CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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I. SUMMARY OF CHANGES: Pub. 100-07, State Operation Manual, is a new CMS manual that replaces the current paper-based State Operations Manual, Pub. 7. It is an Internet-only manual and may be accessed at the CMS Web site: http://www.cms.hhs.gov/manuals

NEW/REVISED MATERIAL - EFFECTIVE DATE: JUNE 1, 2004

Note: Normally, red italic font identifies new material. However, because this release is a new manual, normal text font is used for the initial release.

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N	Chapters 1 to 8
N	Chapter 9 Exhibits
N	Appendices

III. GENERAL INFORMATION

A. BACKGROUND:

As part of an agency wide initiative to update and place all manuals on the Internet, the State Operations Manual (SOM) has been converted from a paper-based manual to an Internet-based manual.

CMS contracted with a private contractor to complete the conversion process for the SOM. As part of the initial conversion process, the paper document was scanned into electronic form and was converted into a straight Microsoft Word document from its previous format in Microsoft Word for TIMS. The layout and design for the manual text will be similar to the paper-based manual, but includes cleared updates, including incorporation of S & C letters thru 12/30/03. S & C letters published after 12/30/03 have not been incorporated into this manual and are considered current policy. These letters will be incorporated in future revisions. The final version includes hyperlinks to the exhibits and appendices referenced in the manual text. The layout and design of the

appendices were changed from landscape to portrait and are no longer formatted into columns. This change was necessary to accommodate the agency's Web-based manual design. One benefit of this change from landscape to portrait is that the documents are smaller and can be downloaded to a palm pilot, or similar electronic device with sufficient memory. Finally, the exhibits section of the manual was updated and old forms deleted.

The National Technical Information Service (NTIS) is continuing production of a paper-based manual version of the new material. For information concerning purchasing this manual contact NTIS at 1-800-363-2068. In addition, CD ROM versions, with subscription updates, may be purchased from NTIS or the Government Printing Office (GPO) at 202-512-1800.

B. SPECIFIC CHANGES:

The revised Internet-only SOM mirrors the old paper-based version in that the manual text contains chapters 1 through 8, appendices and exhibits. The section numbers and chapters remain unchanged in all chapters except chapter 5 and 8. Some noted changes are as follows:

Manual Text:

1. **Chapter One**: Incorporation of the CLIA program.

2. **Chapter Two**: Updated material to incorporate use of the CMS-855 in the Enrollment process; All providers and suppliers will undergo unannounced surveys; Incorporation of Survey and Certification letters across provider types; Manualized OASIS policy, Manualized branch approval process, and the policy on identifying and monitoring HHA branch (es); Expanded Hospice citations and definitions to incorporate web site address, benefit periods, general eligibility requirements and information from current policy memos; Incorporated policy memos on election of Hospice benefit by resident of SNF, NF, ICF/MR, or Non-certified Facility and Operation of Hospice across State lines; Expanded Hospice home visits to add information on hospice home visits when an HHA is applying for certification as a hospice; Updated Advance Directives Requirements to incorporate the current statutory requirements related to advance directives; Updated certification procedures to reflect changes in the law regarding SNF placement agreements; Updated CAH certification procedures to reflect changes in the laws.

3. **Chapter Three**: Sections SOM 3260-3276, Investigation of Complaints Against Providers or Suppliers, was moved to SOM 5100-5190; Sections SOM 3280-3298, Investigation of Complaints Against Other Than Accredited Providers or Suppliers was moved to SOM 5200-5280; Sections SOM 3400-3413, Conducting Investigations for Alleged Violations of 42 CFR 489.24 and/or Related

Requirements in 489.20(l), (m)(q) and (r): Responsibilities of Medicare Participating Hospitals in Emergency Cases, was moved to Section 5300-5370.

4. **Chapter Four**: Incorporated automation of budget reporting requirements.

5. **Chapter Five**: As a result of a recommendation from the Inspector General, Chapter Five of the SOM was generated. Chapter Five is a consolidated chapter of complaint procedures that covers all providers/suppliers in the Medicare and Medicaid program and was developed by extracting various sections on the complaint process from the paper-based manual.

   Chapter Five was edited and reorganized to incorporate the Survey and Certification memo S&C-04-09 "Guidelines to Support Management of Complaints and Incidents and the National Implementation of the ASPEN Complaints/Incidents Tracking System (ACTS)." Due to the nature of how Chapter Five was created, chapter five will undergo a complete rewrite for clarity, readability and "flow."

   A crosswalk from sections from the paper based manual to the Internet-only manual that deals with the complaint process is as follows:

Name of Section	**Old Section Number**	**New Section Number**
Basis for Accredited Provider or Supplier Allegation/Complaint Investigation	3260	5110
RO Direction of Accredited Hospital Complaint Investigation	3262	5120
Forwarding Investigation Report to RO	3266	5140
Accredited Hospital Found in Compliance Following Complaint Validation Survey	3268	5150
Accredited Hospital Found Not in Compliance Following Complaint Validation Survey	3270	5160
Reinstatement to Accreditation Organization Jurisdiction	3272	5170
Termination of Accredited Hospitals	3274	5180
Investigating Complaints Involving ESRD Services Provided by Accredited Hospitals	3276	5190
Investigation of Complaints Against Other Than Accredited Providers or Suppliers	3280-3298	5200-5250
SA Processing General, Certification-Related Complaints	3281	5210
RO Processing General, Certification-Related Complaints	3284	5220
RO Complaint Management	3285	5230
Complaints Involving HIV-Infected Individuals	3297	5250
Investigation Involving Alleged EMTALA Violations	3400	5300
Basis for Investigation	3402	5310
RO Direction of Investigation	3404	5320
Conducting an Investigation	3406	5330
Forwarding Report of Investigation to the RO	3408	5340
RO Review of Investigation	3410	5350
Termination Procedures for Violations of 42 CFR 489.24 and/or the Related Requirements at 42 CFR 489.20 (l), (m), (q), and (r)	3412	5360

RO Procedures for Coordinating Statutorily Mandated QIO Review of Confirmed Dumping Cases	3413	5370
Additional Provisions for the Investigation of Complaints in Nursing Homes	7700	5400
Complaints Involving Unaccredited Laboratories	6136	5500
CLIA-Exempt Laboratory Complaint Investigations- General	6220	5510
Review of CLIA-Exempt Laboratory Complaints	6222	5520
Conducting Complaint Survey for CLIA-Exempt Laboratories	6224	5530
Complaint Investigations and Surveys of Accredited Laboratories Under CLIA	6174	5540
RO Direction of Complaint Investigation of an Accredited Laboratory	6176	5550
Conducting Complaint Survey of an Accredited Laboratory	6178	5560
Forwarding Investigation Report to RO	6180	5570
Accredited Laboratory Found in Compliance Following a Complaint Survey	6182	5580
Accredited Laboratory Found Not in Compliance Following a Complaint Survey	6184	5590

In the process of developing chapter 5, some of the guidance relating to EMTALA was inadvertently deleted. Listed below is the information that needs to be included in the manual.

Additional EMTALA guidance:

When hospitals do not conform to the requirements of §1867 of the Act, the practice is commonly called "dumping." A hospital with an emergency department is defined in 42 CFR §489.24(b) as a hospital that offers services for emergency medical conditions within its capacity to do so. The regulations at 42 CFR §489.24 parallel the provisions of §1867 of the Act and place the following requirements on a hospital that has an emergency department:

- 42 CFR §489.24(a) General. Applicability of provisions of this section
- 42 CFR §489.24(b) Definitions. As used in this section
- 42 CFR §489.24(c) Use of dedicated emergency department for nonemergency services.
- 42 CFR §489.24(d) Necessary stabilizing treatment for emergency medical conditions.
- 42 CFR §489.24(d)(1) General. Subject to the provisions of paragraph (d)(2)
- 42 CFR §489.24(d)(2) Exception: Application to inpatients.
- 42 CFR §489.24(d)(3) Refusal to consent to treatment.

- 42 CFR §489.24(d)(4) Delay in examination or treatment.
- 42 CFR §489.24(d)(5) Refusal to consent to transfer.
- 42 CFR §489.24(e) Restricting transfer until the individual is stabilized.
- 42 CFR §489.24(e)(1) General.
- 42 CFR §489.24(e)(2) Appropriate transfer to another medical facility.
- 42 CFR §489.24(e)(3) Provides whistleblower protection to physicians and qualified medical personnel
- 42 CFR §489.24(f) Recipient hospital responsibilities.
- 42 CFR §489.24(g) Termination of provider agreement
- 42 CFR §489.24(h) Consultation with Quality Improvement Organization (QIO)
- 42 CFR §489.24(i) Release of QIO Assessment
- 42 CFR §489.24(j) Availability of on-call physicians.
- 42 CFR §489.24 (j)(1) On-call list.
- 42 CFR §489.24 (j)(2) Hospital on-call policy and procedures.

If a hospital fails to meet these requirements, CMS may terminate the provider agreement in accordance with 42 CFR §489.53. The Office of the Inspector General (OIG) has the responsibility and authority to assess civil monetary penalties (CMPs) or to exclude physicians from the Medicare program when a hospital or physician violates these requirements. Additionally, individuals suffering personal harm and medical facilities suffering financial loss as a result of a violation of these provisions can bring civil action under State law against the offending hospital and physicians. Filing for such civil action is limited to a period of two years after the date of the alleged violation. This legislation does not preempt any State or local laws, except to the extent that State or local requirements directly conflict with a requirement of this legislation.

5062 - Basis for Investigation (was 3402)

The SA must promptly report to the RO all complaints alleging a violation of the provisions of 42 CFR §489.24 and the related provisions at 42 CFR §489.20(l), (m), (q), and (r). The RO decides whether a complaint alleges a violation of these requirements and warrants an investigation. Refer all complaints to the RO prior to

investigation. To expedite investigation, make your referrals by telephone, e-mail, or FAX.

Complainants are not required to give their names or other identifying information. Either the SA or the RO will make appropriate acknowledgment to the party making the complaint, if known.

6. **Chapter Six:** Complete rewrite of chapter six to include updated policies in response to changes in the regulations.

7. **Chapter Seven:** Incorporation throughout the Chapter of all Qs and As released since chapter 7 was last revised; Incorporation throughout the Chapter of information from Survey and Certification letters issued; Clarification that at least 10% of surveys must begin on the weekend or in the evening/early morning hours before 8:00a.m. or after 6:00 p.m.; Inclusion of revisit policy of May 3 2001; Inclusion of a Medicare-only or dually participating facility's ability to appeal a finding of substandard quality of care when that finding causes it to lose it's ability to offer a Nurse Aide Training and Competency Evaluation Program; and Removal of Complaint-related information for inclusion into Chapter Five "Complaints Procedures."

8. **Chapter Eight**: The State Agency Quality Improvement Program (SAQIP) was deleted and replaced with the State Performance Standards.

Appendices:

- Revision to Appendix A- Interpretive Guidelines for Hospitals which includes newly developed standardized Hospital Survey Protocol;

- Revision to Appendix W- Interpretive Guidelines for Critical Access Hospitals which includes newly developed standardized Critical Access Survey Protocol;

- Revision to Appendix L- Interpretive Guidelines for Life Safety Code;

- Revision to Appendix V- Interpretive Guidelines for EMTALA;

- Revision to Appendix C- Interpretive Guidelines for Laboratories;

- Revision to Appendix B- Interpretive Guidelines for Home Health Agencies;

- Revision to Appendix M- Interpretive Guidelines for Hospices;

- Deletion of Appendix F- Survey Procedures for the Application of Conditions of Participation for Physical Therapists in Independent Practice;

- Deletion of Appendix N- Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care Facilities;

- Deletion of Appendix S- Interpretive Guidelines for Screening Mammography.

Exhibits:

- Deletion of old exhibits from the CMS forms web page and addition of new exhibits.
- Changed Swing Bed exhibits to model letters;
- Discontinuation of Form CMS-1514, "Hospital Request for Certification in the Medicare/Medicaid Program," and replaced it with the "Hospital/CAH Medicare Database Worksheet." Instructions for the use of the new worksheet were included in the guidance letter S&C-04-31, issued on May 13. Please note that survey agencies or State agency surveyors should not schedule onsite visits for the sole purpose of gathering this information. This data should be gathered at appropriate intervals (i.e., tri-annually or when the hospital undergoes significant changes in its operations) at a time when the surveyor is otherwise onsite, for a validation survey, recertification survey or complaint investigation. Additionally, State Medicaid agencies are permitted, but not required, to adapt the worksheet and require the hospitals to complete and return it as a condition for payment under the State Medicaid program.
- Discontinuance of Form CMS-1513, "Ownership and Control Interest Disclosure Statement."
- Discontinuance of Form CMS-2572, "Statement of Financial Solvency."

To download the Filename R1SOM1.zip associated with this instruction, click here.

To download the Filename R1SOM2.zip associated with this instruction, click here.

To download the Filename R1SOM3.zip associated with this instruction, click here.