Department of Veterans Affairs Veterans Health Administration Washington, DC 20420 VHA DIRECTIVE 1101.06 Transmittal Sheet July 27, 2023

# **MULTIPLE SCLEROSIS SYSTEM OF CARE**

#### 1. SUMMARY OF MAJOR CHANGES: This directive:

- a. Adds responsibilities in paragraph 2 to include the Executive Director, Pharmacy Benefits Management Services; Veterans Integrated Services Network Prosthetic Representative; Department of Veterans Affairs (VA) medical facility Chief of Staff/Associate Director of Patient Care Services; VA medical facility Chief, Pharmacy Service; VA medical facility Prosthetic and Sensory Aid Service Chief; Multiple Sclerosis (MS) Regional Specialty Program (RSP) Director; and MS RSP Coordinator.
- b. Removes Appendix B (MS Support Programs) as VA medical facilities that care for Veterans with MS but do not have an MS RSP are no longer referred to as MS Support Programs; they are now referred to as VA medical facilities without MS RSPs. All MS RSPs must provide a point of contact for MS care for all VA medical facilities within the Veterans Integrated Service Network. Veterans with MS in need of specialty care may be referred to MS RSPs via interfacility consult.
- **2. RELATED ISSUES:** VHA Directive 1215, Standards for Veterans Health Administration Centers of Excellence, dated February 14, 2017; VHA Directive 1159, VHA Specialty Care Program Office and National Programs, dated March 9, 2022.
- **3. POLICY OWNER:** The National Neurology Program within the Specialty Care Program Office (11SPEC15) is responsible for the contents of this directive. Questions may be addressed to the Neurology National Program Executive Director at: <a href="https://www.wha1spec15n2@va.gov">wha1spec15n2@va.gov</a>.
- **4. RESCISSIONS:** VHA Directive 1101.06, Multiple Sclerosis System of Care, dated April 14, 2017, is rescinded.
- **5. RECERTIFICATION:** This Veterans Health Administration (VHA) directive is scheduled for recertification on or before the last working day of July 2028. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.
- **6. IMPLEMENTATION SCHEDULE:** This directive is effective 1 year from publication.

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

/s/ Erica Scavella, M.D., FACP, FACHE Assistant Under Secretary for Health for Clinical Services/CMO

**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 July 31, 2023.

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#### **MULTIPLE SCLEROSIS SYSTEM OF CARE**

# 1. POLICY

It is Veterans Health Administration (VHA) policy that all enrolled Veterans with Multiple Sclerosis (MS) have access to the full spectrum of clinically appropriate multidisciplinary specialty services through an MS System of Care that includes the MS Centers of Excellence (MSCoEs) and at least one MS Regional Specialty Program (RSP) per Veterans Integrated Services Network (VISN) to provide consultative MS specialty care to all other Department of Veterans Affairs (VA) medical facilities. **AUTHORITY:** 38 U.S.C. § 7330.

# 2. RESPONSIBILITIES

- a. <u>Under Secretary for Health.</u> The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.
- b. <u>Assistant Under Secretary for Health for Clinical Services.</u> The Assistant Under Secretary for Health for Clinical Services is responsible for supporting the Chief Officer, Specialty Care Program Office (SCPO) with implementation and oversight of this directive and collaborating with the Assistant Under Secretary for Health for Patient Care Services to support implementation of this directive.
- c. <u>Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer.</u> The Assistant Under Secretary for Health for Patient Care Services/CNO is responsible for supporting the program offices within Patient Care Services and collaborating with the Assistant Under Secretary for Health for Clinical Services to support implementation of this directive.
- d. <u>Assistant Under Secretary for Health for Operations.</u> The Assistant Under Secretary for Health for Operations is responsible for:
  - (1) Communicating the contents of this directive to each of the 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.
- e. <u>Chief Officer</u>, <u>Specialty Care Program Office</u>. The Chief Officer, SCPO is responsible for supporting the National Program Executive Director (NPED) in executing their responsibilities as outlined in this directive.
- f. <u>Neurology National Program Executive Director.</u> The Neurology NPED is responsible for:

- (1) Supporting implementation of and compliance with this directive through collaboration with VISN and MSCoE Directors.
- (2) Supporting the MSCoE Directors in developing a plan to establish, collect and assess national performance data for quality improvement for MS care across VHA.
- (3) Collaborating with VISN Directors and MSCoE Directors to designate at least one MS RSP per VISN.
- (4) Serving as the MS communication liaison to MSCoE Directors, VISN Directors and VA medical facility Directors.
- (5) Collaborating with the Executive Director, Office of Rehabilitation and Prosthetics Services on MS-related rehabilitation and prosthetics initiatives of strategic importance to VA.
- g. <u>Executive Director, Pharmacy Benefits Management Services.</u> The Executive Director, Pharmacy Benefits Management (PBM) Services is responsible for collaborating with MSCoE Directors on MS-related formulary initiatives of strategic importance to VA.
- h. <u>Multiple Sclerosis Centers of Excellence Directors.</u> MSCoE Directors are responsible for:
  - (1) Supporting the Neurology NPED in establishing and maintaining this directive.
  - (2) Performing surveillance to identify Veterans with MS in VHA to assess utilization.
- (3) Coordinating with the Neurology NPED to establish, collect and assess national performance and quality data for MS across VHA.
- (4) Informing VISN Directors of any VA medical facilities eligible to become MS RSPs (eligibility criteria is described in paragraph 5.g.) and recommending VA medical facilities for designation as MS RSPs.
- (5) For VA medical facilities designated as an MS RSP, advising the VA medical facility Director on the appointment of an MS RSP Director.
- (6) Identifying advances in MS care and making recommendations to the Neurology NPED and other VA Central Office program offices, as appropriate.
- (7) Collaborating with the Executive Director, PBM Services to provide operational direction and support on MS-related formulary initiatives of strategic importance to VA, including:
- (a) Providing clinical input on agents under review for formulary consideration in accordance with VHA Directive 1108.08, VHA Formulary Management Process, dated July 29, 2022.

- (b) Participating in VA Adverse Drug Event Reporting System (ADERS), including reviewing adverse drug events in Veterans with MS. For additional information see VHA Directive 1070, Adverse Drug Event Reporting and Monitoring, dated May 15, 2020.
- (c) Educating VA health care providers treating Veterans with MS on formulary changes, criteria for use, generic conversions and therapeutic interchanges, pharmacoeconomics and Medication Use Evaluation Trackers.
- (d) Participating in implementing national formulary decisions, cost avoidance initiatives, and evidence-based prescribing of disease modifying therapies (DMTs).
- (8) Providing clinical care updates and education to VA health care providers providing care for Veterans with MS.
- (9) Ensuring educational programs designed to increase VA health care provider knowledge about MS, its management and resources are available through VA. **NOTE:** Information on these opportunities is available on the MSCoE website at: <a href="https://www.va.gov/MS/products/index.asp">https://www.va.gov/MS/products/index.asp</a>.
- i. <u>Veterans Integrated Services Network Director</u>. The VISN Director is responsible for:
- (1) Designating at least one MS RSP per VISN, in collaboration with the Neurology NPED and MSCoE Directors.
- (2) Ensuring that all VA medical facilities within the VISN comply with this directive, based on their designation as an MS RSP, and if barriers to compliance are identified, informing the Chief Officer, SCPO and the Neurology NPED to develop an action plan.
- (3) Providing the necessary resources for VA medical facilities within the VISN to implement and support the MS System of Care and ensure VISN and VA medical facility responsiveness to the health care needs of Veterans with MS.
- (4) Collaborating with the VA medical facility Director and VA medical facility Chief of Staff (CoS)/Associate Director of Patient Care Services (ADPCS) to ensure self-directed care for Veterans with MS is coordinated in accordance with VHA Directive 1310(1), Medical Management of Enrolled Veterans Receiving Self-Directed Care from External Health Providers, dated October 4, 2021.
- j. <u>Veterans Integrated Services Network Prosthetic Representative.</u> The VISN Prosthetic Representative is responsible for collaborating with MSCoE Directors on MS-related prosthetics initiatives of strategic importance to VA and facilitating communication between VA medical facilities within the VISN.
  - k. **VA Medical Facility Director.** The VA medical facility Director is responsible for:
- (1) Ensuring overall VA medical facility compliance with this directive and informing the VISN Director and developing a corrective action plan if barriers to compliance are

identified.

- (2) Ensuring that VA medical facility staff providing care to Veterans who have been diagnosed with MS, or are suspected of having MS, have referral options to an MS RSP.
- (3) Ensuring necessary medical equipment, supplies and subspecialty care are provided to enrolled Veterans with MS in their catchment area.
- (4) Collaborating with the VISN Director and VA medical facility CoS/ADPCS to ensure self-directed care for Veterans with MS is coordinated in accordance with VHA Directive 1310(1).
- (5) For VA medical facilities designated as an MS RSP, designating an MS RSP Director in collaboration with the VA medical facility CoS/ADPCS and MSCoE Director.
- (6) For VA medical facilities designated as an MS RSP, ensuring the space, administrative support and essential staff (MS RSP Team) needed to deliver comprehensive inpatient and outpatient care for Veterans with MS is available. **NOTE**: The MS RSP Team is a multidisciplinary group of health care providers who provide primary and specialty services for Veterans with MS. All staff may serve the given VA medical facility (part-time or full-time) consistent with VHA Directive 1065(1), Productivity and Staffing Guidelines for Specialty Provider Group Practice, dated December 20, 2020. In some circumstances, MS RSP Team members may participate by telehealth. The MS RSP Team is led by the MS RSP Director and must include the MS RSP Coordinator, Registered Nurse or advanced practice provider, Clinical Pharmacy Practitioner or Clinical Pharmacist with expertise with MS medications, Social Worker, Clinical Psychologist (Clinical Health Psychologist, Rehabilitation Psychologist or Neuropsychologist), Physical Therapist or Kinesiotherapist, Occupational Therapist and Speech-Language Pathologist. Other VA health care providers whose services are frequently needed for comprehensive care of Veterans with MS are involved in clinical care as Veteran needs and local availability dictates (e.g., Recreational and Creative Arts Therapist, Assistive Technology Specialist, Urologist, Pulmonologist, Chaplains and providers in Spinal Cord Injuries and Disorders (SCI/D), Radiology, Pain Management, Whole Health and Palliative Medicine/Hospice Care). Dedicated administrative support is recommended.
- I. <u>VA Medical Facility Chief of Staff or VA Medical Facility Associate Director of Patient Care Services.</u> The VA medical facility CoS or ADPCS, depending on the VA medical facility, is responsible for:
- (1) For those VA medical facilities designated as MS RSPs, collaborating with the VA medical facility Director to designate an MS RSP Director. See paragraph 2.n. **NOTE:** Due to the difficulty recruiting and retaining physicians with MS specialty training, an MS RSP Director may become unavailable. If this occurs, the VA medical facility CoS/ADPCS must notify a MSCoE Director and an Interim Director without MS expertise may be appointed by the CoS/ADPCS for up to 2 years with a signed

agreement outlining virtual back-up. When this option is not available, MS RSPs must be placed on inactive status.

- (2) Identifying the MS RSP Coordinator.
- (3) Notifying the VA medical facility Director of challenges complying with this directive and the MS System of Care.
- (4) Collaborating with the VISN Director and VA medical facility Director to ensure self-directed care for Veterans with MS is coordinated in accordance with VHA Directive 1310(1).
- m. <u>VA Medical Facility Chief, Pharmacy Service.</u> The VA medical facility Chief, Pharmacy Service is responsible for identifying Clinical Pharmacy Practitioner or Clinical Pharmacist with expertise with MS medications to work with MS RSPs and VA medical facilities without MS RSPs on appropriate prescription of DMTs, safety monitoring and reporting, adherence strategies and Veteran and caregiver education.
- n. <u>VA Medical Facility Prosthetic and Sensory Aids Service Chief.</u> The VA medical facility PSAS Service Chief is responsible for:
- (1) Coordinating and collaborating with MS RSPs and VA medical facilities without MS RSPs to provide necessary resources and medical equipment determined by the MS RSP Director for MS treatment and care.
- (2) Ensuring VA medical facility Prosthetic and Sensory Aids Service (PSAS) staff collaborate with clinical staff to:
- (a) Provide updates and education on equipment and benefits under PSAS purview, including Prosthetic and Rehabilitative Items and Services (PARIS), the VA Automobile Adaptive Equipment (AAE) program and the Home Improvement and Structural Improvement (HISA) Program. *NOTE:* For more information, see VHA Directive 1173.14, Home Improvement and Structural Alterations (HISA) Program, dated December 26, 2017, 38 C.F.R. §§ 17.3200-3250, 17.3100-3105 and 17.155-159.
- (b) Ensure the streamlined provision of PSAS devices and benefits to Veterans with MS. **NOTE:** See VHA Directive 1173, Prosthetics and Sensory Aid Services, dated March 27, 2023.
- o. <u>Multiple Sclerosis Regional Specialty Program Director.</u> *NOTE:* The position of MS RSP Director is appointed by the VA medical facility Director in collaboration with the CoS/ADPCS and must be filled by a physician (i.e., a neurologist, physiatrist or SCI/D board-eligible specialist with other medical training) with specialty fellowship training or substantial experience and expertise in MS, who may serve the given VA medical facility through a part-time or full-time appointment consistent with VHA Directive 1065(1). This person must have experience in MS (fellowship training is strongly encouraged). The MS RSP Director is responsible for:

- (1) Leading, coordinating and overseeing all clinical and administrative aspects of the MS RSP.
- (2) Developing and maintaining processes and standard operating procedures, knowledge and skills to ensure that Veterans with MS receive comprehensive, high-quality multidisciplinary care.
- (3) Optimizing follow-up and medication safety for Veterans with MS in their catchment area, including reporting to VA ADERS.
  - (4) Offering annual assessments for Veterans with MS in the catchment area.
- (5) Working with the MSCoE Directors to identify Veterans with MS within their catchment area.
  - (6) Ensuring the MS RSP Team receives and reviews MS consults.
- (7) Ensuring the MS RSP Team participates in MSCoE education, training, meetings and other activities related to MS.
- p. <u>Multiple Sclerosis Regional Specialty Program Coordinator</u>. *NOTE:* The position of MS RSP Coordinator is appointed by the VA medical facility Director in collaboration with the CoS/ADPCS and must be filled by a non-physician health care provider (e.g., Registered Nurse or advanced practice provider, Clinical Pharmacy Practitioner or Clinical Pharmacist, Social Worker, Clinical Psychologist, Physical Therapist or Kinesiotherapist, Occupational Therapist or Speech-Language Pathologist) on the MS RSP Team with expertise in MS. The MS RSP Coordinator is responsible for:
- (1) Serving as, or identifying and communicating with, a single point of contact for Veterans with MS and their caregivers at all VA medical facilities in the catchment area.
- (2) Providing case management, assisting with MS treatment and providing education to Veterans, caregivers and other VA medical facility staff.
- (3) Collaborating with the MS RSP Team to ensure optimal clinical management of Veterans with MS.
- (4) Coordinating with the MS RSP Team, Pharmacy, infusion center, PSAS, Radiology, Integrated Veteran Care coordinators and other necessary services to ensure careful planning and provision of items needed for MS RSP.
  - (5) Coordinating conferences for the MS RSP Team.
  - (6) Identifying Veterans with MS and facilitating appointments at MS RSPs.
- (7) Coordinating communication and visits between MS RSPs, other VA medical facilities and community care facilities if needed.

(8) Participating in MSCoE education, training, meetings and other activities related to MS.

# 3. TRAINING

There are no formal training requirements associated with this directive.

# 4. RECORDS MANAGEMENT

All records regardless of format (for example, 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 can be addressed to the appropriate Records Officer.

# 5. BACKGROUND

- a. MS is an inflammatory, degenerative disease of the central nervous system and the most common progressive neurological disease of young adults, with a mean age of onset of 30 years. There are 1 million persons with MS in the United States among which 80,000 are Veterans. MS is an unpredictable and progressive disease that affects the brain, spinal cord and optic nerves and requires different treatment approaches and expertise depending upon the stage and presentation of disease. MS is a unique disease within VA due to its high prevalence in women, onset in young adulthood (commonly during military service) and high proportion of Veterans with MS-related service-connection.
- b. The diagnosis of MS can be challenging. Symptoms of MS vary widely from person to person, may be intermittent and can be challenging to identify on a general clinical examination and there is no definitive diagnostic biomarker test. These challenges can result in misdiagnosis and can thus lead to delays in treatment. The medications to treat MS should be started soon after diagnosis, but they are costly and are associated with potentially severe side effects that generally necessitate frequent clinical, laboratory and radiological monitoring. Although MS does not substantially shorten life expectancy, the disease generally results in progressive neurological disability (e.g., reduced cognitive, visual, motor and sensory function, pain, bladder and bowel dysfunction and mood disorders) that diminishes quality of life.
- c. To adequately care for Veterans with MS requires a multidisciplinary team (see MS RSP Team in paragraph 2.j.(6)) knowledgeable about the care of people with MS. Given the multiple systems that can be affected over the course of the disease, the delivery of care for MS is often shared by the Neurology Service, Physical Medicine and Rehabilitation Service, SCI/D Center and Primary Care service, according to the Veteran's needs and local professional expertise. In some cases, care within an SCI/D Center for Veterans with MS who have SCI/D is appropriate. **NOTE:** For more information, see VHA Directive 1176(2), Spinal Cord Injuries and Disorders System of Care, dated September 30, 2019, and www.va.gov/MS.

- d. To address the unique needs of Veterans with MS, VHA established MSCoEs to coordinate clinical care, education and research. Host VA medical facilities were selected by a peer review committee from a national pool of applications and were made permanent by the Veteran's Benefits, Healthcare and Information Technology Act of 2006 (38 U.S.C. § 7330). That legislation requires that MSCoEs coordinate education, clinical and research activities and to jointly develop a consortium of providers with interest in treating MS to ensure better access to state-of-the-art diagnosis, care and education for autoimmune disease affecting the central nervous system. There are currently two MSCoEs: MSCoE East and MSCoE West. MSCoE East coordinates the network of MS care for VISNs 1-10. MSCoE West coordinates the network of MS care for VISNs 12-23.
- e. Given the size of the population of Veterans with MS seeking treatment in VA and their distribution across the country, a hub and spoke MS System of Care network was developed. This network consists of the MSCoE East and West coordinating centers, the RSPs (the "hubs") and VA medical facilities without MS RSPs (the "spokes").
- f. Each MS RSP is an integrated and coordinated group of health care providers from different disciplines who work together to provide MS specialty services that address the complex physical, psychological and spiritual needs of Veterans with MS. VA medical facilities without MS RSPs can provide primary care, and potentially other aspects of care including some MS care. The network serves all enrolled Veterans diagnosed with MS or suspected of having MS, and those with clinically or radiologically isolated syndromes who are being monitored for meeting criteria for MS or are on MS DMTs.
- g. To be eligible for consideration as an MS RSP, VA medical facility staff must have access to appropriate inpatient and outpatient services to provide access to high-quality specialty MS care for all Veterans with MS enrolled to receive care through VHA. Specific criteria include:
  - (1) The VA medical facility serves at least 100 Veterans with MS.
  - (2) The VA medical facility has subspecialty expertise in MS that allows for:
  - (a) Making an accurate diagnosis of MS and identifying the subtype.
  - (b) Treating acute MS relapses.
  - (c) Assessing and managing disability.
- (3) The VA medical facility has a multidisciplinary MS RSP Team (see paragraph 2.j.(6)).
- (4) The VA medical facility has access to magnetic resonance imaging for diagnosis and monitoring.
  - (5) VA medical facility staff have the ability to prescribe, infuse and monitor Food

and Drug Administration-approved DMTs using PBM-approved safety and monitoring protocols.

- (6) VA medical facility staff have access to an infusion center and a clinical pharmacist with expertise in MS. Recommended optional services include Vocational and Recreational Therapy and Creative Arts Therapy.
- h. Consultation between MS RSPs and VA medical facilities without MS RSPs takes place through telehealth (e.g., E-consultation, videotelehealth) or live visits. Referral and consults by virtual means are encouraged when appropriate. Any VA medical facility may consult with the MSCoE about appropriate evaluations or strategies to meet a Veteran's needs. In addition, Veterans' family members, home caregivers, health care providers and administrative staff who seek information about MS are included in the population served by the MSCoE education and outreach program. See <a href="http://www.va.gov/ms">http://www.va.gov/ms</a> for further information.

# 6. REFERENCES

- a. 38 U.S.C. § 7330.
- b. 38 C.F.R. §§ 17.155-159, 17.3100-3105 and 17.3200-3250.
- c. VHA Directive 1065(1), Productivity and Staffing Guidelines for Specialty Provider Group Practice, dated December 22, 2020.
- d. VHA Directive 1070, Adverse Drug Event Reporting and Monitoring, dated May 15, 2020.
- e. VHA Directive 1108.08, VHA Formulary Management Process, dated July 29, 2022.
  - f. VHA Directive 1173, Prosthetics and Sensory Aid Services, dated March 27, 2023.
- g. VHA Directive 1173.14, Home Improvement and Structural Alterations (HISA) Program, dated December 26, 2017.
- h. VHA Directive 1176(2), Spinal Cord Injuries and Disorders System of Care, dated September 30, 2019.
- i. VHA Directive 1310(1), Medical Management of Enrolled Veterans Receiving Self-Directed Care from External Health Providers, dated October 4, 2021.
  - j. VHA Multiple Sclerosis Centers of Excellence. <a href="http://www.va.gov/ms">http://www.va.gov/ms</a>.