



Protecting, Maintaining and Improving the Health of Minnesotans

Subject: Federal Medicare Compliance Requirements for a Comprehensive Home Care Provider that is a Medicare-Certified Home Health Agency (HHA) and Operating Separate Entity

HHA: means in this document a licensed Comprehensive Home Care Provider that is a Medicare-Certified Home Health Agency.

Purpose:

The purpose of this document is to give Minnesota Licensed Comprehensive Home Care providers who operate a Medicare-Certified Home Health Agency (HHA) in Minnesota options to:

1. Option 1 - Hold one Comprehensive home care provider license and be a Medicare - Certified HHA for the entire licensed entity; or
2. Option 2 - Hold two distinct and separate Comprehensive home care provider licenses with one of these licensees operating as a Medicare-Certified HHA; or
3. Option 3 - Hold one Comprehensive home care provider license and be Medicare - Certified HHA and have a separate entity that is subject to licensure standards and not Medicare HHA requirements.

This document outlines requirements that must be met under these options. Prior to this document being issued, only Options 1 and 2 were available. This document details Option 3. Option 3 allows a provider to obtain one home care license and be a Medicare Certified HHA.

Background

A home care provider operating in Minnesota that wishes to become Medicare-certified must first obtain a Comprehensive home care license. Once this licensed comprehensive home care provider obtains Medicare certification, all Medicare Conditions of Participation (CoP's) are applicable to all individuals served by the home care provider and not just the Medicare beneficiaries. If the Comprehensive Home Care Provider was able to demonstrate that it was also operating a separate entity not certified by Medicare as an HHA, then the Medicare CoP's would not apply to the separate entity. Previously, demonstration of operating a separate entity was

only accomplished by the Comprehensive Home Care Provider obtaining and operating a separate home care license that does not pursue Medicare certification.

- **Licensed Comprehensive Home Care Provider not Medicare-Certified Home Health Agency:** A licensed home care provider¹ that is not Medicare-certified is not required to meet Medicare Conditions of Participation.
- **Licensed Comprehensive Home Care Provider is a Medicare-Certified Home Health Agency:** A licensed home care provider that is Medicare-certified is required to meet Medicare Conditions of Participation.

Medicare Conditions of Participation for Home Health Agencies related to Separate Entities:

As indicated in Chapter 2, Section 2183 of the Medicare State Operations Manual “the Medicare CoPs, in accordance with §1861(o) (6) of the Act, are applicable to all individuals served by the HHA and not just to Medicare beneficiaries.”

The Medicare State Operations Manual also allows for HHAs to establish a separate entity to which the Medicare CoPs do not apply ([Chapter 2 - 2183](#)). A Minnesota comprehensive licensed home care provider that is a Medicare-certified HHA with a separate entity may operate the separate entity under Minnesota licensure requirements. It is not required for the separate entity to comply with Medicare Conditions of Participation IF it is able to demonstrate that it is operating a separate entity consistent with Medicare requirements. Therefore:

A Comprehensive Home Care Provider that wishes to be a Medicare Certified HHA in Minnesota may exercise the option to “categorize” their Comprehensive home care license in order to operate a separate entity. For Medicare HHA certification, this categorization of the comprehensive home care license will allow the licensee to establish a “separate entity” without having to obtain a separate comprehensive home care license.

If you are Medicare-Certified as an HHA, the Medicare Conditions of Participation will apply to all clients of the comprehensive home care licensee unless the licensee is able to demonstrate they are operating a separate entity.

¹ A temporary Comprehensive home care provider is unable to apply for Medicare certification as a HHA. A Basic home care provider is unable to apply for Medicare certification as a HHA.

How to Establish a Separate Entity for Comprehensive Home Care Provider That Is Certified as a Medicare HHA

There are a number of criteria that must be met in order for the HHA to demonstrate they are operating a separate entity. These criteria relate to the operation of the HHA; consumer awareness; and staff awareness.

Note: as identified in Option 2 on Page 1, a provider may choose to pursue a separate home care license to establish an entity separate from the certified entity (instead of establishing a separate entity with one home care license). If a provider chooses to hold more than one home care license as part of establishing its separate entity, the provider will still have to comply with the following criteria in order to prove its differentiation from the certified entity (HHA). **Medicare CoP's will be applicable unless the provider is able to demonstrate it is meeting the following criteria, regardless of whether it chooses to pursue a separate home care license.**

Operation of the HHA

The HHA administrator must be able to describe the organizational, functional, and clinical boundaries of the Medicare-certified program in relation to the separate entity. The separate entity should be separate and distinct from the HHA. The Minnesota Department of Health program staff and surveyors must be able to confirm that the HHA has:

- Separate policies and procedures for admission to the HHA, including separate consent forms;
- Separate clinical records for all patients receiving HHA services;
- Current listing of staff employed by or contracted to the HHA;
- Personnel records;
- Time sheets or other records to demonstrate distinct assignment of personnel to the HHA; and
- Separate budgets.

Consumer Awareness

The HHA must be able to differentiate the services of the HHA from other services offered by the separate entity. Department of Health program staff and surveyors will ask the HHA for a copy of any brochure the HHA uses to describe itself to the community. Any applicable brochures should identify the HHA services as separate and distinct from other programs, departments, or entities operated by the HHA. The HHA should be differentiated from other programs, departments or entities of the organization in listings, advertisements, etc. Written material should clearly identify the HHA as separate and distinct from other programs, departments or entities of the organization.

Staff Awareness

The HHA staff should be knowledgeable about the HHA's policies and procedures, the regulatory requirements related to their role in the delivery of care in an HHA, and be able to identify the difference in services they provide for the HHA and other programs, departments, or entities of the organization.

Personnel who divide time between the separate entity and the HHA must be appropriately trained to deliver HHA services. The HHA maintains separate time sheets for each individual's assigned time to the HHA.

If it is determined that, based on the information provided by the HHA or for other reasons, that the HHA does not have a separate entity, or if the HHA or parent organization is unable or unwilling to provide the information, inform the HHA that:

- It is in violation of the provisions of §§1861(o) and 1891 of the Act which require compliance with the CoPs, particularly those conditions that relate to clinical records and disclosure of the ownership of the HHA.
- It is in violation of its agreement with the Secretary under §1866 of the Act and the regulations related to this agreement (42 CFR Part 489.53(a)) because it has failed to provide information about ownership and information concerning clinical records.
- It is in violation of §1128(b)(12)(A) of the Act because it has denied access to records to determine compliance with the CoPs, including those that relate to the OASIS requirements; and
- It may be in violation of various requirements related to its Medicare cost reports, which mandate information about all of the HHA's clients in order to properly pay Medicare costs, and that the HHA's MAC must be notified about the allegation of separate entities².

MDH is required to report these separate entity situations to the Centers for Medicare and Medicaid Services (CMS), along with any recommendations the State has concerning the operation of two distinct entities. MDH will be required to indicate whether the HHA refused access to records or information that make it impossible for the surveyor to make a determination concerning whether the applicant or approved HHA complies with the HHA CoPs. CMS must then report this information to the MAC and, if necessary, to the State Medicaid Director.

For further information regarding separate entities, please contact the Licensing and Certification Program by email: HEALTH.CM-Cert@state.mn.us or by phone: 651-201-4101.

² See 42 CFR Parts 413.5(b) (3), 413.9, 413.13(f) (2) (ii), 413.17, 413.50(b), 413.53(a), and 413.80(d.).



Application for Home Health Agency (HHA) Attestation and Demonstration of Operating a Separate Entity

The HHA must demonstrate they are meeting the criteria for operating a separate entity to which the Medicare Conditions of Participation do not apply. This application for attestation and required documentation serves as an addendum to the Comprehensive License Application to “categorize” the license in order to establish a separate entity to provide both licensed services and Medicare certified home health services. Applicants must complete the information below and include all attachments required by this checklist. Please identify the attachments using a non-duplicating numbering system and identify the attachment number next to the requiring section.

Please send to:

Minnesota Department of Health
Health Regulation Division
Licensing and Certification Program
P.O. Box 64900
St. Paul, MN 55164-0900
Attn: Certification Specialist
Email address: health.CM-Cert@state.mn.us

HHA Name: _____

HHA License Number: _____

HHA Administrator: _____

Address: _____

City, State, Zip: _____

Phone: _____ **Email:** _____

Submission Requirements

Please submit the following provider-specific documentation to demonstrate your compliance with the HHA criteria for a separate entity:

- Separate policies and procedures for admission to the HHA and the separate entity, including separate consent forms. Attachment #_____
- Separate forms for documentation of clinical records for all clients receiving HHA services and forms for the clients of the separate entity (do not send actual records). Attachment #_____
- Current listing of staff employed by or contracted to the HHA and by the separate entity. Attachment #_____
- Separate brochures that differentiate the services of the HHA from the services offered by the separate entity. Attachment #_____
- Other written material or advertisements that clearly differentiate the organizational, clinical and functional boundaries so that separation of the HHA and the separate entity is evident to the community it serves. Attachment #_____

Attestation Requirements

This section must be completed and signed by a managerial official.

Please initial the following statements and sign below.

- _____ Our Medicare-certified program and our licensed separate entity have separate personnel records.
- _____ Our Medicare-certified program and our licensed separate entity have separate time sheets and other records to demonstrate distinct assignment of personnel to the HHA and the separate entity.
- _____ Our Medicare-certified program and our licensed separate entity have separate budgets.
- _____ Our HHA staff are knowledgeable about the HHA's policies and procedures, the regulatory requirements related to their role in the delivery of care in an HHA, and are able to identify the difference in services they provide for the HHA and other separate entities of the organization.
- _____ Our personnel who divide time between the separate entity and the Medicare Certified Program are appropriately trained to deliver HHA services.
- _____ I understand that the services provided by a separate entity may be evaluated in conjunction with onsite HHA surveys or complaint investigations.
- _____ I understand that Minn. Stat. Sec. 144A.43-144A.481 applies to the separate entity.

I understand that if it is determined that the agency is not operating as a separate entity, or if the agency or parent organization is unable or unwilling to provide the information, the agency will be informed that it is in violation of one or more of the following: the provisions of §§1861(o) and 1891, §1866, §1128(b)(12)(A), 42 CFR Part 489.53(a)), or of various requirements related to its Medicare cost reports. I also understand that MDH is required to report to the Centers for Medicare and Medicaid Services (CMS) any concerns it has regarding the operation of two distinct entities. CMS in turn must report this information to the intermediary and, if necessary, to the State Medicaid Director.

I attest that this information is true, correct, and complete.

Print Name: _____ **Date:** _____

Signature: _____ **Title:** _____