



Center for Clinical Standards and Quality/Survey & Certification Group

Admin Info: 14-22-Deemed Providers/Suppliers & RHCs

DATE: April 11, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Updated State Operations Manual (SOM) Exhibits Concerning Deemed Providers/Suppliers; Rural Health Clinics (RHCs); and Report of a Hospital Death Associated with Restraint or Seclusion

Memorandum Summary

- ***Updated SOM Exhibits:*** We are updating and/or deleting several SOM Exhibits concerning deemed status providers and suppliers; RHCs and swing bed hospitals; and hospital reports of deaths associated with restraint or seclusion. The updates reflect current SOM policy.
- ***Clarification for Validation Surveys:*** Exhibit 37 must be presented to all deemed status providers and suppliers at the entrance conference for all validation surveys, both representative sample and substantial allegation. Likewise deemed status providers and suppliers must be asked to sign Exhibit 287 for all validation surveys.

Deemed Status Providers and Suppliers

The following SOM Exhibits concerning deemed status providers and suppliers are being updated:

- Exhibit 37: Model Letter Announcing Validation Survey of Deemed Status Provider/Supplier
- Exhibit 196: Model Letter Announcing to Deemed Status Provider/Supplier after a Validation Survey that it does not Comply with all Medicare Conditions
- Exhibit 199: Model Letter Announcing to Deemed Status Provider/Supplier after a Substantial Allegation Survey that it will Undergo a Full Survey
- Exhibit 287: Authorization by Deemed Provider/Supplier Selected for Validation Survey

42 CFR 488.7(b) requires a deemed status provider or supplier selected for validation to authorize the validation survey as well as State Survey Agency (SA) oversight of correction of deficiencies. Failure to provide such authorization results in removal of the provider's or supplier's deemed status and may result in the termination of their Medicare agreement. Exhibit 37 announces this requirement to the facility selected for survey, while Exhibit 287 is the required authorization the facility is expected to complete. Both exhibits have been revised to make clear that they must be used for both types of validation surveys: representative sample and substantial allegation (complaint).

SC-13-27, April 19, 2013, clarified in revisions to SOM Chapter 5 that a full survey is not always required after a substantial allegation survey that finds condition-level noncompliance. As a result, it is necessary to update Exhibits 196 and 199.

Exhibit 196 has also been revised to make it applicable not only to deemed status providers and suppliers that have had a representative sample validation survey which found substantial noncompliance, but also to those that have had a substantial allegation survey with such findings, where the CMS Regional Office (RO) is not requiring the SA to conduct a full survey before taking enforcement action. This exhibit is also being revised to correspond to provisions in SOM Chapter 2 concerning plans of correction. Other clarifying revisions have also been made.

Likewise, Exhibit 199 previously applied only to deemed hospitals and presumed that a full survey is conducted after every substantial allegation survey which finds condition-level noncompliance. It has been revised to apply to all types of deemed providers and suppliers, but only in those cases where the RO requires the SA to conduct a full survey after a substantial allegation survey that identified condition-level noncompliance.

Rural Health Clinics

The following RHC exhibit is being deleted:

- Exhibit 25, Model Letter to Rural Health Clinic Regarding Scheduling a Survey, is being deleted, since all surveys must be unannounced.

Hospital Swing Beds

Exhibit 162: Model Letter, Request for a Plan of Correction Following an Initial Survey for Swing-bed Approval in a Hospital, has been revised to correspond to provisions in SOM Chapter 2 concerning plans of correction.

Hospital Restraint/Seclusion Death Reporting

Exhibit 353, which was a worksheet, has been replaced with a link to the new Form CMS-10455, *Report of a Hospital Death Associated with Restraint or Seclusion*, which has been approved by the Federal Office of Management and Budget (OMB) and is posted on the CMS Forms website. Reports of deaths associated with the use of restraint or seclusion which hospitals are required to report to their CMS Regional Office must now be submitted by reporting hospitals on this form.

An advance copy of the revisions to the SOM Exhibits is attached.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

Attachment – Advance copy of Updated SOM Exhibits

cc: Survey and Certification Regional Office Management