CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 68 **Date: November 24, 2010**

This transmittal is being re-issued on December 21, 2010 to insert the Revision number, date issued, effective and implementation dates in the manual instruction, which were erroneously omitted during the original communication. The transmittal number, date issued and all other information remains the same.

SUBJECT: Chapter 9, Exhibits and Table of Contents

I. SUMMARY OF CHANGES: Several exhibits are being revised to reflect current policy and the Table of Contents is being revised accordingly.

REVISED/NEW MATERIAL – EFFECTIVE DATE: November 24, 2010
IMPLEMENTATION DATES: November 24, 2010

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Table of Contents
R	Exhibit 194/Model Letter Announcing to Deemed, Accredited Provider/Supplier Compliance with all Surveyed Medicare Conditions of Participation, Coverage or Certification after a Sample Validation or Substantial Allegation Survey
R	Exhibit 195/Model Notice Announcing to Deemed, Accredited Provider/Supplier that the Facility Does not Comply with all the Conditions of Participation, Coverage or Certification and That There is Immediate and Serious Threat to Patient Health and Safety
R	Exhibit 196/Model Letter Announcing to Deemed, Accredited Provider/Supplier after a Sample Validation Survey That it does not Comply with all Conditions of Participation, Coverage or Certification
R	Exhibit 351/Ambulatory Surgical Center Infection Control Surveyor Worksheet

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2010 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

Medicare State Operations Manual
Chapter 9 - Exhibits

Exhibits
(Rev. 68 Issued: 11-24-10)

Exhibit	Description	Download
194	Model Letter Announcing to *Deemed,* Accredited Provider/Supplier Compliance with all Surveyed Medicare Conditions of Participation, *Coverage or Certification* after a Sample Validation or Substantial Allegation Survey	http://www.cms.gov/manuals/downloads/som107_exhibit_194.pdf
195	*Model Letter* Announcing to *Deemed*, Accredited Provider/Supplier that the Facility Does Not Comply with all the Conditions of Participation, *Coverage or Certification* and That There is Immediate and Serious Threat to Patient Health and Safety	http://www.cms.gov/manuals/downloads/som107_exhibit_195.pdf
196	Model Letter Announcing to Deemed,	http://www.cms.gov/manuals/downloads/som107_exhibit_196.pdf

	Accredited Provider/Supplier after a Sample Validation Survey that it does not Comply with all Conditions of Participation, *Coverage or Certification*	
351	*Ambulatory Surgical Center* Infection Control Surveyor Worksheet	http://www.cms.gov/manuals/downloads/som107_exhibit_351.pdf

EXHIBIT 194

(Rev. 68 Issued: 11-24-10, Effective: 11-24-10, Implementation: 11-24-10)

MODEL LETTER ANNOUNCING *TO DEEMED, ACCREDITED PROVIDER/SUPPLIER* COMPLIANCE WITH ALL SURVEYED MEDICARE CONDITIONS OF PARTICIPATION, *COVERAGE OR CERTIFICATION* AFTER A SAMPLE VALIDATION OR SUBSTANTIAL ALLEGATION SURVEY

(**Date**)

Facility Administrator Name
Facility Name
Address
City, State, ZIP Code

RE: *CMS Certification Number* (CCN) ***[enter CCN assigned to the facility]***

Dear (***Administrator Name***):

I am pleased to inform you that as a result of the (**State agency's**) (**sample validation**)(**substantial allegation**) survey, (**name of *facility***) was found in compliance with all the (Medicare Conditions of Participation*/Medicare Conditions for Coverage or Certification)* and will continue to be "deemed" to meet applicable Medicare requirements based upon accreditation by the (***insert appropriate Accrediting Organization****).*

The (**State agency**) advised you of the Medicare deficiencies noted during the (**sample validation**)(**substantial allegation**) survey of your *facility*, and we are enclosing a complete listing of all deficiencies found by the (**State agency**). We have forwarded a copy of this letter and our findings from this survey (optional -- and your plan and timetable for correcting the Medicare deficiencies cited) to the (***appropriate AO)*** for its review. The (**State agency**) has also been sent a copy of this letter. The (***AO***) may be in touch with you to discuss the Medicare survey findings.

Since your *facility* has been found "in compliance," you do not have to submit a plan for correcting any of the Medicare deficiencies cited by the (**State agency**). However, under Federal disclosure rules a copy of the findings of this Medicare survey must be publicly disclosed within 90 days of the completion. You may therefore wish to submit for public disclosure, if you have not already done so, your comments on the survey findings, and any plans you may have for correcting the cited deficiencies.

We thank you for your cooperation and look forward to working with you on a continuing basis in the administration of the Medicare program.

Sincerely yours,

Associate Regional Administrator
(or its equivalent)

Enclosure: Form CMS-2567

cc:
Central Office
Accrediting Organization
State Agency

EXHIBIT 195

(Rev. 68 Issued: 11-24-10, Effective: 11-24-10, Implementation: 11-24-10)

MODEL NOTICE ANNOUNCING TO *DEEMED,* ACCREDITED *PROVIDER/SUPPLIER* THAT THE *FACILITY* DOES NOT COMPLY WITH ALL THE CONDITIONS OF PARTICIPATION, *COVERAGE OR CERTIFICATION* AND THAT THERE IS IMMEDIATE AND SERIOUS THREAT TO PATIENT HEALTH AND SAFETY

(**Date**)

Facility Administrator Name
Facility Name
Address
City, State, ZIP Code

Re: CMS Certification Number (CCN) ***[enter CCN assigned to the facility]***

Dear (**Administrator *Name***):

Section 1865 of the Social Security Act (the Act) provides that *entities* accredited by *a CMS-recognized national accreditation organization may be* "deemed" to meet the Medicare *health and safety conditions*. Section 1864 of the Act authorizes the Secretary of the Department of Health and Human Services (the Secretary) to conduct surveys of accredited *entities* participating in the Medicare program.

A survey was conducted at (**name of *facility*** on (**date**). At the conclusion of this survey, the findings were discussed with (**you or your representative's name**) and (**you, he, she**) (**was, were**) informed that conditions within (**name of facility**) posed an immediate and serious threat to the health and safety of patients. Specifically, the facility does not meet:

(**Cite Conditions of Participation *(CoPs)/Conditions for Coverage or Certification (CfCs)***).

When a *facility*, regardless of its accreditation status, is found to be out of compliance with one or more *CoPs/CfCs* and immediate *and* serious threat to patient health and safety exists, a determination must be made that the facility no longer meets the requirements for participation as a provider of services in the Medicare program. Such a determination has been made in the case of (**name of *facility***) and, accordingly, the Medicare provider agreement between (**name of *facility*)** and the Secretary is being terminated. This termination will be effective (**date**).

(Add, in the case of hospital or CAH: The Medicare program will not make payment for services furnished to patients who are admitted on or after (**date of**

termination). For inpatients admitted prior to (**date of termination**), payment may continue to be made for a maximum of 30 days of inpatient services furnished on or after (**date of termination**). You should submit as soon as possible, a list of names and Medicare claim numbers of beneficiaries in your facility on (**date of termination**) to the (**name and address of the RO involved**) to facilitate payment for these individuals.**)**

We will publish a public notice in the (**local newspaper**). You will be advised of the publication date for the notice. Termination can only be averted by correction of these deficiencies by (**insert date 5 days after date of letter**). Should we not hear from you, we will assume that the situation has not been corrected. If you have corrected this situation, please advise us immediately. If you notify us by (**date**) that corrections have been made, representatives of the Centers for Medicare & Medicaid Services (CMS) will revisit the facility within 2 working days to verify necessary corrections. If CMS determines that the reasons for termination remain, the effective date of the termination remains (**date**), and you will be so informed in writing. If corrections have been made, the termination procedures will be halted, and you will be notified in writing.

If you do not believe this termination decision is correct, you may request a hearing before an Administrative Law Judge (ALJ) of the Department of Health and Human Services, Departmental Appeals Board. Procedures governing this process are set out in regulations at 42 CFR 498.40 et. seq. A written request for a hearing must be filed no later than 60 days from the date of receipt of this letter. Such a request may be made to the Consortium Survey and Certification Officer, (**address**). We will forward your request to the Chief Administrative Law Judge in the Office of Hearing and Appeals.

At your option you may instead submit a hearing request directly accompanied by a copy of this letter to the following address. Send a copy of your request to this office also:

Departmental Appeals Board, Civil Remedies Division
Room G-644-Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201
Attn: Director, Departmental Appeals Board

You may be represented by counsel at a hearing at your own expense.

Sincerely yours,

Consortium Survey and Certification Officer
(or its equivalent)

Enclosure: Form CMS 2567 Statement of Deficiencies

CC: CMS Central Office
Accrediting Organization
State Agency

EXHIBIT 196

(Rev. 68 Issued: 11-24-10, Effective: 11-24-10, Implementation: 11-24-10)

MODEL LETTER ANNOUNCING TO DEEMED, ACCREDITED PROVIDER/SUPPLIER AFTER A SAMPLE VALIDATION SURVEY THAT IT DOES NOT COMPLY WITH ALL CONDITIONS OF PARTICIPATION, *COVERAGE OR CERTIFICATION*

(90-Day Termination Track: Do Not Use When Immediate and Serious Threat to Patient Health or Safety Deficiencies Exist)

(**Date**)

Administrator Name
Facility Name
Address
City, State, ZIP Code

Re: CMS Certification Number (CCN)

Dear (**Administrator**)

Section 1865 of the Social Security Act (the Act) and pursuant regulations provide that a provider or supplier accredited by **(name of accreditation organization)** will be "deemed" to meet all of the Medicare Conditions of Participation (CoPs) or for Coverage *or for Certification (CfCs)*, as applicable) for **(type of provider/supplier)**, **(add for hospitals:** with the exception of those relating to utilization review, the special medical record and staffing requirements for psychiatric hospitals, and special requirements for hospital providers of long-term care services ("swing beds")). Section 1864 of the Act authorizes the Secretary of the Department of Health and Human Services (the Secretary) to conduct, on a selective sampling basis, surveys of accredited providers/suppliers participating in Medicare as a means of validating reliance on the accreditation process.

When a **(type of provider/supplier)**, regardless of its accreditation status, is found to be out of compliance with the **(CoPs or CfCs)**, a determination must be made that the facility no longer meets the requirements for participation as a provider or supplier of services in the Medicare program. Such a determination has been made in the case of (**facility name**) and accordingly, the Medicare agreement between (**facility name**) and the Secretary is being terminated.

A validation survey conducted by the **(State agency)** at (**name of facility**) on (**date**) found that the facility was not in compliance with all the (CoPs or CfCs) for **(type of facility)**. A listing of all deficiencies found is enclosed (Form CMS-2567, Statement of Deficiencies and Plan of Correction.). These deficiencies have been determined to be of such a serious nature as to substantially limit the facility's capacity to provide adequate care. The date on which the agreement terminates is (**date**). **(Add, in the case of a hospital or CAH:** The Medicare program will not make payment for services furnished to patients who are admitted on or after (**date of termination**). For inpatients admitted prior to (**date of termination**), payment may continue to be made for a maximum of 30 days of inpatient services furnished on or after (**date of termination**). You should submit as soon as possible, a list of names and Medicare claim numbers of beneficiaries in your facility on (**date of termination**) to the (**name and address of the RO involved**) to facilitate payment for these individuals.**)**

We will publish a public notice in the (**local newspaper**). You will be advised of the publication date for the notice. If you feel that these findings are incorrect, you have 15 days from the date of this notice to request an informal review of the findings by this office as provided by 42 CFR 488.456(c)(2). Include in the request any evidence and arguments which you may wish to bring to the attention of the Centers for Medicare & Medicaid Services (CMS). [Public notice language is optional]

Termination can only be averted by correction of the deficiencies within 45 days of your receipt of this letter. Your plan of correction (written on the enclosed statement of Deficiency and Plan of Correction forms) should be returned to us as soon as possible.

An acceptable plan of correction must contain the following elements:

1. The plan for correcting each specific deficiency cited;

2. The plan should address improving the processes that led to the deficiency cited;

3. The plan must include the procedure for implementing the acceptable plan of correction for each deficiency cited;

4. A completion date for correction of each deficiency cited must be included;

5. All plans of correction must demonstrate how the provider/supplier *is* addressing improvements in its systems in order to prevent the likelihood of the deficient practice reoccurring. The plan must include the monitoring and tracking procedures to ensure the plan of correction is effective and that specific deficiencies cited remain corrected and/or in compliance with the regulatory requirements; and

6. The plan must include the title of the person responsible for implementing the acceptable plan of correction.

After termination, if you wish to be readmitted to the program, you must demonstrate to the (**State agency**) and CMS that you are able to maintain compliance. Readmission to the program will not be approved until CMS is reasonably assured that you are able to sustain compliance.

If you do not believe this termination decision is correct, you may request a hearing before an Administrative Law Judge (ALJ) of the Department of Health and Human Services, Departmental Appeals Board. Procedures governing this process are set out in regulations at 42 CFR 498.40 et. seq. A written request for a hearing must be filed no later than 60 days from the date of receipt of this letter. Such a request may be made to the Consortium Survey and Certification Officer, (**address**). We will forward your request to the Chief Administrative Law Judge in the Office of Hearing and Appeals.

At your option you may instead submit a hearing request directly (accompanied by a copy of this letter) to the following address. Send a copy of your request to this office also.

Departmental Appeals Board, Civil Remedies Division
Room G-644-Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201
Attn: Director, Departmental Appeals Board

A request for a hearing should identify the specific issues, and the findings of fact, and conclusions that you consider to be incorrect. You may be represented by counsel at a hearing at your own expense.

Sincerely yours,

Consortium Survey and Certification Officer
(or its equivalent)

Enclosure:
CMS Form-2567 Statement of Deficiencies

cc: **(Accreditation Organization)**

Exhibit 351

Ambulatory Surgical Center

INFECTION CONTROL SURVEYOR WORKSHEET

(Rev. 68 Issued: 11-24-10, Effective: 11-24-10, Implementation: 11-24-10)

Name of State Agency or AO (please print at right) _____

Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the infection control Condition for Coverage. Items are to be assessed primarily by surveyor observation, with interviews used to provide additional confirming evidence of observations. In some cases information gained from interviews may provide sufficient evidence to support a deficiency citation.

The interviews and observations should be performed with the most appropriate staff person(s) for the items of interest (*e.g.*, the staff person responsible for sterilization should answer the sterilization questions).

A minimum of one surgical procedure must be observed during the site visit, unless the ASC is a low volume ASC with no procedures scheduled during the site visit. The surveyor(s) must identify at least one patient and follow that case from registration to discharge to observe pertinent practices. For facilities that perform brief procedures, e.g., colonoscopies, it is preferable to follow at least two cases.

When performing interviews and observations, any single instance of a breach in infection control would constitute a breach for that practice.

Citation instructions are provided throughout this instrument, indicating the applicable regulatory provision to be cited on the Form CMS-2567 when deficient practices are observed.

PART 1 – ASC CHARACTERISTICS

1. ASC Name ***(please print)*** _____

2. Address, State and Zip Code ***(please print)***

_____
Address

_____
City State Zip

3. 10-digit CMS Certification Number | | | | | | | | | | |

4. What year did the ASC open for operation? | | | | |
y y y y

5. Please list date(s) of site visit: | | / | | / | | | | | to | | / | | / | | | | |
m m d d y y y y m m d d y y y y

6. What was the date of the most recent previous federal (CMS) survey: | | / | | / | | | | |
m m d d y y y y

PLEASE COMPLETELY FILL IN EACH BUBBLE USING A DARK PEN.

7. Does the ASC participate in Medicare via accredited "deemed" status?
- ○ YES
- ○ NO

7a. If YES, by which CMS-recognized accreditation organization? (Check only ONE):
- ○ Accreditation Association for Ambulatory Health Care (AAAHC)
- ○ American Association for Accred. of Ambulatory Surgery Facilities (AAAASF)
- ○ American Osteopathic Association (AOA)
- ○ The Joint Commission (TJC)

7b. If YES, according to the ASC, _____ | | | / | | / | | | | |

what was the date of the most | m m d d y y y y

8. What is the ownership of the facility?

- ○ Physician-owned
- ○ Hospital-owned
- ○ National corporation (including joint ventures with physicians)
- ○ Other *(please print)*:

9. What is the primary procedure performed at the ASC (i.e., what procedure type reflects the majority of procedures performed at the ASC)?
(Fill in only ONE bubble)

- ○ Dental
- ○ Endoscopy
- ○ Ear/Nose/Throat
- ○ OB/Gyn
- ○ Ophthalmologic
- ○ Orthopedic
- ○ Pain
- ○ Plastic/reconstructive
- ○ Podiatry
- ○ Other (please print):

10. What additional procedures are performed at the ASC? (***Fill in* all that apply)**
Do not include the procedure type indicated in question 9.

- ○ Dental
- ○ Endoscopy
- ○ Ear/Nose/Throat
- ○ OB/Gyn
- ○ Ophthalmologic
- ○ Orthopedic
- ○ Pain
- ○ Plastic/reconstructive
- ○ Podiatry
- ○ Other (please print):

11. Who does the ASC perform procedures on?
(*Fill in only* ONE *bubble*)

- ○ Pediatric patients only
- ○ Adult patients only
- ○ Both pediatric and adult patients

12. What is the average number of procedures performed at the ASC **per month**?

						per month

13. How many Operating Rooms (including procedure rooms) does the ASC have?

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ *9+*

Number actively maintained:

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ *9+*

14. Please indicate how the following services are provided: ***(fill in all that apply)***

	Contract	Employee	Other	If Other, Please *print:*
Anesthesia	○	○	○	
Environmental Cleaning	○	○	○	
Linen	○	○	○	
Nursing	○	○	○	
Pharmacy	○	○	○	
Sterilization/Reprocessing	○	○	○	

Waste Management	○	○	○	

INFECTION CONTROL PROGRAM

15. Does the ASC have an explicit infection control program?
- ○ YES
- ○ NO

NOTE! If the ASC does not have an explicit infection control program, a condition-level deficiency related to 42 CFR 416.51 **must** be cited.

16. Does the ASC's infection control program follow nationally recognized infection control guidelines?
- ○ YES
- ○ NO

NOTE! If the ASC does not follow nationally recognized infection control guidelines, a deficiency related to 42 CFR 416.51(b) **must** be cited. Depending on the scope of the lack of compliance with national guidelines, a condition-level citation may also be appropriate.

16a. Is there documentation that the ASC considered and selected nationally-recognized infection control guidelines for its program?
- ○ YES
- ○ NO

16b. Which nationally-recognized infection control guidelines has the ASC selected for its program?
(Fill in all that apply)

- ○ CDC/HICPAC Guidelines:
  - ○ Guideline for Isolation Precautions (CDC/HICPAC)
  - ○ Hand hygiene (CDC/HICPAC)
  - ○ Disinfection and Sterilization in Healthcare Facilities (CDC/HICPAC)
  - ○ Environmental Infection Control in Healthcare Facilities (CDC/HICPAC)
- ○ Perioperative Standards and Recommended Practices (AORN)
- ○ Guidelines issued by a specialty surgical *society / organization (List)*

  Please specify (please print and limit to the space provided):

- ○ Others

  Please specify (please print and limit to the space provided):

NOTE! If the ASC cannot document that it considered and selected specific guidelines for use in its infection control program, a deficiency related to 42 CFR 416.51(b) **must** be cited. This is the case even if the ASC's infection control practices comply with generally accepted standards of practice/national guidelines. If the ASC neither selected any nationally recognized guidelines nor complies with generally accepted infection control standards of practice, then the ASC should be cited for a condition-level deficiency related to 42 CFR 416.51.

17. Does the ASC have a licensed health care professional qualified through training in infection control and designated to direct the ASC's infection control program?

○ YES
○ NO

NOTE! If the ASC cannot document that it has designated a qualified professional with training (not necessarily certification) in infection control to direct its infection control program, a deficiency related to 42 CFR 416.51(b)(1) **must** be cited. Lack of a designated professional responsible for infection control should be considered for citation of a condition-level deficiency related to 42 CFR 416.51.

17a. If YES, Is this person an:
(Fill in only ONE bubble)

○ ASC employee
○ ASC contractor

17b. Is this person certified in infection control (i.e., CIC) (Note: §416.50(b)(1) does **not** require that the individual be certified in infection control.)

○ YES
○ NO

17c. If this person is **NOT** certified in infection control, what type of infection control training has this person received?

17d. On average, how many hours per week does this person spend in the ASC directing the infection control program?

hours per week

(Note: §416.51(b)(1) does **not** specify the amount of time the person must spend in the ASC directing the infection control program, but it is expected that the designated individual spends sufficient time on-site directing the program, taking into consideration the size of the ASC and the volume of its surgical activity.)

18. Does the ASC have a system to actively identify infections that may have been related to procedures performed at the ASC?

○ YES
○ NO

18a. If YES, how does the ASC obtain this information?
(Fill in ALL that apply)

○ The ASC sends e-mails to patients after discharge
○ The ASC follows-up with their patients' primary care providers after discharge
○ The ASC relies on the physician performing the procedure to obtain this information at a follow-up visit after discharge, and report it to the ASC
○ Other (please *print)*:

18b. Is there supporting documentation confirming this tracking activity?

○ YES
○ NO

NOTE! If the ASC does not have an identification system, a deficiency related to 42 CFR 416.44(a)(3) and 42 CFR 416.51(b)(3) **must** be cited.

18c. Does the ASC have a policy/procedure in place to comply with State notifiable disease reporting requirements?

○ YES
○ NO

NOTE! If the ASC does not have a reporting system, a deficiency **must** be cited related to 42 CFR 416.44(a)(3). CMS does not specify the means for reporting; generally this would be done by the State health agency.

19. Do staff members receive infection control training?

- ○ YES
- ○ NO

19a. If YES, how do they receive infection control training? *(Fill in all that apply)*

- ○ In-service
- ○ Computer-based training
- ○ Other *(please print):* _____

19b. Which staff members receive infection control training? **(Fill in all that apply)**

- ○ Medical staff
- ○ Nursing staff
- ○ Other staff providing direct patient care
- ○ Staff responsible for on-site sterilization/high-level disinfection
- ○ Cleaning staff
- ○ Other *(please print):* _____

19c. Is training:

- ○ the same for all categories of staff
- ○ different for different categories of staff

19d. Indicate frequency of staff infection control training (Fill in all that apply)

- ○ Upon hire
- ○ Annually
- ○ Periodically / as needed
- ○ Other (please print): _____

19e. Is there documentation confirming that training is provided to all categories of staff listed above?

- ○ YES
- ○ NO

NOTE! If training is not provided to appropriate staff upon hire/granting of privileges, with some refresher training thereafter, a deficiency **must** by cited in relation to 42 CFR 416.51(b) and (b)(3). If training is completely absent, then consideration should be given to condition-level citation in relation to 42 CFR 416.51, particularly when the ASC's practices fail to comply with infection control standards of practice.

20. How many procedures were observed during the site visit?

○ 1 ○ 2 ○ 3 ○ 4 ○ Other

If other, please *print* the number: [ ][ ] *procedures*

PART 2 – INFECTION CONTROL & RELATED PRACTICES

INSTRUCTIONS:

- *Please **completely fill in ONE bubble** for each "Was Practice Performed?" and "Manner of Confirmation" question, unless otherwise noted.*
- ***Please use a dark pen to fully fill in each bubble.***
- Unless otherwise indicated, a "No" response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).
- If N/A is response, please explain why there is no associated observation, or why the question is not applicable, *in the COMMENTS box at the end of each section.*

I. Hand Hygiene

Observations are to focus on staff directly involved in patient are (e.g., physicians, nurses, CRNAs, etc.). Hand hygiene should be observed not only during the case being followed, but also while making other observations in the ASC throughout the survey. Interviews are used primarily to provide additional evidence for what the surveyor has observed, but may in some cases substitute for direct observation to support a citation of deficient practice.

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
A. All patient care areas have: Note: 42 CFR 416.51(a) should be cited only if the answer to both a and b is "No."		
a. Soap and water available	○ Yes ○ No	○ Observation ○ Interview ○ Both
b. Alcohol-based hand rubs available	○ Yes ○ No	○ Observation ○ Interview ○ Both
I. If alcohol-based hand rub is available in patient care areas, it is installed as required. **(There are LSC requirements at 42 CFR 416.44(b)(5) for installation of alcohol-based hand rubs)**	○ Yes ○ No	
B. Staff perform hand hygiene:		
a. After removing gloves	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
b. After direct patient contact	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
c. Before performing invasive procedures (e.g., placing an IV)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
d. After contact with blood, body fluids, or contaminated surfaces (even if gloves are worn)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
C. Regarding gloves, staff:		
a. Wear gloves for procedures that might involve contact with blood or body fluids	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
b. Wear gloves when handling potentially contaminated patient equipment	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
c. Remove gloves before moving to the next tasks and/or patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
D. Additional breaches in hand hygiene, not captured by the questions above, were identified (If YES, please specify further in comments)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Comments: ***(please print and limit comments to the space provided)***	

II. Injection Practices (injectable medications, saline, other infusates)
Observations are to be made of staff who prepare and administer medications and perform injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
A. Needles are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
B. Syringes are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
C. Medication vials are always entered with a new needle	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
D. Medication vials are always entered with a new syringe	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
E. Medications that are pre-drawn are labeled with the time of draw, initials of the person drawing, medication name, strength and expiration date or time	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
Note: A "No" answer should result in citation as a deficient practice in relation to 42 CFR 416.48(a), Administration of Drugs		
F. a. Single dose (single-use) medication vials are used for only one patient (A "No" response must be cited in relation to 42 CFR 416.48(a).)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
b. Manufactured prefilled syringes are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
c. Bags of IV solutions are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
d. Medication administration tubing and connectors are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

G. *Please print* all injectable medications/infusates that are in a vial/container used for **more than one patient:**

Name of Medication	Average number of patients per vial/container

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
H. Multi-dose injectable medications are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

(Note: a "No" answer here is not necessarily a breach in infection control and does not result in a citation. However, a "No" response to the related questions I - K should be cited).

(Fill in N/A if no multi-dose medications/infusates are used).

If YES, please skip to "L"

If NO, please answer "I-K":

I. The rubber septum on a multi-dose vial **used for more than one patient** is disinfected with alcohol prior to each entry	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
J. Multi-dose medications **used for more than one patient** are dated when they are first opened and are discarded within 28 days of opening or according to manufacturer's recommendations, whichever comes first	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
K. Multi-dose medications, **used for more than one patient**, are not stored or accessed in the immediate areas where direct patient contact occurs	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
L. All sharps are disposed of in a puncture-resistant sharps container	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
M. Sharps containers are replaced when the fill line is reached	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
N. Additional breaches in injection practices, not captured by the questions above were identified (If YES, please specify further in comments)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Comments: ***(please print and limit comments to the space provided)***	

III. Single Use Devices, Sterilization, and High Level Disinfection

Pre-cleaning must always be performed prior to sterilization and high-level disinfection

Sterilization must be performed for critical equipment (i.e., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments)

High-level disinfection must be performed for semi-critical equipment (i.e., items that come into contact with non-intact skin or mucous membranes such as reusable flexible endoscopes, laryngoscope blades)

Observations are to be made of staff who perform equipment reprocessing (e.g., surgical techs), unless these activities are performed under contract or arrangement off-site from the ASC.

SINGLE-USE DEVICES

(Choose N/A if single-use devices are never reprocessed and used again)
(Surveyor to confirm there is a contract or other documentation of an arrangement with a reprocessing facility by viewing it)

Practices to be Assessed		**Was Practice Performed?**	**Manner of Confirmation**
A.	a. If single-use devices are reprocessed, they are devices that are approved by the FDA for reprocessing	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
	b. If single-use devices are reprocessed, they are reprocessed by an FDA-approved reprocessor.	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

STERILIZATION

A. Critical equipment is sterilized	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
B. Are sterilization procedures performed on-site? **(If NO, skip to "F")** (A "No" answer does not result in a citation, since ASCs are permitted to provide for sterilization off-site, under a contractual arrangement.) (Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
a. **If YES to B**, please indicate method of sterilization:	○ Steam autoclave ○ Peracetic acid ○ Other *(please print):*	
C. Items are pre-cleaned according to manufacturer's instructions or evidence-based guidelines prior to sterilization	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
D. a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before packaging and sterilization	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
b. A chemical indicator is placed in each load	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
c. A biologic indicator is performed at least weekly and with all implantable loads	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
d. Each load is monitored with mechanical indicators (e.g. time, temperature, pressure)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
e. Documentation for each piece of sterilization equipment is maintained and up to date and includes results from each load	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
E. Items are appropriately contained and handled during the sterilization process to assure that sterility is not compromised prior to use	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
F. After sterilization, medical devices and instruments are stored in a designated clean area so that sterility is not compromised	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
G. Sterile packages are inspected for integrity and compromised packages are reprocessed	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
H. Additional breaches in sterilization practices not captured by the questions above were identified (If YES, please specify further in comments)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Comments: ***(please print and limit comments to the space provided)***	

HIGH-LEVEL DISINFECTION		
Practices to be Assessed	**Was Practice Performed?**	**Manner of Confirmation**
A. Semi-critical equipment is high-level disinfected or sterilized	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
B. Is high-level disinfection performed on site? **(If NO, Skip to "F")**	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
(A "No" answer does not result in a citation, since ASCs are permitted to provide for high-level disinfection off-site, under a contractual arrangement.) (Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)		
a. ***If answer to B was*** **YES**, *please indicate method of high-level disinfection:*	○ Manual ○ Automated ○ Other *(please print):*	
C. Items are pre-cleaned according to manufacturer's instructions or evidence-based guidelines prior to high-level disinfection	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
D. a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before high-level disinfection	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
b. High-level disinfection equipment is maintained according to manufacturer instructions	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
c. Chemicals used for high-level disinfection are:		
I. Prepared according to manufacturer instructions	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
II. Tested for appropriate concentration according to manufacturer's instructions	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
III. Replaced according to manufacturer's instructions	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
IV. Documented to have been prepared and replaced according to manufacturer's instructions	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
d. Instruments requiring high-level disinfection are:		
I. Disinfected for the appropriate length of time as specified by manufacturer's instructions or evidence-based guidelines	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
II. Disinfected at the appropriate temperature as specified by manufacturer's instructions on evidence-based guidelines	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
E. Items that undergo high-level disinfection are allowed to dry before use	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
F. Following high-level disinfection, items are stored in a designated clean area in a manner to prevent contamination	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
G. Additional breaches in high-level disinfection practices, not captured by the questions above were identified (If YES, please specify further in comments)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Comments: ***(please print and limit comments to the space provided)***	

IV. Environmental Infection Control

Observations are to be made of staff who perform environmental cleaning (e.g., surgical technicians, cleaning staff, etc.)

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
A. Operating rooms are cleaned and disinfected after each surgical or invasive procedure with an EPA-registered disinfectant	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
B. Operating rooms are terminally cleaned daily	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
C. High-touch surfaces in patient care areas are cleaned and disinfected with an EPA-registered disinfectant	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
D. The ASC has a procedure in place to decontaminate gross spills of blood	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
E. Additional breaches in environmental cleaning not captured by the questions above were identified (If YES, please specify further in comments)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Comments: ***(please print and limit comments to the space provided)***	

V. Point of Care Devices (e.g., blood glucose meter)

Observations are to be made of staff who perform fingerstick testing (e.g., nurses)

If N/A is *filled in*, please clarify why *in the comments box below* why it was not applicable or not observed.

Practices to be Assessed	**Was Practice Performed?**	**Manner of Confirmation**
1. Does the ASC have a blood glucose meter? **If NO, STOP HERE.**	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
A. A new single-use, auto-disabling lancing device is used for each patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
B. The glucose meter is not used on more than one patient unless the manufacturer's instructions indicate this is permissible	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
C. The glucose meter is cleaned and disinfected after every use.	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
D. Additional breaches in appropriate use of point of care devices (like glucose meters) not captured by the questions above were identified (If YES, please specify further in comments)	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

Comments: ***(please print and limit comments to the space provided)***	