



Date: November 9, 2017

To: Medicare Certified Home and Community Support Service Agencies (HCSSAs)

Subject: Provider Letter 17-35 – Determination of Separate Entities (Replaces PL 01-46 & PL 02-05)

The Centers for Medicare and Medicaid Services (CMS) requires that Medicare-certified home health agencies (HHAs) meet the Medicare Conditions of Participation (CoPs) for all clients being served by the agency, regardless of a client's payment source. With the exception of certain Outcome and Assessment Information Set (OASIS) and comprehensive assessment requirements, the Medicare CoPs apply to all clients served by a certified HCSSA, including those receiving only personal care services. CMS does not allow exceptions or distinguish between the different categories of HCSSA licensure, unless the HHA operates a "separate entity" as described by CMS.

In order to establish a separate entity, the HCSSA must document a separate line of business in the licensed home health (LHHS) or personal assistance services (PAS) license category that indicates a distinct or separate department, division, agency or program is exempt from meeting the Medicare CoPs. If a HCSSA does not demonstrate separateness, the Medicare CoPs will apply.

### **How to Establish a Separate Entity**

The Centers for Medicaid & Medicare Services (CMS) does not define "separate entity;" however, the State Operations Manual (SOM), Section 2183, outlines criteria to help surveyors differentiate a separate line of business. When a HCSSA alleges a separate entity and that the Medicare CoPs do not apply to that entity, the HCSSA must produce evidence in the following categories: operation of the HCSSA; consumer awareness; and, staff awareness.

### **Operation of the HCSSA**

The administrator must be able to describe the organizational, functional, and clinical boundaries (i.e., organizational charts or functional structure) of the Medicare-certified program in relation to the separate entity. Surveyors will also review the following information below to ensure that the operation of the HCSSA is separate and distinct from another entity or business.

- Client records must include:
  - separate consent forms;
  - separate policies and procedures for admission; and
  - separate clinical records for all patients receiving services.
  
- Staff records must include:
  - separate personnel records;
  - a current list of employees that identifies the entity each individual is employed by; and
  - separate employee time sheets, employee work schedules, a percentage allocation form, or employee itinerary or other records to demonstrate the employees' time and salary are divided.
  
- Financial records must include:
  - a separate operating budget or cost report; or
  - separate contracts when services are provided under arrangements.

### **Consumer Awareness**

Surveyors will ask for brochures, telephone listings, advertisements and written material to verify how the HCSSA describes itself to the community. This information should clearly identify that the Medicare-certified home health services are separate and distinct from other programs, departments or entities of the organization.

### **Staff Awareness**

Staff should be knowledgeable about:

- policies and procedures for each applicable entity they work for;
- differences in the services provided by the HCSSA and separate entity; and
- regulatory requirements related to their role in the delivery of care.  
(Personnel who divide time must be appropriately trained to deliver services they are providing.)

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Surveyors will determine whether the organization operates a separate entity exempt from meeting the Medicare COPs based on the evidence provided. HHSC Regulatory Services reports the alleged separate entity along with their findings and recommendations to the CMS Regional Offices (RO).

HHSC Regulatory Services reports to CMS if a Medicare-certified HCSSA refuses to provide information that surveyors require to make a determination concerning a separate line of business. A HCSSA that is unable to demonstrate or is unwilling to provide information will be informed that it may be in violation of various federal requirements.<sup>1</sup>

If you need further information regarding separate entities, please contact a policy specialist in the Policy, Rules and Training section at (512) 438-3161.

Sincerely,

*[signature on file]*

Mary T. Henderson  
Associate Commissioner  
Long-term Care Regulatory

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<sup>1</sup> See State Operations Manual, Chapter 2 – The Certification Process, Part 2183.3 (Rev. 125; effective 10/31/2014)