No. 21A240

In the Supreme Court of the United States

JOSEPH R. BIDEN, JR., PRESIDENT OF THE UNITED STATES, ET AL.,
Applicants,

v.

STATE OF MISSOURI, ET AL.,
Respondents.

RESPONDENTS' APPENDIX

ERIC S. SCHMITT
Attorney General of Missouri

D. JOHN SAUER
Solicitor General
Counsel of Record

JESUS A. OSETE
Deputy Attorney General

Maddie McMillian Green
Assistant Attorney General

Office of the Attorney General
Supreme Court Building
207 W. High St.
P.O. Box 899
Jefferson City, Missouri 65102
Tel.: (573) 751-1800
Fax: (573) 751-0774
John.Sauer@ago.mo.gov
Jesus.Osete@ago.mo.gov

Counsel for Respondents

DOUGLAS J. PETERSON
Attorney General of Nebraska

JAMES A. CAMPBELL
Solicitor General

Office of the Attorney General
2115 State Capitol
Lincoln, Nebraska 68509
Tel.: (402) 471-2682

Index

Sections of the Social Security Act Cited in the CMS Mandate

General Rulemaking Statutes

RULES AND REGULATIONS

SEC. 1102. [42 U.S.C. 1302]

(a) The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services, respectively, shall make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which each is charged under this Act.

(b)(1) Whenever the Secretary publishes a general notice of proposed rulemaking for any rule or regulation proposed under title XVIII, title XIX, or part B of this title that may have a significant impact on the operations of a substantial number of small rural hospitals, the Secretary shall prepare and make available for public comment an initial regulatory impact analysis. Such analysis shall describe the impact of the proposed rule or regulation on such hospitals and shall set forth, with respect to small rural hospitals, the matters required under section 603 of title 5, United States Code, to be set forth with respect to small entities. The initial regulatory impact analysis (or a summary) shall be published in the Federal Register at the time of the publication of general notice of proposed rulemaking for the rule or regulation.

(2) Whenever the Secretary promulgates a final version of a rule or regulation with respect to which an initial regulatory impact analysis is required by paragraph (1), the Secretary shall prepare a final regulatory impact analysis with respect to the final version of such rule or regulation. Such analysis shall set forth, with respect to small rural hospitals, the matters required under section 604 of title 5, United States Code, to be set forth with respect to small entities. The Secretary shall make copies of the final regulatory impact analysis available to the public and shall publish, in the Federal Register at the time of publication of the final version of the rule or regulation, a statement describing how a member of the public may obtain a copy of such analysis.

(3) If a regulatory flexibility analysis is required by chapter 6 of title 5, United States Code[7], for a rule or regulation to which this subsection applies, such analysis shall specifically address the impact of the rule or regulation on small rural hospitals.

REGULATIONS

SEC. 1871. [42 U.S.C. 1395hh]

(a)(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title. When used in this title, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.

(B) Such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances. If the Secretary intends to vary such timeline with respect to the publication of a final regulation, the Secretary shall cause to have published in the Federal Register notice of the different timeline by not later than the timeline previously established with respect to such regulation. Such notice shall include a brief explanation of the justification for such variation.

(C) In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes (at the end of the regular timeline and, if applicable, at the end of each succeeding 1-year period) a notice of continuation of the regulation that includes an explanation of why the regular timeline (and any subsequent 1-year extension) was not complied with. If such a notice is published, the regular timeline (or such timeline as previously extended under this paragraph) for publication of the final regulation shall be treated as having been extended for 1 additional year.

(D) The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final regulation within the applicable regular timeline under this paragraph and that provides an explanation for such failures.

(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

* * * * *

Ambulatory Surgical Centers (ASCs)

SCOPE OF BENEFITS

SEC. 1832. [42 U.S.C. 1395k]

(a) The benefits provided to an individual by the insurance program established by this part shall consist of—

(1) entitlement to have payment made to him or on his behalf (subject to the provisions of this part) for medical and other health services, except those described in subparagraphs (B) and (D) of paragraph (2) and subparagraphs (E) and (F) of section 1842(b)(6); and

(2) entitlement to have payment made on his behalf (subject to the provisions of this part) for—

(A) home health services (other than items described in subparagraph (G) or subparagraph (I));

(B) medical and other health services (other than items described in subparagraph (G) or subparagraph (I)) furnished by a provider of services or by others under arrangement with them made by a provider of services, excluding—

(i) physician services except where furnished by—

(I) a resident or intern of a hospital, or

(II) a physician to a patient in a hospital which has a teaching program approved as specified in paragraph (6) of section 1861(b) (including services in conjunction with the teaching programs of such hospital whether or not such patient is an inpatient of such hospital) where the conditions specified in paragraph (7) of such section are met,

(ii) services for which payment may be made pursuant to section 1835(b)(2),

(iii) services described by section 1861(s)(2)(K)(i), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist;

(iv) services of a nurse practitioner or clinical nurse specialist but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services; and

(C) outpatient physical therapy services (other than services to which the second sentence of section 1861(p) applies), outpatient occupational therapy services (other than services to which such sentence applies through the operation of section 1861(g), and outpatient speech-language pathology services (other than services to which the second sentence of section 1861(p) applies through the application of section 1861(ll)(2));

(D)(i) rural health clinic services and (ii) Federally qualified health center services;

(E) comprehensive outpatient rehabilitation facility services;

(F) facility services furnished in connection with surgical procedures specified by the Secretary—

(i) pursuant to section 1833(i)(1)(A) and performed in an ambulatory surgical center (which meets health, safety, and other standards specified by the Secretary in regulations) if the center has an agreement in effect with the Secretary by which the center agrees to accept the standard overhead amount determined under section 1833(i)(2)(A) as full payment for such services (including intraocular lens in cases described in section 1833(i)(2)(A)(iii)) and to accept an assignment described in section 1842(b)(3)(B)(ii) with respect to payment for all such services (including intraocular lens in cases described in section 1833(i)(2)(A)(iii)) furnished by the center to individuals enrolled under this part, or

(ii) pursuant to section 1833(i)(1)(B) and performed by a physician, described in paragraph (1), (2), or (3) of section 1861(r), in his office, if the Secretary has determined that—

(I) a quality improvement organization (having a contract with the Secretary under part B of title XI of this Act) is willing, able, and has agreed to carry out a review (on a sample or other reasonable basis) of the physician's performing such procedures in the physician's office,

(II) the particular physician involved has agreed to make available to such organization such records as the Secretary determines to be necessary to carry out the review, and

(III) the physician is authorized to perform the procedure in a hospital located in the area in which the office is located,

and if the physician agrees to accept the standard overhead amount determined under section 1833(i)(2)(B) as full payment for such services and to accept payment on an assignment-related basis with respect to payment for all services (including all pre-and post-operative services) described in paragraphs (1) and (2)(A) of section 1861(s) and furnished in connection with such surgical procedure to individuals enrolled under this part;

(G) covered items (described in section 1834(a)(13)) furnished by a provider of services or by others under arrangements with them made by a provider of services;

(H) outpatient critical access hospital services (as defined in section 1861(mm)(3));

(I) prosthetic devices and orthotics and prosthetics (described in section 1834(h)(4)) furnished by a provider of services or by others under arrangements with them made by a provider of services; and

(J) partial hospitalization services provided by a community mental health center (as described in section 1861(ff)(2)(B)).

(b) For definitions of "spell of illness", "medical and other health services", and other terms used in this part, see section 1861.

PAYMENT OF BENEFITS

SEC. 1833. **[**42 U.S.C. 1395l**]**

(a) Except as provided in section 1876, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—

* * * * *

(i)(1) The Secretary shall, in consultation with appropriate medical organizations—

(A) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in an ambulatory surgical center (meeting the standards specified under section 1832(a)(2)(F)(i)), critical access hospital, or hospital outpatient department, and

(B) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in a physician's office.

The lists of procedures established under subparagraphs (A) and (B) shall be reviewed and updated not less often than every 2 years.

* * * * *

Hospices

DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. **[**42 U.S.C. 1395x**]**

For purposes of this title—

* * * * *

Hospice Care; Hospice Program

(dd)(1) The term "hospice care" means the following items and services provided to a terminally ill individual by, or by others under arrangements made by, a hospice program under a written plan (for providing such care to such individual) established and periodically reviewed by the individual's attending physician and by the medical director (and by the interdisciplinary group described in paragraph (2)(B)) of the program—

(A) nursing care provided by or under the supervision of a registered professional nurse,

(B) physical or occupational therapy, or speech-language pathology services,

(C) medical social services under the direction of a physician,

(D)(i) services of a home health aide who has successfully completed a training program approved by the Secretary and

(ii) homemaker services,

(E) medical supplies (including drugs and biologicals) and the use of medical appliances, while under such a plan,

(F) physicians' services,

(G) short-term inpatient care (including both respite care and procedures necessary for pain control and acute and chronic symptom management) in an inpatient facility meeting such conditions as the Secretary determines to be appropriate to provide such care, but such respite care may be provided only on an intermittent, nonroutine, and occasional basis and may not be provided consecutively over longer than five days,

(H) counseling (including dietary counseling) with respect to care of the terminally ill individual and adjustment to his death, and

(I) any other item or service which is specified in the plan and for which payment may otherwise be made under this title.

The care and services described in subparagraphs (A) and (D) may be provided on a 24-hour, continuous basis only during periods of crisis (meeting criteria established by the Secretary) and only as necessary to maintain the terminally ill individual at home.

(2) The term "hospice program" means a public agency or private organization (or a subdivision thereof) which—

(A)(i) is primarily engaged in providing the care and services described in paragraph (1) and makes such services available (as needed) on a 24-hour basis and which also provides bereavement counseling for the immediate family of terminally ill individuals and services described in section 1812(a)(5),

(ii) provides for such care and services in individuals' homes, on an outpatient basis, and on a short-term inpatient basis, directly or under arrangements made by the agency or organization, except that—

(I) the agency or organization must routinely provide directly substantially all of each of the services described in subparagraphs (A), (C), and (H) of paragraph (1), except as otherwise provided in paragraph (5), and

(II) in the case of other services described in paragraph (1) which are not provided directly by the agency or organization, the agency or organization must maintain professional management responsibility for all such services furnished to an individual, regardless of the location or facility in which such services are furnished; and

(iii) provides assurances satisfactory to the Secretary that the aggregate number of days of inpatient care described in paragraph (1)(G)

provided in any 12-month period to individuals who have an election in effect under section 1812(d) with respect to that agency or organization does not exceed 20 percent of the aggregate number of days during that period on which such elections for such individuals are in effect;

(B) has an interdisciplinary group of personnel which—

(i) includes at least—

(I) one physician (as defined in subsection (r)(1)),

(II) one registered professional nurse, and

(III) one social worker,

employed by or, in the case of a physician described in subclause (I), under contract with the agency or organization, and also includes at least one pastoral or other counselor,

(ii) provides (or supervises the provision of) the care and services described in paragraph (1), and

(iii) establishes the policies governing the provision of such care and services;

(C) maintains central clinical records on all patients;

(D) does not discontinue the hospice care it provides with respect to a patient because of the inability of the patient to pay for such care;

(E)(i) utilizes volunteers in its provision of care and services in accordance with standards set by the Secretary, which standards shall ensure a continuing level of effort to utilize such volunteers, and

(ii) maintains records on the use of these volunteers and the cost savings and expansion of care and services achieved through the use of these volunteers;

(F) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, is licensed pursuant to such law; and

(G) <u>meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization.</u>

* * * * *

<u>Psychiatric Residential Treatment Facilities</u>

DEFINITIONS

SEC. 1905. **[**42 U.S.C. 1396d**]**

For purposes of this title—

(a) The term "medical assistance" means payment of part or all of the cost of the following care and services or the care and services themselves, or both * * * *

* * * * *

(h)(1) For purposes of paragraph (16) of subsection (a), the term "inpatient psychiatric hospital services for individuals under age 21" includes only—

(A) inpatient services which are provided in an institution (or distinct part thereof) which is a psychiatric hospital as defined in section 1861(f) or in another inpatient setting that the Secretary has specified in regulations;

(B) inpatient services which, in the case of any individual (i) involve active treatment which meets such standards as may be prescribed in regulations by the Secretary, and (ii) a team, consisting of physicians and other personnel qualified to make determinations with respect to mental health conditions and the treatment thereof, has determined are necessary on an inpatient basis and can reasonably be expected to improve the condition, by reason of which such services are necessary, to the extent that eventually such services will no longer be necessary; and

(C) inpatient services which, in the case of any individual, are provided prior to (i) the date such individual attains age 21, or (ii) in the case of an individual who was receiving such services in the period immediately preceding the date on which he attained age 21, (I) the date such individual no longer requires such services, or (II) if earlier, the date such individual attains age 22;

(2) Such term does not include services provided during any calendar quarter under the State plan of any State if the total amount of the funds expended, during such quarter, by the State (and the political subdivisions thereof) from non-Federal funds for inpatient services included under paragraph (1), and for active psychiatric care and treatment provided on an outpatient basis for eligible mentally ill children, is less than the average quarterly amount of the funds expended, during the 4-quarter period ending December 31, 1971, by the State (and the political subdivisions thereof) from non-Federal funds for such services.

* * * * *

Programs of All-Inclusive Care for the Elderly (PACE)

PAYMENTS TO, AND COVERAGE OF BENEFITS UNDER, PROGRAMS OF ALL–INCLUSIVE CARE FOR THE ELDERLY (PACE)

SEC. 1894. **[**42 U.S.C. 1395eee**]**

* * * * *

(f) REGULATIONS.—

(1) IN GENERAL.—The Secretary shall issue interim final or final regulations to carry out this section and section 1934.

(2) USE OF PACE PROTOCOL.—

(A) IN GENERAL.—In issuing such regulations, the Secretary shall, to the extent consistent with the provisions of this section, incorporate the requirements applied to PACE demonstration waiver programs under the PACE protocol.

(B) FLEXIBILITY.—In order to provide for reasonable flexibility in adapting the PACE service delivery model to the needs of particular organizations (such as those in rural areas or those that may determine it appropriate to use nonstaff physicians according to State licensing law requirements) under this section and section 1934, the Secretary (in close consultation with State administering agencies) may modify or waive provisions of the PACE protocol so long as any such modification or waiver is not inconsistent with and would not impair the essential elements, objectives, and requirements of this section, but may not modify or waive any of the following provisions:

(i) The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.

(ii) The delivery of comprehensive, integrated acute and long-term care services.

(iii) The interdisciplinary team approach to care management and service delivery.

(iv) Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals.

(v) The assumption by the provider of full financial risk.

(C) CONTINUATION OF MODIFICATIONS OR WAIVERS OF OPERATIONAL REQUIREMENTS UNDER DEMONSTRATION STATUS.—If a PACE program operating under demonstration authority has contractual or other operating arrangements which are not otherwise recognized in regulation and which were in effect on July 1, 2000, the Secretary (in close consultation with, and with the concurrence of, the State administering agency) shall permit any such program to continue such arrangements so long as such arrangements are found by the Secretary and the State to be reasonably consistent with the objectives of the PACE program.

(3) APPLICATION OF CERTAIN ADDITIONAL BENEFICIARY AND PROGRAM PROTECTIONS.—

(A) IN GENERAL.—In issuing such regulations and subject to subparagraph (B), the Secretary may apply with respect to PACE programs, providers, and agreements such requirements of part D (or, for periods before January 1, 1999, section 1876) and sections 1903(m) and 1932 relating to protection of beneficiaries and program integrity as would apply to Medicare+Choice organizations under part D (or for such periods eligible organizations under risk-sharing contracts under section 1876) and to medicaid managed care organizations under prepaid capitation agreements under section 1903(m).

(B) CONSIDERATIONS.—In issuing such regulations, the Secretary shall—

(i) take into account the differences between populations served and benefits provided under this section and under part D (or, for periods before January 1, 1999, section 1876) and section 1903(m);

(ii) not include any requirement that conflicts with carrying out PACE programs under this section; and

(iii) not include any requirement restricting the proportion of enrollees who are eligible for benefits under this title or title XIX.

(4) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing the Secretary from including in regulations provisions to ensure the health and safety of individuals enrolled in a PACE program under this section that are in addition to those otherwise provided under paragraphs (2) and (3).

* * * * *

PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

SEC. 1934. [42 U.S.C. 1396u–4]

* * * * *

(f) REGULATIONS.—

(1) IN GENERAL.—The Secretary shall issue interim final or final regulations to carry out this section and section 1894.

(2) USE OF PACE PROTOCOL.—

(A) IN GENERAL.—In issuing such regulations, the Secretary shall, to the extent consistent with the provisions of this section, incorporate the requirements applied to PACE demonstration waiver programs under the PACE protocol.

(B) FLEXIBILITY.—In order to provide for reasonable flexibility in adapting the PACE service delivery model to the needs of particular organizations (such as those in rural areas or those that may determine it appropriate to use nonstaff physicians according to State licensing law requirements) under this section and section 1894, the Secretary (in close consultation with State administering agencies) may modify or waive provisions of the PACE protocol so long as any such modification or waiver is not inconsistent with and would not impair the essential elements, objectives, and requirements of this section, but may not modify or waive any of the following provisions:

(i) The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.

(ii) The delivery of comprehensive, integrated acute and long–term care services.

(iii) The interdisciplinary team approach to care management and service delivery.

(iv) Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals.

(v) The assumption by the provider of full financial risk.

(C) CONTINUATION OF MODIFICATIONS OR WAIVERS OF OPERATIONAL REQUIREMENTS UNDER DEMONSTRATION STATUS.—If a PACE program operating under demonstration authority has contractual or other operating arrangements which are not otherwise recognized in regulation and which were in effect on July 1, 2000, the Secretary (in close consultation with, and with the concurrence of, the State administering agency) shall permit any such program to continue such arrangements so long as such arrangements are found by the Secretary and the State to be reasonably consistent with the objectives of the PACE program.

(3) APPLICATION OF CERTAIN ADDITIONAL BENEFICIARY AND PROGRAM PROTECTIONS.—

(A) IN GENERAL.—In issuing such regulations and subject to subparagraph (B), the Secretary may apply with respect to PACE programs, providers, and agreements such requirements of part C of title XVIII (or, for periods before January 1, 1999, section 1876) and sections 1903(m) and 1932 relating to protection of beneficiaries and program integrity as would apply to Medicare+Choice organizations under such part C (or for such periods eligible organizations under risk–sharing contracts under section 1876) and to medicaid managed care organizations under prepaid capitation agreements under section 1903(m).

(B) CONSIDERATIONS.—In issuing such regulations, the Secretary shall—

(i) take into account the differences between populations served and benefits provided under this section and under part C of title XVIII (or, for periods before January 1, 1999, section 1876) and section 1903(m);

(ii) not include any requirement that conflicts with carrying out PACE programs under this section; and

(iii) not include any requirement restricting the proportion of enrollees who are eligible for benefits under this title or title XVIII.

(4) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing the Secretary from including in regulations provisions to ensure the health and safety of individuals enrolled in a PACE program under this section that are in addition to those otherwise provided under paragraphs (2) and (3).

* * * * *

Hospitals

DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. [42 U.S.C. 1395x]

For purposes of this title—

* * * * *

Hospital

(e) The term "hospital" (except for purposes of sections 1814(d), 1814(f), and 1835(b), subsection (a)(2) of this section, paragraph (7) of this subsection, and subsection (i) of this section) means an institution which—

(1) is primarily engaged in providing, by or under the supervision of physicians, to inpatients (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons;

(2) maintains clinical records on all patients;

(3) has bylaws in effect with respect to its staff of physicians;

(4) has a requirement that every patient with respect to whom payment may be made under this title must be under the care of a physician except that a patient receiving qualified psychologist services (as defined in subsection (ii)) may be under the care of a clinical psychologist with respect to such services to the extent permitted under State law;

(5) provides 24-hour nursing service rendered or supervised by a registered professional nurse, and has a licensed practical nurse or registered professional nurse on duty at all times; except that until January 1, 1979, the Secretary is authorized to waive the requirement of this paragraph for any one-year period with respect to any institution, insofar as such requirement relates to the provision of twenty-four-hour nursing service rendered or supervised by a registered professional nurse (except that in any event a registered professional nurse must be present on the premises to render or supervise the nursing service provided, during at least the regular daytime shift), where immediately preceding such one-year period he finds that—

(A) such institution is located in a rural area and the supply of hospital services in such area is not sufficient to meet the needs of individuals residing therein,

(B) the failure of such institution to qualify as a hospital would seriously reduce the availability of such services to such individuals, and

(C) such institution has made and continues to make a good faith effort to comply with this paragraph, but such compliance is impeded by the lack of qualified nursing personnel in such area;

(6)(A) has in effect a hospital utilization review plan which meets the requirements of subsection (k) and

(B) has in place a discharge planning process that meets the requirements of subsection (ee);

(7) in the case of an institution in any State in which State or applicable local law provides for the licensing of hospitals, (A) is licensed pursuant to such law or (B) is

approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing;

(8) has in effect an overall plan and budget that meets the requirements of subsection (z); and

(9) meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.

* * * * *

Long Term Care Facilities (LTC Facilities)

REQUIREMENTS FOR, AND ASSURING QUALITY OF CARE IN, SKILLED NURSING FACILITIES

SEC. 1819. [42 U.S.C. 1395i–3]

(a) SKILLED NURSING FACILITY DEFINED.—In this title, 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 1861(l)) with one or more hospitals having agreements in effect under section 1866; and

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

* * * * *

(d) REQUIREMENTS RELATING TO ADMINISTRATION AND OTHER MATTERS.—

(1) ADMINISTRATION.—

(A) IN GENERAL.—A skilled nursing 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 (consistent with requirements established under subsection (f)(5)).

(B) REQUIRED NOTICES.—If a change occurs in—

(i) the persons with an ownership or control interest (as defined in section 1124(a)(3)) in the facility

(ii) the persons who are officers, directors, agents, or managing employees (as defined in section 1126(b)) of the facility

(iii) the corporation, association, or other company responsible for the management of the facility, or

(iv) the individual who is the administrator or director of nursing of the facility,

(C) SKILLED NURSING FACILITY ADMINISTRATOR.—The administrator of a skilled nursing facility must meet standards established by the Secretary under subsection (f)(4).

(C) AVAILABILITY OF SURVEY, CERTIFICATION, AND COMPLAINT INVESTIGATION REPORTS.—A skilled nursing facility must—

(i) have reports with respect to any surveys, certifications, and complaint investigations made respecting the facility during the 3 preceding years available for any individual to review upon request; and

(ii) post notice of the availability of such reports in areas of the facility that are prominent and accessible to the public.

The facility shall not make available under clause (i) identifying information about complainants or residents.

(2) LICENSING AND LIFE SAFETY CODE.—

(A) LICENSING.—A skilled nursing facility must be licensed under applicable State and local law.

(B) LIFE SAFETY CODE.—A skilled nursing facility must meet such provisions of such edition (as specified by the Secretary in regulation) of the Life Safety Code of the National Fire Protection Association as are applicable to nursing homes; except that—

(i) the Secretary may waive, for such periods as he deems appropriate, specific provisions of such Code which if rigidly applied would result in unreasonable hardship upon a facility, but only if such waiver would not adversely affect the health and safety of residents or personnel, and

(ii) the provisions of such Code shall not apply in any State if the Secretary finds that in such State there is in effect a fire and safety code, imposed by State law, which adequately protects residents of and personnel in skilled nursing facilities.

(3) SANITARY AND INFECTION CONTROL AND PHYSICAL ENVIRONMENT.—A skilled nursing facility must—

(A) establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment in which residents reside and to help prevent the development and transmission of disease and infection, and

(B) be designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public.

(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 1124) 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.

* * * * *

REQUIREMENTS FOR NURSING FACILITIES

SEC. 1919. [42 U.S.C. 1396r]

(a) NURSING FACILITY DEFINED.—In this title, 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 1861(l)) with one or more hospitals having agreements in effect under section 1866; and

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

* * * * *

(d) REQUIREMENTS RELATING TO ADMINISTRATION AND OTHER MATTERS.—

(1) ADMINISTRATION.—

(A) IN GENERAL.—A nursing 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 (consistent with requirements established under subsection (f)(5)).

(B) REQUIRED NOTICES.—If a change occurs in—

(i) the persons with an ownership or control interest (as defined in section 1124(a)(3)) in the facility

(ii) the persons who are officers, directors, agents, or managing employees (as defined in section 1126(b)) of the facility

(iii) the corporation, association, or other company responsible for the management of the facility, or

(iv) the individual who is the administrator or director of nursing of the facility,

the skilled nursing facility must provide notice to the State agency responsible for the licensing of the facility, at the time of the change, of the change and of the identity of each new person, company, or individual described in the respective clause.

(C) NURSING FACILITY ADMINISTRATOR.—The administrator of a nursing facility must meet standards established by the Secretary under subsection (f)(4).

(V) AVAILABILITY OF SURVEY, CERTIFICATION, AND COMPLAINT INVESTIGATION REPORTS.—A nursing facility must—

(i) have reports with respect to any surveys, certifications, and complaint investigations made respecting the facility during the 3 preceding years available for any individual to review upon request; and

(ii) post notice of the availability of such reports in areas of the facility that are prominent and accessible to the public.

The facility shall not make available under clause (i) identifying information about complainants or residents.

(2) LICENSING AND LIFE SAFETY CODE.—

(A) LICENSING.—A nursing facility must be licensed under applicable State and local law.

(B) LIFE SAFETY CODE.—A nursing facility must meet such provisions of such edition (as specified by the Secretary in regulation) of the Life Safety Code of the National Fire Protection Association as are applicable to nursing homes; except that—

(i) the Secretary may waive, for such periods as he deems appropriate, specific provisions of such Code which if rigidly applied would result in unreasonable hardship upon a facility, but only if such waiver would not adversely affect the health and safety of residents or personnel, and

(ii) the provisions of such Code shall not apply in any State if the Secretary finds that in such State there is in effect a fire and safety code, imposed by State law, which adequately protects residents of and personnel in nursing facilities.

(3) SANITARY AND INFECTION CONTROL AND PHYSICAL ENVIRONMENT.—A nursing facility must—

(A) establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment in which residents reside and to help prevent the development and transmission of disease and infection, and

(B) be designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public.

(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 1124) 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.

* * * * *

Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID)

DEFINITIONS

SEC. 1905. [42 U.S.C. 1396d]
For purposes of this title—

* * * * *

(d) The term "intermediate care facility for the mentally retarded" means an institution (or distinct part thereof) for the mentally retarded or persons with related conditions if—

(1) the primary purpose of such institution (or distinct part thereof) is to provide health or rehabilitative services for mentally retarded individuals and the institution meets such standards as may be prescribed by the Secretary;

(2) the mentally retarded individual with respect to whom a request for payment is made under a plan approved under this title is receiving active treatment under such a program; and

(3) in the case of a public institution, the State or political subdivision responsible for the operation of such institution has agreed that the non-Federal expenditures in any calendar quarter prior to January 1, 1975, with respect to services furnished to patients in such institution (or distinct part thereof) in the State will not, because of payments made under this title, be reduced below the average amount expended for such services in such institution in the four quarters immediately preceding the quarter in which the State in which such institution is located elected to make such services available under its plan approved under this title.

* * * * *

Home Health Agencies (HHAs)

DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. [42 U.S.C. 1395x]
For purposes of this title—

* * * * *

Home Health Services

(m) The term "home health services" means the following items and services furnished to an individual, who is under the care of a physician, by a home health agency or by others under arrangements with them made by such agency, under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician, which items and services are, except as provided in paragraph (7), provided on a visiting basis in a place of residence used as such individual's home—

(1) part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse;

(2) physical or occupational therapy or speech-language pathology services;

(3) medical social services under the direction of a physician;

(4) to the extent permitted in regulations, part-time or intermittent services of a home health aide who has successfully completed a training program approved by the Secretary;

(5) medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and a covered osteoporosis drug (as defined in subsection (kk)), but excluding other drugs and biologicals) and durable medical equipment and applicable disposable devices (as defined in section 1834(s)(2)) while under such a plan;

(6) in the case of a home health agency which is affiliated or under common control with a hospital, medical services provided by an intern or resident-in-training of such hospital, under a teaching program of such hospital approved as provided in the last sentence of subsection (b); and

(7) any of the foregoing items and services which are provided on an outpatient basis, under arrangements made by the home health agency, at a hospital or skilled nursing facility, or at a rehabilitation center which meets such standards as may be prescribed in regulations, and—

(A) the furnishing of which involves the use of equipment of such a nature that the items and services cannot readily be made available to the individual in such place of residence, or

(B) which are furnished at such facility while he is there to receive any such item or service described in clause (A),

but not including transportation of the individual in connection with any such item or service;

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital and home infusion therapy (as defined in subsection (iii)(i)). For purposes of paragraphs (1) and (4), the term "part–time or intermittent services" means skilled nursing and home health aide services furnished

any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week). For purposes of sections 1814(a)(2)(C) and 1835(a)(2)(A), "intermittent" means skilled nursing care that is either provided or needed on fewer than 7 days each week, or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable).

* * * * *

Home Health Agency

(o) The term "home health agency" means a public agency or private organization, or a subdivision of such an agency or organization, which—

(1) is primarily engaged in providing skilled nursing services and other therapeutic services;

(2) has policies, established by a group of professional personnel (associated with the agency or organization), including one or more physicians and one or more registered professional nurses, to govern the services (referred to in paragraph (1)) which it provides, and provides for supervision of such services by a physician or registered professional nurse;

(3) maintains clinical records on all patients;

(4) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing agencies or organizations of this nature, as meeting the standards established for such licensing;

(5) has in effect an overall plan and budget that meets the requirements of subsection (z);

(6) meets the conditions of participation specified in section 1891(a) and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization;

(7) provides the Secretary with a surety bond—

(A) in a form specified by the Secretary and in an amount that is not less than the minimum of $50,000; and

(B) that the Secretary determines is commensurate with the volume of payments to the home health agency; and

(8) meets such additional requirements (including conditions relating to bonding or establishing of escrow accounts as the Secretary finds necessary for the financial security of the program) as the Secretary finds necessary for the effective and efficient operation of the program;

except that for purposes of part A such term shall not include any agency or organization which is primarily for the care and treatment of mental diseases. The

Secretary may waive the requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law.

* * * * *

CONDITIONS OF PARTICIPATION FOR HOME HEALTH AGENCIES; HOME HEALTH QUALITY

SEC. 1891. **[**42 U.S.C. 1395bbb**]**

(a) The conditions of participation that a home health agency is required to meet under this subsection are as follows:

(1) The agency protects and promotes the rights of each individual under its care, including each of the following rights:

(A) The right to be fully informed in advance about the care and treatment to be provided by the agency, to be fully informed in advance of any changes in the care or treatment to be provided by the agency that may affect the individual's well-being, and (except with respect to an individual adjudged incompetent) to participate in planning care and treatment or changes in care or treatment.

(B) The right to voice grievances with respect to treatment or care that is (or fails to be) furnished without discrimination or reprisal for voicing grievances.

(C) The right to confidentiality of the clinical records described in section 1861(o)(3).

(D) The right to have one's property treated with respect.

(E) The right to be fully informed orally and in writing (in advance of coming under the care of the agency) of—

(i) all items and services furnished by (or under arrangements with) the agency for which payment may be made under this title,

(ii) the coverage available for such items and services under this title, title XIX, and any other Federal program of which the agency is reasonably aware,

(iii) any charges for items and services not covered under this title and any charges the individual may have to pay with respect to items and services furnished by (or under arrangements with) the agency, and

(iv) any changes in the charges or items and services described in clause (i), (ii), or (iii).

(F) The right to be fully informed in writing (in advance of coming under the care of the agency) of the individual's rights and obligations under this title.

(G) The right to be informed of the availability of the State home health agency hot-line established under section 1864(a).

(2) The agency notifies the State entity responsible for the licensing or certification of the agency of a change in—

(A) the persons with an ownership or control interest (as defined in section 1124(a)(3)) in the agency,

(B) the persons who are officers, directors, agents, or managing employees (as defined in section 1126(b)) of the agency, and

(C) the corporation, association, or other company responsible for the management of the agency.

Such notice shall be given at the time of the change and shall include the identity of each new person or company described in the previous sentence.

(3)(A) The agency must not use as a home health aide (on a full-time, temporary, per diem, or other basis), any individual to provide items or services described in section 1861(m) on or after January 1, 1990, unless the individual—

(i) has completed a training and competency evaluation program, or a competency evaluation program, that meets the minimum standards established by the Secretary under subparagraph (D), and

(ii) is competent to provide such items and services.

For purposes of clause (i), an individual is not considered to have completed a training and competency evaluation program, or a competency evaluation program if, since the individual's most recent completion of such a program, there has been a continuous period of 24 consecutive months during none of which the individual provided items and services described in section 1861(m) for compensation.

(B)(i) The agency must provide, with respect to individuals used as a home health aide by the agency as of July 1, 1989, for a competency evaluation program (as described in subparagraph (A)(i)) and such preparation as may be necessary for the individual to complete such a program by January 1, 1990.

(ii) The agency must provide such regular performance review and regular in-service education as assures that individuals used to provide items and services described in section 1861(m) are competent to provide those items and services.

(C) The agency must not permit an individual, other than in a training and competency evaluation program that meets the minimum standards established by the Secretary under subparagraph (D), to provide items or services of a type for which the individual has not demonstrated competency.

(D)(i) The Secretary shall establish minimum standards for the programs described in subparagraph (A) by not later than October 1, 1988.

(ii) Such standards shall include the content of the curriculum, minimum hours of training, qualification of instructors, and procedures for determination of competency.

(iii) Such standards may permit approval of programs offered by or in home health agencies, as well as outside agencies (including employee organizations), and of programs in effect on the date of the enactment of this section; except that they may not provide for the approval of a program offered by or in a home health agency which, within the previous 2 years—

(I) has been determined to be out of compliance with subparagraph (A), (B), or (C);

(II) has been subject to an extended (or partial extended) survey under subsection (c)(2)(D);

(III) has been assessed a civil money penalty described in subsection (f)(2)(A)(i) of not less than $5,000; or

(IV) has been subject to the remedies described in subsection (e)(1) or in clauses (ii) or (iii) of subsection (f)(2)(A).

(iv) Such standards shall permit a determination that an individual who has completed (before July 1, 1989) a training and competency evaluation program or a competency evaluation program shall be deemed for purposes of subparagraph (A) to have completed a program that is approved by the Secretary under the standards established under this subparagraph if the Secretary determines that, at the time the program was offered, the program met such standards.

(E) In this paragraph, the term "home health aide" means any individual who provides the items and services described in section 1861(m), but does not include an individual—

(i) who is a licensed health professional (as defined in subparagraph (F)), or

(ii) who volunteers to provide such services without monetary compensation.

(F) In this paragraph, the term "licensed health professional" means a physician, physician assistant, nurse practitioner, physical, speech, or occupational therapist, physical or occupational therapy assistant, registered professional nurse, licensed practical nurse, or licensed or certified social worker.

(4) The agency includes an individual's plan of care required under section 1861(m) as part of the clinical records described in section 1861(o)(3).

(5) The agency operates and provides services in compliance with all applicable Federal, State, and local laws and regulations (including the requirements of section 1124) and with accepted professional standards and principles which apply to professionals providing items and services in such an agency.

(6) The agency complies with the requirement of section 1866(f) (relating to maintaining written policies and procedures respecting advance directives).

(b) It is the duty and responsibility of the Secretary to assure that the conditions of participation and requirements specified in or pursuant to section 1861(o) and subsection (a) of this section and the enforcement of such conditions and requirements are adequate to protect the health and safety of individuals under the care of a home health agency and to promote the effective and efficient use of public moneys.

* * * * *

Comprehensive Outpatient Rehabilitation Facilities (CORFs)

DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. [42 U.S.C. 1395x]
For purposes of this title—

* * * * *

Comprehensive Outpatient Rehabilitation Facility Services

(cc)(1) The term "comprehensive outpatient rehabilitation facility services" means the following items and services furnished by a physician or other qualified professional personnel (as defined in regulations by the Secretary) to an individual who is an outpatient of a comprehensive outpatient rehabilitation facility under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician—

(A) physicians' services;

(B) physical therapy, occupational therapy, speech-language pathology services, and respiratory therapy;

(C) prosthetic and orthotic devices, including testing, fitting, or training in the use of prosthetic and orthotic devices;

(D) social and psychological services;

(E) nursing care provided by or under the supervision of a registered professional nurse;

(F) drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered;

(G) supplies and durable medical equipment; and

(H) such other items and services as are medically necessary for the rehabilitation of the patient and are ordinarily furnished by comprehensive outpatient rehabilitation facilities,

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital. In the case of physical therapy, occupational therapy, and speech pathology services, there shall be no requirement that the item or service be furnished at any single fixed location if the item or service is furnished pursuant to such plan and payments are not otherwise made for the item or service under this title.

(2) The term "comprehensive outpatient rehabilitation facility" means a facility which—

(A) is primarily engaged in providing (by or under the supervision of physicians) diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons;

(B) provides at least the following comprehensive outpatient rehabilitation services: (i) physicians' services (rendered by physicians, as defined in section

1861(r)(1), who are available at the facility on a full-or part-time basis); (ii) physical therapy; and (iii) social or psychological services;

(C) maintains clinical records on all patients;

(D) has policies established by a group of professional personnel (associated with the facility), including one or more physicians defined in subsection (r)(1) to govern the comprehensive outpatient rehabilitation services it furnishes, and provides for the carrying out of such policies by a full- or part-time physician referred to in subparagraph (B)(i);

(E) has a requirement that every patient must be under the care of a physician;

(F) in the case of a facility in any State in which State or applicable local law provides for the licensing of facilities of this nature (i) is licensed pursuant to such law, or (ii) is approved by the agency of such State or locality, responsible for licensing facilities of this nature, as meeting the standards established for such licensing;

(G) has in effect a utilization review plan in accordance with regulations prescribed by the Secretary;

(H) has in effect an overall plan and budget that meets the requirements of subsection (z);

(I) provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000; and

(J) meets such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such facility, including conditions concerning qualifications of personnel in these facilities.

* * * * *

Critical Access Hospitals (CAHs)

MEDICARE RURAL HOSPITAL FLEXIBILITY PROGRAM

SEC. 1820. **[**42 U.S.C. 1395i–4**]**

* * * * *

(e) CERTIFICATION BY THE SECRETARY.—The Secretary shall certify a facility as a critical access hospital if the facility—

(1) is located in a State that has established a medicare rural hospital flexibility program in accordance with subsection (c);

(2) is designated as a critical access hospital by the State in which it is located; and

(3) meets such other criteria as the Secretary may require.

* * * * *

Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. [42 U.S.C. 1395x]
For purposes of this title—

* * * * *

Outpatient Physical Therapy Services

(p) The term "outpatient physical therapy services" means physical therapy services furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient—

(1) who is under the care of a physician (as defined in paragraph (1), (3), or (4) of section 1861(r)), and

(2) with respect to whom a plan prescribing the type, amount, and duration of physical therapy services that are to be furnished such individual has been established by a physician (as so defined) or by a qualified physical therapist and is periodically reviewed by a physician (as so defined);

excluding, however—

(3) any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital; and

(4) any such service—

(A) if furnished by a clinic or rehabilitation agency, or by others under arrangements with such clinic or agency, unless such clinic or rehabilitation agency—

(i) provides an adequate program of physical therapy services for outpatients and has the facilities and personnel required for such program or required for the supervision of such a program, in accordance with such requirements as the Secretary may specify,

(ii) has policies, established by a group of professional personnel, including one or more physicians (associated with the clinic or rehabilitation agency) and one or more qualified physical therapists, to govern the services (referred to in clause (i)) it provides,

(iii) maintains clinical records on all patients,

(iv) if such clinic or agency is situated in a State in which State or applicable local law provides for the licensing of institutions of this nature, (I) is licensed pursuant to such law, or (II) is approved by the agency of such State or locality responsible for licensing institutions of this nature, as meeting the standards established for such licensing; and

(v) meets such other conditions relating to the health and safety of individuals who are furnished services by such clinic or agency on an outpatient basis, as the Secretary may find necessary, and provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000, or

(B) if furnished by a public health agency, unless such agency meets such other conditions relating to health and safety of individuals who are furnished services by such agency on an outpatient basis, as the Secretary may find necessary.

* * * * *

Community Mental Health Centers (CMHCs)

DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. [42 U.S.C. 1395x]
For purposes of this title—

* * * * *

Partial Hospitalization Services

(ff)(1) The term "partial hospitalization services" means the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which plan sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan.

(2) The items and services described in this paragraph are—

(A) individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law),

(B) occupational therapy requiring the skills of a qualified occupational therapist,

(C) services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients,

(D) drugs and biologicals furnished for therapeutic purposes (which cannot, as determined in accordance with regulations, be self-administered),

(E) individualized activity therapies that are not primarily recreational or diversionary,

(F) family counseling (the primary purpose of which is treatment of the individual's condition),

(G) patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment),

(H) diagnostic services, and

(I) such other items and services as the Secretary may provide (but in no event to include meals and transportation);

that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish (taking into account accepted norms of medical practice and the reasonable expectation of patient improvement).

(3)(A) A program described in this paragraph is a program which is furnished by a hospital to its outpatients or by a community mental health center (as defined in subparagraph (B)), and which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour-daily care other than in an individual's home or in an inpatient or residential setting.

(B) For purposes of subparagraph (A), the term "community mental health center" means an entity that—

(i)(I) provides the mental health services described in section 1913(c)(1) of the Public Health Service Act; or

(II) in the case of an entity operating in a State that by law precludes the entity from providing itself the service described in subparagraph (E) of such section, provides for such service by contract with an approved organization or entity (as determined by the Secretary);

(ii) meets applicable licensing or certification requirements for community mental health centers in the State in which it is located;

(iii) provides at least 40 per cent of its services to individuals who are not eligible for benefits under this title; and

(iv) meets such additional conditions as the Secretary shall specify to ensure (I) the health and safety of individuals being furnished such services, (II) the effective and efficient furnishing of such services, and (III) the compliance of such entity with the criteria described in section 1931(c)(1) of the Public Health Service Act.

* * * * *

SCOPE OF BENEFITS

SEC. 1832. [42 U.S.C. 1395k]

(a) The benefits provided to an individual by the insurance program established by this part shall consist of—

(1) entitlement to have payment made to him or on his behalf (subject to the provisions of this part) for medical and other health services, except those described in subparagraphs (B) and (D) of paragraph (2) and subparagraphs (E) and (F) of section 1842(b)(6); and

(2) entitlement to have payment made on his behalf (subject to the provisions of this part) for—

(A) home health services (other than items described in subparagraph (G) or subparagraph (I));

* * * * *

(J) partial hospitalization services provided by a community mental health center (as described in section 1861(ff)(2)(B)).

(b) For definitions of "spell of illness", "medical and other health services", and other terms used in this part, see section 1861.

AGREEMENTS WITH PROVIDERS OF SERVICES; ENROLLMENT PROCESSES

Sec. 1866. [42 U.S.C. 1395cc]

(a)(1) Any provider of services (except a fund designated for purposes of section 1814(g) and section 1835(e)) shall be qualified to participate under this title and shall be eligible for payments under this title if it files with the Secretary an agreement—

* * * * *

(e) For purposes of this section, the term "provider of services" shall include—

(1) a clinic, rehabilitation agency, or public health agency if, in the case of a clinic or rehabilitation agency, such clinic or agency meets the requirements of section 1861(p)(4)(A) (or meets the requirements of such section through the operation of subsection (g) or (ll)(2) of section 1861(g)), or if, in the case of a public health agency, such agency meets the requirements of section 1861(p)(4)(B) (or meets the requirements of such section through the operation of subsection (g) or (ll)(2) of section 1861(g)), but only with respect to the furnishing of outpatient physical therapy services (as therein defined) (through the operation of section 1861(g)) with respect to the furnishing of outpatient occupational therapy services, or

(through the operation of section 1861(ll)(2)) with respect to the furnishing of outpatient speech-language pathology;

(2) a community mental health center (as defined in section 1861(ff)(3)(B)), but only with respect to the furnishing of partial hospitalization services (as described in section 1861(ff)(1)); and

(3) opioid treatment programs (as defined in paragraph (2) of section 1861(jjj)), but only with respect to the furnishing of opioid use disorder treatment services (as defined in paragraph (1) of such section).

* * * * *

Home Infusion Therapy (HIT) Suppliers

DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. [42 U.S.C. 1395x]
For purposes of this title—

* * * * *

(iii)HOME INFUSION THERAPY

(1) The term "home infusion therapy" means the items and services described in paragraph (2) furnished by a qualified home infusion therapy supplier (as defined in paragraph (3)(D)) which are furnished in the individual's home (as defined in paragraph (3)(B)) to an individual—

(A) who is under the care of an applicable provider (as defined in paragraph (3)(A)); and

(B) with respect to whom a plan prescribing the type, amount, and duration of infusion therapy services that are to be furnished such individual has been established by a physician (as defined in subsection (r)(1)) and is periodically reviewed by a physician (as so defined) in coordination with the furnishing of home infusion drugs (as defined in paragraph (3)(C)) under part B.

(2) The items and services described in this paragraph are the following:

(A) Professional services, including nursing services, furnished in accordance with the plan.

(B) Training and education (not otherwise paid for as durable medical equipment (as defined in subsection (n)), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier.

(3) For purposes of this subsection:

(A) The term "applicable provider" means—

(i) a physician;

(ii) a nurse practitioner; and

(iii) a physician assistant.

(B) The term "home" means a place of residence used as the home of an individual (as defined for purposes of subsection (n)).

(C) The term "home infusion drug" means a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in subsection (n)). Such term does not include the following:

(i) Insulin pump systems.

(ii) A self-administered drug or biological on a self- administered drug exclusion list.

(D)(i) The term "qualified home infusion therapy supplier" means a pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider or services or supplier furnishes items or services and that—

(I) furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs;

(II) ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis;

(III) is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5); and

(IV) meets such other requirements as the Secretary determines appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under part C and in the private sector.

(ii) A qualified home infusion therapy supplier may subcontract with a pharmacy, physician, provider of services, or supplier to meet the requirements of this subparagraph.

* * * * *

Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs)

DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. [42 U.S.C. 1395x]

For purposes of this title—

* * * * *

Rural Health Clinic Services And Federally Qualified Health Center Services

(aa)(1) The term "rural health clinic services" means—

(A) physicians' services and such services and supplies as are covered under section 1861(s)(2)(A) if furnished as an incident to a physician's professional service and items and services described in section 1861(s)(10),

(B) such services furnished by a physician assistant or a nurse practitioner (as defined in paragraph (5)), by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(1)), and such services and supplies furnished as an incident to his service as would otherwise be covered if furnished by a physician or as an incident to a physician's service, and

(C) in the case of a rural health clinic located in an area in which there exists a shortage of home health agencies, part-time or intermittent nursing care and related medical supplies (other than drugs and biologicals) furnished by a registered professional nurse or licensed practical nurse to a homebound individual under a written plan of treatment (i) established and periodically reviewed by a physician described in paragraph (2)(B), or (ii) established by a nurse practitioner or physician assistant and periodically reviewed and approved by a physician described in paragraph (2)(B),

when furnished to an individual as an outpatient of a rural health clinic.

(2) The term "rural health clinic" means a facility which—

(A) is primarily engaged in furnishing to outpatients services described in subparagraphs (A) and (B) of paragraph (1);

(B) in the case of a facility which is not a physician-directed clinic, has an arrangement (consistent with the provisions of State and local law relative to the practice, performance, and delivery of health services) with one or more physicians (as defined in subsection (r)(1)) under which provision is made for the periodic review by such physicians of covered services furnished by physician assistants and nurse practitioners, the supervision and guidance by such physicians of physician assistants and nurse practitioners, the preparation by such physicians of such medical orders for care and treatment of clinic patients as may be necessary, and the availability of such physicians for such referral of and consultation for patients as is necessary and for advice and assistance in the management of medical emergencies; and, in the case of a physician-directed clinic, has one or more of its staff physicians perform the activities accomplished through such an arrangement;

(C) maintains clinical records on all patients;

(D) has arrangements with one or more hospitals, having agreements in effect under section 1866, for the referral and admission of patients requiring inpatient services or such diagnostic or other specialized services as are not available at the clinic;

(E) has written policies, which are developed with the advice of (and with provision for review of such policies from time to time by) a group of professional personnel, including one or more physicians and one or more physician assistants or nurse practitioners, to govern those services described in paragraph (1) which it furnishes;

(F) has a physician, physician assistant, or nurse practitioner responsible for the execution of policies described in subparagraph (E) and relating to the provision of the clinic's services;

(G) directly provides routine diagnostic services, including clinical laboratory services, as prescribed in regulations by the Secretary, and has prompt access to additional diagnostic services from facilities meeting requirements under this title;

(H) in compliance with State and Federal law, has available for administering to patients of the clinic at least such drugs and biologicals as are determined by the Secretary to be necessary for the treatment of emergency cases (as defined in regulations) and has appropriate procedures or arrangements for storing, administering, and dispensing any drugs and biologicals;

(I) has a quality assessment and performance improvement program, and appropriate procedures for review of utilization of clinic services, as the Secretary may specify;

(J) has a nurse practitioner, a physician assistant, or a certified nurse-midwife (as defined in subsection (gg)) available to furnish patient care services not less than 50 percent of the time the clinic operates; and

(K) meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are furnished services by the clinic.

* * * * *

DEFINITIONS

SEC. 1905. **[**42 U.S.C. 1396d**]**

For purposes of this title—

(a) The term "medical assistance" means payment of part or all of the cost of the following care and services or the care and services themselves, or both * * * *

* * * * *

(l)(1) The terms "rural health clinic services" and "rural health clinic" have the meanings given such terms in section 1861(aa), except that (A) clause (ii) of section 1861(aa)(2) shall not apply to such terms, and (B) the physician arrangement required under section 1861(aa)(2)(B) shall only apply with respect to rural health clinic services and, with respect to other ambulatory care services, the physician arrangement required shall be only such as may be required under the State plan for those services.

(2)(A) The term "Federally-qualified health center services" means services of the type described in subparagraphs (A) through (C) of section 1861(aa)(1) when furnished to an individual as an patient of a Federally-qualified health center and, for this purpose, any reference to a rural health clinic or a physician described in

section 1861(aa)(2)(B) is deemed a reference to a Federally-qualified health center or a physician at the center, respectively.

(B) The term "Federally-qualified health center" means a entity which—

(i) is receiving a grant under section 330 of the Public Health Service Act,

(ii)(I) is receiving funding from such a grant under a contract with the recipient of such a grant, and

(II) meets the requirements to receive a grant under section 330 of such Act,

(iii) based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Secretary to meet the requirements for receiving such a grant, including requirements of the Secretary that an entity may not be owned, controlled, or operated by another entity, or

(iv) was treated by the Secretary, for purposes of part B of title XVIII, as a comprehensive Federally funded health center as of January 1, 1990;

and includes an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act (Public Law 93-638) or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services. In applying clause (ii), the Secretary may waive any requirement referred to in such clause for up to 2 years for good cause shown.

* * * * *

End-Stage Renal Disease (ESRD) Facilities

MEDICARE COVERAGE FOR END STAGE RENAL DISEASE PATIENTS

SEC. 1881. [42 U.S.C. 1395rr] (a) The benefits provided by parts A and B of this title shall include benefits for individuals who have been determined to have end stage renal disease as provided in section 226A, and benefits for kidney donors as provided in subsection (d) of this section. Notwithstanding any other provision of this title, the type, duration, and scope of the benefit provided by parts A and B with respect to individuals who have been determined to have end stage renal disease and who are entitled to such benefits without regard to section 226A shall in no case be less than the type, duration, and scope of the benefits so provided for individuals entitled to such benefits solely by reason of that section.

(b)(1) Payments under this title with respect to services, in addition to services for which payment would otherwise be made under this title, furnished to individuals who have been determined to have end stage renal disease shall include (A) payments on behalf of such individuals to providers of services and renal dialysis facilities which meet such requirements as the Secretary shall by regulation prescribe for institutional dialysis services and supplies (including self-dialysis services in a self-care dialysis unit

maintained by the provider or facility), transplantation services, self-care home dialysis support services which are furnished by the provider or facility, and routine professional services performed by a physician during a maintenance dialysis episode if payments for his other professional services furnished to an individual who has end stage renal disease are made on the basis specified in paragraph (3)(A)(i) of this subsection, (B) payments to or on behalf of such individuals for home dialysis supplies and equipment, and (C) payments to a supplier of home dialysis supplies and equipment that is not a provider of services, a renal dialysis facility, or a physician for self-administered erythropoietin as described in section 1861(s)(2)(P) if the Secretary finds that the patient receiving such drug from such a supplier can safely and effectively administer the drug (in accordance with the applicable methods and standards established by the Secretary pursuant to such section). The requirements prescribed by the Secretary under subparagraph (A) shall include requirements for a minimum utilization rate for transplantations. Beginning 180 days after the date of the enactment of this sentence, an initial survey of a provider of services or a renal dialysis facility to determine if the conditions and requirements under this paragraph are met shall be initiated not later than 90 days after such date on which both the provider enrollment form (without regard to whether such form is submitted prior to or after such date of enactment) has been determined by the Secretary to be complete and the provider's enrollment status indicates approval is pending the results of such survey.

* * * * *

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, STATE OF NEBRASKA, *Plaintiffs*, v. JOSEPH R. BIDEN, JR., in his official capacity as the President of the United States of America; THE UNITED STATES OF AMERICA; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA in his official capacity as Secretary of the United States Department of Health and Human Services; CENTERS FOR MEDICARE AND MEDICAID SERVICES; MEENA SESHAMANI in her official capacity as Deputy Administrator and Director of Center for Medicare; DANIEL TSAI in his official capacity as Deputy Administrator and Director of Center for Medicaid and CHIP Services; *Defendants*.	No. 4:21-cv-01329

DECLARATION OF RENEE GAYHART

1. My name is Renee Gayhart, and I am the Director of the Division of Health Care Services (DHCS), a division of the Alaska Department of Health and Social Services. I have held that position for approximately three years. I am also a resident of Alaska and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. As Director of DHCS, I am responsible for overseeing state employees on the Health Facility Licensure and Certification (HFLC) team who conduct surveys on behalf of the Centers for Medicare and Medicaid Services (State Surveyors).

3. There are currently 16 State Surveyor positions assigned to HFLC, with 11 of those positions filled as of this date. These are all state employees who perform the surveying work.

4. The State Surveyors inspect health facilities across the state to determine whether they meet state and federal standards; e.g., Medicare and Medicaid requirements. In addition, the team investigates complaints made against health facilities and agencies licensed or certified under our program. The purpose of the inspections is to determine a health care provider's ability to give services which are safe and of an acceptable quality.

5. Federal law guarantees to Medicare beneficiaries that payment will be made for health care services furnished in or by entities that meet stipulated requirements of the Social Security Act. Specifically, State Surveyors have the following responsibilities related to the certification of entities to participate in the Medicare program:

A. Identifying potential Medicare participants, including laboratories seeking to participate in the Clinical Laboratory Improvement Amendments (CLIA) program;

B. Verifying how well the health care entities comply with federal Conditions of Participation or federal requirements;

C. Certifying and recertifying whether entities, including CLIA laboratories, are qualified to participate in the program, and periodically sending those certifications to the appropriate state or federal agencies;

D. Advising providers and potential providers regarding applicable federal regulations to enable them to qualify for participation in the Medicare program and to maintain standards of health care consistent with the federal Conditions of participation or federal requirements. This includes conducting periodic educational programs for the staff and residents (and their representatives) of skilled nursing facilities and nursing facilities

in order to present current regulations, procedures, and policies. These educational programs are required under sections 1819(g)(1)(B) and 1919(g)(1)(B) of the Social Security Act;

E. Operating toll-free telephone hotlines to collect, maintain, and continually update information on Medicare-certified home health agencies. The hotline is also used to receive complaints and answer questions about home health agencies; and

F. Entering data from surveys, follow-up visits, and complaint investigations into the national mainframe computer system that is used for maintaining and retrieving certification data. Surveyors update information about providers, suppliers, and CLIA laboratories in the system when indicated.

6. If a facility is not in compliance with federal Medicare and Medicaid regulations, the State Surveyors send the facility a violation report informing it of its deficiencies. If the applicable requirements are not met, the facility may not receive Medicare and Medicaid reimbursements.

Renee Gayhart

Renee Gayhart
Director, Division of Health Care Services
Department of Health and Social Services
State of Alaska

11.11.2021

Date

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, STATE OF NEBRASKA, *Plaintiffs*, v. JOSEPH R. BIDEN, JR., in his official capacity as the President of the United States of America; THE UNITED STATES OF AMERICA; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA in his official capacity as Secretary of the United States Department of Health and Human Services; CENTERS FOR MEDICARE AND MEDICAID SERVICES; MEENA SESHAMANI in her official capacity as Deputy Administrator and Director of Center for Medicare; DANIEL TSAI in his official capacity as Deputy Administrator and Director of Center for Medicaid and CHIP Services; *Defendants*.	No. 4:21-cv-01329

DECLARATION OF SCOTT YORK

1. My name is Scott York, and I am the Chief Executive Officer (CEO) of the Alaska Psychiatric Institute ("API"), a division of the Alaska Department of Health and Social Services. I am also a resident of Alaska and over the age of majority. API is located in Anchorage, Alaska.

2. I have served as CEO of API since March 2020. I have worked in the healthcare

industry for approximately 37 years. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

3. API is required by state law to admit individuals ordered to receive treatment by the Alaska Superior Court. As CEO of API, I am responsible for managing API such that it can admit all patients who are under a court order for involuntary commitment for mental health treatment.[1]

4. Alaska Psychiatric Institute is licensed by the State of Alaska as a psychiatric hospital for the purpose of receiving reimbursement from the Center for Medicare and Medicaid Services ("CMS").

5. As a licensed hospital, API receives reimbursement from CMS to cover the cost of inpatient mental health treatment for individuals who are admitted to the hospital involuntarily.

6. As a certified hospital, API must comply with CMS Conditions of Participation in order to be reimbursed for treatment costs.

7. For the current fiscal year, API anticipates collecting approximately $7.5 in reimbursement from CMS, which comprises approximately 15.6 percent of the operating budget for the hospital.

8. Presently, API has 248 employees. Approximately 31% of API's employees are known to have not, or are reasonably believed to have not, received a COVID-19 vaccine.

9. Despite the availability of medical and religious exemptions, API nevertheless believes it is likely to lose approximately 20 employees (8% of API's workforce) as a result of the vaccine mandate.

[1] API also admits patients who are voluntarily receiving inpatient treatment, but the number of patients voluntarily admitted to API is relatively minimal.

10. Losing even 5% of its workforce would cause substantial harm to API because it would be extremely difficult to fill those positions with new workers.

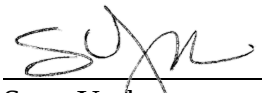
11. First, the positions could not be filled with other, unvaccinated workers. Second, Alaska faces a shortage of qualified healthcare workers. Due to its remote geographic location, high cost of living, and potentially other factors, it is difficult to attract qualified, high-quality healthcare workers to the State of Alaska.

12. API and its patients will be harmed by the negative consequences of the vaccine mandate. Even if a small percentage of API's workforce is lost, hospital operations will be negatively impacted, which, in turn will affect availability of treatment. Capacity will be further limited, and enrollment at API will decline. As a result, patients will be forced to seek treatment elsewhere in a community where the availability of healthcare is already relatively limited.

13. In the State of Alaska, there are a limited number of inpatient psychiatric services, with API being the only freestanding adult psychiatric facility. Thus, if API's capacity is limited, that could potentially impact other services, such as emergency rooms and correctional facilities, since patients at those facilities could not receive immediate treatment at API.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on November 11, 2021.



Scott York
CEO, Alaska Psychiatric Institute

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI,
STATE OF NEBRASKA,

Plaintiffs,

v.

JOSEPH R. BIDEN, JR.,
in his official capacity as the President of the United States of America;

THE UNITED STATES OF AMERICA;

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES;

XAVIER BECERRA in his official capacity as Secretary of the United States Department of Health and Human Services;

CENTERS FOR MEDICARE AND MEDICAID SERVICES;

MEENA SESHAMANI in her official capacity as Deputy Administrator and Director of Center for Medicare;

DANIEL TSAI in his official capacity as Deputy Administrator and Director of Center for Medicaid and CHIP Services;

Defendants.

No. 4:21-cv-01329

DECLARATION OF MARK WHITE

Pursuant to 28 U.S.C. 1746, I declare:

1. I am over 18 years of age and have personal knowledge of the facts set out in this declaration.

2. I am employed by the Arkansas Department of Human Services (DHS) as the Deputy Director and Chief of Staff, Legal, and Legislative Affairs. Part of my responsibilities include

coordinating DHS's work and initiatives across its divisions and offices. I have served in a variety of capacities during my tenure at DHS, including in the Division of Aging, Adult, and Behavioral Health Services.

3. DHS is responsible for the operation of seven healthcare facilities that receive funds through Medicare and/or Medicaid. These facilities will be subject to the CMS vaccine mandate. These facilities serve some of Arkansas's most vulnerable populations including the elderly, children, intellectually disabled individuals, and the mentally ill.

4. The Arkansas Health Center is a nursing home with over 300 beds serving the needs of residents with psychiatric or other medical needs requiring specialized services or programs that are not generally available through community nursing facilities. The Arkansas State Hospital is the State-operated acute psychiatric inpatient hospital. DHS also operates five human development centers (HDC), which are residential facilities serving Arkansans with intellectual and developmental disabilities.

5. Since the inception of the COVID-19 pandemic, employee attrition at these facilities has increased. The following is a summary of employee attrition for fiscal years 2019 through 2021:

Facility	FY19	FY20	FY2021
Arkansas Health Center	20.50%	26.68%	33.33%
Arkansas State Hospital	19.00%	19.42%	26.63%
Arkadelphia HDC	58.77%	55.56%	78.21%
Booneville HDC	24.44%	30.8%	44.44%
Conway HDC	41.98%	40.47%	49.71%
Jonesboro HDC	62.08%	45.13%	79.32%
Southeast Arkansas HDC	45.76%	42.38%	58.06%

6. As these figures show, employee attrition has increased at all of these facilities during fiscal year 2021 compared to previous years. DHS expects attrition to increase as a result of the CMS vaccine mandate.

7. In addition to ongoing attrition, these facilities all currently have staffing shortages. Across these seven facilities, there are over 1,000 positions—representing over 40% of total positions—classified as being "open" or unfilled. Many of these positions would be filled but for the lack of necessary personnel. DHS expects the number of unfilled positions to increase as a result of the CMS vaccine mandate.

8. Approximately 63% of employees at these facilities have been vaccinated for COVID-19. State employees, including those at these DHS facilities, were previously offered a $200 incentive bonus for vaccination. The remaining 37% of the workforce at these facilities, representing nearly 1,000 individuals, have chosen not to become vaccinated.

9. DHS expects that the CMS vaccine mandate will result in increased staffing shortages at these seven facilities, exacerbating the shortages that already exist and increasing the already-high employee attrition. The potential effects of the CMS vaccine mandate are all the more concerning given the vulnerable populations served by these facilities.

Pursuant to 28 U.S.C. 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 12th day of November, 2021.

Mark White

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI et al., Plaintiffs, v. JOSEPH R. BIDEN, JR., et al., Defendants.	Case No. 4:21-CV-01329 **DECLARATION OF ED SMITH**

I, Ed Smith, declare under penalty of perjury that I have personal knowledge of the following:

1. I am a resident of Iowa and over the age of majority.

2. I serve as the President and CEO of St. Anthony Regional Hospital.

3. St. Anthony Regional Hospital is an independent, faith-based, rural hospital located in Carroll, Iowa. Carroll is in West Central Iowa equal distance (approximately 100 miles) between Omaha and Des Moines. St. Anthony provides a broad range of services to the citizens of west central Iowa. These services include: oncology, mental health, cardiology, orthopedics, obstetrics, and senior services. St. Anthony provides the public health function for Carroll County. As such, Carroll County Public Health has been a leader in the state in the response to the COVID-19 pandemic and facilitating vaccinations throughout the county.

4. St. Anthony employs over 750 staff. St. Anthony's current open positions are a reflection of the work force environment in healthcare generally, but also due to the extremely low unemployment rate in Carroll.

5. Currently, St. Anthony has 134 open positions, this includes 30 for our food and nutrition department and 30 on our med/surg/pediatric floor.

6. St. Anthony employees have responded very well to voluntarily becoming vaccinated from COVID-19. Currently, St. Anthony's vaccination rate for its employees is 87%.

7. St. Anthony has instituted a policy that requires employees declining the vaccine to wear an N95 mask and in some cases be tested prior to working each shift. This policy has been accepted by the unvaccinated and has resulted in no infections occurring within our workplace.

8. St. Anthony conducted a survey of unvaccinated employees to understand the amount of risk St. Anthony is facing should a vaccine mandate be implemented. At the time of the survey, we had 115 unvaccinated employees. 20 employees ultimately decided to be vaccinated. 55 employees indicated an intention to claim a religious or medical exemption. And 40 employees said that they would resign rather than comply with a vaccine mandate.

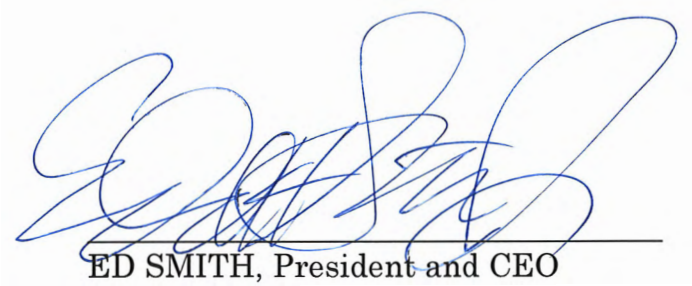
9. St. Anthony is struggling with recruitment of all staff positions in the current environment with qualified applications being limited. The proposed CMS vaccine mandate would only exacerbate our work force challenges.

10. As a rural health care provider, St. Anthony relies on Medicare and Medicaid as our dominant payor source. Medicare is 52% of revenues and Medicaid is 13% of revenues.

11. St. Anthony will be compliant with any CMS regulations. But that compliance will not be without cost. The loss of 40 employees coupled with the tight employment market will force us to evaluate the availability of needed healthcare services to the people in the region we serve.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on November 12, 2021.



ED SMITH, President and CEO
St. Anthony Regional Hospital

DECLARATION OF BRITTANY VANLANDINGHAM, ADMINISTRATOR MONROE CITY MANOR CARE CENTER

I, BRITTANY VANLANDINGHAM, being first duly sworn upon my oath, do hereby state as follows:

1. I am the Administrator of the Monroe City Manor Care Center (MCMCC) location at 1010 highway 24/36 East, Monroe City, Missouri. I am also a resident of Missouri and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. MCMCC is a 60 Bed, for-profit nursing home in Monroe City, Missouri and has been in operation since 1977. MCMCC provides a wide variety of services including skilled nursing, physical therapy, occupational therapy, speech therapy, and custodial nursing care.

3. MCMCC employs no less than 60 employees, including no less than 20 nurses, 20 certified nurse aides, 10 kitchen staff, and 10 other staff members.

4. Each year, MCMCC provides services to approximately 90 patients whose care is paid for by the federal government's Centers for Medicare and Medicaid Services agency (CMS). CMS provides reimbursement to MCMCC for treatment of these patients through the federal Medicare and Medicaid programs. In 2020, MCMCC treated and billed CMS for the treatment of approximately 75 patients. MCMCC received approximately $2,000,000 in reimbursement from CMS in 2020.

5. Most if not all employees of MCMCC receive at least a portion of their

salaries from funds provided by the reimbursement of federal funds from CMS.

6. Due to media reports, I have become aware that CMS will require all employees of MCMCC to be fully vaccinated for COVID-19 no later than January 4, 2022. This information, which has been widely disseminated, indicates that providers who refuse to require vaccinations for all employees will no longer be eligible for CMS reimbursement or to participate in the CMS program.

7. There are a number of MCMCC employees who are refusing to be vaccinated for COVID-19. The vaccination rate of MCMCC employees is under 50%. When surveyed, a majority of these unvaccinated staff stated they would choose to leave healthcare completely over being forced to get the covid-19 vaccine. I believe that many additional employees will voluntarily quit working for MCMCC or I will be forced to terminate their employment at MCMCC on or before January 4, 2022 if the CMS mandate is ultimately imposed.

8. The loss of such additional employees will cause significant difficulty in the continued operation of MCMCC.

9. The recruitment of qualified employees is a significant consideration at MCMCC. I anticipate that the federal CMS vaccine mandate will limit the number of potential qualified applicants and as such will interfere with my ability to hire and maintain enough staff to effectively operate MCMCC. In addition, due to a shortage of qualified staff (particularly nursing staff), the market rates to hire new staff have skyrocketed. The approximate current hourly rate for a CNA at MCMCC is $13, an LPN is $21 and an RN is $26. The rates for these same staff

positions in late 2020 was $11, $18 and $22 respectively.

Pursuant to 28 U.S.C. 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 10th day of November, 2021.

B. Vanlandingham RN LNHA

Brittany Vanlandingham, Administrator
Monroe City Manor Care Center

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. 4:21-cv-01329

DECLARATION OF NIKKI STRONG

1. My name is Nikki Strong and I am the Executive Director of the Missouri Health Care Association. I am also a resident of the State of Missouri and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. Missouri Health Care Association ("MHCA") is Missouri's largest association of licensed, long-term health care facilities, residential care facilities, and assisted living facilities. With nearly 350 facility members, MHCA represents a majority of Missouri's licensed skilled nursing care facilities along with many residential care and assisted living facilities. MHCA's facility members are licensed for approximately 35,000 beds and care for tens of thousands of residents across the state.

3. All of MHCA's skilled nursing facility members will be directly impacted by the interim final rule with comment period (IFC) that Plaintiff States have challenged in this case.

4. Nearly all of MHCA's facility members are currently facing a staffing crisis

and barely able to meet minimum staffing levels to keep their doors open. There are thousands of job openings in skilled nursing facilities around the state.

5. A certain number of employees are necessary for a facility to be able provide care. Without a sufficient number of staff, skilled nursing care facilities cannot stay open and will be forced to close.

6. Many facilities across the state have indicated that they would have to close their facilities if CMS were to issue a vaccine mandate, which would displace thousands of residents across the state and affect the entire health care system. Skilled nursing care facilities are typically the only facilities that can provide the acute care services their residents need. The impact of skilled nursing facility closures due to the mandate will inundate hospital capacity leaving little room for others in the community to receive the care they need. This type of bottleneck to the health care system would likely create a healthcare access issue across the state.

7. A majority of Missouri's facilities have either slowed or stopped admitting new patients as a result of staffing shortages. The inability for skilled nursing facilities to admit new residents further burdens the hospitals in their area.

8. A significant number of facilities across the state have indicated that they could lose up to 25% of their employees or more if CMS were to issue a vaccine mandate. Because of the existing workforce shortage, the majority of facilities cannot afford to lose even 1% of their employees.

9. If mandated to receive the COVID-19 vaccine, many unvaccinated employees in Missouri's skilled nursing facilities have indicated they will quit their jobs. Due to the large number of job openings across the state in numerous sectors outside of the health care or within

the health care sector, employees in skilled nursing facilities have indicated they will leave for jobs outside the health care field where they can make similar or higher wages and either not be required to take the COVID-19 vaccine or have a testing option.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 12th day of November, 2021.

Nikki Strong, Executive Director
Missouri Health Care Association

DECLARATION OF RANDALL W. TOBLER, MD, CEO
SCOTLAND COUNTY HOSPITAL

I, RANDALL W. TOBLER, being first duly sworn upon my oath, do hereby state as follows:

1. I am the CEO of Scotland County Hospital (SCH) located at 450 East Sigler Avenue, in Memphis, Missouri. I am also a resident of Missouri and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. SCH is a 25-bed, non-profit, Critical Access Hospital in rural Northeast Missouri that also owns and operates four Rural Health Clinics. SCH provides a wide variety of medical services including primary healthcare, a 24-hour Emergency Department, general surgery department (Surgery Center), and obstetrics department (Women's Center) and a number of other specialty medical services.

3. As of today, SCH employs 177 full-time, part-time and PRN employees.

4. Each year SCH provides services to hundreds of patients, from in and around Northeast Missouri and Southeast Iowa, whose treatment is paid for by the federal government's Centers for Medicare and Medicaid Services agency (CMS). CMS provides reimbursement to SCH for treatment of these patients through the federal Medicare and Medicaid programs. In 2020, SCH's payer mix consisted of approximately 70% of our patients presenting to our facilities on federal insurances (Medicare/Medicaid).

5. On Friday, November 5, 2021, I received an email from the CMS.gov Newsroom stating "CMS Issued the Interim Final Rule Requiring Mandatory COVID-19 Vaccinations for Workers in Hospitals and Most Health Care Settings." This will require all employees of SCH to be fully vaccinated for COVID-19 no later than January 4, 2022.

Furthermore, employees who have not completed the FDA approved vaccination sequence (2-dose or single dose) by December 5, 2021, would be unable to work in our facility. I understand that providers who fail to ensure vaccinations for all employees working in our facility would no longer be eligible for CMS reimbursement or to participate in the CMS program.

6. Upon information and belief, there are a number of SCH employees who are choosing to not be vaccinated for COVID-19. As of today, 20 of our full-time and part-time staff are weighing whether to comply and at least 5 stated emphatically they will not be vaccinated. We have already suffered staff resignations by 18% during this worldwide pandemic. Presently, the five staff members unwilling to be vaccinated are considered essential workers in critical areas of our hospital & clinics in the nursing, clinical support departments and administration. I believe that several additional employees will voluntarily quit working for SCH or I will be forced to terminate their employment at SCH on or before January 4, 2022, if the CMS mandate is ultimately imposed.

7. The loss of such additional employees will cause significant difficulty in the continued quality and safe operations of SCH.

8. Any employees I would be potentially forced to terminate, pursuant to the federal CMS vaccine mandate, would likely apply for unemployment benefits. Assuming such benefits were granted, this would impose a significant additional financial cost to SCH. Furthermore, this would eliminate gainfully employed American's income taxes being collected by state and federal governments.

9. The recruitment and retention of qualified employees is a significant consideration at SCH. Our healthcare services provided in a remote and underserved area are

critical to our communities. I anticipate that the federal CMS vaccine mandate will limit the number of potential qualified applicants and, as such, will interfere with my ability to hire and maintain enough staff to effectively and safely operate SCH.

Pursuant to 28 U.S.C. 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 10th day of November, 2021.

Randall W. Tobler, MD
CEO, Scotland County Hospital

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. 4:21-cv-01329

DECLARATION OF STEVE BOLLIN, DIRECTOR OF THE DIVISION OF REGULATION AND LICENSURE
MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES

1. My name is Steve Bollin and I am the Director of the Division of Regulation and Licensure ("DRL"), a division of the Missouri Department of Health and Senior Services ("DHSS"). I am also a resident of the State of Missouri and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. DHSS is a state agency that serves the citizens of Missouri by working to improve the health and quality of life for Missourians of all ages.

3. DRL ensures the quality of a variety of entities including hospitals and ambulatory surgical centers, home health and hospice providers, long-term care facilities including residential care, intermediate care, and skilled nursing facilities, emergency medical services, pharmacies and persons authorized to prescribe or dispense controlled substances.

4. As Director of DRL, I am responsible for overseeing the state employees who conduct surveys on behalf of the Center for Medicare and Medicaid Services ("CMS").

5. There are currently approximately 251 surveyors housed within the Division of Registration and Licensing. All surveyors are employed by the State of Missouri.

6. The State Surveyors inspect health facilities across the state to determine whether they meet state and federal standards e.g., Medicare and Medicaid requirements. In addition, the team investigates complaints made against health facilities and agencies licensed or certified under our program. The purpose of the inspections is to determine a health care providers' ability to administer services which are safe and of an acceptable quality.

7. There are approximately 18 surveyors in the Bureau of Hospital Standards who are responsible for administering the state licensing programs for all Missouri hospitals, excluding state and federal facilities. Hospitals are required to renew their licenses annually based on compliance with state regulations in the areas of fire safety and sanitation, nursing service, dietary service, and organization and administration. These surveyors also conduct survey activities through a contract with CMS, related to certification of hospitals participating in the Medicare and Medicaid programs, and they conduct state licensure inspections for new construction and remodeling projects for hospitals, including life safety code.

8. There are approximately 13 surveyors in the Bureau of Ambulatory Care. They are responsible for administering the state licensing program for freestanding ambulatory surgical centers, birthing centers, and abortion facilities, excluding state and federal facilities. These facilities are required to renew their licenses annually based on compliance with state regulations in the areas of fire safety and sanitation, nursing service, dietary service and organization and administration. These surveyors also conduct survey activities through a contract with CMS, related to certification of ambulatory surgical centers and end stage renal dialysis facilities participating in the Medicare and Medicaid programs.

9. There are approximately 6 surveyors in the Bureau of Diagnostic Services. They are responsible for conducting survey activities through contracts with CMS related to certification and registration of rural health clinics, laboratories, and hospitals participating in the Medicare, Medicaid, and Clinical Laboratory Improvement Amendment ("CLIA") programs. They also register and inspect medical facilities that use ionizing radiation for diagnosis or treatment for compliance with state radiation safety regulations. These include diagnostic X-ray departments in hospitals, clinics, mobile diagnostic units, private medical offices, veterinarian offices, chiropractic offices, dental offices, podiatric offices, mammography providers and research/industrial sites. Surveyors also conduct surveys to determine compliance with federal certification standards of all mammography providers in Missouri.

10. There are approximately 15 surveyors in the Bureau of Home Care

and Rehabilitative Standards. They are responsible for conducting on-site surveys for Medicare certification at home health agencies, hospices, comprehensive outpatient rehabilitation facilities ("CORF) and outpatient physical therapy ("OPT") providers through contracts with CMS. They are also responsible for providing technical consultation regarding Missouri licensing requirements for home health agencies and hospices and Medicare standards for home health agencies, hospices, outpatient physical therapy providers and comprehensive outpatient rehabilitation facilities. Additionally, these surveyors conduct on-site surveys at home health agencies and hospices for compliance with state regulations, complete complaint investigations regarding allegations of inappropriate care and other patient concerns, and respond to phone calls received from the federally mandated toll-free "hotline" for the purpose of receiving questions about home health agencies and hospices, or for patients to lodge complaints concerning their provider agency or quality of care provided.

11. There are approximately 8 surveyors in the Bureau of Narcotics and Dangerous Drugs whose responsibilities include conducting on-site surveys for people holding BNDD registrations, ensuring compliance with state and federal controlled substance laws, and completing complaint investigations.

12. There are approximately 191 surveyors in the Section for Long Term Care who are responsible for conducting survey activities through a contract with CMS, related to certification of skilled nursing and intermediate care facilities participating in the Medicare and Medicaid programs. These surveyors conduct

survey inspections and complaint investigations at these facilities.

13. If a facility is not in compliance with federal Medicare and Medicaid regulations, the state surveyors send the facility a statement of deficiencies. If the applicable requirements are not met, the facility may not receive Medicare and Medicaid reimbursements.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 12 day of November, 2021.

Steve Bollin, Director
Division of Regulation and Licensure
Missouri Department of Health and Senior Services

DECLARATION OF TIM SCHRAGE, ADMINISTRATOR SCOTLAND COUNTY CARE CENTER

I, TIM SCHRAGE, being first duly sworn upon my oath, do hereby state as follows:

1. I am the Administrator of the Scotland County Care Center (SCCC) at 434 E. Sigler, Memphis, Missouri. I am also a resident of Missouri and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. SCCC is a 96 bed, not-for-profit nursing home in Memphis, Missouri and has been in operation since 1969. We are considered local government, a political subdivision of the state of Missourui governed by an elected board of directors and supported, in part, by a local county tax base. SCCC provides a wide variety of services including long term care for the disabled, post hospital rehabilitation through the Medicare Skilled Nursing Home benefit, and a Residential Care Facility holding an additional 28 beds.

3. Like many of our rural nursing home districts, we are one of the largest employers in our county, second only to the school system. We have approximately 65 employees ranging from a licensed administrator, accountants, RN Director of Nurses, registered nurses, licensed practical nurses, certified nurses, dietary staff, med tecs, and a host of other staff who are necessary and essential in caring for our residents. CMS provides reimbursement to SCCC for treatment of these patients through the federal Medicare and Medicaid programs, providing some of the funding needed to meet our expenses.

4. Approximately 50% of our total operational revenues come from the Centers for Medicare and Medicaid Services (CMS). This is a huge portion of our income.

5. I have been an administrator for county nursing homes for the past 21 years. I can tell you that rural county nursing homes have faced enormous challenges over the last few years, even before the advent of COVID-19. We have been watching our reserves diminish rapidly because our expenses have overrun our revenues. Since January 2019, our reserves have decreased by 65%. We have had to dip into our reserves in order to meet expenses. For example: over the past three years, minimum wage has increased 33% while our state Medicaid reimbursement increased 1.3%. We are facing a workforce shortage like never before, and not just in nursing. The shortage of nursing staff has caused us to lean heavily "Agency Staffing". Contracting with agency staffing means instead of paying $15 dollars an hour aide,we are charged $40-50 an hour for a Certified Nurses Aide. We are having to pay licensed nurses $65 an hour as compared to about $22 an hour. In the recent 12 month period we have paid $385,000 to Agency Staffing because we had not been able hire enough of our own. If the vaccination mandate is imposed we will lose more staff, struggle to fill those vacancy spots with agency staffing, causing even more financial hardship. Furthermore agency staffing does not have enough staffing for the absence of nurses who are not willing to be vaccinated. We will be facing a huge problem! Without adequate staff we simply cannot take care of our residents. Another

challenge is finding qualified workers. In our rural areas, the pool of qualified workers for specific skills and knowledge is much smaller than the lon-rural areas. We face immense difficulties filling "key", "essential" positions.

6. On November 4, 2021 I received an emergency update notice from the Missouri Department of Health and Human Services. This notice informed us that the Biden-Harris administration issued an emergency regulation mandating that all nursing home staff be fully vaccinated by January 4, 2022 . Furthermore, facilities who failed to ensure ALL staff were vaccinated could no longer be eligible for reimbursement under the Medicare and Medicare programs. The impact of this emergency regulation will have dramatic and devastating consequences.

7. Out of about 65 employees, about 20 employees tell me they are vehemently opposed to taking the vaccine and if the CMS mandate is indeed imposed, they will quit working at SCCC. If that happens, I will lose about 30% of my workforce. If I lose 30% of my workforce, there is no way we can continue to operate.

8. I stand to lose key people who are the foundation of our organization. My billing and accounting person will leave if they are required to get the vaccine. I would have substantial disruption in my billing and accounts receivable which would cause a level of financial distress that I fear we could not overcome. My building plant manager says he will not be forced into taking the vaccination, even if that means losing his job. That would leave me with no one competent enough

to run my building and all the complicated systems and required inspections. You just can't fill these kinds of positions quickly, especially with today's workforce and being in a rural setting.

9. While the intent of this emergency regulation may be to protect our elederly nursing home residents, I fear the result of this regulation may actually create more harm. We could not continue to operate our facility with 30% decrease in our workforce. We would be forced to close our doors and displace the residents who enjoy residing in the Scotland County Care Center and who desire to live in the community where they have lived their entire lives.

Pursuant to 28 U.S.C. 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 10 day of November, 2021.

Tim Schrage
Administrator, Scotland County Care Center

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. 4:21-cv-01329

DECLARATION OF VALERIE HUHN, ACTING DIRECTOR, MISSOURI DEPARTMENT OF MENTAL HEALTH

1. My name is Valerie Huhn and I am the Acting Director of the Missouri Department of Mental Health ("DMH"). I am also a resident of the State of Missouri and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. DMH is a state agency that serves approximately 170,000 Missourians annually through state-operated facilities and contracts with private organizations and individuals.

3. DMH operates six psychiatric facilities, which provide inpatient psychiatric services for adults and children. These facilities are certified by the Center for Medicare and Medicaid Services ("CMS") as psychiatric treatment facilities for the purpose of receiving reimbursement from CMS.

4. These six facilities receive reimbursement from CMS to cover the

cost of inpatient and residential psychiatric treatment for individuals who are Medicaid and/or Medicare eligible.

5. As certified hospitals, these facilities must comply with CMS Conditions of Participation in order to be reimbursed for treatment costs and disproportionate share costs.

6. The Center for Behavioral Medicine is a 65-bed facility in Kansas City, Missouri. There are currently approximately 281 employees. Based on the most recently available information, only 34.6% of the staff at the Center for Behavioral Medicine are fully vaccinated.

7. Fulton State Hospital is a 449-bed facility in Fulton, Missouri. There are currently approximately 857 employees. Based on the most recently available information, 63% of the staff at the Fulton State Hospital are fully vaccinated.

8. Northwest Missouri Psychiatric Rehabilitation Center is a 108-bed facility in St. Joseph, Missouri. There are currently approximately 250 employees. Based on the most recently available information, 52.6% of staff at Northwest Missouri Psychiatric Rehabilitation Center are fully vaccinated.

9. Southeast Missouri Mental Health Center is a 323-bed facility in Farmington, Missouri. There are currently approximately 878 employees. Based on the most recently available information, 60.3% of staff at Southeast Missouri Mental Health Center are fully vaccinated.

10. St. Louis Forensic Treatment Center is a 230-bed facility in St. Louis, Missouri. There are currently approximately 524 employees. Based on the most

recently available information, 67.6% of staff at St. Louis Forensic Treatment Center are fully vaccinated.

11. Hawthorn Children's Psychiatric Hospital is a 28-bed inpatient psychiatric hospital and a 16-bed psychiatric residential treatment facility that provides inpatient and residential services to children and youth. There are currently approximately 170 employees. Based on the most recently available information, 84.7% of staff at Hawthorn Children's Psychiatric Hospital are fully vaccinated.

12. Additionally, DMH operates six habilitation centers, which provide 24-hour accommodation, board, personal care, active treatment, and basic health and nursing care services to individuals with developmental disabilities. These facilities are certified by CMS as Intermediate Care Facilities for Individuals with Intellectual Disabilities ("ICF/IID") for the purpose of receiving reimbursement from CMS.

13. These six facilities receive reimbursement from CMS to cover the cost of services for individuals with developmental disabilities and intellectual disabilities.

14. As certified ICF/IIDs, these facilities must comply with CMS Conditions of Participation in order to be reimbursed for treatment costs and disproportionate share costs.

15. Bellefontaine Habilitation Center is a 133-bed facility in St. Louis, Missouri. There are currently approximately 337 employees. Based on the most

recently available information, 63.8% of staff at Bellefontaine Habilitation Center are fully vaccinated.

16. Higginsville Habilitation Center is a 40-bed facility in Higginsville, Missouri. There are currently approximately 168 employees. Based on the most recently available information, 65.4% of staff at Higginsville Habilitation Center are fully vaccinated.

17. St. Charles Habilitation Center is a 72-bed facility in St. Charles, Missouri. South County Habilitation Center is a 72-bed facility in St. Louis, Missouri. Together, they are currently approximately 326 employees. Based on the most recently available information, 43.9% of staff at St. Charles Habilitation Center are fully vaccinated and 55.1% of staff at South County Habilitation Center are fully vaccinated.

18. SEMO Residential Services has two locations – a 35-bed facility in Poplar Bluff, Missouri and a 25-bed facility in Sikeston, Missouri. There are currently approximately 171 employees. Based on the most recently available information, only 29.6% of staff at the Poplar Bluff location are fully vaccinated and 41.4% of staff at the Sikeston location are fully vaccinated.

19. All twelve DMH facilities and their patients will be directly affected by the interim rule with comment period ("IFC") that Plaintiff States have challenged in this case.

20. In Fiscal Year 2021, 89 % of DMH's budget was funded with CMS federal funding from Medicaid/Medicare and Disproportionate Share payments.

21. As of September 2021, DMH's Division of Behavioral Health hospitals had a registered nurse vacancy rate of 35% and a 54% vacancy rate for licensed practical nurses. The overall vacancy rate for paraprofessionals within the Division of Behavioral Health hospitals was 28%. Within DMH's Division of Developmental Disabilities, the direct care vacancy rate ranges from 11% at St. Louis Developmental Disabilities Treatment Center to 50% at Higginsville Habilitation Center.

22. The loss of additional employees will cause significant difficulty in the continued operation of DMH facilities. Even if a small percentage of DMH's workforce is lost because of the vaccine mandate, operations will be negatively impacted.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 12th day of November, 2021.

Valerie Huhn
Acting Director, Missouri Department of Mental Health

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. 4:21-cv-01329

DECLARATION OF ABIGAIL CYBORON

1. My name is Abigail Cyboron, and I am the Chief Executive Officer of Chase County Community Hospital in Imperial, Nebraska. I am also a resident of the State of Nebraska and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. Chase County Community Hospital will be directly affected by the interim final rule with comment period (IFC) that Plaintiff States have challenged in this case.

4. Chase County Community Hospital is a small rural hospital.

5. Chase County Community Hospital is a critical access hospital.

6. Chase County Community Hospital is licensed for 15 Medicare/Medicaid beds.

7. Chase County Community Hospital's average daily census is 1.6 (this does not include the following patients in swing beds, emergency room, extended emergency room, observation or outpatient surgery recoveries). Our average Medicare acute length of stay is

2.69 days and our average length of stay for swing bed patients is 8.94 days.

8. Chase County Community Hospital receives 64% or $8,079,621 of its annual net revenue/funding from Medicare and/or Medicaid reimbursements.

9. Chase County Community Hospital provides the following patient care: 24/7 emergency room, 24/7 hospital nursing floor, surgeries, radiology exams (CT/MRI/ultrasound/mammography/DXA/nuclear medicine), laboratory tests, physical therapy, respiratory therapy, cardiac rehabilitation, cardiac stress tests, endoscopic procedures, infusion/oncology, joint injections, diabetic education/support, specialty clinic providers and a Rural Health Clinic.

10. Chase County Community Hospital serves a patient population base of four thousand people within a geographic area of three counties.

11. Chase County Community Hospital employs 103 total staff, including 68 health care/clinical/practitioner staff.

12. Chase County Community Hospital is currently experiencing a workforce shortage of health care staff with eight vacancies (this does not include three non-clinical openings that are also difficult to fill). These eight clinical vacancies include one physician (open for the last ten months), three nursing floor registered nurses (open for 12+ months each), one laboratory technologist (open for 18 months), one and one-half radiology technologists (open 13 months), one clinical licensed practical nurse (open for one month), and one-half infection control registered nurse (open six months). These positions are extremely difficult to fill due to the shortage of healthcare staff, our remote location, and the already overburdened health care workforce. We count on traveling health care workers to staff our schedules in nursing, laboratory and radiology. We are currently paying a traveling registered nurse $150

per hour which still leaves us short by two registered nurses. We are having an extremely hard time covering our scheduled shifts due to these shortages. Our current staff is picking up the extra shifts and they are burning out. We have even provided retention bonuses for current healthcare staff along with shift incentives and paying extra money when uncovered shifts are picked up. We are already functioning at a crisis mode, if we lose even one nurse, radiology technologist or laboratory technologist due to this mandate, our 24/7 nursing floor and emergency room services could collapse.

13. Amongst the 103 Chase County Community Hospital's employees, 49 are known to have not or are reasonably believed to have not received a COVID-19 vaccine.

14. Chase County Community Hospital stands to lose ten of its total employees including seven clinical personnel as a result of implementation of the CMS vaccine mandate in the IFC challenged by Plaintiff states in this case.

15. The patients served by Chase County Community Hospital will be affected by this mandate. Our facility is required to be staffed with at least one registered nurse 24/7. If we are unable to, at a minimum, maintain our staffing we may not be able to provide our emergency room services along with nursing floor services. Our laboratory and radiology departments are also needed to support the 24/7 services that our hospital provides so if they are also unable to maintain staffing levels, we won't have these services either. One of the most important jobs we have in our rural area is to provide emergent services. If someone is having a heart attack or a stroke, they may not make it to the other critical access hospital down the road 30 miles. This is assuming the critical access hospital 30 miles away is going to be able to keep their services going. During these surges of COVID we have also struggled terribly getting bed acceptance at larger facilities which has forced us to keep higher level

acuity patients in our facility. This has added additional pressure on all of our health care staff. Again, if we lose any staff, we may not be able to keep these key services going.

16. The healthcare industry has certainly experienced a tremendous amount of pressure brought on by COVID over the last two years. These circumstances have created an environment where it is more difficult to hire and maintain health care staff. The healthcare industry cannot sustain a mandate with this much impact at this time. This mandate will most certainly create disparities in care quality and access here in our rural community. Our healthcare staff fights hard and will continue to fight to provide excellent care for our community but they are reaching a breaking point.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 12th day of November, 2021.

Abigail Cyboron, CEO
Chase County Community Hospital

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. 4:21-cv-01329

DECLARATION OF BRETT EGGLESTON

1. My name is Brett D. Eggleston, and I am the Chief Executive Officer of Callaway District Hospital and Medical Clinics in Callaway, Nebraska. I am also a resident of the State of Nebraska and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. Callaway District Hospital and Medical Clinics will be directly affected by the CMS vaccine mandate that Plaintiff States have challenged in this case.

4. Callaway District Hospital is a small rural hospital.

5. Callaway District Hospital is a critical access hospital.

6. Callaway District Hospital and Medical Clinics operates two rural health clinics located in Custer County, Nebraska.

7. Callaway District Hospital and Medical Clinics is licensed for twelve Medicare/Medicaid beds.

8. Callaway District Hospital and Medical Clinics' average daily census is 1.25 inpatients, 1 swing bed, 22.77 outpatients, 36.8 clinic patients, and 1.93 emergency patients.

9. Callaway District Hospital and Medical Clinics receives approximately 70% of its annual revenue / funding from Medicare and/or Medicaid reimbursements.

10. Callaway District Hospital and Medical Clinics provides inpatient and outpatient hospital care, emergency department, laboratory, radiology, mammography, outpatient specialty, outpatient endoscopy/coloscopy, outpatient geriatric psychiatry and outpatient primary care services.

11. Callaway District Hospital and Medical Clinics serves a primary geographic area of our 694 square mile hospital district. Additionally, more than 50% of patients travel to Callaway District Hospital and Medical Clinics from outside our hospital district boundaries. Many patients travel thirty to sixty miles to access healthcare services.

12. Callaway District Hospital and Medical Clinics employs a staff of sixty-five people.

13. Callaway District Hospital and Medical Clinics is currently experiencing a workforce shortage of health care staff with 4 hospital nursing vacancies. These positions have been open for greater than 6 months.

14. Amongst Callaway District Hospital and Medical Clinics' employees, 30% are known to have not or are reasonably believed to have not received a COVID-19 vaccine. This includes 5 Clinic Registered Nurses, 1 Clinic Office Support Staff, 5 Hospital Registered Nurses, 1 Hospital Licenses Practical Nurse, 1 Hospital Certified Nursing Assistant, 3 Hospital Office Support Staff, 1 Environmental Services Tech, 1 Laboratory Technician, and 2 Radiology Technologists.

15. Callaway District Hospital and Medical Clinics stands to lose 30% of our total staff as a result of implementation of the CMS vaccine mandate in the IFC challenged by Plaintiff states in this case.

16. The projected loss of approximately 30% of our staff as a result of implementation of the CMS vaccine mandate will almost certainly lead to closure of our facility.

17. Closure of Callaway District Hospital and Medical Clinics would leave our rural community without essential healthcare services.

18. Based on my 5 years of experience in rural health care and 3 years as CEO of Callaway District Hospital and Medical Clinics, it is my reasoned opinion that the CMS vaccine mandate threatens rural healthcare infrastructure not only in Custer County but throughout Nebraska.

19. Callaway District Hospital and Medical Clinics is the largest employer in Callaway, Nebraska with an annual payroll of $4 million. Callaway District Hospital & Medical Clinics is a significant driver of the local business and agriculture economy.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 11th day of November, 2021.

Brett D. Eggleston, MHA

Brett D. Eggleston, MHA Chief Executive Officer
Callaway District Hospital and Medical Clinics

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. 4:21-cv-01329

DECLARATION OF DON NAIBERK

1. My name is Don Naiberk, and I am the Administrator of Butler County Health Care Center in David City, Nebraska. I am also a resident of the State of Nebraska and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. Butler County Health Care Center will be directly affected by the CMS vaccine mandate that Plaintiff States have challenged in this case.

4. Butler County Health Care Center is a small rural hospital.

5. Butler County Health Care Center is a Critical Access Hospital.

6. Butler County Health Care Center is licensed for twenty (20) Medicare/Medicaid beds.

7. Butler County Health Care Center receives fifty four percent (54%) of twenty million two hundred fifteen and sixty dollars ($20,215,060) of net annual revenue from

Medicare and Medicaid reimbursements.

8. Butler County Health Care Center provides patient care as a Critical Access Hospital in David City Nebraska.

9. Butler County Health Care Center serves a patient population base of approximately nine thousand five hundred people in our service area which covers almost six hundred (600) square miles.

10. Butler County Health Care Center employs one hundred and thirty four (134) total staff. This includes seventy five (75) clinical staff and fifty nine (59) nonclinical staff. Butler County Health Care Center does not employee any Physicians/APP's, but there are five physicians and two physician's assistants that practice in the community and are part of the Butler County Health Care Center active medical staff.

11. Butler County Health Care Center is currently experiencing a workforce shortage of health care staff with vacancies for registered nurses and medical laboratory technologists. Recruitment efforts to fill the needs in these two areas have been unsuccessful for almost three months. Butler County Health Care Center has relied upon prior CMS rules that did not require COVID-19 vaccination for hiring staff.

12. Amongst Butler County Health Care Center's employees, fourteen percent (14%) are known to have not or are reasonably believed to have not received a COVID-19 vaccine. This includes fourteen percent (14%) of the nursing staff and sixty six percent (66%) of the laboratory staff. The active medical staff of Butler County Health Care Center has forty three percent (43%) of its members that are not vaccinated. This includes forty three percent (43%) of those that provide medical services in the emergency department, and sixty six percent (66%) of physicians that provide obstetric services at Butler County Health Care

Center.

13. Butler County Health Care Center is aware of the potential for medical and religious exemptions under federal law. It is with this awareness that Butler County Health Care Center projects to lose seven percent (7%) of its total staff if implementation of the CMS vaccine mandate occurs. This has been determined through surveying the current staff that is unvaccinated, and determining who might be seeking an exemption and those that do not intend to get vaccinated or seek an exemption.

14. The loss of seven percent (7%) of the total staff of Butler County would make it very difficult to continue operations. The unemployment rate in Butler County and surrounding areas is very low, and all health care facilities are struggling to find staff prior to this mandate. The vaccine mandate would prevent Butler County Health Care Center from providing consistent emergency department services, obstetric services, laboratory services, and acute nursing care.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 12th day of November, 2021.

Donald T. Naiberk, CEO
Butler County Health Care Center

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. 4:21-cv-01329

DECLARATION OF ERIC BARBER

1. My name is Eric Barber, and I am the President and Chief Executive Officer of Mary Lanning Healthcare in Hastings, Nebraska. I am also a resident of the State of Nebraska and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. Mary Lanning Healthcare will be directly affected by CMS vaccine mandate that Plaintiff States have challenged in this case.

4. Mary Lanning Healthcare is a general acute hospital.

5. Mary Lanning Healthcare is licensed for 164 Medicare/Medicaid beds.

6. Mary Lanning Healthcare's average daily census is 85

7. Mary Lanning Healthcare receives approximately 55% of its annual revenue from Medicare and/or Medicaid reimbursements.

8. Mary Lanning Healthcare provides patient care in OB/GYN, NICU,

Cardiology, Neurosurgery, Orthopedics, Emergency Services, Neurology, Urology, Medical Oncology, Radiation Oncology, General Surgery, Psychiatry and Rehabilitation.

9. Mary Lanning Healthcare serves a patient population base of over 100,000 people within a geographic area of approximately 2500 square miles.

10. Mary Lanning Healthcare employs 1,245 total staff, including health care, clinical, physicians and advanced practitioners.

11. Mary Lanning Healthcare is currently experiencing a workforce shortage of health care staff with 42 RN vacancies and a total vacancy of 99.

12. Amongst Mary Lanning Healthcare's employees, 283 are known to have not or are reasonably believed to have not received a COVID-19 vaccine and 56 of those are RN's working in critical care areas.

13. Mary Lanning Healthcare stands to lose hundreds of employees as a result of implementation of the CMS vaccine mandate in the IFC challenged by Plaintiff states in this case.

14. The patients served by Mary Lanning Healthcare will suffer as a result of these staffing shortages and will likely have to try and find care elsewhere. Mary Lanning Healthcare will be forced to make decisions regarding closure of departments, reduction of services, inability to accept patients, increased wait times for services, inability to staff beds, and is already experiencing an inability to transfer patients to alternative hospitals facing similar staffing challenges.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 11 day of November, 2021.

Eric Barber, President & CEO
Mary Lanning Healthcare

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. 4:21-cv-01329

DECLARATION OF JASON PETIK

1. My name is Jason Petik, and I am the Chief Executive Officer of Sidney Regional Medical Center in Sidney, Nebraska. I am also a resident of the State of Nebraska and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. Sidney Regional Medical Center will be directly affected by the interim final rule with comment period (IFC) that Plaintiff States have challenged in this case.

4. Sidney Regional Medical Center is a small rural hospital.

5. Sidney Regional Medical Center is the 2nd Largest Critical Access Hospital System in the State of Nebraska and the nearest like level of services are 45 miles to the south or 90 miles to the north.

6. Sidney Regional Medical Center is licensed for 25 Acute Care Medicare/Medicaid beds. 63 Bed Long Term Care, 28 Beds Assisted Living, and a Rural Health Clinic.

7. Sidney Regional Medical Center's acute care average daily census is 9 Acute, 70 percent occupancy in Long Term Care, 60 percent in Assisted Living, and an average of 75 people through the Rural Health Clinic daily.

8. Sidney Regional Medical Center receives 58 percent of 61 million dollars of net annual revenue/ $35 million of Medicare and Medicaid reimbursements.

9. Sidney Regional Medical Center provides patient care in the Clinic, Radiology, Lab, Speech/Occupational/Physical Therapy, Dietitian Services, Orthopedic Surgery, General Surgery, Trauma Services, Urology Services, Acute Care, ICU Care, IV Therapy (chemo), Emergency Care, Long Term Care, Assisted Living.

10. Sidney Regional Medical Center serves a patient population base of approximately 15,000 people in our service area which covers over 9 Nebraska and 2 Colorado counties, 8,100 square miles.

11. Sidney Regional Medical Center employs 392 total staff, 22 Physician/APPs, 226 other clinical and 147 nonclinical.

12. Sidney Regional Medical Center is currently experiencing a workforce shortage of health care staff with the following vacancies: 1- Central Sterile Tech, 1-Certified Pharm Tech, 3- Cooks, 1- Housekeeper, 4- Patient Account Specialist, 5+- LTC Nurse Aides, 6+- RNs, 1- Respiratory Therapist, 3- Surgical Techs, and 1- Radiology Tech. These positions range in length of vacancies from 3-7 months. Currently there are no contracting companies able to fill our needs as well. Currently we are using 9 Contract employees to cover RN,

Surgical RN, Respiratory Therapist, Surgical Tech, and Speech Therapist positions. We have been attempting to hire health care staff to fill these vacancies without regard vaccination status in reliance upon prior CMS rules.

13. Amongst Sidney Regional Medical Center's employees, 44 percent are known to have not or are reasonably believed to have not received a COVID-19 vaccine. This is representation across all departments at Sidney Regional Medical Center.

14. Sidney Regional Medical Center stands to lose 5-10 percent or 18-39 of its total employees. The main number of losses will probably come from Certified Nurses Assistants, RNs, Therapists, and Pharmacist as a result of implementation of the CMS vaccine mandate in the IFC challenged by Plaintiff states in this case. We have already lost a RN due to the mask mandate. This loss is projected with our awareness of the religious or medical exemptions which may be sought under federal law.

15. Rural communities like Sidney are challenged in many ways to provide quality health care. The most prevalent one is staffing. Recruitment and retention are our two biggest challenge. Base on my experience as a hospital administrator, it is my reasoned opinion that if this Mandate is upheld, SRMC will be put in an almost impossible position to provide the same level and quality of services.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the _12_ day of November, 2021.

Jason Petik, CEO
Sidney Regional Medical Center

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al.,

Plaintiffs,

v.

JOSEPH R. BIDEN, JR., et al.,

Defendants.

No. 4:21-cv-01329

DECLARATION OF KYLE KELLUM

1. My name is Kyle Kellum, and I am the CEO of Cherry County Hospital in Valentine, Nebraska. I am also a resident of the State of Nebraska and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. Cherry County Hospital will be directly affected by the interim final rule with comment period (IFC) that Plaintiff States have challenged in this case.

4. Cherry County Hospital is a small rural hospital.

5. Cherry County Hospital is a critical access hospital.

6. Cherry County Hospital is licensed for 21 Medicare/Medicaid beds.

7. Cherry County Hospital's current average daily census is 6.66

8. Cherry County Hospital currently receives 23% Medicare funding and 9% Medicaid funding of total reimbursements.

9. Cherry County Hospital provides patient care including, but not limited to, primary care, emergency care, obstetrics with C-sections, dialysis, physical therapy, home health, orthopedics, podiatry, cardiology, imaging and laboratory services, general surgery, urology, pain management, neurology, etc. Cherry County Hospital performs and employs our own billing/coding services, dietary/environmental/maintenance personnel to support our clinical teams. Although this is a portion of our team, it is certainly not all-inclusive or a full representation of the services provided to our community and beyond.

10. Cherry County Hospital serves a patient population made up of a primary and secondary services area base of twenty-one thousand people throughout nineteen different zip codes.

11. Cherry County Hospital employs 159 total staff, including 4 providers, 116 clinical staff, and 39 non-clinical staff.

12. Cherry County Hospital is currently experiencing a workforce shortage of health care staff with, at minimum, 18 position vacancies; however, with the difficulties in recruitment, we hire nursing and ambulance staff as we are able regardless of an open vacancy. These positions include the following areas: nursing (3+), laboratory (2), radiology (1), clinic (3), environmental services (2), dietary (1), pharmacy (1), dialysis (1), nursing leadership (1), ambulance (2+), and provider (1). Being in a remote area is very challenging for recruitment. As an example, we have had a laboratory manager position open for over one year, nursing positions open for multiple years due to the shortage of the nursing field, and a family practice physician opening for greater than two years.

13. Amongst Cherry County Hospital's employees, 66 are known to have not or are reasonably believed to have not received a COVID-19 vaccine. This comes from the

following departments:

a. Primary Care Clinic – 8
b. Nursing – 23 staff
c. Surgery – 5 staff
d. Radiology – 3 staff
e. Dialysis – 3 staff
f. Pharmacy – 1
g. Laboratory – 2
h. Maintenance – 1
i. Medical Records/Coding/Billing/Registration – 7
j. Environmental Services – 2
k. Ambulance – 10
l. Therapy – 1

14. Cherry County Hospital stands to lose 50 employees from all areas of the organization, including 8 additional who are currently undecided. As a result of implementation of the CMS vaccine mandate in the IFC challenged by Plaintiff states in this case, Cherry County Hospital stands to lose 39 clinical employees (RN's, radiology and lab techs, providers, etc.) and 11 non-clinical employees (environmental services, billing, coding, and other support areas).

15. The patients served by Cherry County Hospital will have the following negative consequences on their healthcare or the services provided by the Hospital and Clinic as a result of the additional loss of Hospital employees:

a. Loss of the only employed physician in the primary care clinic
b. Loss of all but two clinical staff in the primary care clinic
c. Loss of billing and coding staff in the primary care clinic (with these losses combined, patient access to care would decrease from 25 days for a new appointment to greater than 45 days for a new appointment and risks

closure)

d. Reduction in available laboratory services due to minimal staff
e. Reduction in radiology services due to minimal staff
f. Reduction in physical therapy services due to minimal staff
g. Loss of highly skilled charge nurses, RN's, LPN's, CNA's on the floor decreasing the ability to staff beds
h. Loss of medical records staff which ensure safe transport of medical records for patients needing a higher level of care
i. Loss of billing staff therefore revenue is not able to be collected timely and leads to denials in payment from timely filing requirements
j. Loss of two environmental services staff, which makes keeping a clean and safe environment for our patients impossible and puts the burden of cleaning rooms for new patients on the one remaining staff member as well as on the nursing team. As an organization, we also do all laundry in-house as there are not contracted services in our small community to be able to take this on. This results in an inability to keep up with proper PPE methods and reduces the number of services we can provide as an organization.
k. With the loss of providers and skilled RN's, the community and beyond suffers from the loss of OB and both planned and emergency C-section delivery. We deliver over 110 babies per year and are the closest hospital in our area for such services. This will, without a doubt, result in poor outcomes for mom and newborn.
l. Loss of Home Health as this team would be pulled to help assist on the med/surg area as well as the emergency room.
m. Loss of Dialysis department. This is a critical need in our community and any remaining staff would be pulled to assist on med/surg area as well as the emergency department.
n. Loss of surgery personnel leading to a dramatically limited ability to perform the needed surgical (both elective and emergent) surgeries on patients.
o. Loss of ambulance volunteers/staff. This results in an inability to respond

to calls due to an already thin number of skilled personnel.

p. Loss of emergency department providers.

q. Loss of the chemotherapy department as this team would be pulled to help assist on the med/surg area as well as the emergency room.

r. Loss of cardiac rehabilitation as this team would be pulled to help assist on the med/surg area as well as the emergency room.

s. Loss of many of the remaining staff members who have already voiced they will seek employment elsewhere due to no relief and a heavy workload they would entail.

t. All of this combined, may lead to a closure of Cherry County Hospital as we will not have the staff to care for the patients, the staff to bill for the services, and the staff to keep a sanitary environment.

16. As the CEO of the organization, I cannot express the extent of what is about to happen. Healthcare in this community and beyond (we service the largest county in the State of Nebraska and into South Dakota) will never look the same. Patients will not have the primary care services needed to stay healthy, will not have the staff to care for them in an emergency, and will not have an ambulance service to respond to calls in an emergent manner. Cherry County Hospital is a leader of employment for our county; residents will be forced to move away to support their families resulting in a dramatic impact to the local economy. Very highly skilled providers, nurses, ancillary, and support personnel will walk away from healthcare for good; this is not a maybe, this is an absolute. Patients needing life saving measures such chemotherapy, cardiac rehabilitation, and dialysis (to name a few), will need to drive a minimum of two and three hours to receive the same services they are receiving locally today. This, however, is assuming the overburdened healthcare system in those organizations two and three hours away have the capacity to accept them as patients; which they will not be able to do so. I simply cannot put into words what this mandate will do to our community and

our healthcare system. As the CEO, I am proud of our organization; I see the good and necessary work happening every day and night. This is not a matter of if all of the above will occur should this mandate go through; this is a matter of it will begin occurring in December and increase exponentially by January 4th, 2022.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 12 day of November, 2021.

Kyle Kellum, CEO
Cherry County Hospital

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. 4:21-cv-01329

DECLARATION OF LARRY KAHL

1. My name is Larry Kahl, and I am the Chief Operating Officer for the Nebraska Department of Health and Human Services ("the Department"). I am also a resident of the State of Nebraska and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. According to licensure data maintained by the Department's Division of Public Health, there are a total of 702 federally certified providers and suppliers within the state of Nebraska that are directly regulated by the CMS Interim Final Rule with Comment Period ("IFC") challenged by Plaintiff States in this case. These providers and suppliers are comprised of: fifty Ambulatory Surgical Centers, 35 hospices, five Psychiatric residential treatment facilities (PRTFs), one Program of All-Inclusive Care for the Elderly (PACE), 42 hospitals, 196 long-term care facilities, 13 intermediate care facilities for individuals with intellectual disabilities (ICFs-IID), 67 home health agencies (HHAs), 63 critical access hospitals (CAHs),

six outpatient physical therapy and speech-language pathology clinics, 145 rural health clinics (RHCs), 39 federally qualified health centers (FQHCs), and 40 end-stage renal disease (ESRD) facilities.

4. According to licensure data maintained by the Department's Division of Public Health, nine assisted living facilities and 20 nursing homes in rural Nebraska have closed since January 1, 2019. Therefore, the infrastructure for services at nursing homes is currently reduced within the State.

5. According to the Department's Division of Medicaid and Long-Term Care, the State of Nebraska receives approximately $223,000,000 to $228,000,000 in Federal Financial Participation per state fiscal year for Nebraska's approximately 200 nursing facilities for long term care non-acute stays. The State of Nebraska reimbursed Nebraska hospitals approximately $346,798,356.00 Medicaid funds for State Fiscal Year 2021. These funds are used to reimburse the above facility types for Medicaid covered care and services.

6. According to publicly available data reported by nursing homes to the CDC's National Healthcare Safety Network COVID-19 Long Term Care Facility Module maintained by the Centers for Medicare and Medicaid at https://data.cms.gov/covid-19/covid-19-nursing-home-data, as of October 24, 2021, 101 of the 196 nursing homes in Nebraska (51.8%) had staff vaccination rates under 75%. 24 of the nursing homes (12.3%) had staff vaccination rates under 50%, and 77 of the nursing homes (39.4%) had staff vaccination rates between 50% and 75%.

7. According to the Nebraska Center for Nursing, a Department-supported entity created by Nebraska statute to alleviate the state's nursing shortage, the current nursing shortage in the State of Nebraska is 4,192 and is projected to increase to 5,436 by 2025. This

shortage is particularly acute in rural areas, with eleven rural Nebraska counties having no Registered Nurses and nine rural Nebraska counties having no Licensed Practical Nurses. The Nebraska Center for Nursing's 2020 biennial report is found at https://center4nursing.nebraska.gov/data.

8. The State of Nebraska operates various state-run healthcare providers and suppliers such as a state psychiatric hospital and state ICFs-IID, as well as numerous state employees that will be directly affected by the IFC that Plaintiff States have challenged in this case.

9. The Department operates a psychiatric hospital, Lincoln Regional Center in Lincoln, Nebraska which expended $1,435,482.00 in federal Medicaid and Medicare funding in state fiscal year 2021. The Department has calculated and expects a similar federal Medicaid and Medicare reimbursement for state fiscal year 2022. The vaccination rate of Lincoln Regional Center staff is 70% as of November 8, 2021.

10. The Department operates Beatrice State Developmental Center ("BSDC") in Beatrice, Nebraska, a community of approximately 13,000 people. BSDC is a 24-hour state and federally funded residential treatment facility dedicated to the provision of specialized psychological, medical, and developmental supports to approximately ninety adults with intellectual and developmental disabilities requiring comprehensive, specialized support. The BSDC campus contains several nationally accredited Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF-IID). BSDC's total federal Medicaid and Medicare expenditure for State fiscal year 2021 was $16,813,708. Its total expenditures for State fiscal year 2021 was $26,926,596. Federal Medicaid and Medicare expenditure represented 62.44% of the total expended. The vaccination rate of BSDC staff is 62% as

of November 8, 2021.

11. The Department's Division of Public Health employs 89 individuals who work on programs funded by Medicare and Medicaid. Amongst these 89 employees are 61 surveyors who are responsible for conducting inspections and assessing compliance with state and federal regulations, including the CMS vaccine mandate should it become effective.

12. When the surveyors conduct inspections, they assess compliance with both federal and state regulations at the same time. As to federal regulations, if a facility is determined to be deficient, the Department sends the facility a "2567" form (violation report). The enforcement letter that accompanies the 2567 form, sent by DPH Staff, serves as notice of the facility's deficiencies and gives the facility a set period of time to correct the deficiencies. These surveys must be completed in order for facilities to continue to be certified for participation in Medicare and Medicaid.

13. Beginning on or about August 2021 the State of Nebraska attempted to hire unvaccinated health care workers to help staff its state-run facilities specifically relying upon prior CMS rules allowing this practice.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 12 day of November, 2021.

Larry Kahl, Chief Operating Officer
Nebraska Department of Health and Human Services

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al.,

Plaintiffs,

v.

JOSEPH R. BIDEN, JR., et al.,

Defendants.

No. _____

DECLARATION OF LORI MAZANEC

1. My name is Lori Mazanec, and I am the Chief Executive Officer of Box Butte General Hospital in Alliance, Nebraska. I am also a resident of the State of Nebraska and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. Box Butte General Hospital will be directly affected by the interim final rule with comment period (IFC) that Plaintiff States have challenged in this case.

4. Box Butte General Hospital is a small rural hospital.

5. Box Butte General Hospital is a critical access hospital.

6. Box Butte General Hospital is licensed for twenty-five Medicare/Medicaid beds.

7. Box Butte General Hospital's average daily census is currently 9.94 for the period July-October 2021 compared to 7.76 for the period July-October 2020; Fiscal Year

ending June 30, 2021 average daily census is 8.78.

8. Box Butte General Hospital provides patient care for all patient types - acute, surgical, observation, swing, intensive care and obstetrics and a variety of outpatient services, including: staffed 24-hour Emergency Department, complete Laboratory and Diagnostic Imaging (X-ray, CT, MRI, Nuclear Medicine, Mammography, Advanced Ultrasound Imaging, Bone Density/DEXA Scan); Diabetic Education, Dialysis, Oncology, Rehabilitation (including Cardiac Rehab, Occupational Therapy, Physical Therapy, Sports Medicine and Speech Therapy); Orthopedic Surgery (large joint, foot and ankle, spine, and hand and wrist), Gastroenterology, Urology, Respiratory Therapy, Electro Diagnostics, Surgery, Wound Care, and Behavioral Health. Additional services as part of a Multi-Specialty Clinic include Cardiology, ENT, General Surgery, Oral Surgery, and Podiatry. The hospital also has three Rural Health Clinics located in Alliance, Hemingford, and Hyannis.

9. Box Butte General Hospital serves a patient population base of over 78,000 people (26,800 primary service, 51,800 secondary service), all within a geographic area covering 10 panhandle counties (six counties primary service and four counties secondary service).

10. Box Butte General Hospital employs 289 staff, including 165 number of health care / clinical / practitioner staff.

11. Box Butte General Hospital is currently experiencing a workforce shortage of health care staff with 43 vacancies, including 29 of which are health care / clinical / practitioner staff positions, ranging from more recent openings to others that have been open since 2019 with no applications received. Current health care / clinical / practitioner openings include Hospitalist, Physician Assistant or Nurse Practitioner and Two Family Practice/OB

Physicians; 16 Nursing positions including Registered Nurses, LPNs, Nurse Assistants, Informatics Registered Nurse, Clinical Practice Education Nurse, Quality Data Registered Nurse, and Clinical Inpatient Nurse Manager; Two Phlebotomists; Two Physical Therapists and Therapy Technologist; Radiologic Technologist; Registered Respiratory Therapist; and Certified Occupational Therapy Assistant. Also, the Chief Financial Officer position has been vacant for five months with two rounds of separate candidates interviewed and not filled. Current barriers include the low unemployment rate in Nebraska, existing health care worker shortages prior to the COVID pandemic, role burnout, and challenges of the rural location. For the value level positions in dietary and environmental services, the ease of obtaining unemployment benefits outweighs the benefits of accepting job offers.

12. Amongst Box Butte General Hospital's employees, 42 percent are known to have not or are reasonably believed to have not received a COVID-19 vaccine with a wide range of positions including several health care / clinical / practitioner level. Known physicians, registered nurses, licensed practical nurses, laboratory technologists, senior leadership, nursing leadership among others across the organization are included in this percentage.

13. Box Butte General Hospital stands to lose 15 percent of its total employees from all across the organization, unfortunately. This mandate will not hit one single department, and includes key leadership positions in physicians, nursing, and even executive roles along with registered nurses, laboratory technologists, therapists, radiologic technologists, and many other non-clinical positions. This impacts nearly all Hospital departments including the Emergency Department, Infusion, Laboratory, Patient Care Unit, Ultrasound, Occupational Therapy, Operating Room, Environmental Services, Dietary

Services, Plant Services, Information Technology, Behavioral Health, Dialysis, Wellness Center, and Clinic Services as a result of implementation of the CMS vaccine mandate in the IFC challenged by Plaintiff states in this case.

14. The patients served by Box Butte General Hospital will have the following negative consequences on their healthcare or the services provided by the Hospital as a result of the additional loss of Hospital employees: closure of departments, reduction of services, inability to accept patients and/or staff beds, increased wait times for services, need to access care possibly outside of state lines, dramatic increase in our inability to transfer to alternative hospitals, or even loss of services altogether.

15. The effects of this mandate will have ongoing ripple effects on the Hospital, its patients, remaining employees, and community for some time in the future. With anticipated limited service offerings, remaining employees will experience an even greater amount of burnout, ultimately risking their own health and likelihood, they, too, will leave health care. They will be forced to work extended hours, take significant call hours and shifts, resulting in a risk in patient safety. Not to mention the burden of ensuring all those individuals the hospital contracts with are vaccinated before entering the facility. The ultimate goal of the vaccine mandate, per CMS, is to keep patients safe. Patients are and will continue to be safe in our hospital whether our team is vaccinated or not vaccinated. The current rate of eligible individuals vaccinated in the Nebraska Panhandle is 40 percent. Patients are not coming to the hospital for services and becoming ill with COVID. Patients seek care when sick with COVID and our teams provide the highest level of care and excellence with or without vaccinations. The authority for the COVID pandemic guidelines has been left with the states to govern. It should and needs to continue to remain at the state level.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 11th day of November, 2021.

Lori Mazanec
Box Butte General Hospital

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. 4:21-cv-01329

DECLARATION OF MEL McNEA

1. My name is Mel McNea, and I am the Chief Executive Officer of Great Plains Health in North Platte, Nebraska. I am also a resident of the State of Nebraska and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction

3. Great Plains Health will be directly affected by the CMS vaccine mandate that Plaintiff States have challenged in this case.

4. Great Plains Health is a general acute hospital that serves a patient population base of 136,000 lives and approximately 67,832 square miles, about the size of the state of Pennsylvania. With nearly 100 physicians representing 30 medical specialties, the Great Plains Health system offers advanced medical services, including heart and vascular, cancer, orthopedic services, women's services, a level III trauma center, a level II neonatal intensive

care unit, and one of just two behavioral health units in western Nebraska.

5. Great Plains Health is licensed for 116 Medicare/Medicaid beds.

6. Great Plains Health's average daily census is 56.3

7. Great Plains Health receives 62% funding from Medicare and/or Medicaid reimbursements.

8. Great Plains Health employs 1197 total staff, including 772 clinical staff.

9. Great Plains Health is currently experiencing a workforce shortage of health care staff with 231 vacancies consisting of: 88 vacancies for Registered Nurses and Licensed Practical Nurses, nine vacancies for Advanced Practice Providers, three vacancies for respiratory therapists, 13 diagnostic imaging vacancies, and seven lab vacancies. In attempting to fill these types of vacancies we relied upon prior CMS rules that did not mandate vaccination.

10. Great Plains Health has a 75% compliance rate for staff vaccinations to COVID-19, however, 311 are known to have not be vaccinated. Based on direct conversations with staff or their supervisors it is my reasonable belief that Great Plains Health stands to lose a high percentage of these unvaccinated employees as a result of the CMS vaccine mandate.

11. As a result of the likely loss of a significant number of staff because of the vaccine mandate, including the loss of the only remaining employed anesthesiologist, the patients served by Great Plains Health will experience a number of negative effects on their ability to receive health care including a dangerously reduced number of staffed ICU beds, a reduced ability to obtain timely surgeries or surgery all together due to loss of an anesthesiologist and nursing staff, reduced ability of Great Plains Health to provide cardiac stenting, and an inability to receive forensic sexual assault exams due to loss of SANE-

qualified nurses.

12. Great Plains Health's behavioral health unit which maintains the ability to treat nineteen patients will prospectively need to close or reduce services as most of the clinical staff within this unit is currently not vaccinated. This will leave only nine available behavioral health beds available at Regional West Medical Center in Scottsbluff, Nebraska which is nearly three hours away and itself facing staffing concerns.

13. Great Plains Health maintains that the CMS rule should better align with the OSHA ETS that allows for unvaccinated individuals to produce a negative test weekly. With our enhanced precautions we have in place currently, allowing this alternative to a vaccine mandate would not sacrifice patient or staff safety.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 12th day of November, 2021.

Mel McNea

Mel McNea, MHA, Chief Executive Officer
Great Plains Health

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. 4:21-cv-01329

DECLARATION OF MARK SROCZYNSKI

1. My name is Mark Sroczynski, and I am the Vice President of Operations for Emerald Health Care. I am also a resident of the State of Nebraska and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. The four facilities operated by Emerald Health Care in Nebraska will be directly affected by the CMS vaccine mandate that Plaintiff States have challenged in this case.

4. Emerald Health Care operates Emerald Nursing and Rehab in Columbus, Nebraska, a rural municipality of less than 25,000 people. This facility provides skilled nursing, long-term care, occupational and speech therapy, and hospice care amongst other services. This facility currently has a vacancy rate of approximately 35% for Registered Nurses and Licensed Practical Nurses and a vacancy rate of approximately 37% for Certified Nursing Assistants and Medication Aides. The applicant pool of qualified staff applying to

fill these vacancies is at an historic low. Based on conversations with this facility's staff, it is estimated that an additional loss of at least 10% of the Certified Nursing Assistants currently employed at this facility will occur as a result of the CMS vaccine mandate.

5. Emerald Health Care operates Emerald Nursing and Rehab in Cozad, Nebraska, a rural town of less than 4,000 people. This facility provides skilled nursing, physical, occupational and speech therapy, and cardiac rehabilitation care, amongst other services. This facility has a vacancy rate of approximately 26% for Registered Nurses and Licensed Practical Nurses, a vacancy rate of approximately 49% for Certified Nursing Assistants and Medication Aides, and a vacancy rate of approximately 80% for housekeeping and dietary services. This facility is in dire straits in terms of staffing and stands to lose an additional 25% of its employees as a result of the CMS vaccine mandate based on conversations with this facility's staff. This facility has received at least one qualified application from a former employee of a recently closed facility in a nearby facility who applied to the Emerald Nursing and Rehab Cozad facility because it was not mandating vaccination.

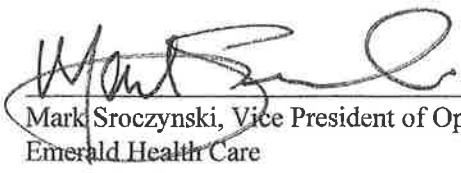
6. Emerald Health Care operates Emerald Nursing and Rehab in Omaha, Nebraska, the state's largest city. This facility provides, skilled nursing, long-term care, rehabilitative services, and amongst other services. This facility has a vacancy rate of approximately 42% for Registered Nurses and Licensed Practical Nurses, a vacancy rate of approximately 32% for Certified Nursing Assistants and Medication Aides, and a vacancy rate of approximately 38% for housekeeping and dietary services. This facility serves a substantial number of minority residents amongst whom the vaccination rate is approximately 50%. Based on conversations with this facility's staff, this facility anticipates an additional loss of approximately 18% of its current employees as a result of the CMS vaccine mandate.

7. Emerald Health Care operates Emerald Nursing and Rehab Lakeview in Grand Island, Nebraska, a city of approximately 50,000 people. This facility provides skilled nursing, assisted living and dementia care, physical, occupational and speech therapy, and stroke and neurological care, amongst other services. This facility has a vacancy rate of approximately 45% for Registered Nurses and Licensed Practical Nurses, a vacancy rate of approximately 27% for Certified Nursing Assistants and Medication Aides. Based on conversations with this facility's staff, this facility anticipates an additional loss of approximately 13% of its current employees as a result of the CMS vaccine mandate.

8. The CMS vaccine mandate will undoubtedly add to the vacancy rate of each of Emerald Health Care's four Nebraska facilities. Such decreases in available staff will result in each facility turning away patients in their respective communities. It is further expected that other long-term care or assisted living facilities in rural areas will likely close due to less patient population density and a limited pool of qualified staff. Closures of other facilities will only compound the inability of Emerald Health Care's to care for patients in rural areas.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 11 day of November, 2021.



Mark Sroczynski, Vice President of Operations
Emerald Health Care

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. 4:21-cv-01329

DECLARATION OF NANCY GLAUBKE

1. My name is Nancy Glaubke, and I am the Chief Executive Officer of Valley County Health System in Ord, Nebraska. I am also a resident of the State of Nebraska and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. Valley County Health System will be directly affected by the interim final rule with comment period (IFC) that Plaintiff States have challenged in this case.

4. Valley County Health System is a small rural hospital.

5. Valley County Health System is a critical access hospital.

6. Valley County Health System is licensed for 16 Medicare/Medicaid beds.

7. Valley County Health System's average daily census is 3.5 patients.

8. Valley County Health System provides patient care services for emergencies, inpatient, swing bed, observation, laboratory, radiology, operating room, rehabilitation

services, respiratory therapy, behavioral health and visiting specialists.

9. Valley County Health System serves a patient population base of 4,200 people within a geographic area of four counties.

10. Valley County Health System employs 210 staff; approximately 65% are clinical and practitioner staff.

11. Valley County Health System is currently experiencing a workforce shortage of health care staff with 14 vacancies, or 6.5% of our total workforce. Of these vacancies 6 are RNs, 2 are CNA/Unit Secretary, 2 Clerical, 2 Housekeepers, 1 Cook, and 1 Certified Nurse Assistant. The nursing positions have been open for over 365 days due to the nationwide shortage of Registered Nurses. Prior to 2020 Valley County Health System didn't have to use outside agency staff. Today, we have contracted with 4 RNs and 1 Lab Tech even though we've doubled our recruiting efforts.

12. Amongst Valley County Health System's employees, 60 (30%) are known to have not or are reasonably believed to have not received a COVID-19 vaccine.

13. Valley County Health System stands to lose all 60 of these employees. That's 30% of our total labor force. We stand to lose 80% of our Imaging Department as a result of implementation of the CMS vaccine mandate in the IFC challenged by Plaintiff states in this case.

14. The patients served by Valley County Health System will suffer from the potential closure of some departments as a result of the additional loss of Hospital employees. If we lose our imaging department we will have to divert many of our emergency patients to other facilities; the closest one is 45 miles away.

15. This has created undue stress on our employees and our community.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 10th day of November, 2021.

Nancy Glaubke, CEO
Valley County Health System

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. 4:21-cv-01329

DECLARATION OF SHANNON MONHEISER

1. My name is Shannon Monheiser, and I am the Administrator of Kimball County Manor and Assisted Living in Kimball, Nebraska. I am also a resident of the State of Nebraska and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. Kimball County Manor and Assisted Living will be directly affected by the CMS vaccine mandate that Plaintiff States have challenged in this case.

4. Kimball County Manor and Assisted Living is comprised of a skilled nursing facility and an assisted living facility. 75% of the patients served in the skilled nursing facility are funded by Medicare or Medicaid and 56% of the assisted living residents are funded by Medicaid.

5. Kimball County Manor and Assisted Living employs 55 full time staff and as such is one of the largest employers in Kimball County, a rural county located in Nebraska's western panhandle.

6. Kimball County Manor and Assisted Living currently has six nursing vacancies and utilizes agency provided nursing that includes foreign nurses. Utilization of agency provided nurses costs Kimball County Manor in excess of $20,000 per week.

7. Kimball County Manor's skilled nursing facility is licensed for forty-nine skilled nursing beds, however, the current census is 45 patients. Kimball County Manor is placing a hold on admitting new patients in anticipation of a loss of staff due to the CMS vaccine mandate, thus already sustaining a loss of at least $36,000 in revenue per month by not filling available beds for which there is an existing demand.

8. Of Kimball County Manor and Assisted Living's 55 employees, 31 are known to be unvaccinated, at least 27 have informed management that they will resign or be terminated rather than be vaccinated. Unvaccinated employees are comprised of various types of personnel, however, 48% of our unvaccinated workforce are nurses.

9. Losing potentially 48% of our workforce, including a substantial percentage of our already depleted nursing staff will force Kimball County Manor and Assisted Living to further reduce skilled nursing services and force current patients to seek long-term care in

facilities that are more than an hour away from our community and place significant financial pressure on our facility as a result, thereby unnecessarily jeopardizing the very existence of Kimball County Manor and Assisted Living.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 11th day of November, 2021.

Shannon Monheiser
Kimball County Manor and Assisted Living

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. 4:21-cv-01329

DECLARATION OF TROY BRUNTZ

1. My name is Troy Bruntz, and I am the President and Chief Executive Officer of Community Hospital in McCook, Nebraska. I am also a resident of the State of Nebraska and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. Community Hospital will be directly affected by the interim final rule with comment period (IFC) that Plaintiff States have challenged in this case.

4. Community Hospital is a small rural hospital.

5. Community Hospital is a critical access hospital.

6. Community Hospital is licensed for 25 Medicare/Medicaid beds.

7. Community Hospital's average daily census has been approximately 8 to 10 patients.

8. Community Hospital receives 56% of its $51 million annual patient service

revenue from Medicare and/or Medicaid reimbursements.

9. Community Hospital provides patient care such as general and specialty surgical services, medical and surgical acute patient services, phase 2 and 3 cardiopulmonary rehabilitation, physical, occupational, and speech therapy, home health and hospice services, radiology tests such as ultrasound, MRI, and CT Scans, and full laboratory testing on a 24 hour a day, 7 day per week basis. Many of these services such as home health and hospice are only available in our entire 7 to 10 county region by our hospital. The next closest facility providing all of these services on a 24 hour per day and 7 day per week basis is 70 miles away.

10. Community Hospital serves a patient population base of 30 thousand people in 7 to 10 counties of Southwest Nebraska and Northwest Kansas.

11. Community Hospital employs 330 total staff. 190 are classified as clinical or clinical support personnel.

12. Community Hospital is currently experiencing a workforce shortage of health care staff with 18 vacancies including 5 registered nurses, 2 licensed practical nurses, a radiology technician, and an ultrasound technician. Many of these positions, including registered nurses, licensed practical nurse, radiology and ultrasound technicians, have been posted for many months without adequate, if any, response.

13. Amongst Community Hospital's employees, 24% (78 out of 330) are known to have not or are reasonably believed to have not received a COVID-19 vaccine. Of the 78, 76 have indicated they will not or are seriously considering not receiving the vaccination. This includes 23 of 63 registered nurses serving our medical surgical inpatient services, emergency department, and labor and delivery services, 4 of 11 radiology and ultrasound technicians, 4 of 18 surgical services staff, 7 of 20 home health and hospice services staff, and 5 of 10 plant

engineering staff. Our physical therapy department labor is contracted but we believe from inquiry for compliance with the first COVID 19 OSHA ETS that currently 11 of 15 staff are not vaccinated.

14. Community Hospital stands to lose well more than 10% of its staffing in nursing services, home health and hospice, physical therapy, radiology, and plant engineering as a result of implementation of the CMS vaccine mandate in the IFC challenged by Plaintiff states in this case.

15. The patients served by Community Hospital will be harmed. Ultrasound services will not be available for our emergency room as they were before. To maintain our emergency room and inpatient services, which are essential, we will be forced to limit or close services such as cardiopulmonary rehabilitation and home health and hospice services. This will be necessary in order to retrain and transfer registered nurses from these services to the emergency room and inpatient care departments. Ultrasound coverage will only be available during normal business hours and radiology services will be delayed. Maintaining our plant assets will be difficult if not nearly impossible for any extended period of time. Staffing of 25 beds, our licensed amount, is already not possible which has created a need for additional transfers. As a result of this ITS, these transfers will be needed much more frequently and to communities hours away at best.

16. We have had discussions with our unvaccinated staff and, at their discretion, they have been honest with us in all cases about their intentions and therefore we have strong evidence of the potential impact on our services. It needs to be understood that even if we can technically staff services with extra shift and call, we are already doing that, have been doing that for more than a year, and our vaccinated staff will not be capable of doing it for much

longer. At that point, considering it is nearly impossible to recruit clinical staff today, more will resign due to the stress and burn out that will inevitably exist.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 10th day of November, 2021.

Troy Bruntz, President & CEO

Community Hospital

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. 4:21-cv-01329

DECLARATION OF TANYA SHARP

1. My name is Tanya Sharp, and I am the Chief Executive Officer of Boone County Health Center in Albion, Nebraska. I am also a resident of the State of Nebraska and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. Boone County Health Center will be directly affected by the interim final rule with comment period (IFC) that Plaintiff States have challenged in this case.

4. Boone County Health Center is a small rural hospital.

5. Boone County Health Center is a critical access hospital.

6. Boone County Health Center is licensed for 25 Medicare/Medicaid beds.

7. Boone County Health Center's average daily census is 9.2

8. Boone County Health Center receives 60% of our funding for inpatient and outpatient visits has a payor source of Medicare or Medicaid. Boone County Health Center

has a 50 Million Dollar annual revenue budget.

9. Boone County Health Center provides patient care in a 25 private bed hospital with two family obstetrical suites. The health center is a hub for five medical clinics in the towns of Albion, Spalding, Newman Grove, Fullerton and Elgin. The health center performs 60,000 procedures annually including lab, imaging, screenings, surgeries, in-patient stays, obstetrics, outpatient procedures, cardiac and pulmonary rehab and wellness management.

10. Boone County Health Center serves a patient population base of 10,000 rural residents that are residents of Boone, Antelope, Greeley, Madison, Nance, Platte and Wheeler counties in north central Nebraska.

11. Boone County Health Center employs 300 staff members with 17 providers (9 MD's and 8 Mid-levels)

12. Boone County Health Center is currently experiencing a workforce shortage of health care staff with 9 current open nursing positions that have been open for over 3 months, without a single application, in addition, positions multiple openings in Housekeeping, Lab and Reception Areas. We have relied on prior CMS rules that did not require vaccination in attempting to fill existing vacancies.

13. Amongst Boone County Health Center's employees, 28 percent are known to have not or are reasonably believed to have not received a COVID-19 vaccine. With the majority of these positions being in clinical roles or provider roles within the organization.

14. Boone County Health Center stands to lose a significant number of staff members as a result of implementation of the CMS vaccine mandate. This projection accounts for potential religious or medical exemptions provided under federal law.

15. The patients served by Boone County Health Center will have the following

negative consequences on their healthcare or the services provided by the Hospital as a result of the additional loss of Hospital employees. This could range from reduction of services, closure of satellite clinic locations, increased availability for clinic visits, increased wait time in the ER, inability to staff hospital beds safely but also the ability to transfer when needed since we are all having the same issues.

16. Boone County Health Center is under a large construction renovation, it has been costly and taxing with the lack of goods and workers. Now with this mandate we are at risk of losing even more construction staff members with contractors requiring proof of vaccination and it is my understanding the burden of proof is on the hospital. This would be almost an unreasonable ask since multiple individuals will be in this space and some here for a day or two. Please consider this being on the contractors not the hospitals responsibility to enforce and provide documentation.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 11th day of November, 2021.

Tanya Sharp, CEO
Boone County Health Center

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. _____

DECLARATION OF TYLER TOLINE

1. My name is Tyler Toline, and I am the Chief Executive Officer of Franciscan Care Services in West Point, Nebraska. I am also a resident of the State of Nebraska and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. Franciscan Care Services will be directly affected by the interim final rule with comment period (IFC) that Plaintiff States have challenged in this case.

4. Franciscan Care Services is a small rural hospital.

5. Franciscan Care Services is a critical access hospital.

6. Franciscan Care Services is licensed for 25 Medicare/Medicaid beds.

7. Franciscan Care Services's average daily census is 8.

8. Franciscan Care Services receives 57 percent / $34,800,000 of its annual revenue / funding from Medicare and/or Medicaid reimbursements.

9. Franciscan Care Services provides patient care in a rural community in Northeast Nebraska. Services we provide include acute care inpatient and observation services, infusion services, obstetric labor and delivery, surgery with specialties such as orthopedic/urology/general/OB, level IV trauma emergency room services serving approximately 250 patients per month, outpatient specialty clinic with 10-30 patients per day, radiology, laboratory, cardiac rehab, physical therapy, occupational therapy, speech therapy, home health and hospice services. We also have five rural health clinics that see approximately 80-120 patients a day. At the end of June 2021, the critical access hospital located in Oakland, Nebraska, approximately 15 miles from us, closed. This has resulted in increased volumes in almost every department for our facility.

10. Franciscan Care Services serves a patient population base of 16,000 people within a geographic area of 6 counties.

11. Franciscan Care Services employs 292 people, including 15 medical staff members.

12. Franciscan Care Services is currently experiencing a workforce shortage of health care staff with 15 vacancies which include 10 clinical positions causing stress to existing staff to cover. RN vacant positions have been open since before the start of the pandemic.

13. Amongst Franciscan Care Services's employees, 23% or 67 employees are known to have not or are reasonably believed to have not received a COVID-19 vaccine

14. Franciscan Care Services stands to lose 23% or 67 of its employees. Departments with most risk include 75% of employees in radiology, 57% in acute patient care, 47% in dietary, 40% in scheduling, 38% in surgery, and 33% in home health care as a result of the implementation of the CMS vaccine mandate in the IFC challenged by Plaintiff states

in this case.

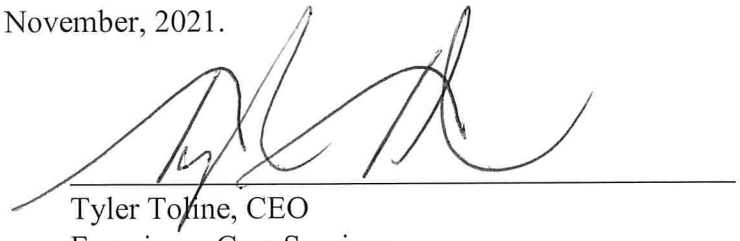
15. The patients served by Franciscan Care Services will experience many negative consequences if the CMS vaccine mandate goes through and we lose 23% of our workforce. We will have to reduce services in the clinic, in outpatient services and in surgery to utilize clinical staff to provide care for acute inpatient, observation, and emergency patients. Emergency room patient volumes and acuity will increase due to inability to care for them in the clinic setting. At this time only 43% of our Med/Surg staff are vaccinated. Of the 35 Med/Surg employees that we have, we may have to terminate 20 of them if the CMS vaccine mandate goes through. Who is going to care for our patients? Also, only 2 of our 8 Radiology employees are vaccinated. We cannot have a fully functioning Radiology department if we only have a staff of 2. We may have to divert emergency patients if we do not have Radiology capabilities. Patients that need long term care (LTC) placement upon discharge will have longer length of stay due to lack of beds in LTC leading to decreased acute care bed availability due to staffing shortages. Wait times to transfer critical care patients will become even longer than what we are currently experiencing due to lack of staffed beds in tertiary care centers. When we have a patient needing an ICU level of care we can call up to 15 facilities and are put on a waiting list or told to call back at a later time. We have had to keep intubated patients and patients requiring 1:1 care in our facility making nursing ratios unsafe for the rest of the acute care patients. Nursing and provider staff are already working longer hours and extra shifts due to increased emergency department volumes and acute care census.

16. These potential staffing loses do not include the related nursing home in West Point that will also have a similar expected percentage loss and will most likely need to discharge residents because of the lack of staffing necessary to take care of them. This will in

turn fill up the hospital beds with residents that should reside in a nursing home.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 11th day of November, 2021.



Tyler Tolne, CEO
Franciscan Care Services

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No. 4:21-cv-01329

DECLARATION OF DEBRA SHACKETT

1. My name is Debra Shackett. I am the County Administrator for the Belknap County, New Hampshire. I am also a resident of New Hampshire and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. The Belknap County Commissioners collectively administer the business of Belknap County, New Hampshire. I have been appointed by the Belknap County Commissioners to be the administrative head of the county and, in that capacity, I am responsible for the efficient and effective administration of various departments within the county.

4. Belknap County Nursing Home is a 94 bed skilled nursing facility that provides long-term care and rehabilitative services to its residents. I, along with the Commission, and a professional nursing home administrator, help oversee the operations of the Belknap County

Nursing Home.

5. The Belknap County Nursing Home is presently experiencing a severe employment crisis that has limited the county's ability to provide needed residence and eldercare to Belknap County's most needy elderly.

6. The Belknap County Nursing Home has halted admissions due to staffing issues which has created problems for the nursing home and has created a long waitlist for admission. The Belknap County Nursing Home already had 20 full-time and 4 part-time nursing position vacancies prior to the imposition of the CMS vaccine mandate. Additionally, there are 2 part-time vacancies in Housekeeping. The staff have been under stress and increased duties throughout the pandemic, and the shortage of positions for this rural facility has increased the pressure on those remaining staff.

7. The recent CMS vaccine mandate will only exacerbate this existing problem.

8. At the Belknap County Nursing Home, we have approximately 36 staff members who have chosen not to participate in vaccination. We have worked to educate and encourage staff that are experiencing vaccine hesitancy. We have also offered them a financial incentive to get vaccinated. Since the timeline for the CMS vaccine mandate has been revealed, we have had only a few staff members indicate that they intend to get vaccinated. Belknap County Nursing Home has also received three healthcare worker resignations and one support staff resignation since that time.

9. Belknap County Nursing Home is already operating at approximately 75% of its 94 bed-capacity. As a result of the CMS vaccine mandate, this problem will worsen. Belknap County Nursing Home will have to decrease its bed capacity to approximately 50%, meaning that only approximately 46 beds will be able to be staffed. This decrease has required

Belknap County Nursing Home to plan to move approximately 19 vulnerable, elderly residents to other nursing home facilities outside of the county.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 12th day of November, 2021.

Debra Shackett
County Administrator
Belknap County, New Hampshire

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI,
STATE OF NEBRASKA,
STATE OF ARKANSAS,
STATE OF KANSAS,
STATE OF IOWA,
STATE OF WYOMING,
STATE OF ALASKA,
STATE OF SOUTH DAKOTA,
STATE OF NORTH DAKOTA, and STATE OF NEW HAMPSHIRE,

Plaintiffs,

vs.

JOSEPH R. BIDEN, JR.,
in his official capacity as the President of the United States of America;

THE UNITED STATES OF AMERICA;

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES;

XAVIER BECERRA in his official capacity as Secretary of the United States Department of Health and Human Services;

CENTERS FOR MEDICARE AND MEDICAID SERVICES;

CHIQUITA BROOKS-LASURE in her official capacity as Administrator for the Centers for Medicare and Medicaid Services;

MEENA SESHAMANI in her official capacity as Deputy Administrator and Director of Center for Medicare;

DANIEL TSAI in his official capacity as Deputy Administrator and Director of Center for Medicaid and CHIP Services;

Defendants.

Case No. 4:21-cv-01329

DECLARATION OF CHRISTOPHER D. JONES

STATE OF NORTH DAKOTA)
) ss.
COUNTY OF BURLEIGH)

Christopher D. Jones states as follows:

1. I am the Executive Director of the North Dakota Department of Human Services. I am also a resident of North Dakota and over the age of majority. I believe the facts in this declaration are true and correct to the best of my knowledge.

2. I submit this declaration to provide documentation for Plaintiffs' Motion for Preliminary Injunction.

3. The North Dakota Department of Human Services (NDDHS) operates three facilities that fall under the Centers for Medicare & Medicaid Services (CMS) Interim Final Rule (IFR).

a. North Dakota State Hospital (NDSH) is located in Stutsman County, and it provides short-term acute psychiatric and substance use treatment, intermediate psycho-social rehabilitation services, forensic services, and safety net services for adults. NDSH also provides residential addiction treatment services for adult male and female clients referred to the Tompkins Rehabilitation Center and provides inpatient evaluation and treatment services for sexually dangerous individuals.

b. Life Skills and Transition Center (LSTC) is in Walsh County and is a comprehensive support agency serving people with intellectual and developmental disabilities. LSTC serves as a crisis and stabilization center, as well as a safety net for people whose needs exceed community resources. People supported by the LSTC may reside in an intermediate care facility setting on campus, in residential habilitation homes in the Grafton community, or in communities across the state.

c. Ruth Meiers Adolescent Treatment Center (RMAC) is in Grand Forks County and is licensed as a ten-bed psychiatric residential treatment facility serving children with serious emotional disturbance using a holistic approach emphasizing behavioral and cognitive change and recognizing needs related to family, community, school, social skills, and therapy (individual, family, and group therapy).

4. NDSH employs approximately three hundred thirty staff, ranging from full-time equivalent positions and temporary hires that work part-time to full time. NDSH contracts with approximately thirty individuals and has approximately seventeen to twenty-five volunteers and four hundred students that would be considered staff under CMS' IFR. LSTC employs approximately three hundred eighteen staff, ranging from part-time to full time. LSTC contracts with one individual and has approximately one hundred volunteers and two students that would be considered staff under CMS' IFR. RMAC employs approximately sixteen staff, ranging from part-time to full time.

5. The critical staff shortages for NDSH exist for registered nurses, licensed practical nurses, and certified nursing assistants and are currently between the vacancy rate of 28% to 38%. The overall staff vacancy rate for NDSH is 28%. The critical staff shortages for LSTC exist for direct care and food service staff and are currently between the rate of 13% to19%. The overall staff vacancy for LSTC ranges from 20% to 26%. The critical staff shortage for RMAC exists for direct care associates and is currently at 48%.

6. As of November 7, 2021, the North Dakota State Department of Health's COVID-19 Vaccine Dashboard indicates that the COVID-19 primary series complete vaccine rate for the three counties in which NDDHS facilities are located are 56.4% for Stutsman County, 61.4% for Walsh County, and 56.6% for Grand Forks County. The approximation vaccination rate for the approximately three hundred thirty full-time equivalent filled positions at NDSH is 76%, three hundred eighteen full-time and temporary filled positions at LSTC is 67%, and RMAC is unknown.

7. In North Dakota, the public and private entities that are deemed subject to the Conditions of Participation process by CMS and fall under the IFR's vaccination requirements

employ tens of thousands of individuals who work in professions ranging from direct caregiving to building maintenance to medicine. Health and human service providers are facing workforce challenges that jeopardize their ability to continue providing quality care and services to the men, women, and children who rely on them for various caregiving and healthcare related supports. Anything that threatens their ability to minimize staff turnover and maximize staff retention threatens the health and safety of the individuals they serve. The imposition of a vaccine mandate presents a risk to health and human services providers' ability to adequately staff their facilities.

8. The approximate amount of federal Medicaid funds received by the NDDHS for NDSH is $2,300,000, LSTC is $29,200,000, and RMAC is $1,700,000 during the 2019-2021 biennium. These amounts do not include any federal Medicaid expansion funding, Medicare funding, or state Medicaid match funding. In accordance with the Schedule of Federal Expenditures included in the State's 2021 Financial Statements, the NDDHS reported federal Medicaid grant expenditures of approximately $913,300,000. This amount does not include any Medicare funding or state Medicaid match funding.

9. NDSH expects there will be loss of eight to twelve current staff that have clearly stated they will quit. NDSH is aware of other staff who are expressing concern or reluctance to receive the vaccination. The exact staffing impact to NDSH is unknown as these numbers are based on polling staff. NDSH is required by law to accept admissions. Therefore, any further shortages of staff will result in mandatory overtime of existing staff or the hiring of travel nursing staff, or both. The staffing impact of a mandatory vaccination policy on LSTC is unknown at this time. What is known, however is that without adequate staffing, LSTC will not be able to provide statewide safety services for its most vulnerable population, both in terms of on-site placements and the crisis services provided statewide. The staffing impact on RMAC is unknown currently if

it must implement mandatory vaccinations. If RMAC faces additional staff losses or additional struggles to hire staff, it will have to limit admissions for adolescent clients.

I declare, under penalty of perjury under the law of North Dakota, that the foregoing is true and correct to the best of my knowledge and belief.

Signed on this 12th day of November, 2021 at Bismarck, North Dakota, United States.

Christopher D. Jones, Executive Director
North Dakota Department of Human Services

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI,
STATE OF NEBRASKA,
STATE OF ARKANSAS,
STATE OF KANSAS,
STATE OF IOWA,
STATE OF WYOMING,
STATE OF ALASKA,
STATE OF SOUTH DAKOTA,
STATE OF NORTH DAKOTA, and STATE OF NEW HAMPSHIRE,

Plaintiffs,

vs.

JOSEPH R. BIDEN, JR.,
in his official capacity as the President of the United States of America;

THE UNITED STATES OF AMERICA;

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES;

XAVIER BECERRA in his official capacity as Secretary of the United States Department of Health and Human Services;

CENTERS FOR MEDICARE AND MEDICAID SERVICES;

CHIQUITA BROOKS-LASURE in her official capacity as Administrator for the Centers for Medicare and Medicaid Services;

MEENA SESHAMANI in her official capacity as Deputy Administrator and Director of Center for Medicare;

DANIEL TSAI in his official capacity as Deputy Administrator and Director of Center for Medicaid and CHIP Services;

Defendants.

Case No. 4:21-cv-01329

DECLARATION OF DR. NIZAR WEHBI

STATE OF NORTH DAKOTA)
) ss.
COUNTY OF BURLEIGH)

Dr. Nizar Wehbi states as follows:

1. I am the North Dakota State Health Officer, which is the administrative officer of the North Dakota State Department of Health ("Department"). I was appointed to such position by Governor Doug Burgum, effective May 1, 2021.

2. The Department reports thirty-three (33) surveyors to the Centers for Medicare & Medicaid Services ("CMS") as a part of our annual budget process.

3. Of these surveyors, twenty-nine (29) surveyors complete on-site surveys of healthcare facilities to determine compliance with CMS standards. Two (2) surveyors complete on-site construction visits for compliance with North Dakota regulatory requirements. Two (2) surveyors are reported as temporary staff who can also be used for CMS survey purposes.

4. All thirty-three (33) surveyors are employees of the state of North Dakota.

5. As a part of their job duties, surveyors determine healthcare facilities' compliance with federal and state regulations by conducting on-site surveys and evaluating the programs, services, staff, buildings, and equipment of inpatient care facilities and outpatient programs to ensure that they meet applicable standards and provide services consistent with generally accepted practices.

6. I declare, under penalty of perjury under the law of North Dakota, that the foregoing is true and correct to the best of my knowledge and belief.

Signed on this 12 day of November, 2021 at Bismarck, North Dakota, United States.

Nizar Wehbi
Dr. Nizar Wehbi

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No.

DECLARATION OF LAURA RINGLING

1. My name is Laura Ringling, and I am Chief of Behavioral Health for the South Dakota Department of Social Services. I am also a resident of South Dakota and over the age of majority. I have personal knowledge of the facts in this declaration, and those facts are true and correct to the best of my knowledge.

2. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. The Human Services Center (HSC) in Yankton is the only state-operated inpatient psychiatric hospital in South Dakota. It is overseen by the South Dakota Department of Social Services.

4. HSC had 207 operating beds in SFY21.

5. HSC receives just under $8 million annually from Medicaid or Medicare, which accounts for approximately 15% of its budget.

6. As of August 2021, HSC's vacancy rate was 22.6%. Nursing and health care

workers in general are in high demand and filling positions has been challenging. Nearly 90% of the vacant positions are for direct care providers.

7. HSC currently has 120 employees whose vaccination status is unknown. However, we expect there will be some staff who leave employment at HSC due to the mandate.

8. Any loss of employees would impact services at HSC as our facility is already experiencing workforce shortages that have taken units offline, most recently an adolescent treatment unit. An inability to adequately staff HSC treatment units would require HSC to reduce the patient population, limit admissions, and potentially take an additional treatment unit offline. This would adversely impact inpatient psychiatric hospital capacity in South Dakota. Additionally, it could require that individuals needing emergency inpatient psychiatric treatment be held in jail settings or emergency rooms until capacity is available.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this the 12th day of November, 2021.

Laura Ringling

Laura Ringling
Chief of Behavioral Health

KRISTEN CAMPBELL
SEAL NOTARY PUBLIC SOUTH DAKOTA SEAL

Kristen Campbell

Commission expires on 8/31/2027

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

STATE OF MISSOURI, et al., *Plaintiffs*, v. JOSEPH R. BIDEN, JR., et al., *Defendants*.	No.

DECLARATION OF STEFAN JOHANSSON

Pursuant to 28 U.S.C. § 1746, I hereby declare that the foregoing is true and correct:

1. I am the interim director for the Wyoming Department of Health. In that capacity, I am responsible for the management and oversight of the entire Department, which includes Medicaid, public health, aging services, behavioral health services, healthcare licensing and survey, and five state-run healthcare facilities. I am a resident of Wyoming and am over the age of majority. I have personal knowledge of all facts stated in this declaration.

2. Healthcare staffing shortages are a significant problem throughout Wyoming. During the COVID-19 pandemic, numerous healthcare facilities in Wyoming have had to rely extensively on contracted labor to cover shortages in healthcare workers, including state-run safety net facilities that serve individuals with mental illnesses, those with intellectual and developmental disabilities, and the elderly. In particular, the Wyoming State Hospital (a state-run psychiatric hospital) has had to fill between 6-11 full time equivalent employees with contracted workers (traveling nurses) over the past several months. Additionally, the Wyoming Retirement Center (a state-run skilled nursing facility) has had to fill between 12-14 full time equivalent employees with contracted

workers over the past several months. Soldiers from the National Guard were recently deployed to support the Wyoming Retirement Center during a major COVID-19 outbreak because of critically low staffing levels.

3. There are currently 97 soldiers from the National Guard supporting Wyoming hospitals, long term care facilities, and public health departments statewide.

4. The Wyoming Department of Health has allocated over $50 million since late 2020 to Wyoming hospitals and long-term care facilities. That money supports procurement of contract labor (e.g., agency/traveling nurses caused by staffing shortages) and supports retention funding for current facility staff that have worked through the pandemic. The $50 million also supports healthcare facilities at risk of losing workers who may terminate for a variety of reasons (exhaustion and burnout, better pay in other sectors, vaccine mandates, etc.). The money also supports continued recruitment of critical workforce (nurses, certified nursing assistants, etc.).

5. Moreover, there are currently two hospitals in Wyoming operating in crisis standards of care or near crisis standards due to critically low staffing levels and increased demand for care. The Wyoming Department of Health is supporting these hospitals with medical equipment and with soldiers from the National Guard.

6. The State of Wyoming itself runs three safety net healthcare facilities that receive funding from Medicaid and Medicare – the Wyoming State Hospital, the Wyoming Retirement Center, and the Wyoming Life Resource Center. The State Hospital has approximately 360 employees and an average daily census (number of patients) of 80 - 90 as of the date of this declaration. The Life Resource Center has approximately 250 employees and an average census of 50 - 60 as of the date of this declaration. The Retirement Center has approximately 75 employees and an average census of 70 as of the date of this declaration.

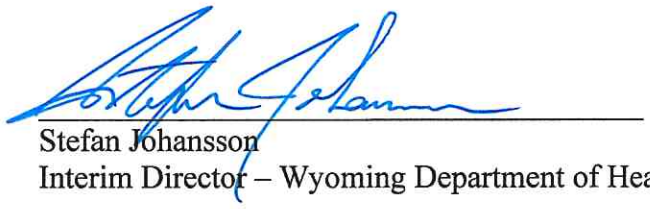
7. The workforce shortages that exist at the Wyoming healthcare facilities are significant. At our state-run facilities, current vacancy rates range from 20-38%. Other public and private healthcare facilities continually report critical levels of staffing due to shortages. In addition to factors that have led to current staffing shortages (exhaustion, burnout, better pay in other sectors), it is likely that vaccine mandates would cause additional loss of staff in the healthcare facilities throughout Wyoming, many of which operate in rural and frontier areas with small or limited labor markets.

8. There are significant numbers of staff at state-run healthcare facilities in Wyoming who have not received a COVID-19 vaccine at this time.

9. Currently in Wyoming there are 12 state surveyors – who perform duties related to assessing compliance with Medicare and Medicaid conditions of participation – all of whom are employed by the State of Wyoming.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 10th day of November 2021.



Stefan Johansson
Interim Director – Wyoming Department of Health