AMYOTROPHIC LATERAL SCLEROSIS SYSTEM OF CARE

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive states authority and policy for the development, implementation and sustainment of the Amyotrophic Lateral Sclerosis (ALS) System of Care.

2. SUMMARY OF MAJOR CHANGES: This directive updates information about ALS and includes the following major changes:

a. Updates and adds responsibilities in paragraph 4 to include Assistant Under Secretary for Health for Clinical Services; Assistant Under Secretary for Health for Operations; Chief Officer, Specialty Care Services; Department of Veterans Affairs (VA) medical facility Prosthetic and Sensory Aid Service Chief; VA medical facility Contract Officer's Representative; ALS Interdisciplinary Care Team; VA medical facility ALS Team physician; and VA medical facility ALS Coordinator.

b. Relocates previous Appendix A (ALS Interdisciplinary Team Clinics and Programs Identified) to the Neurology Program SharePoint.

3. RELATED ISSUES: VHA Directive 1094, Inter-Facility Transfer Policy, dated January 11, 2011; VHA Directive 1176(1), Spinal Cord Injuries and Disorders System of Care, dated September 30, 2019; and VHA Handbook 1101.10(1), Patient Aligned Care Team (PACT) Handbook, dated February 5, 2014; VHA Directive 1173.13, Home Oxygen Program, dated August 5, 2020.

4. RESPONSIBLE OFFICE: The Neurology Program Office within the National Office of Specialty Care Services (11SPEC15) is responsible for the content of this directive. Questions may be addressed to the Executive Director for Neurology at: VHA11SPEC15N2@va.gov.

5. RECISSIONS: VHA Handbook 1101.07, Amyotrophic Lateral Sclerosis (ALS) System of Care Procedures, dated July 7, 2014, and VHA Memorandum 2018-04-12, Amyotrophic Lateral Sclerosis (ALS), dated April 10, 2018, are rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of August 31, 2026. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Kameron Matthews, MD, JD, FAAFP
Assistant Under Secretary for Health
for Clinical Services

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

DISTRIBUTION: Emailed to the VHA Publications Distribution List on August 31, 2021.

CONTENTS

AMYOTROPHIC LATERAL SCLEROSIS SYSTEM OF CARE

AMYOTROPHIC LATERAL SCLEROSIS SYSTEM OF CARE

1. PURPOSE

This Veterans Health Administration (VHA) directive states policy concerning Amyotrophic Lateral Sclerosis (ALS) System of Care for Veterans. It describes the essential components and requirements of the ALS Program that have been implemented nationally to ensure that all eligible Veterans have access to ALS care. **AUTHORITY:** 38 U.S.C. § 7301(b).

2. BACKGROUND

a. A 2006 study released by the Institute of Medicine (IOM), *Amyotrophic Lateral Sclerosis in Veterans: Review of the Scientific Literature,* concluded that "there is limited and suggestive evidence of an association between military service and later development of ALS." The locality of service and history of combat exposure did not influence the incidence of ALS among Veterans. Based upon this study and the typical rapid progression of ALS, the Department of Veterans Affairs (VA) designated ALS a presumptively-compensable illness for all Veterans with 90 days of continuously active service in the military pursuant to 38 C.F.R. § 3.318.

b. The IOM study noted a 1.5-fold increase in incidence of ALS in Veterans. This estimate suggests an annual incidence rate of 4.5 per 100,000 Veterans, yielding an estimated annual incidence of 1,055 Veterans with new onset ALS and a possible Veteran prevalence of 4,220 given current life expectancy of approximately 3 years. In fiscal year (FY) 2020, 4,540 Veterans received care for ALS (1,007 received non-VA care and 3,533 received VA care). Men are more commonly affected than women and onset of symptoms is typically after the age of 50 years.

c. The focus of ALS clinical care is providing optimal quality of life through the management of symptoms. ALS varies considerably among individuals regarding site of onset and rate of progression. The etiology of ALS is not known. Most individuals who develop ALS have a sporadic form of the disease. Inherited forms of ALS are rare; 5-10% of disease cases are familial, with most cases inherited as an autosomal dominant trait.

d. In FY 2009, the Chief Patient Care Services Officer charged a national task group to develop comprehensive services for Veterans with ALS based on national best practices. Consistent support and treatment for individuals with ALS help to manage impairments, complications, and functional disabilities. A report by the national task group called for the establishment of ALS Interdisciplinary Care Teams to collaborate with Primary Care providers, home-based primary care (HBPC) teams and hospice and palliative care services, as appropriate.

3. POLICY

It is VHA policy that eligible Veterans diagnosed with ALS have access to a full spectrum of clinically appropriate interdisciplinary primary and specialty services

throughout their lives.

4. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Assistant Under Secretary for Health for Clinical Services.** The Assistant Under Secretary for Health for Clinical Services is responsible for supporting the Neurology Program Office with implementation and oversight of this directive.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

d. **Chief Officer, Specialty Care Services.** The Chief Officer, Specialty Care Services, is responsible for:

(1) Providing oversight and monitoring for VISN and VA medical facility compliance with this directive, including responding to inquiries regarding implementation.

(2) Supporting the Executive Director for Neurology (EDN) to ensure that all Veterans with ALS that who are eligible to receive VA health care have access to high-quality ALS care.

e. **Executive Director for Neurology.** The EDN is responsible for:

(1) Establishing and maintaining this directive through collaboration with VISN leadership, ALS Executive Committee and other stakeholders.

(2) Working with the Chief Officer, Specialty Care Services to ensure that all Veterans with ALS who are eligible to receive VA health care have access to high-quality ALS care.

(3) Serving as the ALS communication liaison and subject matter expert to VISN leadership and VA medical facilities.

(4) Developing ALS education materials for Veterans and caregivers, including information on VA ALS benefits.

(5) Working with the ALS Executive Committee to develop clinical protocols addressing symptomatic management of ALS.

f. **Chair, Amyotrophic Lateral Sclerosis Executive Committee.** The ALS Executive Committee is composed of six members who possess relevant ALS clinical expertise and reflect the geographic diversity of VHA. The Chair is responsible for:

(1) Ensuring that the ALS Executive Committee provides guidance to the EDN on issues that affect health care of Veterans with ALS, including but not limited to identifying advances in ALS care, gaps in care and providing expertise and education to providers, Veterans and caregivers. ***NOTE:*** *For more information on ALS Executive Committee, see:* https://dvagov.sharepoint.com/:f:/r/sites/VHANeurology/ALS/Shared%20Documents/ALS%20DIRECTIVE?csf=1&web=1&e=STyAY8. *This is an internal VA website that is not available to the public.*

(2) Working with the EDN develop clinical protocols addressing symptomatic management of ALS.

g. **Veterans Integrated Services Network Director.** The VISN Director is responsible for:

(1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

(2) Designating of at least one Regional ALS Interdisciplinary Program in their VISN to address the complex medical, physical, functional, psychological and social effects of ALS (see paragraph 5).

(3) Ensuring that there are appropriate resources for comprehensive care of Veterans with ALS as described in this directive, including for medical, primary, specialty, emergent, surgical, rehabilitative, Whole Health, extended care and long-term care. This includes ensuring availability of medical and surgical supplies deemed medically necessary by ALS providers as described in this directive.

(4) Ensuring Veterans have access to ALS services by implementing and supporting the ALS System of Care.

(5) Ensuring VISN and VA medical facility responsiveness to the health care needs of Veterans with ALS.

h. **Veterans Integrated Services Network Prosthetic Representative.** The VISN Prosthetic Representative is responsible for:

(1) Ensuring VA medical facility Prosthetic and Sensory Aids Service (PSAS) are responsive to consult submission for health care needs of Veterans with ALS.

(2) Ensuring there are appropriate PSAS resources for care of Veterans with ALS.

(3) Ensuring VA medical facility PSAS staff comply with VHA Directive 1173.13, Home Oxygen Program, dated August 5, 2020.

i. **VA Medical Facility Chief, Prosthetic and Sensory Aids Service.** The VA medical facility PSAS Chief is responsible for:

(1) Coordinating and collaborating with the VA medical facility ALS Coordinators to provide necessary resources, items and services determined by the ALS Interdisciplinary Care Team for ALS treatment and care (see paragraph 8).

(2) Procuring home respiratory equipment according to the specifications of the prescription.

(3) Coordinating with appropriate contracted vendor(s) for the delivery and set up of home respiratory or medical equipment.

(4) Collaborating and coordinating with ALS Interdisciplinary Care Team(s) for submission of the respiratory requirements (for example, scope of work) to the Contracting Officer.

(5) Assigning a Contractor Officer's Representative (COR) to monitor ongoing contractual compliance of home respiratory equipment vendors in accordance with external accrediting agency standards and other associated governing bodies.

(6) Taking appropriate action in response to issues of contract compliance reported by the COR.

j. **Contracting Officer's Representative.** The COR serves both an administrative and clinical support role and is responsible for:

(1) Ensuring that home respiratory equipment contracts include vendor requirements that demonstrates appropriate use of equipment, teaches Veterans and caregivers how to use the respiratory equipment at minimum at the time of delivery and at other identified times per the contract.

(2) Communicating the home respiratory equipment changes from the vendor to the COR and the VA medical facility ALS Coordinator to ensure optimal respiratory care.

(3) Ensuring the home respiratory equipment contract complies with relevant external accrediting agency standards.

(4) Ensuring all records from the home respiratory equipment contractor visits are incorporated into the electronic health record.

(5) Participating in meetings with the vendor at least once quarterly to discuss ongoing outpatient concerns and appropriate resolutions, quality assurance, equipment, supply issues and contract compliance.

k. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Appointing a VA medical facility ALS point of contact for Veterans being treated for ALS (see paragraph 6).

(2) Ensuring necessary medical equipment, supplies and subspecialty care are provided to eligible Veterans with ALS.

(3) Ensuring VA medical facility staff providing care to Veterans with ALS or suspected of having ALS, utilize appropriate referral procedures and services as outlined in clinical guidelines.

(4) For those VA medical facilities with an ALS Interdisciplinary Clinic, establishing an ALS Interdisciplinary Care Team, and ensuring that the Team has the clinical and administrative support necessary to efficiently deliver high quality care. ***NOTE:*** *For more information on ALS Interdisciplinary Clinics, see https://dvagov.sharepoint.com/:f:/r/sites/VHANeurology/ALS/Shared%20Documents/ALS%20DIRECTIVE?csf=1&web=1&e=STyAY8. This is an internal VA website that is not available to the public.*

l. **VA Medical Facility Chief of Staff/VA Medical Facility Associate Director for Patient Care Services.** The VA medical facility Chief of Staff (CoS) or the Associate Director for Patient Care Services (ADPCS), depending on the VA medical facility, is responsible for notifying the VA medical facility Director of challenges with complying with the ALS System of Care.

m. **Amyotrophic Lateral Sclerosis Interdisciplinary Care Team.** ***NOTE:*** *For further information on the ALS Interdisciplinary Care Team, see paragraph 5.* The ALS Interdisciplinary Care Team is responsible for:

(1) Providing the Veteran with information and materials about ALS disease, support and advocacy organizations involved in managing care of ALS population.

(2) Ensuring the ALS Interdisciplinary Care Teams adhere to ALS clinical protocols to address symptomatic management of ALS.

(3) Collaborating with the VA medical facility PSAS Chief for submission of the respiratory requirements (for example, scope of work) to the Contracting Officer.

n. **VA Medical Facility Amyotrophic Lateral Sclerosis Team Physician.** ***NOTE:*** *This position exists only at VA medical facilities with ALS Interdisciplinary Clinics.* The VA medical facility ALS Team physician is responsible for:

(1) Leading, coordinating and overseeing all clinical and administrative aspects of the ALS Interdisciplinary Care Team.

(2) Developing and maintaining processes and standard operating procedures, knowledge, and skills to ensure that Veterans with ALS receive comprehensive, interdisciplinary, coordinated and high-quality care.

o. **VA Medical Facility Amyotrophic Lateral Sclerosis Coordinator.** ***NOTE:*** *This position exists in all VA medical facilities regardless of presence of ALS Interdisciplinary Clinics.* The VA medical facility ALS Coordinator is responsible for:

(1) Serving as the point of contact for Veterans with ALS and their caregivers as determined by the VA medical facility Director.

(2) Performing an initial needs assessment to address durable medical equipment (DME) and the availability of community resources and caregiver services (see paragraph 8).

(3) Coordinating with the VA medical facility PSAS Chief to ensure provision of items and services needed for ALS (see paragraph 8).

(4) Arranging appointments at the ALS Interdisciplinary Clinic. For more information, see: https://dvagov.sharepoint.com/:f:/r/sites/VHANeurology/ALS/Shared%20Documents/ALS%20DIRECTIVE?csf=1&web=1&e=STyAY8. ***NOTE:*** *This is an internal VA website that is not available to the public. It lists all VHA ALS clinics, denoting which are interdisciplinary.*

(5) Providing a range of ALS educational information, resources and tools, including information on VA ALS benefits, and providing psychosocial and self-management support to Veterans with ALS and their caregivers. For more information, see: https://dvagov.sharepoint.com/:f:/r/sites/VHANeurology/ALS/Shared%20Documents/ALS%20DIRECTIVE?csf=1&web=1&e=STyAY8. ***NOTE:*** *This is an internal VA website that is not available to the public. It lists all VHA ALS clinics, denoting which are interdisciplinary.*

5. NATIONAL AMYOTROPHIC LATERAL SCLEROSIS SYSTEM OF CARE

a. The ALS System of Care consists of at least one Regional ALS Interdisciplinary Program in each VISN to address the complex medical, physical, functional, psychological and social effects of ALS. Interdisciplinary ALS care has been shown to improve patient outcomes including life expectancy and quality of life. In consultation with their primary and specialty care providers, Veterans with ALS can be referred to a VA medical facility with an ALS Interdisciplinary Care Team in their VISN. ***NOTE:*** *Not all ALS clinics are interdisciplinary. The VISN interdisciplinary clinics may be physically located at a VA medical facility or provided virtually via telehealth.*

b. An ALS Interdisciplinary Care Team is a group of VA medical facility health care providers from different fields who work together or toward the same goal to provide the best care or best outcome, address the continuum of care and nurture a therapeutic relationship from diagnosis to demise for Veterans with ALS. Membership of an ALS

Interdisciplinary Care Team includes at a minimum: ALS Team physician, ALS Coordinator, Social Worker, Speech-Language Pathologist, Physical Therapist, Occupational Therapist, Respiratory Therapist and Dietician. Other team members may include a Primary Care Provider, HBPC team staff member, Physiatrist, Therapeutic, Recreation Specialist, Assistive Technology Specialist, Kinesiotherapist, Clinical Pharmacist practitioner, Psychologist (e.g., Clinical Health Psychologist, Rehabilitation Psychologist, neuropsychologist, or other mental health professional capable of managing the complex mental health needs of these Veterans), Pulmonologist, Gastroenterologist, Palliative Medicine/Hospice Care or Chaplain.

c. Overall, ALS care must be comprehensive, interdisciplinary and co-managed between the Veteran's Primary Care/Patient Aligned Care Team (PACT) and the ALS interdisciplinary Care Team. Care must be delivered efficiently through grouping of clinic appointments, minimal travel to receive care, and expedient delivery of DME.

6. TREATMENT

a. The complex needs of Veterans with ALS are best addressed through a single point of contact. This role is performed by an ALS-experienced neurologist provider or experienced VA medical facility ALS Coordinator. This individual will be appointed by the VA medical facility Director and be the liaison between Specialty Care Services and Primary Care/PACT.

b. Following diagnosis and during prospective follow-up, referral to an ALS Interdisciplinary Clinic should be considered to optimize management, prolong survival and enhance the quality of life.

c. Optimal care is obtained with active co-management by Primary Care/PACT and an ALS Interdisciplinary Care Team.

d. VA medical facilities that lack an ALS Interdisciplinary Clinic must coordinate care with a nearby VA medical facility that has an ALS Interdisciplinary Clinic. For information on ALS Interdisciplinary Clinics, see: https://dvagov.sharepoint.com/:f:/r/sites/VHANeurology/ALS/Shared%20Documents/ALS%20DIRECTIVE?csf=1&web=1&e=STyAY8. ***NOTE:*** *This is an internal VA website that is not available to the public. The use of telehealth and MyHealtheVet is encouraged to facilitate this communication.*

e. Palliative and hospice care must be an early consideration in ALS management. Veterans with ALS meeting hospice criteria (regardless of hospice enrollment status) should be exempt from chronic opioid therapy guidelines and requirements.

7. DUAL CARE

a. VHA Directive 2009-038, VHA National Dual Care Policy, dated August 25, 2009, defines Dual Care as a system-wide approach to the coordination and provision of medical care to eligible Veterans who are seen by both VA and community providers.

b. Dual Care must be coordinated by the VA medical facility Director in accordance with VHA Directive 2009-038.

c. Dual Care must be used to optimize the appropriateness, safety and efficacy of care, medications, prosthetics and supplies provided to eligible Veterans who are seen by both VA and community providers. Community care referrals will include approval for interdisciplinary ALS care.

d. Dual Care must be used to balance the need for accessible, local care with the need for interdisciplinary ALS specialty care. Direct referrals of Veterans to the ALS Care Team from non-VA providers are appropriate where services are available.

8. COORDINATION WITH RELEVANT SERVICES

a. Given the limited life expectancy for Veterans with ALS, the provision of assistive technology (AT) and DME needs to be expedited; this requires coordination with Rehabilitation and Prosthetic Services. The VA medical facility ALS Coordinator must alert the VA medical facility PSAS Chief to assure careful planning for the provision of items needed with this sometimes rapidly progressing disease. The wide variety of items and services offered by PSAS should be considered by the team. Some examples include, but are not limited to:

(1) Low-tech DME devices, which must be available as “stock” for same-day provision. Low-tech devices include but are not limited to the aids for dressing, bathing, grooming, eating and drinking, ambulation aids and standard wheelchairs.

(2) Wheelchair cushions and off-the-shelf orthotic devices.

(3) Non-stock items, for which the PSAS consult has a processing time of 1-5 business days. ***NOTE:*** *This timeframe is for internal processing of the PSAS consult. Item availability depends on factors such as vendor stock availability and contracts.*

(4) Procurement and delivery of all other prescribed devices that are to be expedited to facilitate provision to the Veteran prior to further decline in function (e.g., power wheelchairs, home hospital beds, patient lifts, ventilators with backup, generators, and portable suction).

b. Providers must also discuss the use of Home Improvement Structural Alternations (HISA) grants early in the disease process; HISA can be used to make changes or improvements in the home to improve accessibility for the Veteran.

c. Providers must also discuss the use of the Adaptive Automobile Equipment benefit early in the disease process with appropriate guidance considering the progression of the disease. ***NOTE:*** *For more information see VHA Directive 1173.16, Driver Rehabilitation for Veterans with Disabilities Program, dated November 28, 2017*.

d. The delivery of care for Veterans with ALS is often shared by the Neurology Service, Rehabilitation Medicine Service, Spinal Cord Injuries and Disorders Service,

and Primary Care Medicine, according to the Veteran's needs and the professional expertise available from each of these programs. ***NOTE:*** *For more information see VHA Directive 1176(2), Spinal Cord Injuries and Disorders System of Care, dated September 30, 2019.*

e. Respite care is available to eligible Veterans and is a vital tool to address caregiver stress and needs. ***NOTE:*** *For more information on respite benefits, see VHA Handbook 1140.02, Respite Care, dated November 10, 2008.*

9. TRAINING

There are no formal training requirements associated with this directive.

10. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Officer.

11. REFERENCES

a. 38 U.S.C. §§ 1703, 1710, 1717, 1720, 7301(b).

b. 38 C.F.R. §§ 3.318, 17.155-159, 17.3100-3130.38, 17.3817.3200-3250.

c. VHA Directive 1094, Inter-Facility Transfer Policy, dated January 11, 2011.

d. VHA Directive 1173.13, Home Oxygen Program, dated August 5, 2020.

e. VHA Directive 1173.16, Driver Rehabilitation for Veterans with Disabilities Program, dated November 28, 2017.

f. VHA Directive 1176(2), Spinal Cord Injuries and Disorders System of Care, dated September 30, 2019.

g. VHA Directive 2009-038, VHA National Dual Care Policy, dated August 25, 2009.

h. VHA Handbook 1140.02, Respite Care, dated November 10, 2008.