**MEDICARE REGULATIONS FOR SINGLE-USE ITEMS IN ASCs**

**1. QUESTION:** What are CMS’ ASC Conditions for Coverage (CfC)?

**ANSWER:** In order to receive Medicare or Medicaid payment, ambulatory surgery centers (ASCs) are required to be in compliance with the Federal requirements set forth in the Medicare Conditions for Coverage (CfC). The text of the CMS regulations was published on November 18, 2008 in the Federal Register (73 FR 68502) and contains changes to the Code of Federal Regulations (42 CFR 416.2-416.52). These revisions represent the most significant change in the ASC CfCs since they were originally published August 5, 1982.

**2. QUESTION:** When did the new CfCs take effect?

**ANSWER:** The regulations took effect on May 18, 2009. Compliance with these new ASC CfCs is mandatory. ASCs should ensure that they have completed an extensive review of the regulatory changes and have updated their policies and procedures. CMS sends government surveyors to ASCs to check for compliance with the CfCs.

**3. QUESTION:** What are CMS’ Interpretive Guidelines?

**ANSWER:** The CMS State Operations Manual (Publication 100-07) contains Appendix L which provides detailed guidance for surveyors of ASCs concerning the CfCs.

**4. QUESTION:** What are CMS’ instructions concerning single use devices?

**ANSWER:** The ASC CfC addresses surgical services in §416.42 which states: “Surgical procedures must be performed in a safe manner...” The Statement of Deficiencies Report and Plan of Correction (Form CMS-2567) is the official document that communicates the determination of compliance or noncompliance with Federal requirements. This form asks the surveyor if single-use devices are: 1) never reprocessed and used again, or 2) approved by the FDA for reprocessing, and 3) if they are reprocessed by an FDA-approved reprocessor.

**5. QUESTION:** What is the significance of this instruction?

**ANSWER:** ASCs that formerly re-used certain surgical items to save money will have to revisit their policies and procedures in light of the CfCs or risk censure by the surveyor, or worse.

**6. QUESTION:** What are the practical options for compliance with this new instruction?

**ANSWER:** There are several options.
1. Dispose of single-use items after a single use
2. Contract with an FDA-approved agent for reprocessing eligible items
3. Upgrade the ASC’s sterilization facilities to comply with FDA’s reprocessing standards
4. Switch to multi-use items as approved by the manufacturer

January 1, 2014

The reader is strongly encouraged to review federal and state laws, regulations, code sets (including ICD-9 and ICD-10), and official instructions promulgated by Medicare and other payers. This document is not an official source nor is it a complete guide on reimbursement. The reader is reminded that this information, including references and hyperlinks, changes over time, and may be incorrect at any time following publication.

© 2014 Corcoran Consulting Group. All rights reserved. No part of this publication may be reproduced or distributed in any form or by any means, or stored in a retrieval system, without the written permission of the publisher.
Corcoran Consulting Group  (800) 399-6565 www.corcoranccg.com

Provided Courtesy of MicroSurgical Technology
(888) 279-3323 www.mst-surgical.com
7 QUESTION: What about single-dose vials of medications?

ANSWER: The ASC CfC addresses administration of drugs in §416.48 which states: "Drugs must be prepared and administered according to established policies and acceptable standards of practice". The Interpretive Guidelines for this section require "Following the manufacturer’s label, including storing drugs and biologicals as directed; disposing of expired medication in a timely manner; using single-dose vials of medication for one ASC patient only; etc." [emphasis added]. The worksheets used the ASC surveyor address compliance with the infection control CfC which might result in a deficiency citation.

8 QUESTION: What’s an example of single-use labeling?

ANSWER: The package labeling of IOPIDINE Ophthalmic Solution (Alcon) says: "One drop of IOPIDINE Ophthalmic Solution should be instilled in the scheduled operative eye one hour before initiating anterior segment laser surgery and a second drop should be instilled to the same eye immediately upon completion of the completion of the laser surgical procedure. Use a separate container for each single-drop dose and discard each container after use." [emphasis added].

January 1, 2014

The reader is strongly encouraged to review federal and state laws, regulations, code sets (including ICD-9 and ICD-10), and official instructions promulgated by Medicare and other payers. This document is not an official source nor is it a complete guide on reimbursement. The reader is reminded that this information, including references and hyperlinks, changes over time, and may be incorrect at any time following publication.

© 2014 Corcoran Consulting Group. All rights reserved. No part of this publication may be reproduced or distributed in any form or by any means, or stored in a retrieval system, without the written permission of the publisher.

Provided Courtesy of MicroSurgical Technology
(888) 279-3323 www.mst-surgical.com