\* \* \*

#### **(d) Requirements relating to administration and other matters**

##### **(4) Miscellaneous**

(A) Compliance with Federal, State, and local laws and professional standards

A nursing facility must operate and provide services in compliance with all applicable Federal, State, and local laws and regulations (including the

requirements of section 1320a-3 of this title) and with accepted professional standards and principles which apply to professionals providing services in such a facility.

(B) Other

A nursing facility must meet such other requirements relating to the health and safety of residents or relating to the physical facilities thereof as the Secretary may find necessary.

\* \* \*

**(f) Responsibilities of Secretary relating to nursing facility requirements**

(1) General responsibility

It is the duty and responsibility of the Secretary to assure that requirements which govern the provision of care in nursing facilities under State plans approved under this subchapter, and the enforcement of such requirements, are adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys.

\* \* \*

## 45 C.F.R. § 483.60

### § 483.60. Food and nutrition services.

The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets his or her daily nutritional and special dietary needs, taking into consideration the preferences of each resident.

(a) Staffing. The facility must employ sufficient staff with the appropriate competencies and skills sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at § 483.71. This includes:

(1) A qualified dietitian or other clinically qualified nutrition professional either full-time, part-time, or on a consultant basis. A qualified dietitian or other clinically qualified nutrition professional is one who—

(i) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose.

(ii) Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional.

(iii) Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a state that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a "registered dietitian" by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (a)(1)(i) and (ii) of this section.

(iv) For dietitians hired or contracted with prior to November 28, 2016, meets these requirements no later than 5 years after November 28, 2016 or as required by state law.

\* \* \*

**45 C.F.R. § 483.70**

**§ 483.70. Administration.**

A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

\* \* \*

(e) Staff qualifications.

- (1) The facility must employ on a full-time, part-time or consultant basis those professionals necessary to carry out the provisions of these requirements.
- (2) Professional staff must be licensed, certified, or registered in accordance with applicable State laws.

\* \* \*

(o) Social worker. Any facility with more than 120 beds must employ a qualified social worker on a full-time basis. A qualified social worker is:

- (1) An individual with a minimum of a bachelor's degree in social work or a bachelor's degree in a human services field including, but not limited to, sociology, gerontology, special education, rehabilitation counseling, and psychology; and
- (2) One year of supervised social work experience in a health care setting working directly with individuals.

\* \* \*

**45 C.F.R. § 483.70 (2023)**

**§ 483.70. Administration.**

\* \* \*

(e) Facility assessment. The facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include:

- (1) The facility's resident population, including, but not limited to,
  - (i) Both the number of residents and the facility's resident capacity;
  - (ii) The care required by the resident population considering the types of diseases, conditions, physical and cognitive disabilities, overall acuity, and other pertinent facts that are present within that population;
  - (iii) The staff competencies that are necessary to provide the level and types of care needed for the resident population;
  - (iv) The physical environment, equipment, services, and other physical plant considerations that are necessary to care for this population; and
  - (v) Any ethnic, cultural, or religious factors that may potentially affect the care provided by the facility, including, but not limited to, activities and food and nutrition services.
- (2) The facility's resources, including but not limited to,
  - (i) All buildings and/or other physical structures and vehicles;
  - (ii) Equipment (medical and non-medical);
  - (iii) Services provided, such as physical therapy, pharmacy, and specific rehabilitation therapies;
  - (iv) All personnel, including managers, staff (both employees and those who provide services under contract), and volunteers, as well as their education and/or training and any competencies related to resident care;
  - (v) Contracts, memorandums of understanding, or other agreements with third parties to provide services or equipment to the facility during both normal operations and emergencies; and

(vi) Health information technology resources, such as systems for electronically managing patient records and electronically sharing information with other organizations.

(3) A facility-based and community-based risk assessment, utilizing an all-hazards approach.

\* \* \*

**45 C.F.R. § 483.80**

**§ 483.80. Infection control.**

The facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections.

\* \* \*

(b) Infection preventionist. The facility must designate one or more individual(s) as the infection preventionist(s) (IPs) who are responsible for the facility's IPCP. The IP must:

- (1) Have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field;
- (2) Be qualified by education, training, experience or certification;
- (3) Work at least part-time at the facility; and
- (4) Have completed specialized training in infection prevention and control.

\* \* \*

(d) Influenza, pneumococcal, and COVID-19 immunizations—

(1) Influenza. The facility must develop policies and procedures to ensure that—

- (i) Before offering the influenza immunization, each resident or the resident's representative receives education regarding the benefits and potential side effects of the immunization;
- (ii) Each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has already been immunized during this time period;
- (iii) The resident or the resident's representative has the opportunity to refuse immunization; and
- (iv) The resident's medical record includes documentation that indicates, at a minimum, the following:
  - (A) That the resident or resident's representative was provided education regarding the benefits and potential side effects of influenza immunization; and

(B) That the resident either received the influenza immunization or did not receive the influenza immunization due to medical contraindications or refusal.

(2) Pneumococcal disease. The facility must develop policies and procedures to ensure that—

(i) Before offering the pneumococcal immunization, each resident or the resident's representative receives education regarding the benefits and potential side effects of the immunization;

(ii) Each resident is offered a pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized;

(iii) The resident or the resident's representative has the opportunity to refuse immunization; and

(iv) The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident's representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and

(B) That the resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindication or refusal.

(3) COVID-19 immunizations. The LTC facility must develop and implement policies and procedures to ensure all the following:

(i) When COVID-19 vaccine is available to the facility, each resident and staff member is offered the COVID-19 vaccine unless the immunization is medically contraindicated or the resident or staff member has already been immunized;

(ii) Before offering COVID-19 vaccine, all staff members are provided with education regarding the benefits and risks and potential side effects associated with the vaccine;

(iii) Before offering COVID-19 vaccine, each resident or the resident representative receives education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine;

(iv) In situations where COVID-19 vaccination requires multiple doses, the resident, resident representative, or staff member is provided with



current information regarding those additional doses, including any changes in the benefits or risks and potential side effects associated with the COVID–19 vaccine, before requesting consent for administration of any additional doses;

(v) The resident or resident representative, has the opportunity to accept or refuse a COVID–19 vaccine, and change their decision; and

(vi) The resident’s medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident representative was provided education regarding the benefits and potential risks associated with COVID–19 vaccine; and

(B) Each dose of COVID–19 vaccine administered to the resident; or

(C) If the resident did not receive the COVID–19 vaccine due to medical contraindications or refusal; and

(vii) The facility maintains documentation related to staff COVID–19 vaccination that includes at a minimum, the following:

(A) That staff were provided education regarding the benefits and potential risks associated with COVID–19 vaccine;

(B) Staff were offered the COVID–19 vaccine or information on obtaining COVID–19 vaccine; and

(C) The COVID–19 vaccine status of staff and related information as indicated by the Centers for Disease Control and Prevention’s National Healthcare Safety Network (NHSN).

\* \* \*