Timothy J. Wolf, CRNA
220West 21st Street
Upland, California 91784-1412
Cell 909-731-6414. Home 909-982-4470. Fax 909-981-2887.
tjwolf@concentric.net

October 13, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3887-P
P.O. Box 8017
Baltimore, MD 21244-8017

The following comments concern the "PROVISIONS" section of the proposed regulations.

I. Section 416.42(a) Standard: Anesthesia Risk and Evaluation.

> **A physician must evaluate the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.** Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.

The current wording requiring that a physician evaluate the risk of anesthesia and that a physician evaluate each patient for proper anesthesia recovery presents considerable problems for those ACSs where the anesthesia is administered by Certified Registered Nurse Anesthetists (CRNAs). Surgeons do not want to perform the preanesthesia evaluation of the patient or determine if the patient is a suitable risk for anesthesia. The surgeon has scheduled the patient for the procedure. Therefore, the surgeon believes the patient is an appropriate risk for anesthesia.

However, I have administered anesthesia at ASCs for 20 years. The patient is not always an appropriate risk for anesthesia for the planned procedure.

Fortunately, the surgeons I work with realize the value of having the patient evaluated by the nurse anesthetists working at the facility. Any questions concerning the medical condition of the patient that might present an anesthetic problem are usually brought to our attention prior to the day of surgery. This system allows the required consultations and any additional tests to be performed prior to the scheduled surgery day. During this 20-year period not one patient has required transfer to a hospital because of an anesthetic problem.

In 1986 HCFA amended the COPs for hospitals. The revised regulation requires that the preanesthesia evaluation be performed by an anesthesiologist or person administering the anesthesia no longer than 48 hours prior to administering the anesthesia. The comments in the proposed changes stated:

> "Other factors identified by studies as affecting anesthesia outcome are the skills and knowledge of the anesthetist, familiarity with equipment, adequacy of the preanesthesia workup, and the method and circumstances of anesthesia administration." (Fed. Reg. Vol.51, No. 116, June 17, 1986, page 22028)

Similar wording was used when CMS amended the COP regulations for critical access hospitals. The amendments permit CRNAs to perform the preanesthesia evaluation to assess the risk of anesthesia and to perform the post anesthesia evaluation to determine recovery from the anesthesia. (Fed. Reg. Vol. 66, No. 148, 8/1/2001, page 39924 &39925)

The education of CRNAs prepares the CRNA to evaluate a patient prior to administering an anesthetic. One of the intents of an anesthesia evaluation is to inform the person administering the anesthetic of the medical condition of the patient. It is impossible to administer a safe anesthetic unless the person administering the anesthesia has performed a preanesthesia evaluation.

California law and regulation permit CRNAs to perform the preanesthesia evaluation, determine if the patient is an acceptable risk for anesthesia and authorize the discharge of the patient from an outpatient facility. California law and regulations govern those ASCs that are not certified to participate in the Medicare facility reimbursement system. These laws and regulations

have remained unchanged for nearly 20 years. If there was a patient safety problem California would have amended the laws and regulations.

I realize that the existing CfC wording does not prevent the CRNA administering the anesthetic from performing an evaluation. However, the authority for the evaluation lies with the surgeon. This makes it more difficult for the CRNA to state that the patient is not in acceptable condition for the anesthetic. For the safety of the patient the regulation should require that the person administering the anesthetic perform the preanesthesia evaluation and determine if the patient is an acceptable anesthesia risk. Anesthesia has become safer since the regulation changes in 1986. Therefore, it appears that permitting CRNAs to perform the preanesthesia evaluation has proved to be safe.

II. Section 416.42(a) Standard: Anesthesia Risk and Evaluation.

> A physician must evaluate the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. **Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.**

The ASC CfC regulation requiring a physician to evaluate each patient for proper anesthesia recovery does not serve any practical purpose. Surgeons do not remain at ASCs simply to wait for patients to recovery from anesthesia. Time is valuable. The surgeons are either performing surgery at another facility or seeing patients in the hospital or their office. They are not waiting for patients to recovery from anesthesia. The paper work may indicate that the surgeon evaluated and discharged the patient. However, in reality it was either the CRNA who made the determination or in some cases the PACU nurse. The surgeon can determine anesthesia recovery. However, the CfCs should also permit proper anesthesia recovery for discharge to be determined by CRNAs.

Surgical complications are not the issue. If an anesthesiologist administered the anesthesia the anesthesiologist would fulfill the physician requirement. However, the anesthesiologist does not have the training or privileges to perform surgery. The most common immediate surgical complication is hemorrhage. This would be a rare ASC complication and is identified by vital signs and other common symptoms. If an anesthesiologist was the

physician performing the evaluation for proper anesthesia recovery and the patient had a surgical complication the surgeon would need to be informed and return to evaluate the patient. The same situation would apply if a CRNA was performing the evaluation for proper anesthesia recovery and the patient had a surgical complication. There is no logical reason for the regulation requirement that only a physician can evaluate the patient for proper anesthesia recovery.

However, requiring the presence of a physician during recovery from anesthesia and requiring that the discharge evaluation and order to be written by a physician will result in ASCs utilizing anesthesiologists rather than CRNAs. This is especially true in ASCs with one or two operating rooms. The regulations should address proven safety requirements and not simply presume that a physician performing a function will be safer than if the function was performed by a CRNA. Requiring that an individual with ACLS certification be present until the patient is determined to have recovered from anesthesia would be a proven safety requirement.

I am suggesting wording changes for Section 416.42 (a) that would reflect the above comments and provide equal regulation requirements for ASCs, acute care hospitals and critical accesses hospitals. Strikethrough is wording to be eliminated and underlined is new wording.

Section 416.42(a) Standard: Anesthesia Risk and Evaluation.

> **A physician must evaluate the patient immediately before surgery or other procedure to evaluate the risk ~~of anesthesia and~~ to the patient of the procedure to be performed. Immediately prior to the administration of anesthesia a physician or a certified registered nurse anesthetist must evaluate the patient to determine the risk of anesthesia for the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician or a certified registered nurse anesthetist for proper anesthesia recovery.**

III. Section 416.48(a)(3) Orders given orally for drugs and biologicals must be followed by a written order and signed by the prescribing physician.

CRNAs have prescribing authority or authority to order medications in a number of states. It is common practice for CRNAs to issue medication orders to PACU nurses. Therefore, the wording of Section 416.48(a)(3) should be changed to the following:

> **Section 416.48(a)(3) Orders given orally for drugs and biologicals must be followed by a written order and signed by the prescribing physician or other individual permitted by state law or regulation to order drugs or biologicals.**

IV. Section 416.52 Patient admission, assessment and discharge.

(c) Standard: Discharge. The ASC must-

(3) Ensure each patient has a discharge order, signed by a physician, ~~or~~ the qualified practitioner who performed the surgery or procedure, or a certified registered nurse anesthetist unless otherwise specified by State Law. The discharge order must indicate that the patient has been evaluated for proper anesthesia and medical recovery.

Justification for the changes in part 3 are explained above and are necessary to have consistency in the regulations.

I would like to remind CMS of the following official response comments concerning the final regulations for critical access hospitals that were published in the Federal Register:

> "We acknowledge the commenter's concern regarding the anesthesia risk and evaluation standard for ASCs. Our existing conditions for coverage for ASCs require examination of patients by a physician immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. The ASC conditions of coverage also require evaluation of patients by a physician for proper anesthesia recovery prior to discharge from the ASC. **We expect to review and modify the ASC conditions of coverage including the current anesthetic risk and evaluation standard, through a notice of proposed rulemaking in 2002.** At that time we will consider the commenter's concern." (Fed. Reg. / Vol. 66, No. 148 / August 1, 2001 / page 39925)

CMS is 5 years behind the indicated schedule to propose changes to the ASC regulations and has not addressed the anesthesia risk and evaluation standard as indicated in the official comments published in the Federal Register.

There is one other standard that needs clarification.

V. Section 416.42 (b) Standard: Administration of Anesthesia.
Anesthesia must be administered by only:

(1) A qualified anesthesiologist, or

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist, or an anesthesiologist's assistant as defined in §410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (d) of this section, the anesthetist must be under the supervision of the operating physician and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

The regulations have retained the U. S. Code definition of physician that includes podiatrists and dentists. However, in California the state agency performing the Medicare surveys of ASCs does not recognize a podiatrist or dentist as the physician qualified to fulfill the supervision requirement when a CRNA administers the anesthetic. California state law **does not** require physician supervision of anesthesia services provided by CRNAs. Therefore, there is not any state law restriction that would prevent a podiatrist or a dentist from fulfilling the Medicare supervision requirement. California state law permits podiatrists and dentists to have hospital admitting privileges. The M.D. physician member of the survey agency determined that a podiatrist or a dentist does not qualify to fulfill the Medicare supervision requirement. It is common knowledge that the M.D. physicians want to require that all non-M.D. professionals be under the supervision of M.D. physicians. However, CMS regulations should not be based on the non-competition desires of a class of physicians. Therefore, the following changes are recommended:

§416.42

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA), or an anesthesiologist's assistant as defined in §410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (d) of this section, the anesthetist must be under the supervision of the operating physician and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

The definition of operating physician includes all of the practitioners listed under section 1861(r) of the Social Security Act unless state law has other specific CRNA supervision requirements.

Of course, the most reasonable solution would be to just eliminate the supervision requirement for CRNAs. The Medicare facility reimbursement regulations are not an appropriate method to preempt state law governing licensed professional scopes of practice. The supervision requirement has not proven to provide any additional safety. This has been proven by the elimination of the supervision requirement in 15 states. I am not aware of any information or credible studies indicating that there has been an increase in anesthesia complications concerning anesthesia administered by CRNAs in the states that have opted out of the Medicare facility supervision requirement.

Thank you for considering my comments and suggested wording changes.

Sincerely,

Timothy J. Wolf, CRNA

October 8, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3887-P
P.O. Box 8017
Baltimore, MD 21244-8017

The following comments concern the "PROVISIONS" proposed regulations.

I. Section 416.42(a) Standard: Anesthesia Risk and Evaluation.

> **A physician must evaluate the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.** Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.

The current wording requiring that a physician evaluate the risk of anesthesia and that a physician evaluate each patient for proper anesthesia recovery presents considerable problems for those ACSs where the anesthesia is administered by Certified Registered Nurse Anesthetists (CRNAs). Surgeons do not want to perform the preanesthesia evaluation of the patient or determine if the patient is a suitable risk for anesthesia. The surgeon has scheduled the patient for the procedure. Therefore, the surgeon believes the patient is an appropriate risk for anesthesia.

However, it is the experience of CRNAs that the patient is not always an appropriate risk for anesthesia for the planned procedure. There are a number of ASCs in California that are not certified to participate in the Medicare conditions of coverage. In these facilities the CRNAs are performing the pre-anesthesia evaluation and determining if the patient is an acceptable risk for anesthesia. California law also permits CRNA to determine the recovery from anesthesia and authorize the discharge of the patient from the ASC. California law does not permit accreditation agencies to have accrediting policies that restrict the scope of practice of CRNAs. The California Association of Nurse Anesthetists (CANA) is not aware of any problems caused by CRNAs performing pre-anesthesia evaluations,

determining if the patient is an acceptable risk for the anesthesia and evaluating and authorizing the discharge of the patient from the ASC. The Medicare Conditions of Participation for hospitals have permitted CRNAs to perform these functions since 1986 (FR/Vol.51, No.116/6-17-1986). This 20 year period has shown that CRNAs can perform these functions safely and effectively.

Fortunately, many surgeons realize the value of having the patient evaluated by the nurse anesthetists working at ASCs. Any questions concerning the medical condition of the patient that might present an anesthetic problem are usually brought to the CRNAs attention prior to the day of surgery. This system allows the required consultations and any additional tests to be performed prior to the scheduled surgery day

In 1986 HCFA amended the COPs for hospitals. The revised regulation requires that the preanesthesia evaluation be performed by an anesthesiologist or person administering the anesthesia no longer than 48 hours prior to administering the anesthesia. The comments in the proposed changes stated:

> "Other factors identified by studies as affecting anesthesia outcome are the skills and knowledge of the anesthetist, familiarity with equipment, adequacy of the preanesthesia workup, and the method and circumstances of anesthesia administration." (Fed. Reg. Vol.51, No. 116, June 17, 1986, page 22028)

Similar wording was used when CMS amended the COP regulations for critical access hospitals. The amendments permit CRNAs to perform the preanesthesia evaluation to assess the risk of anesthesia and to perform the post anesthesia evaluation to determine recovery from the anesthesia. (Fed. Reg. Vol. 66, No. 148, 8/1/2001, page 39924 &39925)

The education of CRNAs prepares the CRNA to evaluate a patient prior to administering an anesthetic. One of the intents of an anesthesia evaluation is to inform the person administering the anesthetic of the medical condition of the patient. It is impossible to administer a safe anesthetic unless the person administering the anesthesia has performed a preanesthesia evaluation.

CANA realizes that the existing wording does not prevent the CRNA administering the anesthetic from performing an evaluation. Surgeons do not want to perform the pre-anesthesia evaluation or determine that the patient is an acceptable risk for anesthesia. However, CfCs require the surgeon to perform this evaluation. The authority for the evaluation lies with the surgeon. This makes it more difficult for the CRNA to state that the patient is not in acceptable condition for the anesthetic. For the safety of the patient the regulation should require that the person administering the anesthetic perform the preanesthesia evaluation and determine if the patient is an acceptable anesthesia risk. Anesthesia has become safer since the regulation changes in 1986. Therefore, it appears that permitting CRNAs to perform the preanesthesia evaluation has proved to be safe.

II. Section 416.42(a) Standard: Anesthesia Risk and Evaluation.

> A physician must evaluate the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. **Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.**

The ASC CfC regulation requiring a physician to evaluate each patient for proper anesthesia recovery does not serve any practical purpose. Surgeons do not remain at ASCs simply to wait for patients to recovery from anesthesia. Time is valuable. The surgeons are either performing surgery at another facility or seeing patients in the hospital or their office. They are not waiting for patients to recovery from anesthesia. The paper work indicates that the surgeon evaluated and discharged the patient. However, in reality it was either the CRNA who made the determination or in some cases the PACU nurse. The surgeon can determine anesthesia recovery. However, the CfCs should also permit proper anesthesia recovery for discharge to be determined by CRNAs.

Surgical complications are not the issue. If an anesthesiologist administered the anesthesia the anesthesiologist would fulfill the physician requirement. However, the anesthesiologist does not have the training or privileges to perform surgery. The most common immediate surgical complication is internal hemorrhage. This would be a rare ASC complication and is identified by vital signs and other common symptoms. If an anesthesiologist

was the physician performing the evaluation for proper anesthesia recovery and the patient had a surgical complication the surgeon would need to be informed and return to evaluate the patient. The same situation would apply if a CRNA was performing the evaluation for proper anesthesia recovery and the patient had a surgical complication. There is no logical reason for the regulation requirement that only a physician can evaluate the patient for proper anesthesia recovery.

CANA is suggesting wording changes for Section 416.42 (a) that would reflect the above comments and provide equal regulation requirements for ASCs, acute care hospitals and critical accesses hospitals. Strikethrough is wording to be eliminated and underlined is new wording.

Section 416.42(a) Standard: Anesthesia Risk and Evaluation.

> **A physician must evaluate the patient immediately before surgery or other procedure to evaluate the risk ~~of anesthesia and~~ to the patient of the procedure to be performed. Immediately prior to the administration of anesthesia a physician or a certified registered nurse anesthetist must evaluate the patient to determine the risk of anesthesia for the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician or a certified registered nurse anesthetist for proper anesthesia recovery.**

III. Section 416.48(a)(3) Orders given orally for drugs and biologicals must be followed by a written order and signed by the prescribing physician.

CRNAs have prescribing authority or authority to order medications in a number of states. It is common practice for CRNAs to issue medication orders to PACU nurses. Therefore, the wording of Section 416.48(a)(3) should be changed to the following:

> **Section 416.48(a)(3) Orders given orally for drugs and biologicals must be followed by a written order and signed by the prescribing physician or other individual permitted by state law to order drugs or biologicals.**

IV. Section 416.52 Patient admission, assessment and discharge.

(c) Standard: Discharge. The ASC must-

(3) Ensure each patient has a discharge order, signed by a physician~~,~~ ~~or~~ the qualified practitioner who performed the surgery or procedure, or a certified registered nurse anesthetist unless otherwise specified by State Law. The discharge order must indicate that the patient has been evaluated for proper anesthesia and medical recovery.

Justification for the changes in part 3 are explained above and are necessary to have consistency in the regulations.

CANA would like to remind CMS of the following official response comments concerning the final regulations for critical access hospitals that were published in the Federal Register:

> "We acknowledge the commenter's concern regarding the anesthesia risk and evaluation standard for ASCs. Our existing conditions for coverage for ASCs require examination of patients by a physician immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. The ASC conditions of coverage also require evaluation of patients by a physician for proper anesthesia recovery prior to discharge from the ASC. **We expect to review and modify the ASC conditions of coverage including the current anesthetic risk and evaluation standard, through a notice of proposed rulemaking in 2002.** At that time we will consider the commenter's concern." (Fed. Reg. / Vol. 66, No. 148 / August 1, 2001 / page 39925)

CMS is 5 years behind the indicated schedule to propose changes to the ASC regulations and has not addressed the anesthesia risk and evaluation standard as indicated in the official comments published in the Federal Register.

There is one other standard that needs clarification.

V. Section 416.42 (b) Standard: Administration of Anesthesia.
Anesthesia must be administered by only:
(1) A qualified anesthesiologist, or

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist, or an anesthesiologist's assistant as defined in §410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (d) of this section, the anesthetist must be under the supervision of the operating physician and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

The regulations have retained the U. S. Code definition of physician that includes podiatrists and dentists. However, in California the state agency performing the Medicare surveys of ASCs does not recognize a podiatrist or a dentist as the physician qualified to fulfill the supervision requirement when a CRNA administers the anesthetic. California state law **does not** require physician supervision of anesthesia services provided by CRNAs. Therefore, there is not any state law restriction that would prevent a podiatrist or dentist from fulfilling the Medicare supervision requirement. California podiatrists and dentists have hospital admitting privileges. The M.D. physician member of the survey agency determined that a podiatrist or a dentist does not qualify to fulfill the Medicare supervision requirement. It is common knowledge that the M.D. physicians want to require that all non-M.D. professionals be under the supervision of M.D. physicians. However, CMS regulations should not be based on the non-competition desires of a class of physicians. Therefore, the following changes are recommended:

§416.42

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA), or an anesthesiologist's assistant as defined in §410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (d) of this section, the anesthetist must be under the supervision of the operating physician and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

The definition of operating physician includes all of the practitioners listed under section 1861(r) of the Social Security

Act unless state law has other specific CRNA supervision requirements.

Of course, the most reasonable solution would be to just eliminate the supervision requirement for CRNAs. The Medicare facility reimbursement regulations are not an appropriate method to preempt state law governing licensed professional scopes of practice. The supervision requirement has not proved to provide any additional safety. This has been proven by the elimination of the supervision requirement in 15 states. I am not aware of any information or credible studies indicating that there has been an increase in anesthesia complications concerning anesthesia administered by CRNAs in the states that have opted out of the Medicare facility supervision requirement.

There is not any evidence that regulations restricting the functions CRNAs may perform increase patient safety. CMS/HCFA confirmed this in the official statement published in the Federal Register.

> "There have been no studies published within the last 10 years demonstrating any need for Federal intervention in State professional practice laws governing CRNA practice." (FR/Vol. 66, No. 12 / January 18, 2001)

However, restrictive regulation wording does limit CRNA utilization in ASCs. It is an effective anticompetitive system. A review of the cost of professional liability insurance and the number of claims has not shown any adverse effects in the states that have opted out of the Supervision requirement. Therefore the changes we have proposed should not create any patient safety issues.

Thank you for considering the comments of the California Association of Nurse Anesthetists and our suggested wording changes.

Sincerely,

Karyn Karp, CRNA, President
California Association of Nurse Anesthetists

3

>Public Comments on Medicare and Medicaid Programs; Ambulatory Surgical
>Centers, Conditions for Coverage:========

CMS-3887-P

>
>Title: Medicare and Medicaid Programs; Ambulatory Surgical Centers,
>Conditions for Coverage FR Document Number: 07-04148 Legacy Document
>ID:
>RIN: 0938-AL80
>Publish Date: 08/31/2007 00:00:00
>Submitter Info:
>
>
>First Name: Jorge
>Last Name: Iberico
>Category: Other Health Care Professional - HC075 Mailing Address:
>City:
>Country: United States
>State or Province:
>Postal Code:
>Organization Name:
>
>Comment Info: ================
>
>General Comment:I agree with these proposed rules for the Ambulatory
>Surgical Centers in order to extend their current quality measures and
>standards for Medicare and Medicaid members, especially in surgical
>procedures for the appropriate setting for the delivery of high quality
>and efficient care; and infection control in order to prevent poor
>surgical techniques and follow-up care.
>

October 30, 2007

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: 42 CFR Part 416; Medicare and Medicaid Programs; Ambulatory Surgical Centers, Conditions for Coverage; Proposed Rule

Dear Mr. Weems:

On behalf of the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE) who jointly represent over 15,000 physicians specializing in digestive diseases, we are pleased to have the opportunity to comment on the proposed regulations 42 CFR Part 416; Medicare and Medicaid Programs; Ambulatory Surgical Centers, Conditions for Coverage.

The Conditions for Coverage (CFCs) were originally issued in 1982. In the ensuing twenty years, significant innovations in ASC patient care delivery, safety, and quality assessment have emerged. Our societies support the Agency's efforts to continue to promote high-quality care in the ASC setting by updating the ASC CFCs.

We are in agreement with most of the proposed conditions for coverage and find them generally consistent with accreditation requirements already imposed on ASCs by other entities such as the Joint Commission or the Accreditation Association for Ambulatory Health Care (AAAHC). However, as indicated below, we have concerns with several of the proposed conditions.

We have a broad concern with the Agency's ability to provide the increased support these additional regulations will require.

At present, a newly established ASC can experience significant delays in certification, with further delays generated if a follow-up survey is required. Delays in initial Medicare certification can be economically unsustainable for a smaller single specialty center, particularly for individually owned ASCs in comparison to ASCs owned by larger commercial entities. In anticipation of a survey, the center must be prepared to function by being fully staffed and supplied, but cannot perform any cases except those allowed by the surveyor. An ASC can wait weeks in this situation waiting for the availability of the contractor. This can result in enormous financial burdens for the ASC and cause significant delays in beneficiaries accessing services.

We anticipate that the regulations will result in a more complex survey process; yet, we are not confident that CMS will have the resources needed to support the demands implied by a survey that incorporates the complexity, detail and scope necessary for the implementation of these proposed regulations. We do not want to see even greater delays in the survey process emerge as a result of these new regulations.

While the survey process may be critical to certify an ASC, we do not believe that ASCs should be penalized with further delays generated where quality and safety criteria are met, but administrative details are lacking.

Based on these concerns, our societies recommend that prior to implementation of these new regulations, CMS take steps to assure that adequate resources are in place to assure timely surveys and resurveys so as to minimize delays in the participation or continued participation of ASCs. In this connection, we trust that CMS and its contractors will apply a *rule of reason* to assure that minor deficiencies in administrative conditions (e.g., provision of translator services or definition of grievance) are not considered as the same level of deficiency as a basic health and safety requirement. We hope that CMS will *conditionally* certify or recertify ASCs found out of compliance with a minor or technical condition and provide a period of time to meet the specific standard.

ASCs are an important source of high quality care for Medicare beneficiaries. While these proposed CFCs will support the on-going provision of this high-quality care, we would be disappointed to see their implementation causing delayed access to care for Medicare beneficiaries.

These proposed CFCs will not only increase the administrative demand on CMS, but also substantially increase the administrative burden on ASC operations. While overall we support the Agency's efforts and believe that the new requirements will help in the provision of good patient care, we observe the inconsistency inherent in decreasing Medicare payments for ASCs providing important gastroenterology services to Medicare beneficiaries as the Agency introduces parallel increases in costly administrative requirements.

Condition for Coverage—Quality Assessment and Performance Improvement (QAPI)
With the proposed Quality Assessment and Performance Improvement (QAPI) requirement, CMS has raised the bar for all participating ASCs. In contrast to the traditional retroactive, problem-oriented approach, currently required by CMS, the QAPI program will require the development, implementation, and maintenance of an ongoing quality improvement program that aims to proactively reduce errors and address omissions of care *prior* to performing a procedure. We agree with CMS that this model of on-going monitoring of quality versus the traditional problem-oriented model is better supported by available evidence. In fact we believe that most accredited ASCs already have such programs in place, in accordance with processes implied by the accreditation process.

The gastroenterology community fully supports the implementation of QAPI programs in ASCs. We believe that such programs demonstrate improvement in patient health outcomes, improve patient safety and help decrease medical errors. While we support the concept of instituting the requirement of a QAPI program, we strongly disagree with the estimated staff support and expense suggested by the Proposed Rule, with special reference to the number of hours needed for development and implementation. CMS estimated that fifty-two hours annually per ASC are required for this process. In fact, our experience would suggest that this is a gross underestimate

of staff time. To properly conduct a program of the scope and breadth described in the proposed regulations *at least* one full-time employee (FTE) would be needed for a typical ASC. Further, the scope of this project would require the expertise of an RN level staff member. Given that the majority of gastroenterology ASCs are small employers, this will be a substantial un-reimbursed expense for these practices.

We request that in the final regulations CMS include a more accurate estimate of the number of labor hours required to develop and implement a QAPI program. We recommend an estimate of one FTE (2,000 hours) annually per ASC to support a QAPI program.

Conditions for Coverage—Patient Rights

CMS's new proposal would require ASCs to notify patients of their rights, provide for the exercise of rights, establish the right of privacy and safety, and maintain the confidentiality of clinical records. Based on our review, we found the requirements proposed in this section to be reasonable.

Written policies that detail the rights of patients protect both the facility and the patient and encourage the provision of safe and high quality care. However, we urge CMS to assist us in this endeavor by providing additional detail and clarification on issues surrounding the concept of grievances. In the daily operation of an ASC, administrators, staff, and providers receive a variety of feedback from patients and their family or caregivers that is both positive and negative in nature. Such negative comments may be trivial (e.g., the color of the gown, the temperature in the room) or important (e.g., a concern about privacy). The proposed regulations require ASCs to investigate, document and respond to all grievances, no matter how trivial. We do not believe that CMS meant to imply that every patient complaint rises to the level of a grievance. *The societies request that CMS provide a definition of grievance in the final regulations to provide both surveyors and ASCs with better guidance in terms of what types of situations would fall within the grievance category.*

Beyond more detail on grievances, we ask CMS to provide more detail on the Agency's expectations for dealing with grievances and situations where there is a difference in interpreting compliance. As currently stated, the requirement is too general and requires an inordinate subjective interpretation. A Medicare contractor conducting an ASC survey will have significant influence on interpreting the regulations. We believe that it is in the best interest of both the patient and the ASC if there is less reliance on individual contractor interpretation of these regulations and more national consistency in implementation. *The societies urge CMS to provide more detailed discussion of these issues in the final regulations.*

Condition for Coverage—Patient Admission, Assessment and Discharge

The proposed new requirement in this section would augment current regulations with the proposal for an admission and pre-surgical assessment, post-surgical assessment and a discharge. A discharge protocol with written discharge instructions containing elements delineated in the proposed regulations is the current standard in the industry. However, we request that CMS provide additional clarification on certain of the elements proposed. For example, under the proposed regulations, it is unclear who the responsible individual is for preparing the discharge. Accredited ASCs require that patients meet well-defined criteria for discharge after sedation, and these discharge criteria are delineated in the standard operating procedures for the ASC. Accredited ASCs require pre-operative evaluation of certain organ systems prior to the procedures and after the procedure. The proposed regulations (in the preamble) suggest that an evaluation of *all* organ systems will be required prior to discharge. This requirement would be atypical for discharge from any procedure in any facility. For example, an ophthalmologic

examination is not typically performed prior to patient discharge after an endoscopic procedure. The actual standard specifies that the discharge order signed by a physician must indicate that the patient has been evaluated for proper anesthesia and medical recovery. We think the judgment as to which organ systems need to be reviewed for compliance with this standard should be left to the judgment of the ASC governing body. *The societies recommend that CMS remove or substantially modify this requirement in the final regulations.*

Thank you for the opportunity to submit these comments. If we may provide additional information, you may contact Sheila Madhani, Consultant to ASGE at 202-833-0007, Anne Marie Bicha, AGA Director of Regulatory Affairs, at 240-482-3223, or Julie Cantor-Weinberg, ACG Vice President of National Affairs, at 301-263-9000.

Sincerely,

Amy Foxx-Orenstein, DO, FACG
President, American College of Gastroenterology

Mark Donowitz, MD

Mark Donowitz, MD, AGAF
Chair, American Gastroenterological Association

Grace H. Elta, M.D.

Grace H. Elta, MD, FASGE
President, American Society for Gastrointestinal Endoscopy

ORIGINAL

5

Boston Scientific

Parashar B. Patel
Vice President
Health Economics & Reimbursement

One Boston Scientific Place
Natick, MA 01760

October 30, 2007

The Honorable Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare and Medicaid Programs; Ambulatory Surgical Centers, Conditions for Coverage (CfC), Proposed Rule (CMS-3887-P)

Dear Mr. Weems:

Boston Scientific Corporation (Boston Scientific) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Ambulatory Surgical Centers CfC proposed rule (CMS-3887-P, Federal Register, Vol. 72, No. 169, August 31, 2007).

As the world's largest company dedicated to the development, manufacturing, and marketing of less-invasive and innovative therapies, Boston Scientific supplies medical devices provided in the following medical specialty areas:

- Cardiac Rhythm Management;
- Cardiovascular;
- Endosurgery; and
- Neuromodulation.

Summary
Boston Scientific appreciates CMS's efforts to update the CfCs for ambulatory surgical centers (ASCs) to reflect current practice and to promote patient health and safety. We also applaud CMS's efforts to establish a foundation, in the form of the updated CfCs, that will support ASCs' ability to successfully meet the quality standards that will be published in 2009, and we support organizations like the American Quality Foundation (AQF) that are working to help establish those standards. However, we believe that, even when strong quality standards are put in place, the proposed changes do not go far enough toward ensuring consistent beneficiary safety across individual ASCs and states. Therefore, Boston Scientific offers the following recommendations to CMS:

- Implement consistent and enforceable safety and quality standards and monitoring mechanisms;
- Enhance opportunities for consistent collection of dependable, actionable quality data; and
- Improve patients' ability to exercise their rights by disclosing physicians' financial interests in an ASC "at the point of referral," rather than "prior to the first visit."

Each of these recommendations is addressed in greater detail in the following pages.

- **Implement consistent and enforceable safety and quality standards and monitoring mechanisms.**

  In its CfC proposed rule, CMS states that it is trying to move from a problem-focused approach to a more proactive approach. CMS states, "[u]nder a problem-focused approach, the goal has been to ensure quality through the enforcement of prescriptive health and safety standards. This after-the-fact approach does not generally contribute to ASC improvement or stimulate broad-based quality of care initiatives."[1] Boston Scientific applauds CMS's proactive approach and believes that providing beneficiaries with high quality care in non-hospital settings is an important and appropriate goal. However, we believe that to be able to truly improve the safety and quality of care delivered in ASCs, CMS must establish a uniform baseline for safety and quality that all ASCs are required to follow. We also believe that, even in a proactive ASC system, assuring consistent enforcement of standards is critical.

  We are concerned that, as currently proposed, the CfCs may limit the effectiveness of efforts to ensure safety, because under the proposal individual ASCs will develop and implement their own standards. Ensuring the effectiveness of standards in such a self-regulating environment is made more difficult by the fact that states have the prerogative to enforce standards differently – all while more complex and risky procedures are being allowed in ASCs. Another concern is that the proposal does not discuss how CMS will monitor the quality of care being provided across ASCs.

  Consistency
  The proposed CfCs improve on the existing safety standards, but there is room for even more improvement. For example, in nearly every instance, CMS elects not to propose specific quality indicators or require that specific data be collected. Rather, CMS leaves the establishment and monitoring of progress against quality and safety indicators up to the interpretation of each individual ASC. When coupled with the significant differences in licensing requirements and ASC oversight across different states, CMS's approach of leaving the development and implementation of quality and safety standards could have three unintended consequences:

  1. Substandard quality and safety could go unnoticed and unchecked;
  2. Beneficiaries might not have the same level of safety protection from ASC to ASC or from state to state; and
  3. It will be difficult for CMS and beneficiaries to compare the quality records of multiple ASCs to make informed decisions about whether to allow a facility to be a Medicare provider or, more importantly, whether to seek care at one facility rather than at another.

  At a minimum, the following standards should be consistently implemented by all ASCs and enforced by all states / oversight authorities:
  - *Staff should be trained and experienced in supervising operative settings*
    Currently, the only clearly delineated staff training requirements surround the use of emergency equipment and the ability to administer cardiopulmonary resuscitation.[2]
  - *Immediate transfer to hospitals must be available*
    The current Medicare CfCs for ASCs state that all ASCs must have procedures for the immediate transfer of patients needing hospitalization after an ASC procedure and the interpretive guidelines state that "such situations should be infrequent."[3],[4] However, "infrequent" is not defined in the CfCs, and the availability of transport services does not eliminate the risks of infection, dissection

[1] United States Department of Health and Human Services. Centers for Medicare & Medicaid Services. 42 CFR Part 416 (CMS-3887-P). Medicare and Medicaid Programs; Ambulatory Surgical Centers, Conditions for Coverage: Proposed Rule. Federal Register, Vol. 72, No. 169, August 31, 2007, page 50470.
[2] 42 CFR, §416.44(d).
[3] 42 CFR §416.41.
[4] DHHS, Centers for Medicare and Medicaid Services. State Operations Manual, Appendix L: Guidance to Surveyors: Ambulatory Surgical Services (Rev. 1, 05-21-04).

and perforation associated moving patients who have undergone procedures in ASCs, particularly those that are catheter-based. Because CMS does not have a consistent method to track transfer rates, CMS (nor patients and physicians) cannot confirm whether a given ASC's rate of complications requiring transfer is infrequent or not.

- *Patients' level of surgical risk should consistently be evaluated and documented*
  Although the proposed CfCs do expand the responsibilities of ASCs in terms of risk evaluation and documentation, CMS is proposing to leave the level and method of implementing risk assessment and the degree of documentation required to individual ASCs. Again, inconsistent standards and enforcement could make it difficult to ensure that beneficiaries have consistent and dependable care regardless of what ASC or state they are treated in.

Enforceability

The need for more consistent ASC safety standards is well demonstrated by the significant variability of state licensing requirements and accreditation standards. In a report by the American Hospital Association (AHA), only 43 of 50 states even require ASCs to be licensed whereas all states require hospitals to be licensed.[5] It is not clear how safety standards are enforced in states where licensing is not required. The AHA report also suggests that "states' ability to oversee ASCs on behalf of Medicare is eroding because of the growth in ASCs and states' limited resources. Of state-surveyed ASCs, one-third (872) had not completed a recertification survey in over five years."[6] Few states have restrictions on the procedures that can be performed in ASCs, and few states regulate infection control practices or equipment requirements.[7] According to the OIG, "CMS gives little oversight to ASC surveys and accreditation, and CMS does not make findings readily available to the public as it does for hospitals and other types of providers."[8]

Unfortunately, the CfCs cannot ensure consistent state enforcement, therefore it is even more critical that they establish a baseline of safety and quality and a means of monitoring these elements so that CMS can make informed decisions about what procedures to pay for in ASCs and when an ASC should not be participating in the Medicare program. Moreover, it is critical to have a means of assessing experiential data on risk / adverse event rates for new procedures added to the ASC approved procedures list, so that these procedures can be removed if an increased level of risk is indicated.

Monitoring Mechanisms

Boston Scientific believes that the ability to evaluate safety and quality in ASCs is at least as important, if not more so, than it is for hospitals. Hospitals, by definition, are equipped to deal with unanticipated life-threatening complications. ASCs are not always so equipped. As CMS expands the list of procedures covered in ASCs, the question of patient safety and quality becomes even more urgent. In a recent Open Door forum regarding the final ASC Payment Policy for 2008, CMS indicated in response to a question that the mechanisms to monitor safety and adverse events occurring in ASCs and their related outcomes are not currently in place.[9] As a result, CMS has no way to know whether a procedure is inappropriate for performance in an ASC or whether an adverse event occurring in an ASC could have been avoided or better managed had the procedure been performed in a hospital.

Boston Scientific believes that "Hospital Compare" has provided beneficiaries and policy makers with an easy-to-use means of evaluating the safety and quality of care provided by hospitals.

---

[5] American Hospital Association. The Migration of Care to Non-hospital Settings: Have Regulatory Structures Kept Pace with Changes in Care Delivery? *TrendWatch*. July, 2006.
[6] *Ibid.*
[7] *Ibid.*
[8] *Ibid.*
[9] CMS Open Door Forum on 2008 ASC Payment Policy, Tuesday, July 31, 2007.

We therefore urge CMS to establish a similar mechanism for monitoring the safety and quality of services provided by participating ASCs, such as an "ASC Compare" site.

- **Enhance Opportunities for Consistent Collection of Dependable, Actionable Quality Data**

Boston Scientific welcomes the news that CMS will implement quality measures for 2009. We believe that the foundation for improving quality of care is based on clear conditions for coverage, consistent enforcement of such conditions, and appropriate quality and performance measures. We support CMS's goal of developing and implementing quality and performance measures by 2009. The Quality Assessment and Performance Improvement (QAPI) CfC proposed by CMS appears to be an important step in the right direction, however it is not clear that the information gathered the QAPI process would ever be made available to CMS so that it is actionable.

Moreover, although the QAPI CfC is critical, the QAPI alone is not sufficient to insure consistent quality of care in ASCs. Given the significant interest CMS and all stakeholders have in gaining insights to the quality of care associated with contemporary clinical practice, it is essential that clinical process and outcomes information also be captured to inform decision-making. Some examples include:

- The reporting of specific clinical process information such as surgical infection prevention via prophylactic antibiotic administration. Hospitals are currently required to report this information. It would seem that data collection efforts should be consistent across sites of service;
- The utilization of proper medications at admission and whether the patient was evaluated for anesthesia risk; and
- The reporting of the number of cases requiring transfer to hospitals due to complications.

To help achieve this informed decision making, when CMS proposes quality reporting standards for ASCs CMS should consider modeling ASC quality reporting standards on the Ambulatory Care Quality Alliance (AQA) and the Hospital Quality Alliance (HQA) efforts for hospitals. Another possible starting point for ASC measures is the Surgical Care Improvement Project (SCIP).

- **Enhance Patients' Ability to Exercise their Rights**

In the ASC CfC proposed rule, CMS is proposing to require that "The ASC would also be responsible for meaningfully disclosing, if applicable, physician financial interests or ownership in the ASC facility in accordance with 42 CFR part 420 (Program Integrity). The ASC must disclose the information in writing and furnish it to the patient prior to the first visit."[10]

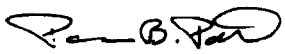
While Boston Scientific agrees that such disclosure is critical, we believe that it is critical to notify patients of financial interests at the point of referral. Our concern is that if a beneficiary is not told of a physician's financial interest in the facility where his or her procedure will be performed until a procedure is scheduled, beneficiaries may not feel comfortable requesting an alternative physician or facility, for fear of offending the surgeon and because seeking an alternative physician or facility could delay the procedure. By requiring disclosure of financial interests at the point of referral, CMS will enable beneficiaries to ask questions of their referring physicians, potentially avoiding delays and uncomfortable situations.

****

[10] Ibid., page 50475.

Thank you for the opportunity to comment on the 2008 Proposed Rule for ASC CfCs. We urge CMS to consider our recommendations in this comment letter, and we welcome the opportunity to discuss our responses to CMS's proposal. Please contact me at (508) 652-7492 or parashar.patel@bsci.com or Scott Reid, Director of Health Policy and Payment, at (202) 637-8021 or reids@bsci.com if you have any questions.

Sincerely,



Parashar Patel
Vice President, Health Economics & Reimbursement
Boston Scientific Corporation

cc: Terrence Kay, Hospital and Ambulatory Policy Group
Donald Thompson, Hospital and Ambulatory Policy Group
Carol Bazell, MD, Outpatient Care Division, Hospital & Ambulatory Policy Group
Kim Neuman, MD, Outpatient Care Division, Hospital & Ambulatory Payment Group
Scott Reid, Boston Scientific Corporation

SHEA
The Society for Healthcare Epidemiology of America

6

October 30, 2007

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3887-P,
P.O. Box 8017,
Baltimore, MD 21244-8017.

Re: Medicare and Medicaid Programs; Ambulatory Surgical Centers, Conditions for Coverage, Proposed Rule CMS-3887-P; Comments on § 416.51 Conditions for coverage— Infection Control.

The Association for Professionals in Infection Control and Epidemiology (APIC) and the Society for Healthcare Epidemiology of America (SHEA) collectively represent more than 14,000 infectious disease and infection control authorities in our nation's healthcare facilities. As organizations with considerable expertise in the prevention, detection, control and treatment of healthcare-associated infections (HAIs), we wish to respond jointly to your questions regarding the proposed conditions for coverage focused on the area of infection control for ambulatory surgical centers (ASCs) as outlined in the document *CMS-3887-P.*

We applaud the foresight of CMS in this arena, as we have a shared vision of preventing HAIs. Elevating HAI prevention and infection control to the level of a condition and noting that infection control is "an essential health and quality standard" reinforces the critical importance of infection prevention in terms of patient safety and quality of care.

We endorse the integration of the infection prevention and control program (IC) into the ASC's Quality Assurance Performance Improvement Requirement (QAPI) and the emphasis on integration of

> "*knowledge gained from past and current experiences to modify policies, procedures or practice that would lead to improvements for those problematic areas identified and monitored as part of the QAPI program.*"

An IC program must be dynamic and utilize assessment of prior events to improve patient care and eliminate HAIs.

SHEA Headquarters *1300 Wilson Boulevard, Suite 300 • Rosslyn, VA 22209 • Phone: 703-684-1006 • Fax: 703-684-1009 • E-mail: info@shea-online.org*

While we support many of the basic tenets of the proposed rule, we also have some suggestions we hope will facilitate early planning as CMS finalizes and implements the proposed rule and considers interpretive guidelines for the final rule.

I. Background

Infection prevention is increasingly important in non-acute settings such as ASCs, which are experiencing continued growth in volumes of surgeries that are performed. We believe every effort should be made to eliminate HAIs in all healthcare settings by applying evidence-based approaches as healthcare facilities care for sicker patients in an increasingly complex environment. We agree with the intent of the proposed changes; however, we do have some concerns regarding several specific concepts and statements made as part of the background and provisions of the proposed rule as outlined below:

Provisions

II. Provisions of the Proposed Regulation, Section 5. Condition for Coverage—Infection Control (§ 416.51)

Designated IC staff

We agree the designation of a specific individual to serve as the ASC's infection control officer (ICO) is essential. Studies such as the landmark Study on the Efficacy of Nosocomial Infection Control (SENIC)[1] have shown an active infection prevention and control program with a dedicated infection control professional (ICP) can lead to a significant reduction in HAI rates in general and surgical site infection (SSI) rates in particular.[2] The variety of issues and responsibilities the ICO will face in an ASC setting underscores the importance of adequate training including an up-to-date knowledge base encompassing all areas that will impact the ASC patient.

Qualifications and current competency

Per the background in the proposed rule,

> *"the infection control program would operate under the direction of that designated individual [i.e. the infection control officer] who would be accountable for the investigation and resolution of infection and communicable disease incidents. In addition, the infection control program would be required to follow an organized plan of action to identify infection control problems and implement corrective measures and preventive mechanisms when necessary."*

We would suggest the ICO should be referred to as an "infection control professional" or ICP. The ASC must designate in writing an individual or group of individuals, qualified through ongoing education, training, experience, or certification[3] as an infection control professional or professionals. CDC has defined an "infection control professional" as "a person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired specialized training in infection control." Verification of ongoing education and training should also be required. The number of ICPs or the number of ICP hours devoted to the infection prevention and control program should not be based on patient census alone, but rather should be determined by an annual risk assessment considering such factors as the scope of the program, characteristics of the patient population, complexity of the ASC and activities that will be carried out,

techniques available for performing essential tasks, risks entailed in the care, treatment, and services provided, and unique or urgent needs of the ASC.

Infection prevention program resources
There must be adequate, dedicated resources allocated to implement and evaluate measures to prevent and control ASC- and community-associated infections and to identify and investigate infections and communicable diseases. Resource allocation should be based on an annual risk assessment.

In order to maintain an active program for the prevention, control, and investigation of infections and communicable diseases, the scope of actual responsibilities and activities for the ASC's ICP is much more extensive than currently exist in many ASCs today.

An effective infection control program should at a minimum, address the following elements: (see Appendix I for more detail)

- Patient and staff prevention and control measures
- A safe and sanitary environment
- Staff/volunteer health, education, and training
- Regulatory and community agency responsibilities
- Annual program evaluation and revision to further the overall program goal of elimination of HAIs.

Staff training and current competency
Another area of concern focuses upon the baseline expectations for infection control training of ASC personnel. The background of the proposed rule states that:

> *"the proposed infection control condition allows flexibility for ASCs to determine how to meet these objectives. This includes the flexibility to determine how much training in infection control is necessary for the ASCs personnel."*

While we agree each ASC, as a part of its regular infection control risk assessment, should have the flexibility to determine which areas of infection control require emphasis as a part of personnel training, a minimum standard of training in the basic essential concepts of infection control should be required.

In the background and provisions of the proposed rule it is noted that CMS

> *"considered requiring ASCs to meet CDC and Occupational Safety and Health Administration (OSHA) standards for providing an environment to avoid infections and communicable disease. However, such a requirement would raise questions as to which CDC or OSHA standards must be met. Moreover, where dual sets of professionally recognized standards exist, we would not wish to restrict ASC flexibility by mandating compliance with a particular body of standards. Therefore, we are not mandating that ASCs follow any specific set of infection control guidelines."*

While we understand the concern of potentially conflicting guidelines, we would suggest that ICPs must consider all related regulations and standards, including OSHA standards to protect health care professionals as well as CDC and other IC guidelines addressing patient safety. We would propose the above paragraph be modified to state:

> "the Infection Prevention and Control program must include documentation that it has considered, selected, and implemented nationally recognized infection control guidelines."

Examples of organizations that promulgate nationally recognized infection control guidelines include, but are not limited to: the CDC/Healthcare Infection Control Practices Advisory Committee (HICPAC), the Occupational Health and Safety Administration (OSHA), the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), the Association of periOperative Registered Nurses (AORN) and the Association for the Advancement of Medical Instrumentation (AAMI).[4-7]

Cleaning, Disinfection and Sterilization

Another important concern lies in the proposed expectations for ASC instrument and equipment sterilization and cleaning. Namely, the proposed rule does ***not***

> *"propos[e] to include a prescriptive requirement that mandates a specific method of cleaning and sterilization of equipment utilized in ASC procedures. We would require each ASC to be responsible for creating and implementing its own policies and procedures for proper instrument cleaning and maintenance of the sterilization equipment to prevent patient exposure to infectious organisms by ensuring all equipment is properly cleaned and sterilized."*

We agree with CMS if the intent is to *not dictate* use of a particular method or piece of equipment. However, we are concerned this language implies that more lenient and ASC-determined policies and procedures for equipment and instrument cleaning, disinfection and sterilization are acceptable, which has the potential to place patients at increased risk in the event minimum standards are not met. Instead, the ASC should select approved and scientifically based methods/equipment for cleaning, disinfection and sterilization as outlined in nationally recognized guidelines. The approach should be no different than that used in standard operating rooms, since inpatient and outpatient surgery should provide a single standard of care.

III. Collection of Information Requirements

Given the broad range of responsibilities of the ICP at the ASC, we are also concerned regarding the estimate of the information collection burden of the Infection Control Provision; namely, the Infection Control Provision is estimated ***not*** to require any further burden in terms of information collection. The time and effort devoted to conduct the necessary activities for an active infection control program could be substantial. This will include, but not be limited to, development of an active IC program and annual risk assessment and evaluation of program effectiveness as detailed in Appendix I. Although we agree strongly with the premise that ASCs should have a dedicated and active IC program, we feel the true burden associated with this requirement may have been underestimated.

IMPACT

V. Regulatory Impact Analysis, 5. Anticipated Effects of the Infection Control Provision (§416.51)

Given the potential issues and responsibilities the ASC's ICP may face as noted above, we are also concerned about the perceived necessary training for the ICP. As per the proposed rule,

> *"the designated person would need to engage in continuing education in infection control on a frequent or at least an annual basis. We estimate that an ASC would spend approximately $500 per calendar year on infection control training for the designated individual. This cost was based on the quantity of technical information that we believe is appropriate to be included in an infection control program. The cost also includes the time spent by the ASC infection control officer (the trainee), the cost for a qualified trainer and the training materials. We estimate that the course would run 4 hours."*

Knowledge regarding infection prevention and control practices, regulatory and accreditation standards, and epidemiologic principles essential for an ICP are not a formal part of standard nursing education and training.[8] Specialized instruction in basic infection control training is thus required.[9, 10] We feel the proposed cost of $500/year is a better indicator of the cost of *continuing* education in IC following initial training. The estimated time commitment for such training currently noted in the CMS proposal (4 hours) appears less than is needed to merely ensure ongoing familiarity with new regulatory requirements and infection prevention guidelines. Thus, the impact of the new rule may have larger cost implications for the ACS than originally estimated.

Proposed Rule, § 416.51 Conditions for coverage— Infection Control

Our preceding remarks were intended to provide background on the scope of an ASC infection and prevention program, the breadth and depth of the knowledge and skills needed by the designated ICP (ICO) and support for more extensive training resources needed for staffing an effective program. These remarks may be useful consideration in future interpretive guidelines for this new standard. We have appended relevant supporting documentation and recommendations that CMS may also find helpful as it drafts Interpretive Guidelines to any final rule.

With regard to the actual proposed rule, we recommend minor wording changes as noted below in **bold**. The specific notation that the program should be "active" mirrors language found in the rules that cover hospitals "Conditions of Participation: Infection Control" [§482.42; §482.42(a); §482.42(a) (1) and §482.42(a) (2)] and emphasizes the need to continually assess and evaluate the program to identify risk areas and keep pace with changing standards and guidelines.

*The Ambulatory Surgical Center (ASC) must maintain an **active** infection **prevention and** control program for patients and ASC staff that seeks to minimize infections and communicable diseases.*

(a) Standard: Sanitary environment. The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.

*(b) Standard: Infection **prevention and** control program. The ASC must maintain an **active** program designed to prevent, control, and investigate infections and communicable diseases. The program is--*

(1) Under the direction of a designated and qualified professional who has ***sufficient knowledge, skills, and*** *training in infection control* ***to manage an effective infection prevention and control program***

(2) An integral part of the ASC's quality assessment and performance improvement program; and

(3) Responsible for providing a plan of action for preventing, identifying, ***investigating,*** *and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.*

(c) Standard: Responsibility of Chief Executive Officer, Medical Staff and Director of OR Services

The chief executive officer, medical staff and director of OR services must—

(1) Ensure that the quality assessment and performance improvement program address problems identified by the infection control professional or professional(s) and

(2) Be responsible for the implementation of successful corrective action plans in affected problem areas

In summary, we strongly support the enhanced focus by CMS on infection prevention and control in ASCs, and we appreciate the opportunity to comment on this proposed rule. We are eager to offer our infection control expertise and participate with CMS in the development of the final rule and, more specifically, in the development of the interpretive guidelines pertaining to the rule once finalized. We are committed to improving the safety of healthcare and the prevention of HAIs, and we look forward to working with CMS toward this goal.

Sincerely,

Denise M. Murphy

Victoria Fraser

Denise M. Murphy, MPH,BSN, RN, CIC
APIC President

Victoria J. Fraser, MD
SHEA President

1. Haley RW, Culver DH, White JW, et al. The efficacy of infection surveillance and control programs in preventing nosocomial infections in US hospitals. Am J Epidemiol 1985; 121:182-205.
2. McConkey SJ, L'Ecuyer PB, Murphy DM, Leet TL, Sundt TM, Fraser VJ. Results of a comprehensive infection control program for reducing surgical-site infections in coronary artery bypass surgery. Infect Control Hosp Epidemiol 1999; 20:533-8.
3. Certification Board in Infection Control and Epidemiology Incorporated. Accessed on October 22, 2007 at www.cbic.org .
4. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol 1999;20(4):250-78. Accessed on October 25, 2007 at http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf.
5. Sehulster L, Chinn RY. Guidelines for environmental infection control in health-care facilities. Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR Recomm Rep 2003;52 (RR-10):1-42. Accessed on October 25, 2007 at http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Enviro_guide_03.pdf.

6. Centers for Disease Control and Prevention. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007. Accessed on October 23, 2007 at http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Isolation2007.pdf.
7. Occupational Safety & Health Administration. Standard on Bloodborne Pathogens (1930.1030), 1993, revised 2003. Accessed on August 23, 2005 at www.osha.gov/SLTC/bloodbornepathogens/standards.html.
8. SHEA/CDC Training Courses in Healthcare Epidemiology. Accessed on October 23, 2007 at http://www.shea-online.org/about/shea_courses.cfm.
9. Horan-Murphy E BB, Chenoweth C, et al. APIC/CHICA-Canada infection control and epidemiology: Professional and practice standards. Am J Infect Control 1999;27:47-51. Accessed Oct 23, 2007 at http://www.apic.org/Content/NavigationMenu/PracticeGuidance/Standards/Standards.htm.
10. Association for Professionals in Infection Control and Epidemiology. EPI Courses - Education for the Prevention of Infection. Accessed on October 22, 2007 at http://www.apic.org/scriptcontent/custom/education/ice_courses.cfm?section=education.

Appendix I: Elements of an effective Infection Prevention and Control Program

Patient and staff prevention and control measures

- Defining, monitoring, preventing and controlling healthcare-associated infections and communicable diseases in accordance with the Centers for Disease Control and Prevention (CDC) guidelines;
- Developing measures for preventing, identifying and investigating post-operative infections following same day and outpatient surgery;
- Developing measures for identifying, investigating, and reporting healthcare-associated infections and communicable diseases to public health as required by local, state or federal regulations;
- Developing measures for the early identification of patients who may have a communicable disease and require isolation or special precautions in accordance with nationally recognized guidelines;
- Assessing and identifying patients and ASC personnel, including contract staff (e.g., agency nurses, housekeeping staff) and volunteers, at risk for infections and communicable diseases or with potential to transmit infection to patients;
- Obtaining and reviewing reports of monitored infections and communicable diseases on patients and health care workers, including all ASC personnel, contract staff (e.g., agency nurses, housekeeping staff, etc) and volunteers, in a timely manner;
- Developing measures for the prevention of infections, especially infections caused by organisms that are antibiotic-resistant or in other ways epidemiologically significant; device-associated infections e.g., those associated with intravascular devices and indwelling urinary catheters, which are often placed during outpatient surgical procedures; SSIs; and those infections associated with respiratory therapy, ventilated patients, immunosuppressed patients, and other factors which compromise a patient's resistance to infection;
- Developing implementing, and monitoring adherence to evidence-based protocols for the prevention of device-associated bloodstream infections and surgical site infections (SSIs);
- Developing measures addressing aseptic technique practices used in surgery and invasive procedures performed outside the operating room;
- Developing measures for prevention of communicable disease outbreaks, such as airborne, food borne, blood borne, and other diseases as defined by local, state and federal recommendations, guidelines, regulations, and laws;
- Developing, implementing, and monitoring a comprehensive hand hygiene program;
- Collaborating with ASC and physician staff in the selection, evaluation, implementation, and monitoring of products.

A safe and sanitary environment

- Working with the ASC administration to provide a safe environment consistent with nationally recognized infection prevention and control standards;
- Utilizing techniques for standard precautions and other categories of patient care ("isolation") precautions as recommended by the CDC;
- Educating patients, visitors, caregivers, and staff, as appropriate, about infections and communicable diseases and methods to reduce transmission in the ASC and in the community;
- Monitoring and evaluating practices of asepsis including assuring the proper cleaning, disinfection, and sterilization of medical devices, instruments, and equipment used in surgery or pre/post-operative care;
- Developing, implementing, and monitoring measures that prevent the transmission of infectious agents associated with the physical environment that address ventilation and

water quality control issues (e.g., measures taken to maintain a safe environment during internal or external construction and renovation);
- Working with the ASC to ensure maintenance of safe air handling systems in areas of special ventilation such as operating and procedure rooms;
- Providing education on important infection control concepts such as hand hygiene, respiratory protection, proper handling of multidose vials, asepsis, sterilization, disinfection, housekeeping, liquid and solid waste disposal, sharps disposal, separation of clean items from dirty items, as well as other means for limiting contamination of the environment;
- Working with ASC leadership and environmental services personnel to ensure the maintenance of a sanitary environment including cleaning and disinfecting environmental surfaces, carpeting and furniture; textiles reprocessing, storage and distribution; regulated and non-regulated waste; and pest control.

Staff/volunteers health, education and training

- Conducting new employee orientation and annual training in preventing and controlling HAIs and methods to prevent exposure and transmission of infections and communicable diseases, including bloodborne pathogens;
- Monitoring for appropriate use of personal protective equipment including gowns, gloves, masks and eye protection devices;
- Screening and evaluation of health care workers, including all ASC staff, contract workers (e.g., agency nurses, housekeeping staff, etc), and volunteers, for infections and communicable diseases as indicated, and for the evaluation of staff and volunteers exposed to patients with infections and communicable disease as indicated (for the purposes of this statement, infections and communicable diseases refer to infections and communicable diseases likely to cause significant infectious or other risk to the exposed individual as identified by the hospital or federal, state or local public health authorities, (e.g., OSHA));
- Screening or evaluating immunization status for designated infectious diseases in employees and other healthcare providers and personnel, as recommended by the CDC and its Advisory Committee on Immunization Practices (ACIP) and developing a health care worker vaccination program.

Regulatory and community agency responsibilities

- Developing procedures for working with local, state, and federal health authorities in emergency preparedness situations. We note that CMS proposed an additional disaster preparedness standard to the Governing Body and Management (416.41). We would suggest that although natural or man-made disasters are mentioned, pandemic influenza and other infectious agent risks remain as foremost concerns and the ICP has a critical role in planning and use of ASC resources in any such scenario;
- Developing and monitoring adherence to policies and procedures developed in coordination with federal, state, and local emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks.

Infection prevention and control (IC) program plan:

- Developing an annual infection control risk assessment and assigning priorities for HAI elimination in conjunction with ASC leadership;
- Performing no less than annual evaluation of the IC program plan to assess goal of elimination of HAIs and program modifications to achieve goal.

RESULTS OF A COMPREHENSIVE INFECTION CONTROL PROGRAM FOR REDUCING SURGICAL-SITE INFECTIONS IN CORONARY ARTERY BYPASS SURGERY

Samuel J. McConkey, MB; Paul B. L'Ecuyer, MD; Denise M. Murphy, RN, MPH; Terry L. Leet, PhD; Thoralf M. Sundt, MD; Victoria J. Fraser, MD

ABSTRACT

OBJECTIVE: To evaluate the efficacy of a comprehensive infection control program on the reduction of surgical-site infections (SSIs) following coronary artery bypass graft (CABG) surgery.

DESIGN: Prospective cohort study.

SETTING: 1,000-bed tertiary-care hospital.

PATIENTS: Persons undergoing CABG with or without concomitant valve surgery from April 1991 through December 1994.

INTERVENTIONS: Prospective surveillance, quarterly reporting of SSI rates, chlorhexidene showers, discontinuation of shaving, administration of antibiotic prophylaxis in the holding area, elimination of ice baths for cooling of cardioplegia solution, limitation of operating room traffic, minimization of flash sterilization, and elimination of postoperative tap-water wound bathing for 96 hours. Logistic regression models were fitted to assess infection rates over time, adjusting for severity of illness, surgeon, patient characteristics, and type of surgery.

RESULTS: 2,231 procedures were performed. A reduction in infection rates was noted at all sites. The rate of deep chest infections decreased from 2.6% in 1991 to 1.6% in 1994. Over the same period, the rate of leg infections decreased from 6.8% to 2.7%, and of all SSI from 12.4% to 8.9%. The adjusted odds ratio (OR) for all SSIs for the end of 1994 compared to December 31, 1991, was 0.37 (95% confidence interval [CI_{95}], 0.22-0.63). For deep chest and mediastinal infections, the adjusted OR comparing the same period was 0.69 (CI_{95}, 0.28-1.71).

CONCLUSIONS: We observed significant reductions in SSI rates of deep and superficial sites in CABG surgery following implementation of a comprehensive infection control program. These differences remained significant when adjusted for potential confounding covariables (*Infect Control Hosp Epidemiol* 1999;20:533-538).

Cardiothoracic surgical procedures are increasing in the United States. Over 600,000 open heart procedures are performed annually, accounting for approximately 1% of national healthcare expenditures.[1,2] The devastating consequences of deep chest infections following coronary artery bypass graft (CABG) surgery are well recognized,[3-19] but leg and superficial chest infections also have substantial impacts on patient morbidity,[2,20-22] length of stay, and total cost. For these reasons, prevention and control of cardiothoracic surgical-site infections (SSIs) have become vital components of hospital quality assurance and cost containment.[1,13,20,23]

Recent studies in mixed surgical patient series have demonstrated that specific infection control interventions may reduce the SSI rate by 20% to 50%.[24-27] However, the risk of SSI is influenced by the wound classification, patient morbidity (eg, American Society of Anesthesiologists score), and technical factors (eg, duration of the procedure).[28] Infection control prevention strategies need to be tailored to individual surgical subspecialties.[29] Further evaluation of SSI prevention programs is needed in large cohorts of patients from different surgical subspecialties.

There is little information on the efficacy of specific infection control interventions in the prevention of SSIs in cardiothoracic surgery,[2,30] and only recently has critical attention been focused on site-specific infection rates.[2,20-22,31] We investigated the efficacy of a comprehensive infection control program in the prevention of SSIs in cardiothoracic surgery at Barnes Hospital.

METHODS

General

Barnes Hospital is a 1,000-bed tertiary-care facility affiliated with Washington University School of Medicine and BJC Health System (St Louis, MO). The Division of Cardiothoracic Surgery performs approximately 600 CABG procedures (alone or in combination) per year; 70% of patients are referred from outside the St Louis area. The cardiothoracic surgical staff includes seven attending physicians, four cardiothoracic surgical residents or fel-

From the Division of Infectious Diseases (Drs. McConkey, L'Ecuyer, and Fraser); the Division of Cardiothoracic Surgery (Dr. Sundt), Washington University School of Medicine; the Department of Infection Control (Ms. Murphy), Barnes Hospital; the Center for Healthcare Quality and Effectiveness (Dr. Leet), BJC Health System, St Louis, Missouri.

Address reprint requests to Victoria J. Fraser, MD, Division of Infectious Diseases, Washington University School of Medicine, 660 South Euclid Ave, Box 8051, St Louis, MO 63110.

98-OA-183. McConkey SJ, L'Ecuyer PB, Murphy DM, Leet TL, Sundt TM, Fraser VJ. Results of a comprehensive infection control program for reducing surgical-site infections in coronary artery bypass surgery. Infect Control Hosp Epidemiol *1999;20:533-538.*

TABLE 1
INFECTION CONTROL INTERVENTIONS IN CORONARY ARTERY BYPASS SURGERY AT BARNES HOSPITAL, 1991

1. Prospective surveillance of superficial and deep chest and leg surgical-site infections
2. Quarterly reporting of surgeon- and assistant-specific surgical-site infection rates
3. Chlorhexidene shower by the patient on the night before and on the morning of surgery
4. Hair removal, only if necessary, by clipping or electric razor on the morning of surgery
5. Administration of antibiotic prophylaxis (cefazolin [1 g] or vancomycin [1 g]) in the preoperative holding area 30-120 minutes prior to incision, with repeat intraoperative doses as needed
6. Elimination of open ice baths for cooling of cardioplegia solution
7. Limitation of operating room traffic by locking doors between the operating room and the intensive-care unit during cases
8. Minimization of intraoperative flash sterilization, with strict documentation of its use
9. Elimination of tap-water wound bathing within the first 96 hours postoperatively
10. Sterile wound dressings for 96 hours, and wound bathing (if needed) using sterile water and povidone-iodine only

lows, four surgical assistants, two nurse specialists, and two rotating general surgical junior residents. Four operating rooms are used routinely. Attending staff and cardiothoracic surgery house staff are directly involved in the primary procedure, and surgical assistants perform the saphenous vein harvesting.

Prior to 1991, there was no uniform program for prevention of SSIs in cardiothoracic surgery at Barnes Hospital; individual surgeons had various practices. The timing and composition of antibiotic prophylaxis was not standardized. Routine skin preparation included a 3.5-minute skin scrub with povidone-iodine followed by three applications of povidone-iodine solution to the skin site. A transparent drape impregnated with povidone-iodine was applied to the chest prior to incision. There was no data collection or reporting of SSIs.

Interventions

In 1991, Barnes Hospital funded a part-time hospital epidemiologist, and, because of the high-volume and high-cost nature of cardiothoracic surgery, initial efforts were focused on development of a comprehensive program for prevention of cardiothoracic SSI. The Department of Infection Control in Barnes Hospital has five full-time infection control practitioners under the direction of the hospital epidemiologist from the Division of Infectious Diseases. Prospective surveillance for SSIs included all cardiothoracic procedures involving CABG surgery, including CABG alone, CABG with valve replacement, and CABG with other procedure(s), and was consistent throughout the study period. Procedures not involving CABG (eg, isolated valve replacement alone) are followed separately and are excluded from this analysis. Formal postdischarge surveillance was not performed, but the same hospital microbiology laboratory serves the offices of all cardiothoracic surgeons, so some late infections were detected by the two expert computer systems. These two expert computer systems (GermWatcher and GermAlert, Washington University School of Medicine, St Louis, MO) screen microbiology reports for nosocomial infections from both inpatients and outpatients, and their sensitivity and specificity have been validated previously by infection control staff.[32] Surgical-site infections were confirmed by infection control staff through review of medical records and by communicating with the nurse specialists of the Division of Cardiothoracic Surgery, who directly observed the wounds. The definitions of the National Nosocomial Infection Surveillance (NNIS) System were used throughout.[33] Deep incisional and organ space infections were combined into deep chest infections, due to the difficulty distinguishing the two. Wound cultures were obtained at the discretion of the surgeon or nurse specialist. The surveillance process was uniform for the duration of the study.

The Infection Control Department identified cases of SSI from the adverse outcome reports on the cardiothoracic unit, the two expert computer systems, and nursing and medical staff reports in the cardiothoracic surgery unit and clinic. In 1991, standardized protocols for infection control management of elective cardiothoracic surgery patients were developed and implemented by the Infection Control Department and the Division of Cardiothoracic Surgery. In July 1991, the Infection Control Department began reporting confidential surgeon- and surgical-assistant–specific SSI rates for superficial and deep sites of the chest and leg to surgeons, surgical assistants, the chief of cardiothoracic surgery, and the Infection Control Committee quarterly. Table 1 details other interventions. Infection control specialists performed periodic observations to monitor and reinforce compliance with the protocols. By early 1992, all protocols were in place. Once the intervention program was established, approximately 20% of an infection control specialist's time was required to maintain it.

Statistical Analysis

The change in site-specific infection rates from 1991 to 1994 was assessed using the chi-square test for trend.[34] The relative risks and the chi-square test were used for univariate analysis of categorical data. All P values were two-sided. To adjust for the effects of other factors known to affect SSI rates[31] (eg, patient characteristics, comorbidities, surgery type, etc), which may have changed over the study period, unconditional logistic regression models were created using a continuous time variable as the main effect and using several potential confounders and interaction terms to control for possible sources of bias.[35] Four separate logistic regression models were built using four different

TABLE 2
DEMOGRAPHICS, MEDICAL CHARACTERISTICS, AND THEIR UNADJUSTED ASSOCIATIONS WITH SURGICAL-SITE INFECTIONS AND DEATH FOR 2,230 PATIENTS WHO HAD CORONARY ARTERY BYPASS GRAFT SURGERY

			SSI		Deep Chest Infection		Death	
Patient Characteristic	**Frequency**		**RR**	***P***	**RR**	***P***	**RR**	***P***
Age >65	1,258	56.4	0.98	.883	0.81	.600	1.59	.024
Male	1,482	66.4	0.71	.002	1.00	1.000	0.51	.001
Diabetes	693	31.1	2.20	<.001	3.90	<.001	1.26	.216
COPD	259	11.6	1.29	.110	1.80	.140	2.38	<.001
Ever smoked	1,514	67.9	1.14	.250	3.00	.012	0.86	.440
Heart failure	285	12.8	1.62	.001	1.65	.220	4.52	<.001
Renal failure	308	13.8	1.36	.031	1.44	.320	3.35	<.001
Concurrent valve surgery	192	8.6	1.04	.830	0.50	.580	2.95	<.001
Previous CABG	254	11.4	0.67	.045	0.84	1.000	1.69	.037
BIMA	30	1.3	2.34	.010	7.80	.002	1.49	.397
Emergent	324	14.5	0.66	.018	2.12	.030	2.75	<.001
Urgent	276	12.4	0.99	1.000	1.71	.185	1.32	.279
Death	101	4.5						

Abbreviations: BIMA, bilateral internal mammary artery grafts; CABG, coronary artery bypass graft; COPD, chronic obstruction pulmonary disorder; RR, risk ratio; SSI, surgical-site infection.

outcomes: presence or absence of any postoperative SSIs, deep chest infection, leg infection, and mortality during the initial hospitalization or within 30 days of surgery. Each of these models focused on the change over time as the main effect and used demographic factors, comorbidity, operation type, and the surgeon as covariables. Severity of illness was quantified using some of the variables that contribute to the clinical severity score described by Higgins et al,[36] including heart failure, chronic obstructive pulmonary disease, diabetes, renal failure, and smoking status. When these variables were used in the models instead of the clinical severity score itself, better-fitting models were obtained. Surgeon, age, gender, race, urgency of surgery, type of surgery (valve surgery, internal mammary artery graft, saphenous vein graft), preoperative length of stay, and previous sternotomy also were considered. The Box-Tidwell transformation, which adds a logarithmic term, of the form x* log (x), to the model, was used to assess linearity for continuous variables; polynomial terms were added if they produced a better model.[37] Potential interactions due to all second-degree product terms were considered using a stepwise backwards elimination procedure based on the likelihood-ratio test. Interaction terms with $P>.005$ (reflecting correction for the effect of multiple testing) were excluded. Other variables were removed only if doing so did not substantially change the estimated coefficients of time variables but improved the precision of the estimate.[35] Residual diagnostics did not show any case with an unexpectedly large contribution to the model.[37] In summary, the ORs for the changes in the outcome over time have been adjusted in the model to take into account all the risk factors for which we had information. Nested analysis was done for each surgeon looking at all SSIs, deep chest infections, and leg infections, while adjusting for the variables mentioned above. SPSS (version 7.5; SPSS, Chicago, IL) software was used for the statistical analysis and logistic modeling.

RESULTS

Between April 1, 1991, and December 31, 1994, 2,231 CABG procedures (alone or combination) were performed. Detailed information was available on 2,230 cases. Their demographic and medical characteristics and the unadjusted associations with SSIs and death are shown in Table 2. Wound infection rates demonstrated an initial upward trend in the first year and a subsequent decline (Table 3; chi-square test for trend on the rate of all SSIs, $P<.001$). The mean clinical severity score[36] and the median postoperative length of stay (Table 3) show that the severity of the patients' underlying conditions and the possible predisposing factors for SSI did not change over the study period. The median postoperative length of stay in hospital did decrease over the 4-year period, by approximately 22%.

The results of the multiple logistic regression analyses are in Table 4, where the modeled adjusted rates at the end of each year in the study are compared to the baseline rate for December 31, 1991 (thus the odds ratios [ORs] for this time period are 1.0). All outcomes show a downward trend over the 4 years. For all SSIs and leg infections, the decrease is statistically significant (OR for all SSIs, 0.37; 95% confidence interval [CI_{95}], 0.22-0.63; OR for leg infection, 0.11; CI_{95}, 0.05-0.27). There was no evidence that the changes in SSIs over time differed by surgeon ($P=.59$).

DISCUSSION

We noted significant reductions in SSIs following the implementation of a comprehensive infection control surveillance and control program for SSIs in cardiothoracic surgery. Overall, there was approximately a 60% reduction in SSIs at all sites, with much of the reduction realized in the final 2 years of the study, following consistently high infection rates in 1991 and 1992. The implementation of the intervention program took place over 1 year, and the quarterly feedback of SSI rates must be expected to have a delay before show-

TABLE 3
TREND OF SURGICAL-SITE INFECTION RATES, MEAN CLINICAL SEVERITY SCORE,* AND THE MEDIAN POSTOPERATIVE LENGTH OF STAY FOR CORONARY ARTERY BYPASS GRAFT SURGERY PATIENTS, APRIL 1991 TO DECEMBER 1994

	1991	1992	1993	1994	P
All surgical-site infections	12.4	17.5	16.1	8.2	<.001
Deep chest infections	2.58	1.98	1.56	1.61	.63
Leg infections	6.8	11.1	7.5	2.7	<.001
Severity score	3.72	3.65	3.76	3.67	
Median postoperative length of stay	9 d	9 d	8 d	7 d	

* Calculated as in reference 36.

ing an effect. While it is difficult to establish a direct cause-and-effect relationship between the program and the reductions in infection rates in this uncontrolled cohort study, such a relationship is supported by the temporal sequence of events and the adjustments for potential sources of bias.

One obvious confounding effect is the severity of the patients' illnesses and comorbidity. A clinical score for severity of illness has been developed by Higgins et al[36] and validated for predicting morbidity or death in cardiothoracic surgery patients. In our study, the components of this score for each individual case were used as covariables in the logistic regression models to adjust for severity of illness. Their inclusion in the models did not alter the downward trend in the rates of SSI, indicating that the decline in the rate of SSIs was not caused by a change in the severity of patient's illnesses. It refutes the hypothesis that in later years there were fewer patients with important comorbidity or severe diseases (who might have a greater chance of getting an infection). Basic demographic factors such as age, gender, and smoking status were included as covariables to exclude the possibility that they might be confounding the relation between infection rates and time. We also corrected for surgical factors (eg, surgeon and operation type).

Correcting for the declining length of stay was more difficult. As this study did not include scheduled outpatient follow-up visits to detect late SSI, it could be argued that the shorter length of stay in later years could lead to a detection bias. However, a wound infection often results in a prolonged postoperative stay, so the shorter stays in later years may have been partly the result of the lower rate of SSI. Some late SSIs may have been missed; however, all of the surgeons saw outpatients in the hospital complex and used the hospital microbiology laboratory, and the expert surveillance system did identify outpatient infections. Regardless, it does not seem plausible that a change in postoperative length of stay from a median of 9 days in 1991 to 7 days in 1994 could explain overall SSI rates dropping by 50%.

It is possible that the effect of observing and recording infection rates in the hospital led to improvement in work performance (Hawthorne effect). This observing, recording, and feedback were integral parts of the intervention program and cannot be separated from it. The study was not blinded, and those assessing the outcomes were involved in the design and implementation of the interventions. Finally, the observed reductions could reflect unknown factors that caused a progressive improvement in the outcomes of cardiothoracic surgery patients independent of the infection control interventions.

This study involved patients at a single tertiary-care institution and a small group of surgeons with relatively homogenous practice patterns; infection rates and the effect of an infection control program may differ in other institutions with different patient populations.

The most definitive evidence for the efficacy of a medical intervention comes from a well-powered randomized controlled experiment, but the nature of these interventions makes it difficult to perform such an experiment in a single institution. A multicenter trial with randomization at the hospital level would be possible but difficult. Failing that, a cohort study with adjustment for known or suspected factors, as described above, may be the best possible design.

THE CONTROL PROGRAM

It is difficult to identify which specific interventions were effective in reducing SSI. Tests for heterogeneity of effect between surgeons did not show a statistically significant difference. Other investigators have focused on single interventions. Implementation of prospective surveillance

TABLE 4
ADJUSTED ODDS RATIOS FOR SURGICAL-SITE INFECTION AND MORTALITY OVER TIME, FROM THE MULTIPLE LOGISTIC REGRESSION MODELS

	December 31, 1991	December 31, 1992 (CI_{95})	December 31, 1993 (CI_{95})	December 31, 1994 (CI_{95})
Adjusted OR of any SSI	1.0	1.09 (0.89-1.33)	0.78 (0.60-1.02)	0.37 (0.22-0.63)
Adjusted OR of deep chest infection	1.0	0.88 (0.65-1.20)	0.78 (0.43-1.43)	0.69 (0.28-1.71)
Adjusted OR of leg infection	1.0	1.05 (0.81-1.37)	0.51 (0.35-0.75)	0.11 (0.05-0.27)
Adjusted OR of mortality	1.0	0.88 (0.72-1.08)	0.77 (0.52-1.16)	0.68 (0.37-1.25)

Abbreviations: CI_{95}, 95% confidence interval; OR, odds ratio; SSI, surgical-site infection.
* Adjusted odds ratios with 95% confidence intervals indicating the risk of infection at the end of each year with December 31, 1991, as baseline for comparison. These are derived from the multiple logistic regression models. In some models a quadratic time variable produced the best fit, but in others time modeled best as a linear variable.

and the confidential reporting of surgeon- and assistant-specific infection rates have been associated with 20% to 50% reductions in SSI rates and have been recognized as critical components of prevention programs in four large, multi-year mixed surgical patient series.[24-27] Elimination of hair shaving through use of hair clippers for cardiothoracic surgery was associated with 83% and 75% reductions in deep chest and deep leg SSIs at one institution.[2] While use of antibiotic prophylaxis in cardiothoracic surgery procedures that do not utilize foreign materials, grafts, or prosthetic devices remains controversial, without a clear consensus of efficacy, timely administration of antibiotic prophylaxis (ie, immediately prior to incision) has been recommended by many for all cardiothoracic surgeries involving a median sternotomy.[38-42]

Other components of the comprehensive intervention (eg, chlorhexidene showers, reduction in flash sterilization, limitation in operating room traffic, elimination of open ice baths for cardioplegia solution, and elimination of tap-water wound bathing for the first 96 hours postoperatively) probably contributed through independent mechanisms, as well as through positive influences on operating room discipline, but these components have not been evaluated individually. The Study of the Efficacy of Nosocomial Infection Control demonstrated that a combination of adequate surveillance, having at least one infection control nurse per 250 hospital beds, reporting individual wound infection rates to surgeons, and the use of a trained hospital epidemiologist was associated with a 31% lower rate of SSIs, and the authors suggested that a comprehensive approach was needed for prevention of SSI.[26] Further, O'Conner et al demonstrated a 24% reduction in hospital mortality following CABG with regional implementation of a multifactorial quality-improvement intervention and emphasized that one can interpret the efficacy of only the whole intervention, not individual components, in the complex setting of modern cardiovascular care.[43]

We demonstrated significant reductions in SSI rates among cardiothoracic surgery patients following implementation of a comprehensive infection control program. We think adoption of similar programs at other institutions would be a cost-effective strategy for control and prevention of cardiothoracic SSI. Additional studies are needed to evaluate the efficacy of infection control programs in other surgical subspecialties and to evaluate program efficacy in different types of institutions. These studies will require long-term surveillance of infection rates and follow-up of compliance.

REFERENCES

1. Taylor GJ, Mikell FL, Moses HW, Dove JT, Katholi RE, Malik SA, et al. Determinants of hospital charges for coronary artery bypass surgery: the economic consequences of postoperative complications. *Am J Cardiol* 1990;65:309-313.
2. Sellick JA Jr, Stelmach M, Mylotte JM. Surveillance of surgical wound infections following open heart surgery. *Infect Control Hosp Epidemiol* 1991;12:591-596.
3. Culliford A, Cunningham J, Zeff R, Isom O, Teiko P, Speucer F. Sternal and costochondral infections following open-heart surgery: a review of 2,594 cases. *J Thorac Cardiovasc Surg* 1976;72:714-726.
4. Bor DH, Rose RM, Modlin JF, Weintraub R, Friedland GH. Mediastinitis after cardiovascular surgery. *Rev Infect Dis* 1983;5:885-897.
5. Breyer RH, Mills SA, Hudspeth AS, Johnston FR, Cordell AR. A prospective study of sternal wound complications. *Ann Thorac Surg* 1984;37:412-416.
6. Sarr M, Gott V, Townsend T. Mediastinal infection after cardiac surgery. *Ann Thorac Surg* 1984;38:415-423.
7. Grossi EA, Culliford AT, Krieger KH, Kloth D, Press R, Baumann FG, et al. A survey of 77 major infectious complications of median sternotomy: a review of 7,949 consecutive operative procedures. *Ann Thorac Surg* 1985;40:214-223.
8. Cheung EH, Craver JM, Jones EL, Murphy DA, Hatcher CR Jr, Guyton RA. Mediastinitis after cardiac valve operations: impact upon survival. *J Thorac Cardiovasc Surg* 1985;90:517-522.
9. Newman LS, Szczukowski LC, Bain RP, Perlino CA. Suppurative mediastinitis after open heart surgery: a case control study of risk factors. *Chest* 1988;94:546-553.
10. Cosgrove DM, Lytle BW, Loop FD, Taylor PC, Stewart RW, Cutl CC, et al. Does bilateral internal mammary artery grafting increase surgical risk? *J Thorac Cardiovasc Surg* 1988;95:850-856.
11. Kouchoukos NT, Wareing TH, Murphy SF, Pelate C, Marshal WG Jr. Risks of bilateral internal mammary artery bypass grafting. *Ann Thorac Surg* 1990;49:210-219.
12. Demmy TL, Park SB, Liebler GA, Burkholder JA, Maher TD, Benchart DH, et al. Recent experience with major sternal wound complications. *Ann Thorac Surg* 1990;49:458-462.
13. Loop F, Lytle B, Cosgrove D, Mahtood S, McHenry MC, Gootmastic M, et al. Sternal wound complications after isolated coronary artery bypass grafting: early and late mortality, morbidity, and cost of care. *Ann Thorac Surg* 1990;49:179-187.
14. Grossi EA, Esposito R, Harris LJ, Crooke GA, Galloway AL, Colvin SB, et al. Sternal wound infections and use of internal mammary artery grafts. *J Thorac Cardiovasc Surg* 1991;102:342-347.
15. Nishida H, Grooters RK, Soltanzadeh H, Thieman KC, Schneider RF, Kim WP. Discriminate use of electrocautery on the median sternotomy incision: a 0.16% wound infection rate. *J Thorac Cardiovasc Surg* 1991;101:488-494.
16. Gaynes R, Marosok R, Mowry-Hanley J, Laughlin C, Foleg K, Friedman C, et al. Mediastinitis following coronary artery bypass surgery: a 3-year review. *J Infect Dis* 1991;163:117-121.
17. Ehrenkranz NJ, Pfaff SJ. Mediastinitis complicating cardiac operations: evidence of postoperative causation. *Rev Infect Dis* 1991;13:803-814.
18. Ko W, Lazenby WD, Zelano JA, Isom W, Krieger KH. Effects of shaving methods and intraoperative irrigation on suppurative mediastinitis after bypass operations. *Ann Thorac Surg* 1992;53:301-305.
19. He GW, Ryan WH, Acuff TE, Bowman RT, Douthit MB, Yang CQ, et al. Risk factors for operative mortality and sternal wound infection in bilateral internal mammary artery grafting. *J Thorac Cardiovasc Surg* 1994;107:196-202.
20. Nelson R, Dries D. Economic implications of infection in cardiac surgery. *Ann Thorac Surg* 1986;42:240-246.
21. L'Ecuyer PB, Murphy D, Little JR, Fraser VJ. The epidemiology of chest and leg wound infections following cardiothoracic surgery. *Clin Infect Dis* 1996;22:424-429.
22. Bjerke NB, Bifano S. Epidemiology of surgical site infections following coronary artery bypass graft surgery. In: Program of the 6th Annual Meeting of the Socicty for Healthcare Epidemiology of America; 1996; Washington, DC. Abstract 24.
23. Boyce JM, Potter-Bynoe G, Dziobek L. Hospital reimbursement patterns among patients with surgical wound infections following open heart surgery. *Infect Control Hosp Epidemiol* 1990;11:89-93.
24. Cruse PJE, Foord R. The epidemiology of wound infection: a 10-year prospective study of 62,939 wounds. *Surg Clin North Am* 1980;60:27-40.
25. Condon RE, Schulte WJ, Malangoni MA, Anderson-Teschendorf MJ. Effectiveness of a surgical wound surveillance program. *Arch Surg* 1983;118:303-307.
26. Haley RW, Culver DH, White JW, Morgan WM, Emori TG, Mann VP, et al. The efficacy of infection surveillance and control programs in preventing nosocomial infections in US hospitals. *Am J Epidemiol* 1985;121:182-205.
27. Olson MM, Lee JT. Continuous, 10-year wound infection surveillance. *Arch Surg* 1990;125:794-803.
28. Culver DH, Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG, et al. Surgical wound infection rates by wound class, operative procedure, and patient risk index. *Am J Med* 1991;91(suppl 3B):152S-157S.
29. Haley RW. Nosocomial infections in surgical patients: developing valid measures of intrinsic patient risk. *Am J Med* 1991;91(suppl 3B):145S-151S.
30. Ferrazzi P, Allen R, Crupi G, Reyes I, Parenzan L, Maisonnet M. Reduction of infection after cardiac surgery: a clinical trial. *Ann Thorac Surg* 1986;42:321-325.

31. Uuorisalo S, Haukipuro K, Pokela R, Sgrjala H. Risk features for surgical-site infections in coronary artery bypass surgery. *Infect Control Hosp Epidemiol* 1998;19:240-247.
32. Kahn M, Steib S, Fraser V, Dunagan W. Expert system for culture-based infection control surveillance. Proceedings: The Annual Symposium on Computer Applications in Medical Care. 1993;171-75.
33. Garner JS, Jarvis WR, Emori TG, Horan TC, Hughes JM. CDC definitions for nosocomial infections, 1988. *Am J Infect Control* 1988;16:128-140.
34. Armitage P, Berry G. *Statistical Methods in Medical Research*. 3rd ed. Oxford, England: Blackwell Science; 1994.
35. Kleinbaum DG, Kupper LL, Morgenstern H. *Epidemiologic Research*. Belmont, CA: Lifetime Learning Publishers; 1982.
36. Higgins TL, Estafanous FG, Loop FD, Beck GJ, Blum JM, Paranandi L. Stratification of morbidity and mortality outcome by preoperative risk factors in coronary artery bypass patients. *JAMA* 1992;267:2344-2348.
37. Hosmer DW, Lemeshow S. *Applied Logistic Regression*. New York, NY: Wiley; 1989.
38. American Society of Health-System Pharmacists Commission on Therapeutics. ASHP therapeutic guidelines on antimicrobial prophylaxis in surgery. *Clin Pharm* 1992;11:483-513.
39. Page CP, Bohnen JM, Fletcher R, McManus AT, Solomkin JS, Wittmann DH. Antimicrobial prophylaxis for surgical wounds: guidelines for clinical care. *Arch Surg* 1993;128:79-88.
40. Dellinger EP, Gross PA, Barrett TL, Krause PJ, Mortone WJ, McGowan JE Jr, et al. Quality standard for antimicrobial prophylaxis in surgical procedures. *Clin Infect Dis* 1994;18:422-427.
41. Antimicrobial prophylaxis in surgery. *The Medical Letter* 1995;37:79-82.
42. Nichols RL. Update: antibiotic prophylaxis in surgery. *Infect Dis Clin Pract* 1996;5(suppl 2):S77-S84.
43. O'Conner GT, Plume SK, Olmstead EM, Morton JR, Maloney CT, Nugent WC, et al. A regional intervention to improve the hospital mortality associated with coronary artery bypass graft surgery. *JAMA* 1996;275:841-846.

AMERICAN JOURNAL OF EPIDEMIOLOGY
Vol. 121, No. 2
Printed in U.S.A.

THE EFFICACY OF INFECTION SURVEILLANCE AND CONTROL PROGRAMS IN PREVENTING NOSOCOMIAL INFECTIONS IN US HOSPITALS

ROBERT W. HALEY,[1,2] DAVID H. CULVER,[1] JOHN W. WHITE,[1] W. MEADE MORGAN,[1] T. GRACE EMORI,[1] VAN P. MUNN[1] AND THOMAS M. HOOTON[1,3]

Haley, R. W. (SENIC Project, CDC, Atlanta, GA 30333), D. H. Culver, J. W. White, W. M. Morgan, T. G. Emori, V. P. Munn and T. M. Hooton. The efficacy of infection surveillance and control programs in preventing nosocomial infections in US hospitals. *Am J Epidemiol* 1985;121:182–205.

In a representative sample of US general hospitals, the authors found that the establishment of intensive infection surveillance and control programs was strongly associated with reductions in rates of nosocomial urinary tract infection, surgical wound infection, pneumonia, and bacteremia between 1970 and 1975–1976, after controlling for other characteristics of the hospitals and their patients. Essential components of effective programs included conducting organized surveillance and control activities and having a trained, effectual infection control physician, an infection control nurse per 250 beds, and a system for reporting infection rates to practicing surgeons. Programs with these components reduced their hospitals' infection rates by 32%. Since relatively few hospitals had very effective programs, however, only 6% of the nation's approximately 2 million nosocomial infections were being prevented in the mid-1970s, leaving another 26% to be prevented by universal adoption of these programs. Among hospitals without effective programs, the overall infection rate increased by 18% from 1970 to 1976.

cost control; costs and cost analysis; cross infection; evaluation studies; health services research; health surveys; hospitals

In the acute-care hospitals in the United States in 1976, an estimated 2.1 million nosocomial (hospital-acquired) infections complicated the 37.7 million admissions,

Received for publication November 4, 1983, and in final form July 9, 1984.

Abbreviation: SENIC, Study on the Efficacy of Nosocomial Infection Control.

[1] Hospital Infections Program, Center for Infectious Diseases, Centers for Disease Control, Public Health Service, US Department of Health and Human Services, Atlanta, GA.

[2] Current address: Division of Epidemiology and Preventive Medicine, Department of Internal Medicine, Southwestern Medical School, University of Texas Health Science Center at Dallas, 5323 Harry Hines Boulevard, Dallas, TX.

[3] Current address: Department of Internal Medicine, University of Washington School of Medicine, Harborview Medical Center, 6010 43rd Street, NE, Seattle, WA.

Address for reprints: SENIC Project, % Public Inquiries Office, Centers for Disease Control, Atlanta, GA 30333.

This work was supported in part by funds from interagency agreements with the National Institute of Allergy and Infectious Diseases, National Institutes of Health, and the Health Care Financing Administration and from 1 per cent evaluation funds through the Office of Health Planning and Evaluation, Office of the Assistant Secretary for Health.

Methods and interim results were presented at the Second International Conference on Nosocomial Infections, Atlanta, GA, August 6, 1980; the fifteenth annual meeting of the Society for Epidemiologic Research, Cincinnati, OH, June 10, 1982; the twenty-seventh annual meeting of the Interscience Conference on Antimicrobial Agents and Chemotherapy, Miami, FL, October 1, 1982; and the eighth annual meeting of the Association for Practitioners in Infection Control, San Diego, CA, May 5, 1983.

The authors wish to acknowledge the contributions of Dr. John V. Bennett, for invaluable advice and direction throughout this project; Dr. David J. Sencer,

for a nationwide infection rate of 5.7 nosocomial infections per 100 admissions (1). Based on conservative estimates of the extra days and hospital charges attributable to these infectious complications (2–4), nosocomial infections added over 7.5 million extra hospital days and over one billion dollars to the charges for hospital care in 1976. There has been little agreement over what proportion of these infections can be prevented (5).

Largely as a result of the staphylococcal pandemic that swept the nation in the late 1950s and early 1960s (6), hospitals voluntarily undertook efforts to control their infection problems by forming infection control committees. In the 1960s, the Centers for Disease Control (CDC), Atlanta, Georgia, began recommending that hospitals conduct surveillance over the occurrence of nosocomial infections to obtain epidemiologic evidence on which to base rational control measures (7, 8). At first, the recommendations suggested that the surveillance and control activities be conducted by a physician (termed a "hospital epidemiologist") who had received specific training in hospital epidemiology. By 1970, however, several studies had indicated that these duties could be carried out best by a specially trained infection control nurse (9–12). On the basis of pilot studies in eight community hospitals in which different staffing levels were evaluated (13), CDC recommended one full-time nurse for every 250 occupied hospital beds.

Dr. William H. Foege, William C. Watson, Jr., Dr. Philip S. Brachman, Joseph A. Giordano, and Dr. Walter R. Dowdle, for unfailing confidence and support; Dr. Dennis R. Schaberg and Dr. Seth N. Leibler, for assistance in developing and validating the study methods; Ferdinand D. Tedesco and Dr. Gary C. Schatz, for tenacious management of the field work; Dr. Richard H. Shachtman, Dr. Dana Quade, and their staff in the Department of Biostatistics, University of North Carolina School of Public Health, and Dr. Howard E. Freeman, Dr. Bertram H. Raven, and their staff at the Institute for Social Science Research, University of California at Los Angeles, for extensive contributions during the design and data collection phases of the project; and the myriad CDC personnel who participated in the collection, analysis, and reporting of the data.

After these approaches were popularized through an international conference on nosocomial infections in 1970 (12) and diverse publications (14–17), a nationwide movement toward the establishment of organized infection surveillance and control programs ensued, and by 1975, over half of the nation's hospitals had organized surveillance programs with infection control nurses (18). During the 1970s, CDC training courses for infection control personnel stressed conducting surveillance of infections, writing and applying policies for preventive patient-care practices (e.g., urinary catheter care), and reducing wasteful environmental culturing (19–21). A time-honored preventive technique that was reintroduced in the early 1970s was the practice of regularly reporting the rates of surgical wound infections to the surgeons on the hospital staff to encourage more careful operating technique (22).

In January 1974, CDC initiated the SENIC Project (Study on the Efficacy of Nosocomial Infection Control) with three major objectives: to estimate the magnitude of the nosocomial infection problem in US hospitals; to describe the extent to which hospitals had adopted the new infection surveillance and control program approach; and to determine whether and, if so, to what extent, this approach was effective in reducing nosocomial infection risks (23). Besides scientific curiosity over the efficacy of this approach, interest in the study was due in part to a realization that the viability of the infection surveillance and control program concept would eventually depend on its cost-benefit ratio. Since the costs of an infection control nurse and surveillance activities cannot be charged directly to patients or third-party carriers as other patient-care technologies are, it seemed inevitable that, as fiscal pressures on hospitals increased, these preventive programs would receive a progressively lower priority in the operating budgets of hospitals. A preliminary estimate suggested that an infection surveillance and control program

would have to reduce infections by only 6 per cent for the costs of the program to be offset by the savings from reduced hospitalization (24, 25). Although several uncontrolled surveillance studies in individual hospitals suggested that the establishment of an infection surveillance and control program reduced the subsequent infection risks by 30 to 50 per cent (9, 26–30), no studies employing simultaneous control observations were available to determine with reasonable assurance whether even the 6 per cent level of prevention could be achieved.

CDC therefore undertook the SENIC Project to determine whether the infection surveillance and control programs established in a random sample of US hospitals had a significant influence on the subsequent change in the hospitals' nosocomial infection rates over a five-year period. Moreover, reflecting contemporary topics of controversy (31), the objectives also included determining whether the surveillance or the control function was more important in reducing infection risks and whether certain previously recommended program components, such as the infection control nurse's staffing ratio, were important determinants of the programs' efficacy. Given that the composition of an effective infection surveillance and control program might be different for different types of infections, the project was designed to study the efficacy question separately for infections involving four different sites. This report conveys the final results and conclusions of the SENIC Project.

METHODS

Collection of data

The data analyzed in this report were collected in the three phases of the SENIC Project: phase I, the Preliminary Screening Questionnaire Survey; phase II, the Hospital Interview Survey; and phase III, the Medical Records Survey. The methods used to select the hospitals, the hospital workers, and the patients for the study and to collect the data have been described in detail (23) and will only be summarized here.

In phase I, we mailed a six-page questionnaire to all 6,586 US hospitals and obtained complete responses from 86 per cent of our target population referred to as the SENIC Universe of hospitals: all general medical and surgical hospitals that are short-term, not federal- or state-owned, have 50 beds or more, and are located in the contiguous 48 United States. The questionnaire was designed to obtain the information needed to calculate two prespecified indexes: a *surveillance index* measuring the extent to which each hospital conducted active surveillance over the occurrence of nosocomial infections and disseminated the resulting information, and a *control index* measuring the intensity of efforts to intervene in the care of patients to reduce infection risks.

The questionnaire and the specifications for calculating the two indexes have been published (23, 31). In short, the surveillance index was calculated by first summing the weighted responses to questions covering the methods used for detecting nosocomial infections, analyzing the surveillance data, and disseminating the findings to the hospital staff members. The resulting sum was then adjusted by similar weighted sums of responses covering the qualifications and level of surveillance activities of the infection control nurse and the hospital epidemiologist (chairperson of the infection control committee or program supervisor). The control index was calculated similarly from questions covering sources of program direction, authorities of the infection control staff, teaching activities, and policies for preventive patient-care practices, adjusted by measures of the qualifications and level of control activities of the infection control nurse and the hospital epidemiologist. These two indexes represented the fundamental measures of the infection surveillance and control programs that were being evaluated in the

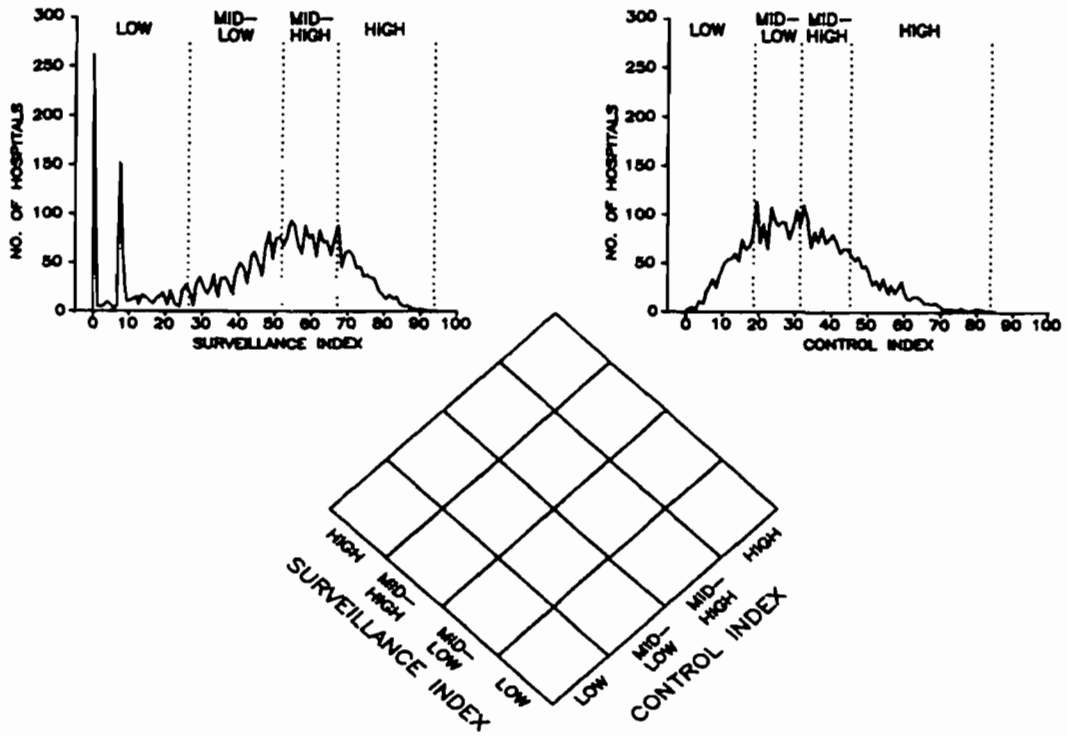


FIGURE 1. Distribution of the surveillance and control indexes among US hospitals and their use in the stratification and selection of the SENIC sample.

study. The distribution of each of the indexes is shown in figure 1.

For phases II and III, we selected a random sample of hospitals for more detailed study. To assure a broad representation of infection surveillance and control approaches, we divided each of the indexes into four levels by the 20th, 50th, and 80th percentiles of their distributions (figure 1). The 3,599 hospitals in the target population that responded to the phase I survey were then classified into the 16 strata determined jointly by the categorized surveillance and control indexes (figure 1). Each of these 16 strata was then substratified by categories of hospital size and medical school affiliation to assure a wide range of applicability of the results. From the resulting substrata, a random sample of 338 hospitals was selected (32).

In phase II, we sent a team of trained CDC interviewers to each of the sample hospitals to interview personally the 12 hospital personnel most likely to have important duties related to infection surveillance and control. In addition, a random sample of the staff nurses on each service and shift were interviewed by a written questionnaire administered in group sessions. The responses obtained in the interviews were used to corroborate and supplement the responses obtained in the earlier mailed questionnaire survey (phase I).

In phase III, to estimate the nosocomial infection rates in 1970 (before any of the sample hospitals had established their infection surveillance and control programs (18)) and in 1976 (the time of the phase I survey), we randomly selected in each hospital approximately 500 adult, general medical and surgical patients admitted in 1970 and 500 admitted in the 12-month period April 1975–March 1976. This yielded 169,518 and 169,526 patients representative of all adult, general medical and surgical patients admitted to US hospitals dur-

ing each of the two years, respectively. Each patient's entire medical record was reviewed by a highly trained medical records analyst, employed and managed by CDC, who abstracted patient demographic information, all discharge diagnoses, surgical procedures, and postoperative diagnoses (from the discharge and operative summaries) and selected clinical data for each hospital day, including daily peak temperature, signs and symptoms of infection from physicians' and nurses' notes, reports of all bacteriologic cultures, urinalyses, and chest roentgenograms, all antimicrobial agents received, and other risk factors for infection, including the presence or absence of a urinary catheter and continuous ventilatory support on a respirator. The collection of these day-specific clinical data covered 1,782,172 patient-days in 1970 and 1,603,307 in 1975–1976. To these basic clinical data, standardized diagnostic algorithms were uniformly applied to diagnose the nosocomial and community-acquired infections occurring at the four sites of infection that account for over 80 per cent of all nosocomial infections: urinary tract infection, surgical wound infection, pneumonia, and bacteremia (1, 23).

Analytic strategy

Parallel analyses were performed for each site of infection. For each sample hospital, the change in the infection rate from 1970 to 1975–1976 was measured by logit (P_2) − logit (P_1), where logit $(P_i) = \log (P_i/(100 - P_i))$, $i = 1,2$, and the hospital's estimated infection rate (percentage of patients infected) in 1970 is denoted by P_1 and the estimated infection rate in 1975–1976 is denoted by P_2.

To identify and control for influences other than the infection surveillance and control program on the change in a hospital's infection rate, we defined and investigated a number of hospital-level variables. First, to control for changes in the level of infection risk of the patients ("hospital case mix") over the five-year period and for differences between hospitals, we developed a patient-level multivariate risk index for each of the four sites of infection, using information on intrinsic risk factors (e.g., age, sex, underlying illnesses) and in-hospital exposures (e.g., service, duration of urinary catheterization, being on a respirator, type of surgical operation, duration of surgery, etc.). The methods used to derive and validate the indexes, their distributions, and practical extensions for them have been published (33, 34). Using these indexes, we calculated the change in a hospital's average patient risk. Using information obtained in the 1970 and 1976 surveys of hospitals conducted by the American Hospital Association (35), we analyzed two types of hospital characteristics: changes in those dynamic characteristics (e.g., nurse-to-patient ratio) that we thought likely to influence the change in a hospital's infection rate, and structural characteristics (viz., hospital size, medical school affiliation, type of ownership or control, and region) that were of interest as potential proxies for important changes in a hospital that we were unable to measure.

Finally, in the design phase of the Project, we identified three types of factors thought to have a possible influence on our ability to diagnose nosocomial infections, i.e., factors that might influence our *observed* infection rates without affecting the *true* rates. First, although pilot studies had indicated that our method of inferential medical record review could provide sufficient accuracy and reproducibility in the collection of the data, we anticipated substantial variation in the diagnostic practices of physicians in different hospitals. We therefore used the signs and symptoms of infection recorded in the physicians' and nurses' notes and the laboratory tests performed on each patient to define hospital-specific measures of diagnostic medical practices, discussed in a companion paper (36), and controlled for the influence of changes in these measures on the observed change in infection rates.

Second, since some nosocomial infections become manifest after the patient leaves the hospital, the patient's length of stay could have influenced our ability to diagnose his or her nosocomial infection. The crude average length of stay of the sample patients in a hospital could not be used to assess this influence, because the prolongation of stay due to a nosocomial infection always leads to a high degree of association between the observed infection rates and the average length of stay. Using the uninfected patients in our sample, we developed a model for predicting a patient's length of stay from his or her personal and hospital characteristics. With this model, we were able to replace the actual length of stay of each infected patient by the predicted length of stay had he or she not acquired an infection. Combining these predicted values for infected patients with the actual length of stay of uninfected patients, we were able to calculate the change in a hospital's average length of stay unaffected by the nosocomial infection experience of the hospital.

Third, previous studies had suggested the possibility that implementation of a surveillance program itself might lead to improved detection of nosocomial infections from medical records (37, 38). Preliminary analyses were performed to identify variables representing the establishment of surveillance or the addition of an infection control nurse or a trained hospital epidemiologist that had strong positive associations with the change in the infection rates.

Since an infection surveillance and control program was hypothesized to be a complex activity of diverse people intended to influence the patient-care practices of nurses, physicians, and other hospital workers, we used as the fundamental measure of the intensity of the infection surveillance and control program an indicator variable whose value was determined by the sampling stratum from which a hospital was chosen (figure 1). A hospital was considered to have established a high intensity infection surveillance and control program if it was located in one of the six strata nearest the high-surveillance/high-control stratum (see diagram in table 1 for example). Finding this indicator variable to be significantly associated with the change in infection rates after controlling for the effects of other influences would constitute evidence of the efficacy of infection surveillance and control activities. Additional indicator variables, defining subsets of the sampling matrix weighted toward surveillance or control, were used to determine whether the preventive effect was due more to a surveillance-oriented or a control-oriented program. Finally, the synergistic influences of individual features of an infection surveillance and control program (e.g., having an infection control nurse per 250 beds, a well trained hospital epidemiologist, or certain preventive patient-care policies) considered important prior to the study were investigated by analyzing their possible interactions with the infection surveillance and control program indicator variable.

Having identified the factors that were likely to have influenced the change in the hospital's infection rate from 1970 to 1975–1976, we undertook a series of analyses to understand the myriad interrelationships among these factors and the change in the infection rates. Early in the investigation, we discovered that the relationships between these factors and the change in the infection rates were somewhat different among patients at high risk of infection than among those at low risk of infection. Therefore, parallel analyses were performed on the change in hospital's infection rates in each of the following seven groups of patients defined by site-specific patient-risk levels: the change in surgical wound infection rates was analyzed separately in groups at high and low risk of surgical wound infection; the change in urinary tract infection rates was analyzed separately in groups at high and low risk of urinary tract infection; the change in pneu-

TABLE 1

*Multiple regression models explaining the change in hospitals' surgical wound infection (SWI) rates from 1970 to 1975–1976**

Model for high-risk patients† (R^2 = 0.52)				Model for low-risk patients‡ (R^2 = 0.42)			
Predictor variable§	Coefficient	*F* value	*p* value	Predictor variable§	Coefficient	*F* value	*p* value
Intercept	−5.627			Intercept	−2.242		
logit(1970 SWI rate)	−1.476	41.94	<0.0001	logit(1970 SWI rate)	−0.627	155.38	<0.0001
sqrt(1970 SWI rate)	0.709	13.69	0.0002				
Δsqrt(ratio of FTE nurses to beds)	0.626	5.36	0.0114	Δlog(average length of stay)	0.453	5.63	0.0092
Δlogit(average patient risk for SWI†) in regions outside the Northeast	0.788	26.02	<0.0001				
Δlog(% patients undergoing surgery)	−0.791	14.17	0.0001	Δlog(% patients undergoing surgery)	−0.462	12.66	0.0002
Δ(% patients undergoing surgery)^2	0.206×10^{-3}	6.52	0.0058	Δsqrt(ratio of house staff to beds)	0.941	7.27	0.0047
If (hospital in the Northeast)	0.175	7.44	0.0041	If (large hospital in the South not affiliated with a medical school)	−0.319	9.69	0.0010
If (small hospital in the West)	−0.287	9.11	0.0013	If (nonprofit hospital in the West)	−0.251	6.72	0.0050
If ‖EITHER [( or Hospital epidemiologist is a physician) + Feedback SWI rates to surgeons] OR (Hospital epidemiologist with course + Reduced evironmental culturing)‖ ‖	−0.225	17.17	<0.0001	If ‖  + Feedback SWI rates to surgeons‖ ‖	−0.210	11.76	0.0003
If ‖BOTH [( or Hospital epidemiologist is a physician) + Feedback SWI rates to surgeons] AND (Hospital epidemiologist with course + Reduced environmental culturing)‖¶	−0.429	14.05	<0.0001	If ‖BOTH ( + Feedback SWI rates to surgeons) AND (Hospital epidemiologist with course + Reduced environmental culturing)‖¶	−0.519	15.16	<0.0001

* Dependent variable: logit(1975–1976 SWI rate) − logit(1970 SWI rate).

† Risk for SWI, estimated for each patient from his or her risk factors (33), >2%; mean risk for all patients in the analysis = 7.3%.

‡ Risk for SWI, estimated for each patient from his or her risk factors (33), <2%; mean risk for all patients in the analysis = 0.9%.

§ Δ signifies the change from 1970 to 1975–1976; "if" signifies an indicator variable coded 1 when the simple condition within parentheses was true or when the complex condition within the braces was established between 1970 and 1975–1976, and coded 0 otherwise. s, surveillance; c, control; FTE, full-time-equivalent.

‖ Will be referred to as a "moderately effective" program.

¶ Will be referred to as a "very effective" program.

monia rates was analyzed separately in surgical (high risk) and medical (low risk) patient groups; and the change in bacteremia rates was analyzed among all patients.

Stepwise multiple linear regression was used as the principal model-building technique. The pool of potential predictor variables used in developing these models included the following classes of variables: 1) the 1970 rate (to control for the fact that the change in the rate was found to depend on the level of the baseline rate in 1970); 2) the five-year change in medical practice variables (e.g., the urine culturing rates) and in the average patient length of stay; 3) the five-year change in average patient risk; 4) the five-year change in dynamic hospital characteristics (e.g., the nurse-to-patient ratio); 5) the 1976 measurements of the hospital structural characteristics (e.g., categories of hospital size, region, etc.); and 6) characteristics of the infection surveillance and control program adopted between 1970 and 1975–1976. We also explored interactions among the variables in these classes judged to have potentially plausible influences on the change in rates, e.g., interactions of infection surveillance and control program characteristics with hospital size and medical school affiliation. Nonlinear influences were captured by including log, square, and square root transformations of the continuous variables in the predictor pool.

After the impact of infection surveillance and control programs had been estimated by the seven linear models, we estimated the nationwide secular trends by calculating the average change in infection rates that occurred in the groups of US hospitals that had implemented very effective, moderately effective, and ineffective infection surveillance and control programs between 1970 and 1975–1976. Using the sampling weights determined by the stratified study design (32), we obtained these estimates, and their standard errors, and adjusted them for the influence of those factors believed to have had an influence on the observed (but not the true) infection rates (e.g., diagnostic medical practices).

Finally, again using weights determined by the sampling design, we estimated the numbers of nosocomial infections at each site that were actually being prevented by the infection surveillance and control programs functioning in US hospitals in 1975–1976 and the numbers of nosocomial infections that could have been prevented if all hospitals had adopted the combinations of infection surveillance and control program activities that had the greatest effect on the risks of infection at each site.

Results

Basic linear models explaining changes in infection rates

Baseline rates. In each of the seven models (tables 1–4), the level of the 1970 rate had a strong influence on the change in the infection rate, its negative sign indicating that the infection rates in hospitals starting with high rates in 1970 tended to decrease, whereas the rates in hospitals starting with low rates tended to increase. In four of the models, the 1970 rate appeared twice, the second term having a positive sign, indicating that the relationship between the 1970 rate and the subsequent change in the rate was not linear.

Diagnostic medical practice rates. In all models except the two for surgical wound infection, changes in diagnostic medical practice rates (36) were strongly related to the changes in the observed infection rates. Among patients at high risk of urinary tract infection (table 2), the observed urinary tract infection rate tended to have increased more in hospitals in which there were increases in the percentage of patients without signs or symptoms of urinary tract infection for whom their physicians performed urine cultures; in hospitals in which there were increases in the percentage of urine cultures for which a colony count was performed (the colony count rate); and in hospitals in which there were increases in the percentage of fevers above 37.9 C

TABLE 2

*Multiple regression models explaining the change in hospitals' nosocomial urinary tract infection (UTI) rates from 1970 to 1975–1976**

Model for high-risk patients† (R^2 = 0.66)				Model for low-risk patients‡ (R^2 = 0.50)			
Predictor variable§	Coefficient	*F* value	*p* value	Predictor variable§	Coefficient	*F* value	*p* value
Intercept	−6.460			Intercept	−3.859		
logit(1970 UTI rate)	−1.549	108.23	<0.0001	logit(1970 UTI rate)	−0.791	169.08	<0.0001
sqrt(1970 UTI rate)	0.853	39.84	<0.0001	(1970 UTI rate)^2	0.081	10.26	0.0080
Δurine culturing rate in asymptomatic patients	0.058	39.07	<0.0001	Δ(urine culturing rate in asymptomatic patients)^2	0.271×10^{-3}	16.14	<0.0001
Δ(urine culturing rate in asymptomatic patients)^2	-0.533×10^{-3}	16.32	<0.0001	Δ(worked-up fever rate)^2	0.540×10^{-4}	4.95	0.0134
Δlog(urine culturing rate in asymptomatic patients)	−0.165	13.89	0.0001				
Δ(worked-up fever rate)^2	0.576×10^{-4}	8.23	0.0022				
If (colony count rate was 0 in 1970)	−0.472	33.56	<0.0001				
Δ(colony count rate)^2	0.681×10^{-4}	36.40	<0.0001				
Δ(colony count rate)^2 in nonprofit hospitals	-0.569×10^{-4}	16.50	<0.0001				
If (hospital epidemiologist with training course)	0.151	7.26	0.0037				
Δlog(ratio of FTE nurses to patients)	−0.241	9.78	0.0009	Δlog(ratio of FTE physicians to patients)	-0.451×10^{-1}	8.27	0.0022
If (hospital was nonprofit)	0.164	5.40	0.0104	If (affiliated with a medical school and in the Northeast)	0.362	7.19	0.0039
If (municipal hospital in the South)	−0.215	6.36	0.0060	If (municipal hospital in the South)	−0.259	7.93	0.0026
							
If { AND (≥1 FTE infection control nurse per 250 beds OR Hospital with <200 beds and equivalent staffing level to do surveillance)}¶	−0.364	20.78	<0.0001	If { AND (≥1 FTE infection control nurse per 250 beds OR Hospital with <200 beds and equivalent staffing level to do surveillance)}¶	−0.531	16.78	<0.0001

* Dependent variable: logit(1975–1976 UTI rate) − logit(1970 UTI rate).

† Risk for UTI, estimated for each patient from his or her risk factors (33), >2%; mean risk for all patients in the analysis = 8.2%.

‡ Risk for UTI, estimated for each patient from his or her risk factors (33), <2%; mean risk for all patients in the analysis = 0.8%.

§ Δ signifies the change from 1970 to 1975–1976; "if" signifies an indicator variable coded 1 when the simple condition within parentheses was true or when the complex condition within the braces was established between 1970 and 1975–1976, and coded 0 otherwise. s, surveillance; c, control; FTE, full-time-equivalent.

¶ Will be referred to as a "very effective" program.

(100.2 F) that had an appropriate workup (the worked-up fever rate). For the low-risk patients (table 2), the urine culturing rate among patients without signs or symptoms and the worked-up fever rate were again important. The multiple terms for some of the medical practice rates in the models indicate a complex nonlinear association. For example, the influence of a given increase in the colony count rate on the observed change in the urinary tract infection rate among high-risk patients was less in hospitals that initially (1970) had a colony count rate of zero (table 2).

Among surgical patients (table 3), the observed postoperative pneumonia rate tended to increase more in hospitals in which there were increases in the percentage of patients with signs or symptoms of pneumonia in the postoperative period for whom a chest x-ray was done and in hospitals in which there were increases in the percentage of patients without signs or symptoms of pneumonia in the postoperative period for whom a chest x-ray was done. Among medical patients (table 3), the pneumonia rate tended to increase more in hospitals in which the worked-up fever rate increased. The bacteremia rates (table 4) tended to increase more in hospitals in which there was an increase in the percentage of patients with signs or symptoms of any infection for whom physicians ordered appropriate cultures.

Length of stay. Although none of the changes in the diagnostic medical practice rates significantly influenced the changes in surgical wound infection rates, changes in the patient's length of stay in the hospital did influence the changes to some degree (table 1). Among patients at low risk of surgical wound infection, whose length of stay tended to be short (approximately five days), hospitals in which their average length of stay decreased tended to have had a decrease in the observed surgical wound infection rate. This association was presumably due to the fact that an earlier discharge caused more of the surgical wound infections to become manifest after the patients had left the hospital, thus reducing the chance that evidence of the infection would be recorded in their hospital record. Changes in average length of stay were not significantly associated with changes in surgical wound infection rates for high-risk surgical patients, whose length of stay tended to be much longer (approximately 11 days), or with changes in infection rates at any of the other sites.

Surveillance bias. Evidence was found in four of the models that changes in staffing or surveillance practices that might allow for more thorough detection of infections or more complete recording in the medical records were associated with increases in the observed infection rates. For surgical wound infection in high-risk patients (table 1), an increase in the ratio of full-time-equivalent staff nurses to beds tended to be associated with an increase in the observed surgical wound infection rate, the presumptive explanation being that with a greater abundance of nurses, each nurse would have more time to detect and record the critical finding of purulent drainage that would signal a surgical wound infection.

Additions of infection surveillance and control program staffing or surveillance were associated with increases in the observed rates of infection in three models, presumably reflecting a tendency for infection surveillance and control program personnel and surveillance to influence the completeness of documentation of infections in patients' medical records. Hospitals with a hospital epidemiologist who took a training course in hospital infection control, for example, tended to have had increases in their observed urinary tract infection rates among high-risk patients (table 2). Those that established a position for an infection control nurse for at least every 250 occupied beds tended to have had increases in their observed postoperative pneumonia rates among surgical patients (table 3), and those that established at least a minimal surveillance program (surveil-

TABLE 3

*Multiple regression models explaining the change in hospitals' nosocomial pneumonia rates from 1970 to 1975–1976**

Model for surgical patients† (R^2 = 0.48)				Model for medical patients‡ (R^2 = 0.38)			
Predictor variable§	Coefficient	*F* value	*p* value	Predictor variable§	Coefficient	*F* value	*p* value
Intercept	−2.861			Intercept	1.179		
logit(1970 pneumonia rate)	−0.663	198.82	<0.0001	sqrt(1970 pneumonia rate)	−1.687	151.73	<0.0001
Δ(chest x-ray rate in symptomatic patients)²	0.392×10^{-4}	8.88	0.0015	Δ(worked-up fever rate)²	0.351×10^{-4}	12.41	0.0003
Δchest x-ray rate in asymptomatic patients	0.347×10^{-2}	6.07	0.0071				
If (had at least one FTE infection control nurse per 250 hospital beds)	0.172	3.66	0.0282	If (at least a medium-low surveillance program)	0.195	7.47	0.0033
Δlogit(average patient risk for pneumonia†)	0.237	6.64	0.0052	Δ(average patient risk for pneumonia‡)² in the South	0.221×10^{-1}	6.10	0.0070
				Δ(% patients on medical service)²	-0.928×10^{-4}	9.79	0.0009
If (affiliated with a medical school)	0.210	6.49	0.0056	If (affiliated with a medical school)	0.329	18.24	<0.0001
If (municipal hospital affiliated with a medical school)	0.431	6.65	0.0052	If (hospital in the West)	0.312	16.16	<0.0001
				If (small hospital in the South)	−0.253	11.80	0.0004
 AND ≥1 FTE infection control nurse per 250 beds‖¶	−0.320	7.00	0.0043	If  ‖‖	−0.137	4.60	0.0164

* Dependent variable: logit(1975–1976 pneumonia rate) − logit(1970 pneumonia rate).

† Mean risk for all surgical patients, estimated for each patient from his or her risk factors (33), 1.3%.

‡ Mean risk for all medical patients, estimated for each patient from his or her risk factors (33), 0.3%.

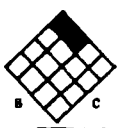
§ Δ signifies the change from 1970 to 1975–1976; "if" signifies an indicator variable coded 1 when the simple condition within parentheses was true or when the complex condition within the braces was established between 1970 and 1975–1976, and coded 0 otherwise. s, surveillance; c, control; FTE, full-time equivalent.

‖ Will be referred to as a "moderately effective" program.

¶ Will be referred to as a "very effective" program.

TABLE 4

*Multiple regression model explaining the change in hospitals' nosocomial bacteremia rates from 1970 to 1975–1976**

Model for all patients† ($R^2 = 0.47$)			
Predictor variable‡	Coefficient	*F* value	*p* value
Intercept	−11.207		
logit(1970 bacteremia rate)	−1.645	61.11	<0.0001
sqrt(1970 bacteremia rate)	3.172	28.87	<0.0001
Δ(overall culturing rate in symptomatic patients)[2]	0.162×10^{-3}	15.14	0.0001
Δ(average patient risk for bacteremia§)[2]	2.124	19.42	<0.0001
Δlog(% patients undergoing surgery)	0.228	7.08	0.0041
Δ(ratio of total emergency visits to total admissions)[2]	0.829×10^{-3}	7.84	0.0027
Δsqrt(ratio of house staff to beds)	−0.747	5.07	0.0125
If (affiliated with a medical school and located in North Central or Northeast)	0.552	35.15	<0.0001
If (hospital in the West)	0.235	10.04	0.0008
If (small hospital)	−0.278	22.35	<0.0001
If (municipal hospital in the South)	−0.212	7.06	0.0041
If ‖  ‖	−0.163	6.46	0.0057
If ‖  ‖ AND ≥1 FTE infection control nurse per 250 beds AND a hospital epidemiologist‖¶	−0.433	15.82	<0.0001

* Dependent variable: logit(1975–1976 bacteremia rate) − logit(1970 bacteremia rate).

† The comparatively low rates of bacteremia precluded stratifying the analysis on patient risk.

‡ Δ signifies the change from 1970 to 1975–1976; "if" signifies an indicator variable coded 1 when the simple condition within parentheses was true or when the complex condition within the braces was established between 1970 and 1975–1976, and coded 0 otherwise. s, surveillance; c, control; FTE, full-time-equivalent.

§ Estimated for each patient from his or her risk factors (33).

‖ Will be referred to as a "moderately effective" program.

¶ Will be referred to as a "very effective" program.

lance index of medium-low or higher) tended to have had increases in their observed rates of pneumonia among medical patients (table 3).

Average underlying patient risk. After controlling for the effects of the level of the 1970 rates and for changes in those factors that appeared to have influenced our ability to detect nosocomial infections, we found changes in other hospital characteristics that also were associated with changes in the infection rates. The most important change was in the underlying nosocomial infection risk of the hospitals' patient populations. Stratifying the analysis by the patients' level of risk was adequate to control for this influence in the surgical wound infection model for low-risk surgical patients and in both urinary tract infection models. In the other models, increases in average patient risk were strongly associated with the tendency toward increasing infection rates (tables 3 and 4).

Dynamic hospital characteristics. In addition to the changes in average patient risk, changes in other dynamic hospital characteristics appeared to have had important influences on the changes in infection rates. For both high- and low-risk surgical patients, an increase in the degree of

a hospital's orientation toward surgery (percentage of the hospital's patients who underwent surgery) tended to be associated with a decrease in its surgical wound infection rate (table 1). This seems to support the explanation that a greater caseload of surgery was accompanied by greater surgical proficiency (39–41). In contrast, similar changes in the surgical-to-medical case mix tended to be associated with increases in the rates of bacteremia, reflecting in general the increased risk of bacteremia for surgical patients (42) (table 4).

Increases in the ratio of full-time-equivalent nurses to patients were strongly associated with a tendency toward decreasing urinary tract infection rates among high-risk patients (table 2), and changes in the ratio of house staff to patients or beds were likewise inversely associated with changes in the urinary tract infection rate among low-risk patients (table 2) and with changes in the bacteremia rate (table 4). These inverse associations suggest that improved staffing ratios are accompanied by better patient care (43). For low-risk surgical patients (table 1), although the nurse-to-bed ratio was not significantly associated, an increase in the ratio of house staff to beds tended to be associated with an increase in the surgical wound infection rate, a finding that is consistent with a previous suggestion that patients of surgeons in training may have higher rates of postoperative complications (40).

Structural hospital characteristics. Besides the effects of changes in dynamic hospital characteristics, important changes in infection rates were associated with static structural characteristics of the hospitals. There tended to have been significant increases in the adjusted rates of urinary tract infection, pneumonia, and bacteremia for hospitals affiliated with medical schools; increases in the rates of surgical wound infection and urinary tract infection for hospitals in the Northeast; increases in the rates of pneumonia and bacteremia for hospitals in the West; decreases in the rates of surgical wound infection and bacteremia for small hospitals; and decreases in the rates of urinary tract infection and bacteremia for municipal hospitals in the South.

Establishment of infection surveillance and control programs

Surgical wound infections. After controlling for the influence of other changes within the hospitals, similar infection surveillance and control program approaches were found to be effective in reducing surgical wound infections in both high- and low-risk patients (table 1). Among high-risk surgical patients (85 per cent of whom underwent "clean" or "clean-contaminated" operations and 15 per cent of whom underwent "contaminated" or "dirty" ones (34)), the approach found to be effective involved two components. The first entailed a) establishing a strong infection surveillance and control program with both surveillance and control activities (see diagram in table 1), or at least having a hospital epidemiologist (defined as "a physician or microbiologist with special interest in infection control who supervises the infection control program") who was a physician (regardless of clinical specialty), and b) establishing a system for reporting surgical wound infection rates obtained through surgical wound infection surveillance back to the hospital's practicing surgeons. The second component (an "effectual hospital epidemiologist") consisted of having a hospital epidemiologist interested enough in infection control to have taken a course on the subject and active enough in the hospital to have effected (or at least to have allowed) a reduction in the hospital's level of routine environmental culturing. Among high-risk surgical patients, establishing one but not both of these components resulted in a "moderately effective" program that reduced the surgical wound infection rate among high-risk patients by 20 per cent, whereas establishing both of these components resulted in a "very effective" program that reduced the rates by 35

per cent (tables 1 and 5). The percentage reduction in the surgical wound infection rate in hospitals with very effective programs was essentially the same for high-risk patients with contaminated or dirty wounds as for those with clean and clean-contaminated wounds.

Among low-risk surgical patients (98 per cent of whom underwent clean or clean-contaminated operations and 2 per cent of whom underwent contaminated or dirty ones (34)), a more stringent program was required to achieve similar levels of prevention. In this model (table 1), the first component had to include establishing a strong infection surveillance and control program with both surveillance and control activities and a system for reporting surgical wound infection rates back to the hospital's practicing surgeons; having a physician hospital epidemiologist was not a sufficient substitute for a strong, balanced infection surveillance and control program. The second component (an effectual hospital epidemiologist) was as defined before. Having the first component alone was moderately effective (a 19 per cent decrease in surgical wound infection rates), whereas having the second one alone was not. Having both components together, however, proved to be a very effective program, resulting in a 41 per cent decrease (tables 1 and 5).

These infection surveillance and control program effects were consistent across the range of hospitals except for one group. Among the municipal hospitals affiliated with medical schools (average size 675 beds), the establishment of a moderately effective program had no effect on the surgical wound infection rate among high-risk surgical patients. Moreover, we were unable to assess the efficacy of the very effective programs in this group of large urban teaching institutions because none of those in our sample had established the types of programs found to be very effective. Among low-risk surgical patients, the effect of a moderately effective program in these hospitals was not significantly different from that found in all other hospitals, although the data suggest that it may also be weaker. We were also unable to detect any significant effects of measures such as establishing a policy for the timing of the preoperative shave (established in only 13 per cent of the sample hospitals) and the use of prophylactic antimicrobial drugs as they were being used in the early to mid-1970s.

Urinary tract infections. For preventing nosocomial urinary tract infections among high-risk patients (60 per cent of whom had an indwelling urinary catheter and 47 per cent of whom had one indwelling for more than two days), an intensive surveillance program with at least a moderately low level of control activities (see diagram in table 2) and augmented by at least one full-time-equivalent infection control nurse per 250 occupied hospital beds was very effective, reducing the urinary tract infection rate by 31 per cent. In small hospitals (<200 beds), this level could be achieved without having one full-time-equivalent infection control nurse per 250 beds as long as there were enough other staff members (e.g., chairperson of the infection control committee, nursing supervisor, laboratory staff members) performing the intensive type of surveillance required; however, in larger hospitals (≥200 beds), only those with at least one full-time equivalent infection control nurse per 250 beds had significant reductions in their rates.

For patients at low risk of urinary tract infection (only 8 per cent of whom had an indwelling urinary catheter and only 2 per cent of whom had one indwelling for more than two days), establishing a very intensive infection surveillance and control program (a high level on both the surveillance and the control indexes) and employing at least one full-time-equivalent infection control nurse per 250 beds (or, in small hospitals, an equivalent staffing pattern as discussed above for high-risk patients) resulted in a very effective program, producing a 44 per cent reduction in the urinary tract infection rate (tables 2 and 5). Among

TABLE 5

Percentage reduction in nosocomial infection risk for high- and low-risk patients in hospitals that established very effective and moderately effective infection surveillance and control programs (ISCP) between 1970 and 1975–1976

Site of infection	Patient risk group* (% of patients included)	Quality of hospital's ISCP*	% of US hospitals	% reduction in risk†	
				Estimate	95% confidence interval
Surgical wound infection	High risk (50%)	Very effective	5.2	34.9	18.5–48.0
		Moderately effective	51.1	20.1	11.2–28.2
	Low risk (50%)	Very effective	3.7	40.5	22.7–54.2
		Moderately effective	28.7	19.1	8.8–28.3
Urinary tract infection	High risk (27%)	Very effective	6.7	30.5	18.7–40.6
	Low risk (73%)	Very effective	3.6	41.2	24.2–54.4
Pneumonia	Surgical (38%)	Very effective	6.5	27.4	7.9–42.7
	Medical (62%)	Moderately effective	47.2	12.8	1.2–23.1
Bacteremia	All patients	Very effective	4.4	35.1	19.7–47.6
		Moderately effective	13.9	15.1	3.7–25.1

* Defined in tables 1–4.

† Calculated from regression coefficients (β) in tables 1–4 by % reduction = $100 \cdot (1 - e^{\beta})$.

these low-risk patients, the preventive effect was most evident among middle-aged women (30–49 years) and among older patients of both genders (over 65 years), but was not evident among the few patients with short-term urinary catheterization.

Pneumonia. For preventing postoperative pneumonia in surgical patients, establishing a high-intensity surveillance program, regardless of the level of control activities (see diagram in table 3), and again having at least one full-time-equivalent infection control nurse per 250 occupied beds were necessary for having a very effective program. A 27 per cent reduction in postoperative pneumonia rates resulted from the establishment of such a program (tables 3 and 5).

For preventing pneumonia in medical patients, the evidence for the effectiveness of infection surveillance and control efforts was not nearly as strong as it was for the other sites and among other patient groups. Establishing a more balanced infection surveillance and control program with both surveillance and control activities (see diagram in table 3) resulted in a moderately effective program, leading to a 13 per cent reduction in the infection rate. For preventing pneumonia in either group of patients, we were unable to detect any significant effect for other measures such as establishing a policy for routinely changing and decontaminating the breathing circuit on respirators or for routinely providing preoperative breathing instruction to patients undergoing abdominal surgery.

Bacteremia. For preventing nosocomial bacteremia, establishing a high-intensity control program, regardless of the level of surveillance activities (see diagram in table 4), constituted a moderately effective program with a 15 per cent reduction in the rate of nosocomial bacteremia. However, hospitals that established a similarly high-intensity control program but with at least a medium-high level of surveillance and including at least one full-time-equivalent infection control nurse per 250 beds and a hospital epidemiologist had very effective programs and experienced a 35 per cent reduction in the bacteremia rates (tables 4 and 5).

Importance of the infection control nurse

The previously recommended feature of having a full-time-equivalent infection control nurse for every 250 occupied beds was found to be an integral component of very effective programs in four of the seven linear models. Since the 250-bed cutpoint had been chosen a priori on the basis of previous information (9–14), we explored the data for a potentially more lenient cutpoint by redefining the final infection surveillance and control program interaction variables to include additional hospitals with successively higher numbers of beds per full-time-equivalent infection control nurse. In each of the four models, the estimated reduction in rates declined sharply as the number of occupied beds per full-time-equivalent infection control nurse increased from 250 to 400 beds and then leveled off, thus strongly supporting the 250-bed recommendation.

Effect of infection surveillance and control programs on secular trends

After controlling for changes in the factors of each model thought to have influenced the observed but not the true rates, e.g., diagnostic medical practices, we found that among hospitals that established ineffective (or no) programs, the site-specific infection rates increased by 9 to 31 per cent (table 6). Although these increases were due to multiple influences, the consistency of the increases at all sites strongly suggests an increasing secular trend in the absence of an effective infection surveillance and control program. To estimate the magnitude of the secular trend in the complete absence of the influence of an infection surveillance and control program, we analyzed the trend in the 33 per cent of the hospitals in the target population that had established no programs or programs that were ineffective at all sites. Weighting the site-specific increases by the relative fre-

TABLE 6

Percentage change in nationwide nosocomial infection rates from 1970 to 1975–1976 among hospitals that established infection surveillance and control programs (ISCP) of differing quality

Site of infection	Patient group	Quality of ISCP*							
		Very effective		Moderately effective		Ineffective		All hospitals	
		% change	Z value†	% change	Z value†	% change	Z value†	% change	Z value†
Surgical wound infection	High risk	−48.0	−3.08	−4.8	−0.63	13.8	2.09	−0.6	−0.11
	Low risk	−23.6	−2.28	20.4	2.48	21.3	4.15	18.9	4.51
Urinary tract infection	High risk	−35.8	−4.51			18.5	3.84	13.8	3.04
	Low risk	−41.6	−2.58			30.7	6.89	27.0	6.19
Pneumonia	High risk (surgical)	−7.3	−0.50			9.3	2.07	8.0	1.85
	Low risk (medical)			−7.7	−1.47	10.0	1.84	1.2	0.32
Bacteremia	All patients	−27.6	−2.40	18.6	2.24	25.5	5.20	21.6	5.07

* Defined in tables 1–4.

† Test of the null hypothesis that the percentage change was 0; $Z > 1.64$ or $Z < -1.64$ is statistically significant in one-tailed test at the $p = 0.05$ level.

quency of infections at the four sites, we found that the overall infection rate among these hospitals increased by approximately 18 per cent over the five years.

In contrast, among hospitals that established very effective programs, the site-specific infection rates decreased by 7 to 48 per cent (table 6). Although approximately 14 per cent of the target population hospitals established programs that were very effective for at least one site, only 0.5 per cent of the hospitals established programs that were very effective for all sites. Among these hospitals, the overall infection rate decreased by approximately 36 per cent. Among hospitals that established at least moderately effective programs for all four sites, the infection rates tended to remain stable over the five-year period. Two apparent exceptions were explained by strong confounding factors not adjusted for in table 6: The 20.4 per cent increase in surgical wound infection rates for low-risk surgical patients was due in part to disproportionately low 1970 surgical wound infection rates for this group, and the 18.6 per cent increase in bacteremia rates was due in part to the presence of a disproportionately large number of medical school-affiliated hospitals in the northeastern region, where rates generally increased. Among all hospitals in the target population, the overall infection rate increased by approximately 10 per cent over the five years.

Total infections prevented

Nearly one third (32 per cent) of all nosocomial infections could have been prevented if all hospitals had adopted the most effective programs (table 7). Since, however, relatively few hospitals had established very effective programs at each site (table 5) and very few had established a program that was maximally effective at all sites, only 6 per cent of the nation's nosocomial infections were actually being prevented in 1975–1976, leaving an additional 26 per cent still potentially preventable (table 7).

DISCUSSION

From these results, we conclude that an infection control nurse working with a phy-

TABLE 7

Estimated numbers of nosocomial infections that were being and could have been prevented by infection surveillance and control programs (ISCP) in US hospitals in 1975–1976

Site	1 No. predicted without ISCPs	2 No. that actually occurred	3a (3b) Actually prevented by ISCPs		4a (4b) Could have been prevented if ISCPs in all hospitals		5a (5b) Not prevented	
			No.	(%)	No.	(%)	No.	(%)
Surgical wound	586,000	510,000	76,000	(13)	207,000	(35)	131,000	(22)
Urinary tract	916,000	903,000	13,000	(2)	297,000	(33)	284,000	(31)
Pneumonia	236,000	227,000	9,000	(4)	52,000	(22)	43,000	(18)
Bacteremia	108,000	103,000	5,000	(5)	38,000	(35)	33,000	(30)
SENIC sites	1,846,000	1,743,000	103,000	(6)	594,000	(32)	491,000	(26)
Other sites	429,000	405,000	24,000	(6)*	138,000	(32)*	114,000	(26)
All sites	2,275,000	2,148,000	127,000	(6)	732,000	(32)	605,000	(26)

Derivation of columns: Column 2 derived in part 1 of this series (1); column 3a derived from column 2 and percentages in table 5; column 1 = column 2 + column 3a, and column 3b = column 3a + column 1; column 4b derived from the prevention percentages in table 5; column 4a = column 1 × column 4b; and column 5a(5b) = column 4a(4b) − column 3a(3b).

* The percentages of nosocomial infections at other sites (not studied in SENIC) that were or could have been prevented by ISCPs are assumed to be the same as those for the combined four sites studied in the SENIC Project.

sician who has a special interest in infection control and practicing epidemiologic surveillance and control techniques can prevent up to one third of the nosocomial infections to which the modern general hospital is prone. As expected before the study, the exact constellation of measures that seems to be the most effective varies somewhat for the different sites of infection. For example, a program with both surveillance and control components oriented toward reporting surgical wound infection rates back to the hospital's practicing surgeons appears to be required to prevent surgical wound infections. A very intensive surveillance program with at least minimal control activities is the most effective for preventing urinary tract infections and postoperative pneumonias. Also, very intensive control activities with at least moderate levels of surveillance efforts are needed to prevent nosocomial bacteremia. These differences emphasize that a program aimed at preventing infections at one site might not be very effective at preventing them at other sites; moreover, preventing infections at all sites requires a most intensive program.

Despite these differences in emphasis, the consistency of the findings at all four sites strongly supports the value of the three central components of modern infection control: ongoing surveillance of infections, active control efforts, and qualified staff members. The rationale for the efficacy of surveillance came from the observations of investigators in the 1950s who found that the seriousness of a hospital's infection problems and the need for preventive efforts were often not apparent to hospital administrators, physicians, and nurses until they were given quantitative measures of the problem derived from surveillance data. Subsequent experience indicated that having epidemiologic information not only motivated these important groups to take preventive action but also uncovered previously unsuspected infection risks arising from within the hospital and from outside sources. These early observations are strongly supported by our findings that only those hospitals with highly organized surveillance activities had reduced their risks of urinary tract infection and

postoperative pneumonia and that only those with at least minimal-to-moderate levels of surveillance had had a maximal impact on the risks of surgical wound infection, pneumonia among medical patients, and bacteremia. These findings are particularly noteworthy in view of the apparently growing tendency for hospitals to reduce the levels of their surveillance activities in response to financial pressures.

Subsequent analysis of our surveillance index has indicated that the hospitals with effective surveillance programs were those that employed an infection control nurse to uncover nosocomial infections on clinical ward rounds on a regular basis, analyzed the rates of infection with at least basic epidemiologic techniques, and periodically used the data in decision-making. The impact of reporting the findings from surveillance to hospital personnel was clearly seen in the effects of reporting surgical wound infection rates to the hospital's practicing surgeons, a practice strongly indicated to be effective by previous studies (29, 30).

Infection control techniques, in general, and reporting surgical wound infection rates to practicing surgeons, in particular, were found to be just as effective in preventing surgical wound infections among high-risk patients as among low-risk patients. In interpreting this finding, it is important to understand the composition of the high- and low-risk groups. As explained in more detail in an accompanying paper (34), our multivariate risk index classifies patients on the basis of both the probability of wound contamination and the patient's susceptibility to infection. Over 85 per cent of patients in the high-risk group had undergone clean or clean-contaminated operations but were placed in the high-risk group by virtue of factors that indicated high susceptibility to infection regardless of the likelihood of wound contamination (e.g., multiple underlying conditions, emergent or long operations). Our finding that the very effective surveillance and control measures can lead to reductions in surgical wound infection rates among the so-called dirty operations, a finding also suggested by the results of previous clinical trials (44–46), should lead to fundamental changes in current approaches to the prevention of surgical wound infections (34).

That we were unable to find evidence of the effectiveness of reporting infection rates of urinary tract infection, pneumonia, or bacteremia may have been due to the scarcity of organized programs for reporting on infections other than surgical wound infection in the mid-1970s. The effectiveness of these programs in preventing surgical wound infections suggests that further research to test the effectiveness of programs for reporting rates of other types of infections to practicing physicians, surgeons, nurses, and paramedical personnel might be useful.

Despite the strong evidence of the effectiveness of surveillance activities, our study was unable to determine precisely which methods and schedules should be used in performing surveillance. At the time that our data were collected, most hospitals were detecting infections by ward rounds, review of laboratory records, and similar clinical activities on a continuous daily basis in most areas of the hospital; only a few were relying on periodic prevalence studies, limiting surveillance to specific wards or units, and other "targeted" surveillance methods (47). To infer that these more recent surveillance techniques are as effective as the continuous hospital-wide method by extrapolation from our findings requires the tenuous assumption that the newer techniques produce the same effects as continuous hospital-wide surveillance, only with less effort and expenditure. Since the exact mechanisms by which surveillance works were not independently tested, such extrapolations must be guided by the careful thought of experts. One appealing approach to reducing the expense of surveillance while maintaining its continuous hospital-wide scope is to limit surveillance efforts to

groups of patients who can be predicted to be at high risk of developing infection. In a companion paper (34), we describe a simple multivariate risk index that can be applied at the bedside to identify patients at high risk for surgical wound infection. Further studies are needed to refine this and other suggestions (48–50) to determine whether these surveillance methods are as effective as the traditional approach evaluated in this study.

A criticism of the early approaches to infection control was that they dwelt too heavily on surveillance to the exclusion of active efforts to intervene in the hospital and to control the infection problems. The great importance of combining active control efforts with surveillance activities was strongly supported by our findings. Only those hospitals with very active control efforts had reduced their risks of bacteremia and of urinary tract infection among low-risk patients, and only those with at least minimal-to-moderate levels of control activity had had a maximal impact on the risks of surgical wound infection, urinary tract infection among high-risk patients, and pneumonia among medical patients. Hospitals with these high-intensity control programs tended to have based their activities on the various books, manuals, and other scientific literature available at the time, established written policies specifying proper patient-care techniques bearing on infection control (e.g., urinary catheter care), and taken an active role in teaching hospital personnel about infection control techniques, often in concert with regular inservice education (18).

Another uniform finding throughout our analyses was the importance of having qualified personnel to conduct the surveillance and control activities. One of the difficulties in studying this important aspect was the lack of precise titles and definitions of the main roles played by medical, nursing, and laboratory personnel in infection surveillance and control programs. For example, the role played by physicians varies among three paradigms: the practicing physician with no special interest in the subject who is asked to serve as chairperson of the infection control committee for a term of one or two years (in approximately 40 per cent of hospitals); the physician (most often a pathologist) or microbiologist, often a full-time employee of the hospital, who chairs the committee because of special interest and knowledge in the subject (in approximately 50 per cent of hospitals); and the infectious disease specialist with special training in hospital epidemiology, often referred to as the hospital epidemiologist (in about 10 per cent of hospitals, mostly those affiliated with medical schools) (5). In support of previous opinions (12, 14, 17), we found that a balanced infection surveillance and control program in which surgical wound infection rates are reported to surgeons is roughly twice as effective if the program is supervised by an effectual supervisor who is a physician, and that having both an interested physician or microbiologist and an infection control nurse per 250 beds approximately doubles the effectiveness of the best program in preventing nosocomial bacteremia.

In contrast to the finding for bacteremia for which physician and microbiologist supervisors appeared to be equally effective, only a subset of the programs with such supervisors were found to be effective in preventing surgical wound infections—specifically, those with a supervising physician (not a microbiologist) who had taken a training course in infection control and had reduced the hospital's level of environmental culturing. The finding that a physician was required for the program to prevent surgical wound infections supports the prior view that successful interaction with the hospital's practicing surgeons in order to influence their surgical technique—the ultimate determinant of surgical wound infection risks—is better performed by a physician than by a person in a nonclinical position (49). In practice, however, this distinction may not be too important since

only 7 per cent of the supervisors were not physicians, most of these being nurses and less than 1 per cent being doctoral microbiologists (5).

Since the modern concepts of infection control have never been substantially stressed in the curricula of medical or nursing schools or even in residency or fellowship programs in pathology and infectious diseases, some type of training course has long been recommended for physicians who find themselves placed in charge of an infection control program (14, 17). We found that the supervisor's having taken a training course in infection control was as important as having a medical background; however, the hospitals with physician supervisors that tended to have reduced their surgical wound infection rates were only those in which the level of environmental culturing had also been reduced. Since reducing the level of environmental culturing was one of the major ideas taught in the training courses in the early 1970s (19–21) and since in most hospitals the chairperson of the infection control committee would have to initiate or at least support such a reduction for it to be done, we chose this as a marker for the person who could actually put into action what he or she had learned in a training course. Thus, rather than implying any direct influence of reductions in environmental culturing on infection rates, this finding emphasizes the importance of having an interested, trained, and effective physician who can get the right things put into practice.

We found no evidence that a program headed by a highly trained infectious disease specialist serving as a hospital epidemiologist was any more effective than others; however, only 9 per cent of the hospitals had an infectious disease specialist serving as the supervisor of the program (5), and by the mid-1970s, few of them had received the types of training that are available in 1983 through the two professional organizations that now serve their needs for training, the Association for Practitioners in Infection Control and the Society of Hospital Epidemiologists of America. To the extent that they are physicians highly trained in infection control who are able to put into effect the principles learned in their infection control training, however, our data indicate that they will probably contribute substantially to the control of nosocomial infections, particularly in large academic and municipal hospitals which have more complex requirements. Their effectiveness will depend, however, largely on their ability to establish and manage the types of intensive surveillance and control activities required, including routine reporting of surgical wound infection rates to practicing surgeons.

Even stronger was the evidence in support of having at least one full-time-equivalent infection control nurse per 250 occupied hospital beds. Since 96 per cent of persons holding this position throughout the nation were nurses in 1976, we were unable to determine whether those without training in nursing (primarily laboratorians) were performing as effectively, although we previously reported that the types of skills and approaches offered by the two groups are quite different (51). The 250-bed cutpoint for the staffing ratio of the infection control nurse, chosen a priori on the basis of previous information (13–15, 17), was found to be an important component of an effective infection surveillance and control program in four of the models. Our finding that the preventive effect from having an infection control nurse was progressively lost as the number of beds increased above the 250 cutpoint suggests that this should remain the recommended staffing level, particularly in view of increasing pressures to have infection control nurses participating peripherally in quality assurance, utilization review, and risk management activities. Interestingly, the infection control efforts in some small hospitals (those with fewer than 200 beds) were effective in reducing infection rates even without substantial time commitments by

an infection control nurse; however, in each of these small hospitals, equivalent amounts of time were spent in surveillance and control activities by other interested personnel such as the director of nursing service, the chairperson of the infection control committee, and personnel from the microbiology laboratory. In larger hospitals, an infection control nurse per 250 beds was required, presumably reflecting the greater need for full-time staff members in more administratively complex institutions. When viewed together, these findings constitute a strong mosaic of evidence for the effectiveness of the infection control nurse in the practice of "shoe-leather epidemiology" to prevent infectious diseases in the hospital.

These findings have important implications for the future organization and funding of care in the nation's hospitals. We have confirmed, for the first time, the magnitude of the nationwide nosocomial infection rate at approximately 5.7 infections per 100 admissions in a statistically representative sample of acute-care US hospitals (1). Moreover, after controlling for the influences that are likely to have artifactually influenced the rates, we find that there was an increasing secular trend in the nationwide infection rate from 1970 to 1975–1976 among hospitals that did not establish effective prevention programs. Potentially related to the increased use of invasive devices and immunocompromising technologies (52–54), this secular trend suggests that nosocomial infections will become an increasingly important source of morbidity, mortality, and economic burden unless effective prevention programs are universally established to reverse the trend. The consistent downward secular trend among the hospitals that had established very effective programs suggests that the great benefits of increased hospital technology can be realized while the costs of infectious complications are reduced. Also, if the degree of prevention remains at or above the 32 per cent level of effectiveness, the nationwide economic savings derived from the prevention of nosocomial infections will far exceed the expenditures on infection surveillance and control efforts (24, 25). This will be particularly true if further innovation reduces the costs of carrying out infection surveillance and control measures (55–57) or if basic and applied research identifies new methods of increasing our preventive power beyond the 32 per cent mark that is now achievable.

References

1. Haley RW, Culver DH, White JW, et al. The nationwide nosocomial infection rate: a new need for vital statistics. Am J Epidemiol 1985;121:159–67.
2. Freeman J, Rosner BA, McGowan JE Jr. Adverse effects of nosocomial infection. J Infect Dis 1979;140:732–40.
3. Green JW, Wenzel RP. Postoperative wound infection: a controlled study of the increased duration of hospital stay and direct cost of hospitalization. Ann Surg 1977;185:264–8.
4. Haley RW, Schaberg DR, Crossley KB, et al. Extra charges and prolongation of stay attributable to nosocomial infections: a prospective interhospital comparison. Am J Med 1981;70:51–8.
5. Haley RW. The "hospital epidemiologist" in US hospitals, 1976–1977: a description of the head of the infection surveillance and control program. Infect Control 1980;1:21–32.
6. Nahmias AJ, Eickhoff TC. Staphylococcal infections in hospitals: recent developments in epidemiologic and laboratory investigation. N Engl J Med 1957;265:74–81.
7. Langmuir AD. The surveillance of communicable diseases of national importance. N Engl J Med 1963;268:182–92.
8. Brachman PS. Surveillance of institutionally acquired infections. In: Proceedings of the National Conference on Institutionally Acquired Infections, Minneapolis, University of Minnesota School of Public Health, September 4–6, 1963. PHS publication no. 1188. Washington, DC: US GPO, 1964:138–47.
9. Streeter S, Dunn H, Lepper M. Hospital infection—a necessary risk? Am J Nurs 1967;67:526–33.
10. Thoburn R, Fekety FR, Cluff LE, et al. Infections acquired by hospitalized patients. Arch Intern Med 1968;121:1–10.
11. Wenzel K. The role of the infection control nurse. Nurs Clin North Am 1970;5:89–98.
12. Garner JS, Bennett JV, Scheckler WE, et al. Surveillance of nosocomial infections. In: Proceedings of the International Conference on Nosocomial Infections, August 3–6, 1970. Chicago: American Hospital Association, 1971:277–81.
13. Eickhoff TC, Brachman PS, Bennett JV, et al. Surveillance of nosocomial infections in community hospitals. I. Surveillance methods, effective-

ness, and initial results. J Infect Dis 1969;120:305–17.
14. Centers for Disease Control. Outline for surveillance and control of nosocomial infections. Atlanta, GA: CDC, 1972 (Reprinted September 1973, May 1974, November 1976).
15. Mallison GF. A hospital program for control of nosocomial infections. Assoc Pract Infect Control Newsletter 1975;2:1–5.
16. Stamm WE. Elements of an active, effective infection control program. Hospitals 1976;50:60–6.
17. Kaslow RA, Garner JS. Hospital personnel. In: Bennett JV, Brachman PS, eds. Hospital infections. Boston: Little, Brown & Co, 1979:32.
18. Haley RW, Shachtman RH. The emergence of infection surveillance and control programs in US hospitals: an assessment, 1976. Am J Epidemiol 1980;111:574–91.
19. Eickhoff TC. Microbiological sampling. Hospitals 1970;44:86–7.
20. Centers for Disease Control. Statement on microbiological sampling in the hospital by the committee on infections within hospitals, American Hospital Association. National Nosocomial Infections Study, first and second quarters 1973. DHEW publication no. (CDC)75-8257, July 1974:18–20.
21. Committee on Infections within Hospitals, American Hospital Association. Statement on microbiologic sampling in the hospital. Hospitals 1974;48:125–6.
22. Cruse PJE, Foord R. A five-year prospective study of 23,649 surgical wounds. Arch Surg 1973; 107:206–10.
23. Haley RW, Quade D, Freeman HE, et al. Study on the efficacy of nosocomial infection control (SENIC Project): summary of study design. Am J Epidemiol 1980;111:472–85.
24. Sencer DJ, Axnick NW. Utilization of cost-benefit analysis in planning prevention programs. Acta Med Scand (Suppl) 1975;576:123–8.
25. Haley RW. Preliminary cost-benefit analysis of hospital infection control programs (the SENIC Project). In: Dascher F, ed. Proven and unproven methods in hospital infection control. New York: Gustav Fischer Verlag, 1978:93–6.
26. Moore WL Jr. Nosocomial infections: an overview. Am J Hosp Pharm 1974;351:832–8.
27. Shoji KT, Axnick K, Rytel MW. Infections and antibiotic use in a large municipal hospital 1970–1972: a prospective analysis of the effectiveness of a continuous surveillance program. Health Lab Sci 1974;11:283–92.
28. Fuchs PC. Epidemiology of hospital-associated infections. Chicago: American Society of Clinical Pathologists, 1979:74–8.
29. Cruse PJE, Foord R. The epidemiology of wound infection: a 10-year prospective study of 62,939 wounds. Surg Clin North Am 1980;60:27–40.
30. Altemeier WA. Surgical infections: incisional wound. In: Bennett JV, Brachman PS, eds. Hospital infections. Boston: Little, Brown & Co, 1979:287–306.
31. Haley RW, Culver DH, Emori TG, et al. Progress report on the evaluation of the efficacy of infection surveillance and control programs. Am J Med 1981;70:971–5.
32. Quade D, Culver DH, Haley RW, et al. The SENIC sampling process: design for choosing hospitals and patients and results of sample selection. Am J Epidemiol 1980;111:486–502.
33. Hooton TM, Haley RW, Culver DH, et al. The joint associations of multiple risk factors with the occurrence of nosocomial infection. Am J Med 1981;70:960–70.
34. Haley RW, Culver DH, Morgan WM, et al. Identifying patients at high risk of surgical wound infection: a simple multivariate index of patient susceptibility and wound contamination. Am J Epidemiol 1985;121:206–15.
35. American Hospital Association. Guide to the health care field. Chicago: American Hospital Association, 1977.
36. Haley RW, Culver DH, Morgan WM, et al. Increased recognition of infectious diseases in US hospitals through increased use of diagnostic tests, 1970–1976. Am J Epidemiol 1985;121:168–81.
37. Mulholland SG, Creed J, Dierauf LA, et al. Analysis and significance of nosocomial infection rates. Ann Surg 1974;180:827–30.
38. Haley RW, Hooton TM, Schoenfelder JR, et al. Effect of an infection surveillance and control program on the accuracy of retrospective chart review. Am J Epidemiol 1980;111:543–55.
39. Luft HS, Bunker JP, Enthoven AC. Should operations be regionalized?: the empirical relation between surgical volume and mortality. N Engl J Med 1979;301:1364–9.
40. Luft HS. The relation between surgical volume and mortality: an exploration of causal factors and alternative models. Med Care 1980;18:940–59.
41. Farber BF, Kaiser DL, Wenzel RP. Relation between surgical volume and incidence of postoperative wound infection. N Engl J Med 1981; 305:200–4.
42. Haley RW, Hooton TM, Culver DH, et al. Nosocomial infections in US hospitals, 1975–1976: estimated frequency by selected characteristics of patients. Am J Med 1981;70:947–59.
43. Haley RW, Bregman DA, et al. The role of understaffing and overcrowding in recurrent outbreaks of staphylococcal infection in a neonatal special-care unit. J Infect Dis 1982;145:875–85.
44. Seropian R, Reynolds BM. Wound infections after preoperative depilatory versus razor preparation. Am J Surg 1971;121:251–4.
45. Moylan JA, Kennedy BV. The importance of gown and drape barriers in the prevention of wound infection. Surg Gynecol Obstet 1980;151:465–70.
46. Alexander JW, Fischer JE, Boyajian M, et al. The influence of hair removal on wound infections. Arch Surg 1983;118:347–52.
47. Emori TG, Garner JS, Haley RW. Techniques and uses of nosocomial infection surveillance in US hospitals, 1976–1977. Am J Med 1981;70:933–40.
48. Wenzel RP, Osterman CA, Hunting KJ, et al. Hospital acquired infections. I. Surveillance in a

university hospital. Am J Epidemiol 1976; 103:251–60.
49. Kaiser AB. Effective and creative surveillance and reporting of surgical wound infections. Infect Control 1982;3:41–3.
50. Wenzel RP, Osterman CA, Donowitz LG, et al. Identification of procedure-related nosocomial infections in high risk patients. Rev Infect Dis 1981;3:701–7.
51. Emori TG, Haley RW, Garner JS, et al. Comparison of surveillance and control activities of infection control nurses and infection control laboratorians in United States hospitals, 1976–1977. Am J Infect Control 1982;10:3–16.
52. Stamm WE. Infections related to medical devices. Ann Intern Med 1978;89:764–9.
53. Weinstein RA. Pressure monitoring devices: overlooked source of nosocomial infection. JAMA 1976;236:936–8.
54. Young LS. Nosocomial infections in the immunocompromised adult. Am J Med 1981;70:398–404.
55. Buxton AS, Highsmith AK, Garner JS, et al. Contamination of intravenous infusion fluid: effects of changing administration sets. Ann Intern Med 1979;91:173–8.
56. Craven DE, Connolly MG Jr, Lichtenberg DA, et al. Contamination of mechanical ventilators with tubing changes every 24 or 48 hours. N Engl J Med 1982;306:1505–9.
57. Eickhoff TC. Nosocomial infections. N Engl J Med 1982;306:1545–6.

Background

416.52 Condition for Coverage - Patient Admission, Assessment and Discharge

We are supportive of practices that improve quality of care and patient outcomes. The core objectives are critical to patient safety and are very reasonable. However the means of accomplishing the objectives through the five criteria as required below is too restrictive.

(1) The patient can tolerate a surgical experience; (2) the patient's anesthesia risk and recovery are properly evaluated; (3) the patient's post-operative recovery is adequately evaluated; (4) the patient receives effective discharge planning; and (5) the patient is successfully discharged from the ASC.

416.42(a) *"the patient's post-operative recovery is adequately evaluated" is the section we would like to comment on.*

It is imperative that anesthesiologist develop appropriate discharge criteria. This discharge criteria can be evaluated by well trained nursing personnel and should not require a direct evaluation from the anesthesiologist. If criteria is not met by anticipated discharge time then an anesthesiologist would do a direct evaluation. This creates a more efficient and well established model using well trained nursing personnel who are capable and qualified to make assessments around preset criteria.

#8 Attachment

CMS-3887-P

Background

416.52 Condition for Coverage - Patient Admission, Assessment and Discharge

We are supportive of practices that improve quality of care and patient outcomes. The core objectives are critical to patient safety and are very reasonable. However the means of accomplishing the objectives through the five criteria as required below is too restrictive.

(1) The patient can tolerate a surgical experience; (2) the patient's anesthesia risk and recovery are properly evaluated; (3) the patient's post-operative recovery is adequately evaluated; (4) the patient receives effective discharge planning; and (5) the patient is successfully discharged from the ASC.

416.42(a) *"the patient's post-operative recovery is adequately evaluated" is the section we would like to comment on.*

It is imperative that anesthesiologist develop appropriate discharge criteria. This discharge criteria can be evaluated by well trained nursing personnel and should not require a direct evaluation from the anesthesiologist. If criteria is not met by anticipated discharge time then an anesthesiologist would do a direct evaluation. This creates a more efficient and well established model using well trained nursing personnel who are capable and qualified to make assessments around preset criteria.

9

AMERICAN ASSOCIATION OF AAASC AMBULATORY SURGERY CENTERS
P.O. Box 5271, Johnson City, TN 37602-5271
423 915 1001 fax 423 282 3712
www.AAASC.org

October 30, 2007

VIA HAND DELIVERY

Kerry Weems, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3887-P
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3887-P – Ambulatory Surgical Centers Conditions for Coverage

Dear Acting Administrator Weems:

On behalf of the American Association of Ambulatory Surgery Centers (AAASC), please accept the following comments regarding proposed revisions to the Ambulatory Surgery Center (ASC) Conditions for Coverage, CMS 3887-P. AAASC is a professional medical association of physicians, nurses, and administrators who specialize in providing surgical procedures in cost-effective outpatient environments, primarily in Medicare-certified ASCs. Most AAASC members own or operate in Medicare-certified ASCs, and so have considerable experience complying with the Medicare Conditions for Coverage (CfCs).

We believe that it is appropriate to modernize the existing CfCs for ASCs to reflect current practice, particularly since many of the current standards have been unchanged since they were originally set forth in 1982. We appreciate the agency's careful consideration of the wide variation in the size and structure of surgery centers. We commend the agency for attempting to strike an appropriate balance in the revised standards to apply to this diverse group of providers in a way that encourages high quality patient care without being burdensome to many small providers. Unfortunately, as proposed, there is little in the proposed rule that will have a meaningful impact on enhancing the quality of care delivered in today's ASCs. In fact, many of the changes would actually significantly alter current ASC regulation and unnecessarily impact access to surgical care in many states.

Given the agency's current proposal to apply a uniform set of standards, we offer comments along several themes. First, we urge the agency to provide as much flexibility to ASCs as possible in determining how they comply with the agency's conditions. What may be appropriate for a small single specialty ASC may be irrelevant to the safe operation of a large multispecialty ASC. Second, there should be a clear connection between a proposed change in the standards and the ability of that change to improve the quality or safety of ASC services. Along that line, we are concerned that some proposals are more likely to create administrative burden and confusion for ASC patients than they are to improve patient care. Third, we urge the agency to recognize that there are multiple regulatory components within Medicare affecting *what* services are provided and *how* ASCs operate. The agency's new definition of overnight stay is unnecessary given the rigorous process CMS employs to create the list of procedures which are payable in the ASC setting for Medicare beneficiaries.

We share the agency's desire to ensure that patients receive safe and appropriate care and that the conditions for coverage promote an environment where those goals are pursued prospectively. In many cases, we agree with the agency's proposed changes. In the comments that follow, we highlight several areas in which there is room for improvement in the agency's proposal.

A. Definitions (§ 416.2)

If implemented, the proposal to redefine an ASC as a distinct entity that operates "exclusively" for the purpose of providing surgical services to patients not requiring an "overnight stay," and then, in turn, to define an overnight stay as meaning recovery requiring active medical monitoring beyond 11:59 p.m. (i.e., midnight) on the day of the procedure, "regardless of whether it is provided in the ASC," could cause immediate havoc with ASCs and the patients they treat. We are particularly concerned with this new definition because it would prohibit Medicare-certified ASCs from performing any procedures – including procedures for non-Medicare patients – requiring active medical monitoring beyond midnight, even if such stays are permitted for non-Medicare patients in the state where the ASC is licensed. Because the Medicare program already prohibits coverage of procedures requiring an overnight stay for its beneficiaries, we see no reason for this unwarranted intrusion into the authority of the states to regulate the provision of services for non-Medicare patients.

The proposed rule provides no rationale for why it is necessary to change the current CfC definition of an ASC as an entity that operates for the purpose of providing surgical services to patients not requiring "hospitalization." *See* 42 C.F.R. § 416.2. The origins of this regulatory definition can be found in Section 1833(i)(1)(A) of the Social Security Act, which establishes the ASC benefit and provides Medicare coverage for "those surgical procedures...performed on an inpatient basis *in a hospital* but which also can be performed safely on an ambulatory basis in an ambulatory surgical center" (emphasis supplied). In other words, the Medicare statute envisions ASCs as a surgical alternative for patients *not requiring hospitalization*, which is how ASCs have been defined since Medicare coverage was first established for ASC services in 1982.

By defining an ASC by reference to hospitalization, rather than overnight stay, the current CfC rules allow overnight stays for non-Medicare patients, either in the ASC itself or in a licensed or certified recovery care unit that is distinct from the ASC and not a hospital, where such recovery care is permitted under state law. In reliance on the current policy, ASCs throughout the country have invested significant time, money, and resources in developing recovery care programs for non-Medicare patients that may be needlessly jeopardized by the CfC proposed rule. We are aware of at least 14 states that permit patients to remain in ASCs overnight.[1] In addition, a number of states permit extended recovery stays of up to 24, 48 and, in some cases, 72 hours in the ASC or separately licensed or certified recovery care units.

As the Medicare Payment Advisory Commission (MedPAC) observed in 2000, these recovery care centers "make up a distinct class of health care facilities that provide limited medical and nursing care to people who require short-term inpatient observation or overnight lodging for services that include pain control, drug administration and fluid maintenance."[2] According to MedPAC, "[o]ver the past two decades, these facilities have increased in number and in private-sector use as technological advances have allowed more types of surgeries to be safely performed in an ambulatory setting."[3] At the same time, post-surgical recovery care centers improve the quality of care furnished to patients by matching resources more closely to the needs of patients. In particular, highly specialized and focused professional staff is more familiar with the expected post-operative course of treatment and likely problems of patients served by recovery care centers. In addition, the nurse-to-patient ratio often is better in a recovery care center than in a hospital. Finally, by moving post-operative stays from acute care hospitals to recovery care centers, patients may avoid complications inherent to the hospital environment, especially the risk of nosocomial infection.

There is no apparent reason for CMS to cause the harm and disruption that would occur from overriding state licensure laws and regulations through a new CfC definition of ASC that would prohibit non-hospital recovery care for non-Medicare patients, even though such care is permitted in several states. If the concern is that procedures which require overnight recovery care may not be appropriate for Medicare's elderly patient population, we believe the agency's recent rule revising the ASC procedure list is the appropriate vehicle to affect the type of care delivered to Medicare beneficiaries in ASCs. The criteria for procedures to be placed on the list already include a prohibition on Medicare coverage for any services that routinely require an overnight stay.

As drafted in the CfCs, the prohibition on overnight stay would also inappropriately restrict care of non-Medicare patients, including conflicting with state laws and regulations permitting such practice. There is no evidence that overnight recovery is

---

[1] Those states are Alabama, Arizona, Arkansas, Colorado, Georgia, Illinois, Kansas, Nevada, New York, North Carolina, Ohio, Oklahoma, Tennessee, and Utah.

[2] Medicare Payment Advisory Commission, *Medicare Payment for Post-Surgical Recovery Care Centers*, at 3 (November 2000).

[3] Id. at v.

unsafe, and in fact many states have explicit statutory provisions providing for this practice. In fact, patients served in post-surgical recovery care centers tend to be relatively healthy, with few co-morbid conditions. Moreover, many of the specific procedures most suitable for post-surgical recovery care, such as plastic surgery, ear, nose and throat procedures, anterior cruciate ligament reconstruction and breast reduction surgery, are not frequently performed in the Medicare age group.

CMS should not adopt a definition of ASC that prevents Medicare-certified facilities from providing these kinds of services to non-Medicare patients. Members of the ASC community are concerned that if faced with the choice of retaining Medicare certification under the proposed definition of ASC or forgoing the provision of recovery care services to non-Medicare patients, a significant number of facilities simply may choose to opt out of Medicare, thus needlessly limiting beneficiary access.

We strongly urge CMS to retain the current CfC definition of an ASC as an entity that "operates exclusively for the purpose of providing surgical services *to patients not requiring hospitalization.*" The proposed revision would override state law and regulation, limit access to ASC services of Medicare and non-Medicare patients, and provide no assurance that the criterion would improve the quality or safety of ASC procedures. If CMS wishes to further define an ASC, and prevent the rolling back of services that had previously been available in ASCs, we propose the following definition that would continue to permit overnight stays for non-Medicare patients where permitted under state law:

> *Ambulatory Surgical Center or ASC* means any distinct entity that operates exclusively for the purpose of providing surgical services to patients whose recovery under normal circumstances will not require hospital inpatient care, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

CMS might also consider defining ASC by reference to the provision of "outpatient" care because of their linkage to the outpatient hospital prospective payment system (OPPS). Like the hospital outpatient standard, there would again be no specific requirement to discharge a patient at a particular time. Language along the lines of the following would distinguish an ASC from a hospital outpatient department:

> *Ambulatory Surgical Center or ASC* means any distinct entity that is not provider-based, as defined in § 413.65 of this chapter, and that operates exclusively for the purpose of providing surgical services on an outpatient basis, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

Finally, if CMS persists in retaining a provision prohibiting overnight stays, we urge you to preserve the right of ASCs to perform procedures which might involve overnight stays for non-Medicare patients, where permitted under state law, by modifying the proposed rule's definition. CMS should not restrict ASCs' ability to discharge such a patient to an

alternative setting if the patient's medical condition requires more skilled care than what is available in the patient's home.

Retaining the proposed overnight stay criterion will promote the migration of many cases into the hospital outpatient or inpatient setting at a higher cost to the Medicare program and the beneficiary. Providers fear jeopardizing their Medicare participation or payment because of the unforeseen need to transfer a patient or keep them in the facility beyond midnight. Implementing such a standard does not encourage safer or higher quality care—it merely promotes more expensive care.

B. Specific Conditions for Coverage

1. Governing Body and Management (§ 416.41)

The ASC community generally supports the proposal to expand the Governing Body and Management condition to require the governing body to (1) assure direct oversight and accountability for the quality assessment program, and (2) create and maintain an internal disaster preparedness plan. We believe an effective quality assessment program and internal disaster preparedness plan are essential to promoting quality care and patient safety, so that responsibility for their development and implementation is an appropriate responsibility of the governing body.

We have two concerns with the language used in the proposed disaster preparedness plan standard at § 416.41(c):

- While the first section of the Standard for the Disaster preparedness plan (§ 416.41 (c) (1)) is clearly focused on the obligation to prepare for a disaster affecting an ASC's own patients and staff, the second section (§ 416.41(c)(2)) appears to address the need to prepare for a disaster outside the confines of the ASC. Specifically, we are concerned that requiring ASCs to "coordinate" their plans with state and local agencies, as currently proposed in § 416.41(c)(2), could be broadly construed as imposing an affirmative duty on ASCs to integrate their facilities into state and local disaster relief efforts.

  The typical ASC is neither staffed nor equipped to handle more than the emergency care of its own patients and, thus, would not be a suitable emergency care site in the event of a broader, external disaster. Generally, when disasters have struck communities, ASCs have volunteered their staff for the provision of disaster services at the immediate site of the disaster or at local hospitals. We recognize the legitimate need of state and local authorities to receive assurances that ASCs have appropriate plans in place for handling their own patients during a disaster. Therefore, to meet this need, while avoiding the implication of broader duties not appropriate for many ASCs, we suggest renaming the proposed standard as "Internal disaster preparedness plan" and rephrasing the proposed standard at § 416(c)(2) to provide as follows: "The ASC *communicates* the plan to State and local agencies, as requested or as required under applicable law."

- We also believe that the proposed standard in § 416(c) (3) requiring that corrective action in response to disaster preparedness drills be implemented "immediately" may be counterproductive. In many cases, meaningful corrective action takes time to implement; the most immediate fix is not always the best or most effective. At the same time, undue delay in addressing known short comings with a disaster preparedness plan should not be tolerated either. Thus, we believe the right balance here is struck with a requirement for prompt or timely corrections, rather than immediate action.

2. Quality Assessment and Performance Improvement (§ 416.43)

The ASC community supports the proposal to revise the existing quality assessment standard to require a more proactive quality assessment and performance improvement (QAPI) program. As you know, the ASC community has been active in developing measures appropriate to the ASC setting. Those measures, under review by the National Quality Forum, will hopefully form the foundation of quality reporting initiatives in ASCs as mandated by the Congress in the Tax Relief and Health Care Act of 2006 (Public Law 109-432).

The AAASC was a founding member of the ASC Quality Collaboration, the group convened to develop and seek NQF approval for ASC-specific quality measures. We wholeheartedly support the quality measures developed by the collaborative, and look forward to their future implementation by CMS in response to the TRHCA requirements. Attached to our comment letter in Appendix B is a copy of the ASC Quality Collaborative's comments on the specific measures under review by the NQF. We look forward to a continuing dialogue with CMS on how best to implement those measures in the ASC setting.

We appreciate that the proposed rule does <u>not</u> try to prescribe a "one-size-fits-all" QAPI program but, instead, provides ASCs with the flexibility to select their own quality indicators and performance measures, to set their own priorities for program activities and to design performance improvement projects that reflect the scope and complexity of each ASC's services and operations. We agree that ASCs should be able to determine how best to implement a QAPI program appropriate for improving the processes and outcomes relevant to the services they provide and the patients they serve.

3. Laboratory and Radiologic Services (§ 416.49)

In the proposed rule, CMS revises the standards for radiology to say that all radiological services, whether furnished directly or under arrangements, must be furnished in accordance with the portable x-ray conditions. This inappropriately eliminates ASCs' ability to comply with the radiological services standard by demonstrating compliance with the hospital conditions for radiology, as is currently allowed. The portable X-ray conditions are inappropriate for many ASCs, add administrative burden to these facilities, and fail to contribute to improved safety or quality for ASC patients.

We are aware that CMS is concerned about the proliferation of diagnostic imaging services in many communities and commensurate growth in Medicare expenditures for these services. Unlike referrals for diagnostic imaging, the diagnosis is already known for most patients treated in an ASC and a surgical intervention determined to be the best treatment. As such, the imaging service must be integral to the performance of the surgical procedure in order for it to be reimbursed by Medicare.

The portable x-ray conditions present a number of significant problems for a typical ASC:

- First, § 486.102(b) of the portable x-ray conditions states that portable x-ray services must be provided under the supervision of a licensed physician "who is qualified by advanced training and experience in the use of x-ray for diagnostic purposes" (emphasis added) – essentially meaning a radiologist. In ASCs, however, radiologic services are typically are performed under the direct or personal supervision of a surgeon or non-radiologist physician. Indeed, a radiologist's supervision would be neither practical nor useful in cases where the radiology services are performed intraoperatively to aid and guide the surgeon.

- Second, § 486.104(a) of the portable x-ray conditions require formal training in x-ray technology through an accredited program, college or university for all operators of portable x-ray equipment. However, many technicians who assist surgeons in the practice of imaging guidance services in ASCs would not meet these requirements and have no opportunity to be grandfathered into compliance. These technicians are specifically trained by the ASC to operate the particular imaging modality used during a procedure. The portable X-ray standards are aimed at technologists performing diagnostic radiology services using a broad array of imaging modalities and for whom operating of the imaging equipment is their primary responsibility. Given the acute shortage of radiology technicians trained to compliance with the portable X-ray standard, imposition of this criterion represents an insurmountable barrier to providing imaging services integral to the performance of a surgical procedure.

- Third, § 486.106 of the portable x-ray conditions requires a written physician's order specifying "the reason an x-ray test is required, the area of the body to be exposed, the number of radiographs to be obtained, and the views needed," as well as documentation in the patients record of "a description of the procedures ordered and performed, the referring physician, the operator(s) of the portable x-ray equipment who performed the examination, the physician to whom the radiograph was sent, and the date it was sent." In many cases, the reason for the test being done is often provided in the clinical documentation rather than the order. As described in the proposed rule, order and documentation requirements have practical utility for diagnostic imaging procedures, but are irrelevant to intraoperative imaging services. In the case of imaging services performed post-operatively, for example to confirm placement of a device, a written order and other documentation would naturally be included in the patient's record. A standard in the CfCs is not necessary to enforce this practice, as appropriate

documentation is necessary for an ASC to bill for an imaging service integral to the performance of a surgical procedure.

In short, mandatory compliance with the portable x-ray conditions would be impractical for the intraoperative radiology services most commonly performed in ASCs today, including fluoroscopic and ultrasonic guidance. This, in turn, would make it difficult, if not impossible, for most ASCs to perform procedures requiring imaging guidance – procedures that now are routinely performed in ASCs.

The most appropriate way to resolve this issue is to retain the current option of allowing ASCs to furnish radiology services in accordance with the hospital conditions of participation pertaining to radiology services at 42 C.F.R. § 482.26. Unlike the portable x-ray conditions, the hospital conditions allow the provision of radiology services integral to surgical procedures by providing more flexible supervision, personnel and documentation requirements. Specifically, the hospital conditions only require general supervision of "ionizing radiology services" by a "qualified full-time, part-time, or consulting radiologist.[4] Moreover, a radiologist is needed to "interpret only these radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge."[5] Similarly, the hospital conditions allow the facility medical staff to designate the qualifications of radiology technicians and contain less prescriptive ordering and documentation standards more suitable to the provision of imaging services integral to the performance of a surgical procedure.[6]

ASCs that provide radiology services are familiar with the hospital conditions and have been safely operating in accordance with those requirements for many years. Further, the hospital conditions of participation also govern therapeutic radiologic procedures. Because ASCs will be able to provide brachytherapy and other therapeutic radiologic services to Medicare beneficiaries under the revised ASC payment system, it is important for the revised CfCs to address this type of service as well.

Therefore, absent any evidence of patient safety or quality of care concerns with radiology services now routinely performed in ASCs, we urge CMS to retain the option of compliance with the hospital conditions of participation for radiology services.

4. Patient Rights (§ 416.50)

The ASC community is fully committed to safeguarding patient rights. We completely support the principle of including a patient rights provision in the conditions for coverage. Nonetheless, several of the proposed standards at § 416.50 should be revised.

- Proposed § 416.50(a)(1) requires that all patients receive written notice of their rights in a language they understand. This requirement sets an unreasonably high

[4] 42 C.F.R. § 482.26(c)(1).

[5] Id.

[6] Id. at § 482.26(b)(4), (c)(2) and (d).

standard for ASCs that treat diverse patient populations speaking multiple languages. The ASC community supports the idea that ASCs should translate their notices of patient rights into the languages of non-English speaking groups frequently encountered at their facilities. The Department of Health and Human Services recognized, in its 2003 *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*, that some flexibility was needed in addressing the needs of limited English proficient (LEP) patient populations:

> "The languages spoken by the LEP individuals with whom the recipient has contact determine the languages into which vital documents should be translated. A distinction should be made, however, between languages that are frequently encountered by a recipient and less commonly-encountered languages. Some recipients may serve communities in large cities or across the country. They regularly serve LEP persons who speak dozens and sometimes over 100 different languages. To translate all written materials into all of those languages is unrealistic. Although recent technological advances have made it easier for recipients to store and share translated documents, such an undertaking would incur substantial costs and require substantial resources....As a result, the extent of the recipient's obligation to provide written translations of documents should be determined by the recipient on a case-by-case basis..."[7]

Similar flexibility should be applied in the ASC conditions for participation. Thus, we suggest deleting the reference to "verbal and written" notice in § 416.50(a)(1), so that ASCs are able to determine the most effective means of notifying patients of their rights. In accordance with the *HHS LEP Guidance*, in appropriate cases this may include, for example, providing "written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of...written materials, free of cost," rather than a full written translation.[8]

- Second, the requirement in proposed § 416.50(a)(1)(ii) mandating that written ownership disclosure information be furnished to patients *prior to* the first visit to an ASC could disrupt patient care and inconvenience patients. The proposal to include this standard is not practical nor will it lead to improvements in patient care. The decision as to where surgery is performed is made by the physician and patient, and so if there is to be a requirement for prior disclosure of a physician's

[7] 68 Federal Register 47311, 47319 (Aug. 8, 2003).

[8] Id.

ownership interest in an ASC, that duty properly should rest with the physician, as many state's currently require in their medical practice acts.[9]

Moreover, prior notice from the facility is not practical when surgery is scheduled on short notice. The facility's ability to furnish a patient information verbally and in writing prior to their first visit is often precluded by scheduling constraints. The facility has no means of ensuring that the physician making the referral to the ASC provided the information to the patient (the point at which decisions about what care is appropriate and where it should be delivered are made). It may also lead to unnecessary delays in patients receiving needed services if the ASC cannot mail information to the patient until the patient or physician contacts the ASC to schedule a procedure. In many cases, the ASC's initial contact with the patient occurs on the day of their procedure, as many physician offices handle scheduling and patient education without involving the staff of the ASC.

It does not benefit patient care to have ASCs turn patients away because they did not receive an ownership disclosure notice prior to arriving at the facility. If the intent of CMS is to evaluate how patient referral decisions are made, it would make more sense to furnish information on which physicians have an ownership interest in an ASC rather than the nature of the financial relationships. This can easily be posted in a public area of an ASC along with the other notices of patients' rights. CMS could also collect the ownership information through the enrollment process or by separate reporting to its administrative contractors.

- Third, the advance directives requirements in proposed § 416.50(a)(2) are unduly burdensome and inappropriate for ASCs. Most procedures performed at ASCs involve elective short-stay surgery, where advance directives are not applicable as a practical matter. As a result, to the extent a patient has executed a "do not resuscitate" or similar directive; patients are informed that they must agree such a directive will be suspended during their treatment at the ASC. Thus, CMS's proposal to require that ASCs provide verbal and written information concerning its policies on advance directives is likely to be confusing and unnecessarily alarming to patients. Further as health care facilities devoted to non-emergent care, ASCs are not the appropriate type of health care provider to actively promote their use. The health care providers at ASCs working directly with patients should not be placed in the position to provide such legal advice.

  We agree that ASCs should be explicit with patients about whether they will honor an advance directive. Accreditation standards provide a more practical

[9] For example, see For example, see California Business and Professions Code § 650.01(f) (a physician who makes a referral to "an organization in which the [physician] has a financial interest, shall disclose the financial interest...in writing, at the time of the referral or request for consultation"). In addition to California, at least 20 other states require physicians to disclose ownership interests to patients, including Arizona, Connecticut, Florida, Georgia, Hawaii, Kansas, Louisiana, Maryland, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia and West Virginia.

approach; that is, ensuring that the patient be made aware of the ASCs' policy concerning advanced directives. In addition, the proposal to require "prominent" documentation of advance directives is unnecessary, given their limited application to ASCs.

- Fourth, we suggest rephrasing the grievance reporting requirement at proposed § 416.50(a)(3)(iii). We do not think that it would be appropriate for ASCs to inundate government officials with immaterial and unsubstantiated patient complaints, and recommend revising this provision to require the following:

  > All allegations must be promptly reported to a person in authority at the ASC and, if determined to constitute a violation of applicable laws, regulations or health care program requirements, to appropriate federal, state or local authorities.

- Finally, the confidentiality of clinical records standard at proposed § 416.50(d) creates unnecessary confusion with the more comprehensive HIPAA privacy standards applicable to ASCs.[10] More specifically, the proposed rule provides that "[a]ccess to or release of patient records is permitted only with written consent of the patient or the patient's representative or as authorized by law." While this is not inconsistent with the HIPAA standards, we note that the HIPAA standards permit routine disclosures *without* patient consent for purposes of payment, treatment and health care operations. Rather than having surveyors perform this two-step analysis, it would be far better if the ASC conditions simply cross-referenced the HIPAA standards; i.e., access to or release of patient information and clinical records is permitted only in accordance with 42 C.F.R. Parts 160, 162, and 164.

5. Infection Control (§ 416.51)

CMS proposes to add a new standard for ASCs to operate an infection control program for patients and ASC staff that seeks to minimize infections and communicable diseases. The new standard elevates infection control from its current position as part of the physical environment standard.

Significantly lower risk of infection is one of the primary advantages of ASCs over hospital-based surgery. The exemplary infection control record of the ASC industry, as a whole, has been hard-earned through proactive and widespread use of state-of-the-art preventive measures, as well as extensive education and training. For the most part, this success has been achieved without prescriptive regulatory standards, and we appreciate that the proposed infection control condition does not mandate any specific set of infection control guidelines and allows flexibility for ASCs to determine how to meet the objectives of preventing, controlling and investigating infections.

[10] See 45 C.F.R. §164.02 & §164.05

As discussed in the rule, ASCs have been required to have an infection control program in place under the current CfCs. As such, the new standard imposes few changes that will require ASCs to modify their activities. However, the new standard does require ASCs to include infection control as one of the areas monitored as part of the proposed QAPI program. We appreciate the agency's continued commitment to allowing ASCs to choose which professionally recognized standards to implement to best meet the needs of their facility and how best to measure the success of those programs. As with the proposed QAPI program standards, the most effective infection control programs are those tailored to the unique needs of each individual facility.

We also note that CMS would now require each ASC to designate a qualified professional, such as a registered nurse, as an infection control officer. The standard further requires that professional to undergo annual continuing education training. We are concerned that the agency has specified a 'target' amount of continuing education of 4 hours per year that the infection control officer must complete. Given the many ways in which infection control information is disseminated, we hope that the interpretive guidance for the standards will allow ASCs multiple avenues to demonstrate that their infection control officer has received adequate training.

We also ask that CMS confirm that the requirement in proposed § 416.51(b)(1) that an ASC's infection control program be directed by a "qualified professional who has training in infection control" should not be read as mandating any particular infection control credentials or certification. Rather, consistent with the general approach in this section, this statement includes the flexibility for each ASC to determine the qualifications and training needs for its infection control officer. However, it would be helpful to have confirmation of that interpretation in the final rule.

We also request that CMS provide flexibility in designating the infection control officer so that a qualified professional could serve as the infection control officer for multiple facilities connected by common ownership or investment. In such a situation, a dedicated professional may be more effective than an individual in each facility because their exposure to the experiences in multiple facilities may speed the dissemination of best practices and coordinate the collection and reporting of infection control data through the QAPI program.

We appreciate the agency's flexibility in allowing ASCs to determine the method of cleaning and sterilization of equipment utilized in ASC procedures. ASCs have long recognized that the proper cleaning and sterilization of equipment used in multiple patient encounters is critical to ensuring the health of their patients and staff.

6. Patient admission, assessment, and discharge (§ 416.52)

CMS has proposed a new condition that would impose additional requirements for pre-surgical and post-surgical assessments and discharge. The agency has stated that its rationale for proposing these requirements rests on the expansion of the list of procedures for which CMS will provide payment in ASCs and the greater risks faced by older

patients undergoing surgical procedures. CMS states that the agency seeks "to ensure that accurate and thorough assessments are conducted."

We question the rationale for this new condition. CMS has indeed expanded the number of procedures that will be eligible for Medicare reimbursement in the ASC setting, but has done so only after subjecting each new procedure not only to detailed review by its medical advisors, but also to public comment as a means of ensuring that every one of them can indeed be safely performed for Medicare beneficiaries in the ASC setting. In short, CMS has already thoroughly and rather exhaustively evaluated the safety risks of performing these procedures in the ASC setting, and has done so with full consideration of the general medical condition of the typical Medicare beneficiary.

Further, analysis of the procedures that are newly eligible for Medicare payment in the ASC setting reveals that the more than two-thirds are procedures that CMS considers to be office-based because they are performed in physician offices more than half the time. The remaining procedures are already performed in the hospital outpatient setting for Medicare beneficiaries and are clearly appropriate ambulatory services. Outdated Medicare coverage standards have been the principal barrier to ASC access for these services. The recent revisions in these standards will merely allow Medicare beneficiaries the option of having these services performed in an ASC – a choice that has been available to privately insured individuals in the ASC setting for years. Imposing additional conditions because these outpatient procedures will now be covered by Medicare in the ASC is not justified, particularly since CMS has deemed them safe.

We know of no evidence demonstrating that the current standards have been ineffective in safeguarding Medicare beneficiaries. Before imposing additional clinical and administrative requirements on the ASC provider community, CMS should reveal any evidence it has concerning systemic issues that would necessitate these additional requirements.

Pre-surgical and post-surgical assessments

The existing standard for a pre-surgical assessment at §416.42 (a) adequately addresses this important prerequisite to ASC services, by requiring that "[a] physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed." Several additional requirements included in §416.52 should be reconsidered and revised:

- The proposed pre-surgical assessment standard adds a new requirement to determine the patient's mental ability to undergo the procedure. This new requirement is not consistent with currently accepted medical practice patterns. Requiring determination of a patient's mental ability to undergo the procedure appears to invoke a requirement for a psychological and/or psychiatric assessment in the immediate preoperative period, after the patient has already arrived at the ASC. This is not the appropriate time or place for such an assessment, which, if necessary, is arranged under the direction of the physician as part of the process

of determining whether the patient is a surgical candidate. When indicated, this type of assessment is performed well in advance of scheduling the procedure at the ASC, while treatment options are still being considered.

- Also of concern is the proposed standard for a post-surgical assessment, which would include a requirement that a "thorough assessment of the patient's post-surgical condition must be completed and documented in the medical record." The preamble to this proposed rule suggests that in order to complete a "thorough" assessment, the physician would need to assess all body systems. CMS has moved beyond standard practice to propose requirements that are not medically necessary. Consider the examples of cataract surgery, gastrointestinal endoscopies and pain management injections, which are some of the most commonly performed procedures for Medicare beneficiaries in the ASC setting. It is not necessary for a physician to perform a post-operative assessment of *all* body systems for these services. There is no evidence-based clinical rationale for such a broad requirement. Physicians are highly trained professionals capable of determining which body systems require review in their post-operative assessments, which are by nature variable according to the procedure performed. The proposed requirement does not acknowledge this.

- We agree that the postoperative condition of the patient should be assessed and documented in the medical record. This is consistent with current standards of medical practice. However, we propose that the requirement for a post-operative assessment be revised to state, "The patient's post-surgical condition must be documented in the medical record by a qualified practitioner." This would assure documentation of the post-operative assessment, while still allowing the practitioner sufficient flexibility to determine the assessment appropriate to the nature and scope of the procedure performed as well as the specific medical condition of the individual patient.

Discharge orders

We are also concerned with the new requirements with respect to discharge orders. The existing requirement at §416.62 (a), "[b]efore discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery," is appropriate and should be retained. However, we find that the current language is flawed in limiting the evaluation to "proper anesthesia recovery," which excludes patients that may not have had anesthesia. This standard should be moved to the newly created discharge standard and revised to read, "Before discharge from the ASC, each patient must be evaluated by a physician."

- With respect to the proposed requirements proposed under the discharge standard, we agree that providing written discharge instructions is appropriate and reflective of standard medical practice. However, the language requiring that the ASC "ensure the patient has a safe transition to home and that the post-surgical needs

are met" is overly broad. Requiring an ASC to ensure a "safe transition to home" assumes that the ASC has control over the patient after he or she leaves the ASC, that the ASC has control over the automobile or other vehicle used to transport the patient, and that the ASC has control over the environs the patient encounters after they have left the confines of the ASC. It further assumes that the patient is returning home, when this may not be the case, either because the patient does not live at home in the first place or because the patient has made arrangements to stay in another location following their procedure. We are also concerned by the requirement that ASCs are to ensure "that the post-surgical needs are met." This is very broad, and as currently written, beyond the scope of the ASC. The patient may have post-surgical needs that are not within the scope of services provided by the ASC, but rather by the physician performing the procedure or another provider, such as a physical therapist. The ASC should not be put in the position of having to ensure the patient's care by other providers. We favor retention of the current discharge standard at §416.62 (d) which requires that, "[a]ll patients are discharged in the company of a responsible adult, except those exempted by the attending physician." This standard is appropriate and has been a sufficient safeguard for decades. The proposed language at §416.52 (c)(2) should be abandoned.

- The requirement for a discharge order, signed by a physician or the other qualified practitioner who performed the surgery or procedure indicating that the patient has been evaluated for proper anesthesia and medical recovery should be revised. While it is appropriate to require a discharge order from a physician, the proposed language is overly restrictive and does not recognize current practice patterns. In many facilities anesthesiologists are available to care for patients once the procedure has been completed, and the patient has been moved to the recovery area. In such facilities, it is accepted medical practice for either the surgeon or the anesthesiologist to write the discharge order once the patient has recovered satisfactorily. Therefore the proposed language at §416.52 (c)(3) should be revised to read, "Each patient must have a discharge order, signed by a physician or other qualified practitioner unless otherwise specified by State law."

Finally, we note the lack of similar standards for pre-operative assessments, post-operative assessments and discharge requirements for surgical services provided to Medicare beneficiaries in a hospital. Although Medicare pays HOPDs for procedures with much higher associated risk, there are no comparable conditions requiring assessments or dictating the manner in which the patient is to be discharged in those facilities. Further, the conditions proposed here are much more stringent than those that have been developed by independent accrediting bodies, which are generally regarded as the appropriate standard setting bodies for health care providers. These organizations have recognized expertise in developing provider-specific standards and guidelines that are appropriate and effective in ensuring safe delivery of patient care without being unduly burdensome.

In summary, CMS should retain the current standards at §416.42 (a) and §416.42 (d) as there is no evidence that revision is needed. The expansion of the ASC list to include additional procedures that CMS has deemed safe for Medicare beneficiaries in the ASC setting is not a satisfactory rationale for imposing additional provider burdens, many of which are not consistent with current standards of medical practice and are marked by unnecessary inflexibility. The recommendations we are making with respect to the standards and conditions in §416.52 are complicated. To summarize our suggestions, we have attached Appendix A, which illustrates how the standards and conditions in this section should be revised.

***

Thank you for your consideration of our comments on the proposed Conditions for Coverage. Please contact Marian Lowe, AAASC's Washington Representative, if you have any questions or need additional information.

Sincerely,

Joseph Banno, MD
President
American Association of Ambulatory
Surgery Centers

Appendix A

Summary of Current, CMS Proposed and ASC Community Proposed Conditions for Coverage

Current Conditions for Coverage	Conditions for Coverage Proposed by CMS	Conditions for Coverage Proposed by ASC Coalition
§416. 42 (a) Standard: Anesthetic risk and evaluation. A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.	§416.52 (a) Standard: Admission and pre-surgical assessment. (1) Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with State law and ASC policy. (2) Upon admission, each patient must have a pre-surgical assessment that includes, at a minimum, an updated medical record entry documenting an examination for any changes in the patient's condition since the most recently documented medical history and physical assessment. The assessment must include documentation to determine the patient's physical and mental ability to undergo the surgical procedure, and any allergies to drugs and biologicals. (3) The patient's medical history and physical assessment must be placed in the	§416.52 (a) Standard: Admission and pre-surgical assessment. (1) Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with State law and ASC policy. (2) The patient's history and physical must be placed in the patient's medical record before the surgical procedure is started. (3) A qualified practitioner must document any allergies to drugs and biologicals in the patient's medical record. (4) A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.

	patient's medical record before the surgical procedure is started.	
	§416.52 (b) Standard: Post-surgical assessment. (1) A thorough assessment of the patient's post-surgical condition must be completed and documented in the medical record. (2) Post-surgical needs must be addressed and included in the discharge notes.	§416.52 (b) Standard: Post-surgical assessment. (1) The patient's post-surgical condition must be documented in the medical record by a qualified practitioner.
§416. 42 (d) Standard: Discharge. All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.	§416.52 (c) Standard: Discharge. The ASC must - (1) Provide each patient with written discharge instructions. (2) Ensure the patient has a safe transition to home and that the post-surgical needs are met. (3) Ensure each patient has a discharge order, signed by a physician or the other qualified practitioner who performed the surgery or procedure unless otherwise specified by State law. The discharge order must indicate that the patient has been evaluated for proper anesthesia and medical recovery.	§416.52 (c) Standard: Discharge. (1) The ASC must provide each patient with written discharge instructions. (2) Before discharge from the ASC, each patient must be evaluated by a physician. (3) Each patient must have a discharge order, signed by a physician or other qualified practitioner unless otherwise specified by State law. (4) All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.

ASC Quality Collaboration

October 30, 2007

VIA HAND DELIVERY

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3887-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3887-P; Background

Dear Acting Administrator Weems:

On behalf of the ASC Quality Collaboration, a cooperative effort of organizations and companies interested in ensuring that ambulatory surgical center (ASC) quality data is appropriately developed and reported, please accept the following comments regarding CMS-3887-P, Section I. Background as it pertains to quality measures appropriate to ambulatory surgical centers (ASCs). Early in 2006, the ASC Quality Collaboration came together to initiate the process of developing standardized ASC quality measures. The organization's stakeholders include ASC corporations, ASC associations, professional societies, accrediting bodies and government entities. We are pleased that Section 109 of the Tax Relief and Health Care Act of 2006 (TRHCA) will afford ASCs the opportunity to share standardized quality indicators with CMS and the public.

In this proposed rule, CMS solicits comments on quality measures appropriate to ASCs. Specifically, CMS has requested information regarding the extent to which ASCs are currently using quality measures, the data sources for those measures, and the extent to which data are maintained electronically. CMS also expressed an interest in how the measures were developed and why they are appropriate to measure the care provided to Medicare patients in ASCs. We appreciate this opportunity to share our knowledge of these matters with the agency.

I. Use of Quality Measures

Approximately 4600 ASCs are certified by the Medicare program. As certified providers, these ASCs maintain internal programs designed to assess the quality of care provided. These programs must monitor key indicators of quality and appropriateness on an ongoing basis and the information gathered is to be used to improve patient care.

In addition to being certified, many ASCs are also accredited by organizations such as the Accreditation Association for Ambulatory Health Care, the American Osteopathic Association

and The Joint Commission. Participation in this voluntary activity gives ASCs an opportunity for ongoing independent third party assessments of quality and performance against nationally recognized standards. Accreditation requirements include participation in quality improvement and benchmarking activities.

ASCs also have the opportunity to participate in clinical benchmarking programs offered by ASC industry associations such as FASA and the American Association of Ambulatory Surgery Centers; professional societies such as the Association of Perioperative Registered Nurses; and non-profit organizations, such as the AAAHC Institute for Quality Improvement . Participation allows ASCs to compare clinical indicators with their peers and identify opportunities for improvement.

While ASCs currently use a broad variety of programs and measures to assess quality and performance, these are not standardized across the industry.

II. Development of Outpatient Surgical Facility Quality Measures by the ASC Quality Collaboration

The quality of facility services for outpatient surgery is most appropriately evaluated by measures specifically designed to assess processes or outcomes of care germane to the specific services rendered by facilities that provide these services. It is crucial that measures selected for the evaluation of facility quality reflect processes or outcomes of care that are attributable to and reasonably the responsibility of the facility itself -- its staff, the equipment, the environment of care offered to its patients, and its roles in the delivery of patient care.

When the ASC Quality Collaboration was formed, we undertook a detailed evaluation of existing nationally endorsed quality measures to determine which could be directly applied to the outpatient surgery facility setting. Though several existing measures addressed surgical care, none had been developed specifically for the ASC setting. In fact, many of these measures are specific to procedures that are either uncommonly performed in outpatient facilities, or not performed at all for Medicare beneficiaries in the outpatient surgical setting. Other measures expressly exclude patients with a stay of less than 24 hours, effectively eliminating the entire ASC patient population. Still other measures focus on processes of care that are specific responsibilities of physicians, such as the selection and ordering of antibiotics.

Finding no nationally endorsed measures designed for public reporting and accountability specific to facilities performing outpatient surgery, the ASC Quality Collaboration developed a number of facility-level measures of ASC quality. These measures were based on those already commonly used by the ASC community for internal quality assessment and external benchmarking. After refining these standardized measures, the ASC Quality Collaboration piloted them in a sample of twenty ASCs and was able to confirm their feasibility and usability. To date, these measures have been reviewed by a technical advisory panel and a steering committee of the National Quality Forum (NQF). As a result of these evaluations, five measures have been recommended for endorsement. Public and NQF member comment on these five measures closed in September and NQF member voting is currently in progress. We anticipate that final action on these measures could be taken as early as November 2007.

One of the principles that guided the ASC Quality Collaboration was harmonization – the idea that the measures developed through our efforts should be applicable to all facilities offering ambulatory surgery, allowing comparison of quality across sites of service. The ASC measures currently under consideration for endorsement by the NQF are appropriate for other outpatient surgical settings, effectively addressing the need to harmonize quality measures whenever possible.

Of the five measures, four are outcome measures that have applicability to all outpatient surgical facilities and thereby ensure broad facility participation regardless of case mix. These measures focus on 1) patient falls, 2) patient burns, 3) hospital transfer/admission and 4) wrong site/wrong side/wrong patient/wrong procedure/wrong implant. The fifth measure is a process measure which evaluates the timing of the administration of intravenous antibiotics for prophylaxis of surgical site infection. This prophylactic antibiotic timing measure has been specifically designed to harmonize with, and be complementary to, similar measures (see, for example, PQRI #20 and PQRI #30) developed to evaluate physician performance in this area. Please see Attachment A for detailed information on the five outpatient surgical facility-specific quality measures.

The prophylactic antibiotic timing measure also addresses the statutory requirement under TRHCA for evaluation of medication errors. In their recent *MEDMARX® Data Report: A Chartbook of Medication Error Findings from the Perioperative Settings from 1998-2005*, the U.S. Pharmacopeia detailed the various types of medication errors in outpatient surgery, one of which was "wrong time." The report specifically recommended "[d]eveloping strategies to ensure that medications, especially antimicrobial agents, are administered at the correct time."

As of this writing, we are not aware of any other measures specifically addressing facility quality in the delivery of outpatient surgical services that have either been nationally endorsed for public reporting and accountability or are in the process of evaluation for endorsement. Therefore, we strongly recommend CMS consider these five facility-specific measures for ASC reporting, if they are endorsed by the NQF.

III. Appropriateness of ASC Quality Collaboration Measures

As noted above, the measures developed by the ASC Quality Collaboration were based on those commonly used by the ASC community for internal quality assessment and external benchmarking. As such, they measure processes or outcomes of care that are appropriate to the ASC setting. The specific rationale and applicability of each of the five measures that are currently in process for potential NQF endorsement are discussed in more detail below.

A. Patient Burn

There are numerous case reports in the literature regarding patient burns in the surgical and procedural setting. The diversity of the causative agents underscores the multitude of potential risks that must be properly mitigated to avoid patient burns.

The literature on burns suggests that electrosurgical burns are most common. In 2000, a Joint Commission Sentinel Alert indicated "burns from electrocautery used with a flammable prep solution" as one of the seven most frequent operative and postoperative complications.[1] A survey of members of the American College of Surgeons found that 18% of respondents had personally experienced an electrosurgical burn to their patient during laparoscopy.[2] A recent publication from the ECRI highlights the increased risk of burns with newer surgical devices that apply higher currents at longer activation times.[3]

Although electrical burns are most prevalent, other mechanisms of burn injury are frequently reported in case studies and case series. For example, a case series of 19 patients with intraoperative burn accidents severe enough to require subsequent surgical treatment found that although 13 were caused by electrical burns, five were caused by chemical burns and one had an unclear etiology.[4] A closed claims analysis of 3000 claims found that of 54 burns, 28 were caused by patient warming devices.[5]

Surgical fires are rare; however, their consequences can be grave, killing or seriously injuring patients and surgical staff. The risk of surgical fires is present whenever and wherever surgery is performed, whether in an operating room, a physician's office, or an outpatient clinic.[6,7] Based on anecdotal evidence, there are at least 20-30 surgical patient fires each year in the United States.[8]

Recognizing the diversity of mechanisms by which a patient could sustain an unintentional burn in the ASC setting, the ASC Quality Collaboration chose a broad definition of burn, encompassing all six recognized means by which a burn can occur - scalds, contact, fire,

---

[1] Joint Commission. Joint Commission Sentinel Event Alert. Issue 12, February 4, 2000. Operative and Postoperative Complications: Lessons for the Future. Chicago, IL

[2] Tucker R. Laparoscopic electrosurgical injuries: survey results and their implications. *Surg Laparosc Endosc.* 1995;5(4):311-7.

[3] ECRI. Higher currents, greater risks: preventing patient burns at the return-electrode site during high-current electrosurgical procedures. *Health Devices.* 2005;34(8):273-9.

[4] Demir E, O'Dey D, and Pallua N. Accidental burns during surgery. *J Burn Care Res.*. 2006 ;27(6):895-900.

[5] Cheney F, Posner K, Caplan R, and Gild W. Burns from warming devices in anesthesia. A closed claims analysis. *Anesthesiology.* 1994;80(4):806-10.

[6] Barker S and Polson J. Fire in the operating room: a case report and laboratory study. *Anesth Anal.* 2001;93:960-965.

[7] Agency for Healthcare Research and Quality (AHRQ). A clinician's guide to surgical fires: how they occur, how to prevent them, how to put them out. Available at: http://www.guideline.gov/summary/summary.aspx?doc_id=3688&nbr=002914&string=surgery+AND+burns. Last accessed October 4, 2007.

[8] ECRI. Devastation of patient fires. *Health Devices.* 1992;21:3-39.

chemical, electrical, or radiation. This will allow stakeholders to develop a better understanding of the incidence of these events and further refine means to ensure prevention.

B. Patient Fall

"Falls per 100,000 patient days" has been endorsed as a serious reportable event by the NQF.[9]

According to the Agency for Healthcare Research and Quality's *Prevention of Falls in Acute Care* guideline, patient falls may be reduced by following a four-step approach: 1. evaluating and identifying risk factors for falls in the older patient; 2. developing an appropriate plan of care for prevention; 3. performing a comprehensive evaluation of falls that occur in the hospital; and 4. performing a post-fall revision of plan of care as appropriate.[10]

This measure serves as an indirect assessment of adherence to these guidelines by quantifying the outcome of a patient fall.

While ASCs have been demonstrated to have a relatively low incidence of adverse events in general, information regarding the incidence of patient falls is not currently available. However, stakeholders have expressed a general interest in ASC oversight and the public reporting of such adverse events.[11] Due to the use of anxiolytics, sedatives, and anesthetic agents as adjuncts to procedures, patients undergoing outpatient surgery are at increased risk for falls.

C. Hospital Transfer / Admission

The need for transfer/admission is an unanticipated outcome and could be the result of insufficient rigor in patient or procedure selection. Hospital transfers/admissions also result in unplanned cost and time burdens that must be borne by patients and payors.

While ambulatory surgery has been shown to have good outcomes, routine procedures can still result in complications.[11] A recent study on same-day surgical patients demonstrated that of the 20,817 ambulatory surgical patients evaluated, 1,195 (5.7 percent) returned to the hospital within 30 days or were admitted directly after surgery. Of those unanticipated admissions and readmissions, 313 (1.5 percent) were directly related to the original procedure. Pain was the

---

[9] National Quality Forum. *Serious Reportable Events in Healthcare.* Washington, DC: NQF, 2002.

[10] Agency for Healthcare Research and Quality. National Guideline. Preventing Falls in Acute Care. Available at: http://www.guideline.gov/summary/summary.aspx?doc_id=3510&nbr=002736&string=patient+AND+falls. Last accessed October 4, 2007.

[11] Department of Health and Human Services, Office of Inspector General. *Quality Oversight of Ambulatory Surgical Centers.* Available at: http://www.oig.hhs.gov/oei/reports/oei-01-00-00452.pdf. Last accessed October 4, 2007.

most commonly reported reason for return, occurring in 120 (38 percent) of the admitted patients.[12]

Selected states have expressed an interest in the public reporting of such events[13,14,15,16,17]. While hospital transfers and admissions undoubtedly represent good patient care when necessary, high rates of transfer and/or admission may be an indicator that practice patterns are in need of review.

D. Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

"Surgery performed on the wrong body part", "surgery performed on the wrong patient", and "wrong surgical procedure performed on a patient" have all been endorsed as serious reportable surgical events by NQF.[9]

This outcome measure serves as an indirect measure of providers' adherence to the Joint Commission's "Universal Protocol" guideline for eliminating wrong site, wrong procedure, wrong person surgery. The Universal Protocol is based on the consensus of experts and is endorsed by more than forty professional medical associations and organizations.[18]

The Agency for Healthcare and Research Quality's *Making Healthcare Safer* evidence report includes the following statements regarding the incidence of wrong site surgery:[19]

---

[12] Coley K et al. Retrospective evaluation of unanticipated admissions and readmissions after same day surgery and associated costs. *J Clin Anesth.* 2002;14:349-353.

[13] Florida Agency for Health Care Administration. *Ambulatory Surgical and Emergency Department Data.* Available at: http://www.fdhc.state.fl.us/SCHS/apdunit.shtml. Last accessed October 4, 2007.

[14] Indiana State Department of Health. *Reporting a Complaint.* Available at: http://www.in.gov/isdh/regsvcs/asc_index.htm. Last accessed October 4, 2007.

[15] New York State Department of Health. *Statewide Planning and Research Cooperative System.* Available at: http://www.health.state.ny.us/statistics/sparcs/. Last accessed April 30, 2007.

[16] Commonwealth of Pennsylvania, Patient Safety Authority. Available at: http://www.psa.state.pa.us/psa/cwp/view.asp?a=1165&q=441808&psaNav=|. Last accessed October 4, 2007.

[17] Texas Department of State Health Services. Available at: http://www.dshs.state.tx.us/HFP/safety.shtm. Last accessed April 30, 2007.

[18] Joint Commission. *Universal Protocol For Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery.* Available at: www.jointcommission.org/NR/rdonlyres/E3C600EB-043B-4E86-B04E-CA4A89AD5433/0/universal_protocol.pdf. Last accessed October 4, 2007.

[19] Agency for Healthcare Research and Quality (AHRQ). *Making Healthcare Safer. A Critical Analysis of Patient Safety Practices. Chapter 43.2 – Strategies to Avoid Wrong Site Surgery.* Available at: http://www.ahrq.gov/clinic/ptsafety/chap43b.htm. Last accessed October 4, 2007.

"From January 1995 to March 2001, JCAHO reviewed voluntary reports of 1,152 'sentinel events'. Wrong-site surgery accounted for 114 (9.9%) of these reports and included procedures in neurosurgery, urology, orthopedics, and vascular surgery. Despite the high profile of JCAHO's Sentinel Event Policy, it is believed that under-reporting by healthcare organizations apparently affects these statistics. Only 66 percent of the 1,152 total events were self-reported by the institutions involved. The remainder came from patient complaints, media stories and other sources. Using a mandatory reporting system, the New York State Department of Health received 46 reports of wrong-site surgery from 1998 through 2004 compared with the 114 cases JCAHO received nationally over a period three times longer, suggesting that voluntary incident reporting may underestimate the true incidence by a factor of 20 or greater.

The Physicians Insurers Association of America (PIAA) reviewed claims data from 22 malpractice carriers representing 110,000 physicians from 1985 to 1995. These claims included 331 cases of wrong-site surgery. The complete PIAA database documents almost 1,000 closed malpractice claims involving wrong-site surgery. However, this figure also underestimates the prevalence of wrong-site surgery, as every case does not result in a claim. Most wrong-site surgeries involve relatively minor procedures such as arthroscopy, rather than limb amputations or major neurosurgical procedures. Consequently sequelae are minimal. The State Volunteer Mutual Insurance Company (Tennessee) released a series of 37 wrong-site surgery claims from 1977 to 1997. Performing the correct procedure on the wrong side constituted the most common error (e.g., arthroscopic knee surgery on the wrong knee in 15 of the 37 cases). Twenty-six of the patients experienced no sequelae beyond a scar, and only three patients suffered permanent disability. Given the rarity of significant harm, estimates of the incidence of wrong-site surgery derived from litigation data likely underestimate the true prevalence of this problem, as do estimates based on incident reports."

In order to encompass the outcomes of all key identification verifications, the ASC Quality Collaboration's measure incorporates not only wrong site, wrong side, wrong patient and wrong procedure, but also wrong implant in its specifications.

E. Prophylactic Intravenous Antibiotic Timing

The CMS Surgical Infection Prevention performance measure states the following:[20]

"Surgical site infections occur in 2-5 percent of clean extra-abdominal surgeries and up to 20 percent of intra-abdominal surgeries.[21] Each infection is estimated to increase a

---

[20] Centers for Medicare and Medicaid Services (CMS). 7th Statement of Work. Quality of care measure specifications: surgical infection prevention. Baltimore, MD: Centers for Medicare and Medicaid Services; 2002 Aug 1. Various p. Available at: http://www.qualitymeasures.ahrq.gov/summary/summary.aspx?ss=1&doc_id=9513&string=. Last accessed October 4, 2007.

[21] Horan T, Culver D, Gaynes R, Jarvis W, Edwards J, and Reid C. Nosocomial infections in surgical patients in the United States, January 1986-June 1992. National Nosocomial Infections Surveillance (NNIS) System. Infect Control Hosp Epidemiol. 1993;14(2):73-80.

hospital stay by an average of 7 days and add over $3,000 in charges (1992 data).[22] *Patients who develop surgical site infections are 60 percent more likely to spend time in an ICU, five times more likely to be readmitted to the hospital, and have twice the incidence of mortality.*[23] *Despite advances in infection control practices, surgical site infections remain a substantial cause of morbidity and mortality among hospitalized patients. Studies indicate that appropriate preoperative administration of antibiotics is effective in preventing infection. Systemic and process changes that promote compliance with established guidelines and standards can decrease infectious morbidity.*[23]

The goal of pre-surgical antibiotic prophylaxis is to establish bactericidal tissue and serum levels at the time of skin incision. In a recent study of 2,847 surgery patients at Latter-Day Saints Hospital in Salt Lake City, it was demonstrated that the lowest incidence of post-operative infection was associated with antibiotic administration one hour prior to surgery."[24]

There is no literature available on variation in adherence to recommended prophylactic IV antibiotic timing among ASC providers. However, variability in the accuracy of timing of administration has been demonstrated in other settings.[24]

IV. Data Sources

Most ASCs use medical records, various clinical logs and occurrence/incident reports as the data sources for their quality assessment and improvement projects. Typically these are paper-based tools for data charting, although selected centers have the ability to generate certain forms as electronic documents in formats such as Microsoft Word.

V. Extent of Electronic Data

Few ASCs have electronic medical records. Hospital-owned ASCs are the most likely to have electronic databases and electronic medical records, however this ownership structure is the least common in the industry.

Selected states have implemented ASC data reporting requirements. The data elements required and means of reporting are quite variable, but most reporting is internet-based. In many cases the data is reported in a summary format, though a few states require patient-level data.

---

[22] Marton W, Jarvis W, Culver D, and Haley R. Incidence and nature of endemic and epidemic nosocomial infections. In: Bennett J, Brachman P, editor(s). Hospital infections. 3rd ed. Boston, MA: Little, Brown and Co.; 1992. 577-596.

[23] Kirkland K, Briggs J, Trivette S, Wilkinson W, and Sexton D. The impact of surgical-site infections in the 1990s: attributable mortality, excess length of hospitalization, and extra costs. Infect Control Hosp Epidemiol. 1999;20(11):725-30.

[24] Burke J. Maximizing appropriate antibiotic prophylaxis for surgical patients: an update from LDS Hospital, Salt Lake City. Clin Infect Dis. 2001;33(Suppl 2):S78-83.

Depending on the state, the ASC may be required to prepare an electronic file in a specific format (such as XML) for uploading to the state website or may directly enter data into the state website.

VI. Quality Reporting Methodology for ASCs

To date, CMS has implemented a number of quality reporting systems that employ a variety of methods to collect patient-level quality data. Most of these systems require that data be submitted electronically to a repository. As recently proposed, hospital outpatient departments would adopt the same methodology currently used by hospitals for inpatient reporting. That process requires abstraction of clinical data based on chart review, followed by compilation and submission in specific XML format to an approved data submission vendor. This vendor then transmits the data to the QIO Clinical Warehouse.

On the other hand, under the CMS Physician's Quality Reporting Initiative (PQRI), physicians report patient-level quality data using administrative claims. Using either HCPCS Level II G codes or AMA Category II CPT codes adopted specifically for quality reporting, the physician is able to submit quality data in conjunction with codes for services rendered on the CMS-1500. Given the administrative burden of medical record extraction, physicians are likely to continue using a claims-based approach to quality reporting in the future.

We have carefully evaluated these approaches, taking into account the characteristics and resources of the typical ASC. Though there is significant variability, CMS data indicates a median of two operating/procedure rooms per facility (mean = 2.5). FASA's 2006 ASC Salary & Benefits Survey shows that the majority (62.2%) of ASCs have 20 or fewer full time equivalents, including both clinical and non-clinical staff. It is unusual for an ASC to have a medical records department staffed with multiple individuals.

Our evaluation of alternative reporting methodologies has focused on their complexity, staff resources needed for implementation, requirements for hardware and software, training requirements, and additional expenses, particularly related to contracting with data submission vendors. In all these areas, we find the administrative claims data approach to be the most practical, feasible and economical solution for ASCs.

The administrative and financial burden of reporting quality measures should be fully considered. CMS has estimated that approximately 73 percent of ASCs would be considered small businesses according to the Small Business Administration (SBA) size standards (see 72 Fed. Reg. 42538 (August 2, 2007) and 72 Fed. Reg. 42812 (August 2, 2007)). In this respect, ASCs more closely resemble individual physician practices than hospitals.

Further, ASCs will continue submitting their Medicare claims using the CMS-1500 at least through 2008. Therefore, ASCs are in a position to report quality data in the same manner as physicians, which will allow CMS to leverage the processes it has already developed under PQRI. If ASCs move to the UB-04 in the future (a change we support), these codes can continue to be reported on the new form and comparisons across multiple years would remain feasible.

We request CMS work with ASC leaders to develop HCPCS Level II G codes that would allow facility-level quality measures to be reported using a claims-based approach. Reporting data on the claim form using HCPCS codes is achievable across ambulatory settings and can be accommodated on both the CMS-1500 and the UB-04.

VII. Public Display of Quality Data

The ASC Quality Collaboration supports the development of transparency regarding health care information and welcomes a fair presentation of ASC cost and quality information to assist consumers in making decisions.

The success of transparency efforts is closely linked to how effectively information is shared with the public. A data reporting infrastructure should allow patients and payers to compare quality across Medicare's payment silos when a service or procedure can be delivered in multiple ambulatory settings.

Consumers should be able to access quality and cost information on websites that are organized to allow easy comparisons, while also protecting the rights of providers to assure the information is correct, up-to-date, and clearly presented. Specifically, web-based presentation of quality and cost data should address or incorporate the following principles.

1) Information should be presented on all available sites of service so consumers can compare a hospital outpatient department and an ASC for a procedure that could be performed in both locations.

2) There should be a mechanism for providers to raise concerns with any information to be posted prior to its public presentation.

3) There should be a provider narrative section for each provider-specific item presented to the consumer. This narrative box would allow the provider to advise the consumer of any concerns the provider has regarding the reliability or accuracy of the information presented.

4) In addition to reporting quality measures, other useful information such as accreditation status, state licensure and Medicare certification should be made available.

We request more detailed consideration and expanded description on this vital matter from CMS in future rulemaking.

VIII. Summary of Recommendations

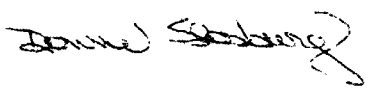
The ASC Quality Collaboration fully supports public reporting of facility-level quality measures that evaluate outcomes or processes of care specific to the facility services rendered in the outpatient surgical setting. CMS should adopt facility-level quality measures that have been endorsed by the NQF specifically for ASC reporting. The five measures developed by the ASC Quality Collaboration that are currently being considered for NQF endorsement are all important indicators of the quality of care ASCs provide to Medicare beneficiaries.

Given the limited electronic capabilities and the manual processes required for quality assessment in ASCs, CMS should implement a claims-based reporting system for ASCs, similar to the quality reporting system the agency has implemented for physicians. Such a system would allow patient-level data collection without undue financial and administrative burden.

Presentation of quality data deserves careful consideration to achieve the most effective communication of information. At a minimum, the method CMS selects for sharing data should allow interested parties to directly compare measures of outpatient surgical facility services across facility types.

Thank you for considering these comments. I would be happy to assist with questions or provide additional information at your request.

Sincerely,



Donna Slosburg, BSN, LHRM, CASC
Executive Director
ASC Quality Collaboration
727-867-0072
donnaslosburg@ascquality.org

Appendix A

ASC Quality Collaboration Measures "*Recommended for Endorsement*" by the National Quality Forum (NQF)

PLEASE NOTE: These measures are subject to change pending additional action by the NQF.

Patient Burn	
Intent	To capture the number of admissions (patients) who experience a burn prior to discharge
Numerator/Denominator	Numerator: Ambulatory Surgery Center (ASC) admissions experiencing a burn prior to discharge Denominator: All ASC admissions
Inclusions/Exclusions	Numerator Inclusions: ASC admissions experiencing a burn prior to discharge Numerator Exclusions: None Denominator Inclusions: All ASC admissions Denominator Exclusions: None
Suggested Data Sources	ASC operational data, including administrative records, medical records, incident/occurrence reports and quality improvement reports
Data Element Definition and Allowable Values	Admission: completion of registration upon entry into the facility; Allowable values: The count for this data element would be represented by any whole number 0 or greater Burn: Unintended tissue injury caused by any of the six recognized mechanisms: scalds, contact, fire, chemical, electrical or radiation, (e.g. warming devices, prep solutions, electrosurgical unit or laser); Allowable values: The count for this data element would be represented by any whole number 0 or greater

Prophylactic IV Antibiotic Timing	
Intent	To capture whether antibiotics given for prevention of surgical site infection were administered on time
Numerator/Denominator	Numerator: Number of Ambulatory Surgery Center (ASC) admissions with an order for a prophylactic IV antibiotic for prevention of surgical site infection who received the prophylactic antibiotic on time Denominator: All ASC admissions with a preoperative order for a prophylactic IV antibiotic for prevention of surgical site infection
Inclusions/Exclusions	Numerator Exclusions: None Denominator Exclusions: ASC admissions with a preoperative order for a prophylactic IV antibiotic for prevention of infections other than surgical site infections (e.g. bacterial endocarditis); ASC admissions with a preoperative order for a prophylactic antibiotic not administered by the intravenous route
Suggested Data Sources	ASC operational data, including administrative records, medical records, incident/occurrence reports and quality improvement reports
Data Element Definition and Allowable Values	Admission: completion of registration upon entry into the facility; Allowable values: The count for this data element would be represented by any whole number 0 or greater Antibiotic administered on time: Antibiotic infusion is initiated within one hour prior to the time of the initial surgical incision or the beginning of the procedure (e.g., introduction of endoscope, insertion of needle, inflation of toumiquet) or two hours prior if vancomycin or fluoroquinolones are administered; Allowable values: 0 minutes to 24 hours reporting in military time format from 0:00 to 23:59; hours from 00 to 23 and minutes from 00 to 59. If unable to determine (UTD), "UTD" is assigned. Prophylactic antibiotic: an antibiotic prescribed with the intent of reducing the probability of an infection related to an invasive procedure. For purposes of this measure, the following antibiotics are considered prophylaxis for surgical site infections: Ampicillin/sulbactam, Aztreonam, Cefazolin, Cefmetazole, Cefotetan, Cefoxitin, Cefuroxime, Ciprofloxacin, Clindamycin, Erythromycin, Gatifloxacin, Gentamicin, Levofloxacin, Metronidazole, Moxifloxacin, Neomycin and Vancomycin

Patient Fall in the ASC

Intent	To capture the number of admissions (patients) who experience a fall within the ASC
Numerator/Denominator	Numerator: Ambulatory Surgery Center (ASC) admissions experiencing a fall within the confines of the ASC Denominator: All ASC admissions
Inclusions/Exclusions	Numerator Inclusion: ASC admissions experiencing a fall within the confines of the ASC Numerator Exclusion: ASC admissions experiencing a fall outside the ASC Denominator Inclusion: All ASC admissions Denominator Exclusion: ASC admissions experiencing a fall outside the ASC
Suggested Data Sources	ASC operational data, including administrative records, medical records, incident/occurrence reports and quality improvement reports
Data Element Definition and Allowable Values	Admission: completion of registration upon entry into the facility; Allowable values: The count for this data element would be represented by any whole number 0 or greater Fall: a sudden, uncontrolled, unintentional, downward displacement of the body to the ground or other object, excluding falls resulting from violent blows or other purposeful actions. (National Center for Patient Safety)

Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

Intent	To capture any ASC admissions (patients) who experience a wrong site, side, patient, procedure or implant
Numerator/Denominator	Numerator: All Ambulatory Surgery Center (ASC) admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure or wrong implant Denominator: All ASC admissions
Inclusions/Exclusions	Numerator Inclusions: All ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure or wrong implant Numerator Exclusions: None Denominator Inclusions: All ASC admissions Denominator Exclusions: None
Suggested Data Sources	ASC operational data, including administrative records, medical records, incident/occurrence reports, quality improvement reports
Data Element Definition and Allowable Values	Admission: completion of registration upon entry into the facility; Allowable values: The count for this data element would be represented by any whole number 0 or greater Wrong: not in accordance with intended site, side, patient, procedure or implant; Allowable values: The count for this data element would be represented by any whole number 0 or greater

Hospital Transfer/Admission

Intent	To capture any ASC admissions (patients) who are transferred or admitted to a hospital prior to discharge from the ASC
Numerator/Denominator	Numerator: Ambulatory Surgery Center (ASC) admissions requiring a hospital transfer or hospital admission upon discharge from the ASC Denominator: All ASC admissions
Inclusions/Exclusions	Numerator Inclusions: ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC Numerator Exclusions: None Denominator Inclusions: All ASC admissions Denominator Exclusions: None
Suggested Data Sources	ASC operational data, including administrative records, medical records, incident/occurrence reports and quality improvement reports
Data Element Definition and Allowable Values	Admission: completion of registration upon entry into the facility; Allowable values: The count for this data element would be represented by any whole number 0 or greater Hospital transfer/admission: any transfer/admission from an ASC directly to an acute care hospital including hospital emergency room; Allowable values: The count for this data element would be represented by any whole number 0 or greater Discharge: occurs when the patient leaves the confines of the ASC

10

SCA

Surgical Care Affiliates

October 30, 2007

VIA HAND DELIVERY

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3887-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3887-P - Medicare and Medicaid Programs: Ambulatory Surgical Centers, Conditions for Coverage; Proposed Rule

Dear Acting Administrator Weems:

On behalf of Surgical Care Affiliates, please accept the following comments regarding this rule, which proposes changes to the conditions for coverage (CfCs) for ambulatory surgical centers (ASCs). 72 Fed. Reg. at 50469 (August 2, 2007). We appreciate the consideration that has gone into updating these policies. We share the agency's objective of assuring that patients receive safe and appropriate care in ASCs.

With interests in 136 ASCs in 35 states, Surgical Care Affiliates is one of the largest operators of ASCs in the United States. ASCs offer outpatient surgery in a convenient, safe environment characterized by superior patient care.

I. Proposed Revisions to the ASC Conditions for Coverage

We support the comments which have been submitted under separate cover from the ASC Coalition, of which we are a member. Those comments provide detailed recommendations regarding the proposed revisions to the ASC CfCs. SCA fully supports the proposed infection control condition and the proposed quality assessment and performance improvement condition, and is particularly appreciative of the flexibility that is reflected in these proposed requirements. While we generally support the intent of many of the other conditions CMS has proposed, the details of certain of the requirements are problematic. In particular, we draw your attention to the following key issues:

Definition of an ASC (§ 416.2): The proposed definition of an ASC would prohibit Medicare-certified ASCs from performing any procedures – including procedures for non-

Medicare patients – requiring active medical monitoring beyond midnight, even when these stays are permitted for non-Medicare patients in the state where the ASC is licensed. The Medicare program already prohibits coverage of procedures requiring an overnight stay for its beneficiaries, so there is no apparent reason for this intrusion into the authority of the states to regulate the provision of services for non-Medicare patients. Based on long-standing guidance on the matter of overnight stays from CMS, many of our ASCs have invested significant time, money, and resources in developing recovery care programs for non-Medicare patients that would be jeopardized by this proposed rule. We strongly urge CMS to retain the current definition of an ASC as an entity that "operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization."

Patient admission, assessment, and discharge (§ 416.52): The rationale for this new condition is not convincing. CMS has already thoroughly evaluated the safety risks of performing the procedures Medicare covers in the ASC setting, with full consideration of the general medical condition of the typical Medicare beneficiary. Several of the newly proposed requirements lack flexibility and do not reflect current patterns of medical practice.

First, the proposed addition of a new requirement to determine the patient's mental ability to undergo the procedure is not consistent with current practice patterns. When medically indicated, these types of assessments are arranged at the direction of the physician as part of determining whether the patient is a surgical candidate, and as such, are performed when treatment options are still being considered, and well in advance of scheduling the procedure at the ASC. We believe the existing standard for a pre-surgical assessment at §416.42 (a), "[a] physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed", is appropriate and sufficient.

We are also concerned by the proposed standard for a post-surgical assessment, which would require the physician to assess *all* body systems. There is no evidence-based clinical rationale for such a broad requirement. Physicians are highly trained professionals capable of determining which body systems require review in their post-operative assessments, which vary according to the procedure performed. The proposed requirement does not acknowledge this.

Finally, the proposed requirement for a discharge order signed by the physician or other qualified practitioner who performed the surgery or procedure is very concerning. It is appropriate to require a discharge order from a physician, but the proposed language is overly restrictive and does not recognize current practice patterns. Anesthesiologists are active participants in the care of patients in many facilities. In such facilities, it is accepted medical practice for either the surgeon or the anesthesiologist to write the discharge order once the patient has recovered satisfactorily. The proposed requirement should be revised to reflect this.

Laboratory and Radiologic Services (§ 416.49): Given that ASCs will now be eligible for reimbursement for ancillary radiologic services that are integral to surgical procedures, we agree that it is appropriate to update the conditions for radiologic services. CMS has proposed that all radiological services be furnished in accordance with the portable x-ray conditions. However, those conditions would pose significant problems for most ASCs.

First, the portable x-ray conditions state that services must be provided under the supervision of a licensed physician "who is qualified by advanced training and experience in the use of x-ray for diagnostic purposes" – essentially meaning a radiologist. In addition, the portable x-ray conditions include formal training requirements for technologists. However, in ASCs, imaging services are typically performed under the direct or personal supervision of a non-radiologist physician. Most technicians have training that is limited to the radiologic modalities in use at the ASC; their administration of these radiologic services is provided under the direct or personal supervision of the non-radiology physician performing the case. A consulting radiologist often provides general supervision of the facility's radiological services. Finally, the portable x-ray conditions include detailed requirements for physician orders and documentation which are standard for diagnostic imaging procedures, but are irrelevant to intraoperative imaging guidance services, which are the most commonly performed radiological services in the ASC setting.

It will be important for the new radiologic conditions to address the provision of therapeutic radiologic services, such as brachytherapy. The hospital conditions of participation address these types of services, in addition to providing appropriate standards and safeguards for diagnostic imaging. These conditions are also sufficiently flexible to allow for current standard practices associated with intraoperative imaging guidance. Accordingly, we believe ASCs should be required to furnish radiology services in accordance with the hospital condition of participation for radiologic services at 42 C.F.R. § 482.26, rather than the portable x-ray conditions.

Patient Rights (§ 416.50): SCA supports the principle of a patient rights provision in the conditions for coverage. However, we believe that several of the proposed standards should be revised to allow additional flexibility and to take certain practical matters into account.

First, requiring that all patients receive *written* notice of their rights in a language they understand would be very challenging for ASCs serving patient populations that speak multiple languages. CMS should allow the option of an oral interpretation of the ASC's written notice of patient rights, thereby giving flexibility in addressing the needs of patients with limited English proficiency.

Second, the proposed requirement for the provision of verbal and written ownership disclosure *prior to* the first visit to an ASC is not practical. As acknowledged by several states' requirements, the duty of prior disclosure of a physician's ownership interest in an ASC rests with the physician. However, we do believe it would be reasonable for CMS to require ASCs to display a list of physician owners in a public and readily visible area of the ASC.

II. ASC Quality Reporting Measures

We also wish to express our support for the comments that have been submitted under separate cover by the ASC Quality Collaboration, another organization of which we are a member. Although this notice of proposed rulemaking does not put forth CMS's specific proposals for ASC quality measures, the ASC Quality Collaboration's remarks highlight important considerations for future rulemaking. Specifically, we wish to emphasize the following:

Quality measures for ASCs: We are pleased that ASCs will have the opportunity to report quality measures to CMS and the public in the near future. CMS should select quality measures with careful attention to whether the measure assesses processes or outcomes of care that are attributable to and reasonably the responsibility of the facility, as opposed to the physician. Given the broad range of surgical services offered in the ASC setting, we also encourage CMS to adopt measures that reflect processes or outcomes that are common to the various surgical and procedural subspecialties in order to allow broad facility participation regardless of case mix. We believe the quality measures developed by the ASC Quality Collaboration fulfill these requirements, and would be supportive of reporting these measures if they receive the endorsement of the National Quality Forum.

Quality reporting system for ASCs: CMS should implement a claims-based quality reporting system for ASCs, similar to the quality reporting system the agency has implemented for physicians. This would allow ASCs to leverage existing resources to comply with quality reporting requirements. Such a system would allow patient-level data collection without undue financial and administrative burden.

Publication of quality measures for outpatient surgery settings, including ASCs: The manner in which quality data is shared with the public should be carefully considered. At a minimum, CMS should develop a method for sharing data that would allow interested parties to easily and directly compare the quality of outpatient surgical facility services across facility types.

***

Thank you for considering the comments submitted here and under the auspices of the ASC Coalition and the ASC Quality Collaboration. We appreciate the opportunity to share our views on these important aspects of the proposed revisions to the ASC conditions for coverage and future ASC quality measures.

Sincerely,

Joe Clark
Executive Vice President and Chief Operating Officer
Surgical Care Affiliates
P.O. Box 382497
Birmingham, AL 35243

11

ASC COALITION

October 30, 2007

Kerry Weems, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3887-P
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3887-P – Ambulatory Surgical Centers Conditions for Coverage

Dear Acting Administrator Weems:

On behalf of the undersigned members of the ambulatory surgical center (ASC) community, please accept the following comments regarding changes proposed for the Ambulatory Surgical Centers Conditions for Coverage (CfCs). These comments are submitted by a diverse coalition of national and state associations and companies representing all types of ASCs – single- and multi-specialty, physician owned, joint ventures between hospitals and physicians, and joint ventures between physicians and management companies. These facilities range from the very small to the very large and are located in all parts of the nation.

We believe that it is appropriate to modernize the existing CfCs for ASCs to reflect current practice, particularly since many of the current standards have been unchanged since they were originally set forth in 1982. We appreciate the agency's careful consideration of the wide variation in the size and structure of surgery centers. We commend the agency for attempting to strike an appropriate balance in the revised standards to apply to this diverse group of providers in a way that encourages high quality patient care without being burdensome to many small providers. Unfortunately, as proposed, there is little in the proposed rule that will have a meaningful impact on enhancing the quality of care delivered in today's ASCs. In fact, many of the changes would actually significantly alter current ASC regulation and unnecessarily impact access to surgical care in many states.

Given the agency's current proposal to apply a uniform set of standards, we offer comments along several themes. First, we urge the agency to provide as much flexibility to ASCs as possible in determining how they comply with the agency's conditions. What may be appropriate for a small single specialty ASC may be irrelevant to the safe operation of a large multispecialty ASC. Second, there should be a clear connection between a proposed change in the standards and the ability of that change to improve the quality or safety of ASC services. Along that line, we are concerned that some proposals are more likely to create administrative burden and confusion for ASC patients than they are to improve patient care. Third, we urge

the agency to recognize that there are multiple regulatory components within Medicare affecting *what* services are provided and *how* ASCs operate. The agency's new definition of overnight stay is unnecessary given the rigorous process CMS employs to create the list of procedures which are payable in the ASC setting for Medicare beneficiaries.

We share the agency's desire to ensure that patients receive safe and appropriate care and that the conditions for coverage promote an environment where those goals are pursued prospectively. In many cases, we agree with the agency's proposed changes. In the comments that follow, we highlight several areas in which there is room for improvement in the agency's proposal.

A. Definitions (§ 416.2)

If implemented, the proposal to redefine an ASC as a distinct entity that operates "exclusively" for the purpose of providing surgical services to patients not requiring an "overnight stay," and then, in turn, to define an overnight stay as meaning recovery requiring active medical monitoring beyond 11:59 p.m. (i.e., midnight) on the day of the procedure, "regardless of whether it is provided in the ASC," could cause immediate havoc with ASCs and the patients they treat. We are particularly concerned with this new definition because it would prohibit Medicare-certified ASCs from performing any procedures – including procedures for non-Medicare patients – requiring active medical monitoring beyond midnight, even if such stays are permitted for non-Medicare patients in the state where the ASC is licensed. Because the Medicare program already prohibits coverage of procedures requiring an overnight stay for its beneficiaries, we see no reason for this unwarranted intrusion into the authority of the states to regulate the provision of services for non-Medicare patients.

The proposed rule provides no rationale for why it is necessary to change the current CfC definition of an ASC as an entity that operates for the purpose of providing surgical services to patients not requiring "hospitalization." *See* 42 C.F.R. § 416.2. The origins of this regulatory definition can be found in Section 1833(i)(1)(A) of the Social Security Act, which establishes the ASC benefit and provides Medicare coverage for "those surgical procedures...performed on an inpatient basis *in a hospital* but which also can be performed safely on an ambulatory basis in an ambulatory surgical center" (emphasis supplied). In other words, the Medicare statute envisions ASCs as a surgical alternative for patients *not requiring hospitalization*, which is how ASCs have been defined since Medicare coverage was first established for ASC services in 1982.

By defining an ASC by reference to hospitalization, rather than overnight stay, the current CfC rules allow overnight stays for non-Medicare patients, either in the ASC itself or in a licensed or certified recovery care unit that is distinct from the ASC and not a hospital, where such recovery care is permitted under state law. In reliance on the current policy, ASCs throughout the country have invested significant time, money, and resources in developing recovery care programs for non-Medicare patients that may be needlessly jeopardized by the CfC proposed rule. We are aware of at least 14 states that permit patients to remain in ASCs overnight.[1] In addition, a

[1] Those states are Alabama, Arizona, Arkansas, Colorado, Georgia, Illinois, Kansas, Nevada, New York, North Carolina, Ohio, Oklahoma, Tennessee, and Utah.

number of states permit extended recovery stays of up to 24, 48 and, in some cases, 72 hours in the ASC or separately licensed or certified recovery care units.

As the Medicare Payment Advisory Commission (MedPAC) observed in 2000, these recovery care centers "make up a distinct class of health care facilities that provide limited medical and nursing care to people who require short-term inpatient observation or overnight lodging for services that include pain control, drug administration and fluid maintenance."[2] According to MedPAC, "[o]ver the past two decades, these facilities have increased in number and in private-sector use as technological advances have allowed more types of surgeries to be safely performed in an ambulatory setting."[3] At the same time, post-surgical recovery care centers improve the quality of care furnished to patients by matching resources more closely to the needs of patients. In particular, highly specialized and focused professional staff is more familiar with the expected post-operative course of treatment and likely problems of patients served by recovery care centers. In addition, the nurse-to-patient ratio often is better in a recovery care center than in a hospital. Finally, by moving post-operative stays from acute care hospitals to recovery care centers, patients may avoid complications inherent to the hospital environment, especially the risk of nosocomial infection.

There is no apparent reason for CMS to cause the harm and disruption that would occur from overriding state licensure laws and regulations through a new CfC definition of ASC that would prohibit non-hospital recovery care for non-Medicare patients, even though such care is permitted in several states. If the concern is that procedures which require overnight recovery care may not be appropriate for Medicare's elderly patient population, we believe the agency's recent rule revising the ASC procedure list is the appropriate vehicle to affect the type of care delivered to Medicare beneficiaries in ASCs. The criteria for procedures to be placed on the list already include a prohibition on Medicare coverage for any services that routinely require an overnight stay.

As drafted in the CfCs, the prohibition on overnight stay would also inappropriately restrict care of non-Medicare patients, including conflicting with state laws and regulations permitting such practice. There is no evidence that overnight recovery is unsafe, and in fact many states have explicit statutory provisions providing for this practice. In fact, patients served in post-surgical recovery care centers tend to be relatively healthy, with few co-morbid conditions. Moreover, many of the specific procedures most suitable for post-surgical recovery care, such as plastic surgery, ear, nose and throat procedures, anterior cruciate ligament reconstruction and breast reduction surgery, are not frequently performed in the Medicare age group.

CMS should not adopt a definition of ASC that prevents Medicare-certified facilities from providing these kinds of services to non-Medicare patients. Members of the ASC community are concerned that if faced with the choice of retaining Medicare certification under the proposed definition of ASC or forgoing the provision of recovery care services to non-Medicare patients, a

[2] Medicare Payment Advisory Commission, *Medicare Payment for Post-Surgical Recovery Care Centers*, at 3 (November 2000).

[3] Id. at v.

significant number of facilities simply may choose to opt out of Medicare, thus needlessly limiting beneficiary access.

We strongly urge CMS to retain the current CfC definition of an ASC as an entity that "operates exclusively for the purpose of providing surgical services *to patients not requiring hospitalization.*" The proposed revision would override state law and regulation, limit access to ASC services of Medicare and non-Medicare patients, and provide no assurance that the criterion would improve the quality or safety of ASC procedures. If CMS wishes to further define an ASC, and prevent the rolling back of services that had previously been available in ASCs, we propose the following definition that would continue to permit overnight stays for non-Medicare patients where permitted under state law:

> *Ambulatory Surgical Center or ASC* means any distinct entity that operates exclusively for the purpose of providing surgical services to patients whose recovery under normal circumstances will not require hospital inpatient care, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

CMS might also consider defining ASC by reference to the provision of "outpatient" care because of their linkage to the outpatient hospital prospective payment system (OPPS). Like the hospital outpatient standard, there would again be no specific requirement to discharge a patient at a particular time. Language along the lines of the following would distinguish an ASC from a hospital outpatient department:

> *Ambulatory Surgical Center or ASC* means any distinct entity that is not provider-based, as defined in § 413.65 of this chapter, and that operates exclusively for the purpose of providing surgical services on an outpatient basis, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

Finally, if CMS persists in retaining a provision prohibiting overnight stays, we urge you to preserve the right of ASCs to perform procedures which might involve overnight stays for non-Medicare patients, where permitted under state law, by modifying the proposed rule's definition. CMS should not restrict ASCs' ability to discharge such a patient to an alternative setting if the patient's medical condition requires more skilled care than what is available in the patient's home.

Retaining the proposed overnight stay criterion will promote the migration of many cases into the hospital outpatient or inpatient setting at a higher cost to the Medicare program and the beneficiary. Providers fear jeopardizing their Medicare participation or payment because of the unforeseen need to transfer a patient or keep them in the facility beyond midnight. Implementing such a standard does not encourage safer or higher quality care—it merely promotes more expensive care.

B. Specific Conditions for Coverage

1. Governing Body and Management (§ 416.41)

The ASC community generally supports the proposal to expand the Governing Body and Management condition to require the governing body to (1) assure direct oversight and accountability for the quality assessment program, and (2) create and maintain an internal disaster preparedness plan. We believe an effective quality assessment program and internal disaster preparedness plan are essential to promoting quality care and patient safety, so that responsibility for their development and implementation is an appropriate responsibility of the governing body.

We have two concerns with the language used in the proposed disaster preparedness plan standard at § 416.41(c):

- While the first section of the Standard for the Disaster preparedness plan (§ 416.41 (c) (1)) is clearly focused on the obligation to prepare for a disaster affecting an ASC's own patients and staff, the second section (§ 416.41(c)(2)) appears to address the need to prepare for a disaster outside the confines of the ASC. Specifically, we are concerned that requiring ASCs to "coordinate" their plans with state and local agencies, as currently proposed in § 416.41(c)(2), could be broadly construed as imposing an affirmative duty on ASCs to integrate their facilities into state and local disaster relief efforts.

  The typical ASC is neither staffed nor equipped to handle more than the emergency care of its own patients and, thus, would not be a suitable emergency care site in the event of a broader, external disaster. Generally, when disasters have struck communities, ASCs have volunteered their staff for the provision of disaster services at the immediate site of the disaster or at local hospitals. We recognize the legitimate need of state and local authorities to receive assurances that ASCs have appropriate plans in place for handling their own patients during a disaster. Therefore, to meet this need, while avoiding the implication of broader duties not appropriate for many ASCs, we suggest renaming the proposed standard as "Internal disaster preparedness plan" and rephrasing the proposed standard at § 416(c)(2) to provide as follows: "The ASC *communicates* the plan to State and local agencies, as requested or as required under applicable law."

- We also believe that the proposed standard in § 416(c) (3) requiring that corrective action in response to disaster preparedness drills be implemented "immediately" may be counterproductive. In many cases, meaningful corrective action takes time to implement; the most immediate fix is not always the best or most effective. At the same time, undue delay in addressing known short comings with a disaster preparedness plan should not be tolerated either. Thus, we believe the right balance here is struck with a requirement for prompt or timely corrections, rather than immediate action.

2. Quality Assessment and Performance Improvement (§ 416.43)

The ASC community supports the proposal to revise the existing quality assessment standard to require a more proactive quality assessment and performance improvement (QAPI) program. As you know, the ASC community has been active in developing measures appropriate to the ASC setting. Those measures, under review by the National Quality Forum, will hopefully form the

foundation of quality reporting initiatives in ASCs as mandated by the Congress in the Tax Relief and Health Care Act of 2006 (Public Law 109-432).

We appreciate that the proposed rule does not try to prescribe a "one-size-fits-all" QAPI program but, instead, provides ASCs with the flexibility to select their own quality indicators and performance measures, to set their own priorities for program activities and to design performance improvement projects that reflect the scope and complexity of each ASC's services and operations. We agree that ASCs should be able to determine how best to implement a QAPI program appropriate for improving the processes and outcomes relevant to the services they provide and the patients they serve.

3. Laboratory and Radiologic Services (§ 416.49)

In the proposed rule, CMS revises the standards for radiology to say that all radiological services, whether furnished directly or under arrangements, must be furnished in accordance with the portable x-ray conditions. This inappropriately eliminates ASCs' ability to comply with the radiological services standard by demonstrating compliance with the hospital conditions for radiology, as is currently allowed. The portable X-ray conditions are inappropriate for many ASCs, add administrative burden to these facilities, and fail to contribute to improved safety or quality for ASC patients.

We are aware that CMS is concerned about the proliferation of diagnostic imaging services in many communities and commensurate growth in Medicare expenditures for these services. Unlike referrals for diagnostic imaging, the diagnosis is already known for most patients treated in an ASC and a surgical intervention determined to be the best treatment. As such, the imaging service must be integral to the performance of the surgical procedure in order for it to be reimbursed by Medicare.

The portable x-ray conditions present a number of significant problems for a typical ASC:

- First, § 486.102(b) of the portable x-ray conditions states that portable x-ray services must be provided under the supervision of a licensed physician "who is qualified by advanced training and experience in the use of x-ray for diagnostic purposes" (emphasis added) – essentially meaning a radiologist. In ASCs, however, radiologic services are typically are performed under the direct or personal supervision of a surgeon or non-radiologist physician. Indeed, a radiologist's supervision would be neither practical nor useful in cases where the radiology services are performed intraoperatively to aid and guide the surgeon.

- Second, § 486.104(a) of the portable x-ray conditions require formal training in x-ray technology through an accredited program, college or university for all operators of portable x-ray equipment. However, many technicians who assist surgeons in the practice of imaging guidance services in ASCs would not meet these requirements and have no opportunity to be grandfathered into compliance. These technicians are specifically trained by the ASC to operate the particular imaging modality used during a procedure. The portable X-ray standards are aimed at technologists performing

diagnostic radiology services using a broad array of imaging modalities and for whom operating of the imaging equipment is their primary responsibility. Given the acute shortage of radiology technicians trained to compliance with the portable X-ray standard, imposition of this criterion represents an insurmountable barrier to providing imaging services integral to the performance of a surgical procedure.

- Third, § 486.106 of the portable x-ray conditions requires a written physician's order specifying "the reason an x-ray test is required, the area of the body to be exposed, the number of radiographs to be obtained, and the views needed," as well as documentation in the patients record of "a description of the procedures ordered and performed, the referring physician, the operator(s) of the portable x-ray equipment who performed the examination, the physician to whom the radiograph was sent, and the date it was sent." In many cases, the reason for the test being done is often provided in the clinical documentation rather than the order. As described in the proposed rule, order and documentation requirements have practical utility for diagnostic imaging procedures, but are irrelevant to intraoperative imaging services. In the case of imaging services performed post-operatively, for example to confirm placement of a device, a written order and other documentation would naturally be included in the patient's record. A standard in the CfCs is not necessary to enforce this practice, as appropriate documentation is necessary for an ASC to bill for an imaging service integral to the performance of a surgical procedure.

In short, mandatory compliance with the portable x-ray conditions would be impractical for the intraoperative radiology services most commonly performed in ASCs today, including fluoroscopic and ultrasonic guidance. This, in turn, would make it difficult, if not impossible, for most ASCs to perform procedures requiring imaging guidance – procedures that now are routinely performed in ASCs.

The most appropriate way to resolve this issue is to retain the current option of allowing ASCs to furnish radiology services in accordance with the hospital conditions of participation pertaining to radiology services at 42 C.F.R. § 482.26. Unlike the portable x-ray conditions, the hospital conditions allow the provision of radiology services integral to surgical procedures by providing more flexible supervision, personnel and documentation requirements. Specifically, the hospital conditions only require general supervision of "ionizing radiology services" by a "qualified full-time, part-time, or consulting radiologist.[4] Moreover, a radiologist is needed to "interpret only these radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge."[5] Similarly, the hospital conditions allow the facility medical staff to designate the qualifications of radiology technicians and contain less prescriptive ordering and documentation standards more suitable to the provision of imaging services integral to the performance of a surgical procedure.[6]

[4] 42 C.F.R. § 482.26(c)(1).

[5] Id.

[6] Id. at § 482.26(b)(4), (c)(2) and (d).

ASCs that provide radiology services are familiar with the hospital conditions and have been safely operating in accordance with those requirements for many years. Further, the hospital conditions of participation also govern therapeutic radiologic procedures. Because ASCs will be able to provide brachytherapy and other therapeutic radiologic services to Medicare beneficiaries under the revised ASC payment system, it is important for the revised CfCs to address this type of service as well.

Therefore, absent any evidence of patient safety or quality of care concerns with radiology services now routinely performed in ASCs, we urge CMS to retain the option of compliance with the hospital conditions of participation for radiology services.

4. Patient Rights (§ 416.50)

The ASC community is fully committed to safeguarding patient rights. We completely support the principle of including a patient rights provision in the conditions for coverage. Nonetheless, several of the proposed standards at § 416.50 should be revised.

- Proposed § 416.50(a)(1) requires that all patients receive written notice of their rights in a language they understand. This requirement sets an unreasonably high standard for ASCs that treat diverse patient populations speaking multiple languages. The ASC community supports the idea that ASCs should translate their notices of patient rights into the languages of non-English speaking groups frequently encountered at their facilities. The Department of Health and Human Services recognized, in its 2003 *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*, that some flexibility was needed in addressing the needs of limited English proficient (LEP) patient populations:

> "The languages spoken by the LEP individuals with whom the recipient has contact determine the languages into which vital documents should be translated. A distinction should be made, however, between languages that are frequently encountered by a recipient and less commonly-encountered languages. Some recipients may serve communities in large cities or across the country. They regularly serve LEP persons who speak dozens and sometimes over 100 different languages. To translate all written materials into all of those languages is unrealistic. Although recent technological advances have made it easier for recipients to store and share translated documents, such an undertaking would incur substantial costs and require substantial resources....As a result, the extent of the recipient's obligation to provide written translations of documents should be determined by the recipient on a case-by-case basis..."[7]

Similar flexibility should be applied in the ASC conditions for participation. Thus, we suggest deleting the reference to "verbal and written" notice in § 416.50(a)(1), so that ASCs

[7] 68 Federal Register 47311, 47319 (Aug. 8, 2003).

are able to determine the most effective means of notifying patients of their rights. In accordance with the *HHS LEP Guidance*, in appropriate cases this may include, for example, providing "written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of...written materials, free of cost," rather than a full written translation.[8]

- Second, the requirement in proposed § 416.50(a)(1)(ii) mandating that written ownership disclosure information be furnished to patients *prior to* the first visit to an ASC could disrupt patient care and inconvenience patients. The proposal to include this standard is not practical nor will it lead to improvements in patient care. The decision as to where surgery is performed is made by the physician and patient, and so if there is to be a requirement for prior disclosure of a physician's ownership interest in an ASC, that duty properly should rest with the physician, as many state's currently require in their medical practice acts.[9]

  Moreover, prior notice from the facility is not practical when surgery is scheduled on short notice. The facility's ability to furnish a patient information verbally and in writing prior to their first visit is often precluded by scheduling constraints. The facility has no means of ensuring that the physician making the referral to the ASC provided the information to the patient (the point at which decisions about what care is appropriate and where it should be delivered are made). It may also lead to unnecessary delays in patients receiving needed services if the ASC cannot mail information to the patient until the patient or physician contacts the ASC to schedule a procedure. In many cases, the ASC's initial contact with the patient occurs on the day of their procedure, as many physician offices handle scheduling and patient education without involving the staff of the ASC.

  It does not benefit patient care to have ASCs turn patients away because they did not receive an ownership disclosure notice prior to arriving at the facility. If the intent of CMS is to evaluate how patient referral decisions are made, it would make more sense to furnish information on which physicians have an ownership interest in an ASC rather than the nature of the financial relationships. This can easily be posted in a public area of an ASC along with the other notices of patients' rights. CMS could also collect the ownership information through the enrollment process or by separate reporting to its administrative contractors.

- Third, the advance directives requirements in proposed § 416.50(a)(2) are unnecessarily extensive given their limited applicability in ASCs. Because most procedures performed

[8] Id.

[9] For example, see For example, see California Business and Professions Code § 650.01(f) (a physician who makes a referral to "an organization in which the [physician] has a financial interest, shall disclose the financial interest...in writing, at the time of the referral or request for consultation"). In addition to California, at least 20 other states require physicians to disclose ownership interests to patients, including Arizona, Connecticut, Florida, Georgia, Hawaii, Kansas, Louisiana, Maryland, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia and West Virginia.

at ASCs involve elective short-stay surgery in patients who are candidates for outpatient procedures, advance directives that include a "do not resuscitate" or similar directive are often suspended. It is standard practice for ASCs to discuss any policies leading to this temporary suspension of "do not resuscitate" directives with patients to ensure that they consent.

As health care facilities devoted to the provision of surgical care to patients who are candidates for the outpatient setting, it does not seem reasonable to require ASCs to actively promote the use of advance directives in the manner that CMS suggests. Specifically, we do not think it is appropriate to require ASCs to provide official state advance directive forms on request. In addition, the proposal to require "prominent" documentation of advance directives is unnecessary; we believe that routine documentation is sufficient. We also believe that ASCs should be allowed flexibility in the manner in which their advance directive policies are shared with the patient. In this instance, accreditation standards provide a more practical approach; that is, ensuring that the patient be made aware of the ASCs policy concerning advanced directives. We recommend replacing the current proposed 416.50(a)(2) with the accreditation standard that "information is made available to patients and staff concerning... advance directives".

- Fourth, we suggest rephrasing the grievance reporting requirement at proposed § 416.50(a)(3)(iii). We do not think that it would be appropriate for ASCs to inundate government officials with immaterial and unsubstantiated patient complaints, and recommend revising this provision to require the following:

  > All allegations must be promptly reported to a person in authority at the ASC and, if determined to constitute a violation of applicable laws, regulations or health care program requirements, to appropriate federal, state or local authorities.

- Finally, the confidentiality of clinical records standard at proposed § 416.50(d) creates unnecessary confusion with the more comprehensive HIPAA privacy standards applicable to ASCs.[10] More specifically, the proposed rule provides that "[a]ccess to or release of patient records is permitted only with written consent of the patient or the patient's representative or as authorized by law." While this is not inconsistent with the HIPAA standards, we note that the HIPAA standards permit routine disclosures *without* patient consent for purposes of payment, treatment and health care operations. Rather than having surveyors perform this two-step analysis, it would be far better if the ASC conditions simply cross-referenced the HIPAA standards; i.e., access to or release of patient information and clinical records is permitted only in accordance with 42 C.F.R. Parts 160, 162, and 164.

5. Infection Control (§ 416.51)

[10] See 45 C.F.R. §164.02 & §164.05

CMS proposes to add a new standard for ASCs to operate an infection control program for patients and ASC staff that seeks to minimize infections and communicable diseases. The new standard elevates infection control from its current position as part of the physical environment standard.

Significantly lower risk of infection is one of the primary advantages of ASCs over hospital-based surgery. The exemplary infection control record of the ASC industry, as a whole, has been hard-earned through proactive and widespread use of state-of-the-art preventive measures, as well as extensive education and training. For the most part, this success has been achieved without prescriptive regulatory standards, and we appreciate that the proposed infection control condition does not mandate any specific set of infection control guidelines and allows flexibility for ASCs to determine how to meet the objectives of preventing, controlling and investigating infections.

As discussed in the rule, ASCs have been required to have an infection control program in place under the current CfCs. As such, the new standard imposes few changes that will require ASCs to modify their activities. However, the new standard does require ASCs to include infection control as one of the areas monitored as part of the proposed QAPI program. We appreciate the agency's continued commitment to allowing ASCs to choose which professionally recognized standards to implement to best meet the needs of their facility and how best to measure the success of those programs. As with the proposed QAPI program standards, the most effective infection control programs are those tailored to the unique needs of each individual facility.

We also note that CMS would now require each ASC to designate a qualified professional, such as a registered nurse, as an infection control officer. The standard further requires that professional to undergo annual continuing education training. We are concerned that the agency has specified a 'target' amount of continuing education of 4 hours per year that the infection control officer must complete. Given the many ways in which infection control information is disseminated, we hope that the interpretive guidance for the standards will allow ASCs multiple avenues to demonstrate that their infection control officer has received adequate training.

We also ask that CMS confirm that the requirement in proposed § 416.51(b)(1) that an ASC's infection control program be directed by a "qualified professional who has training in infection control" should <u>not</u> be read as mandating any particular infection control credentials or certification. Rather, consistent with the general approach in this section, this statement includes the flexibility for each ASC to determine the qualifications and training needs for its infection control officer. However, it would be helpful to have confirmation of that interpretation in the final rule.

We also request that CMS provide flexibility in designating the infection control officer so that a qualified professional could serve as the infection control officer for multiple facilities connected by common ownership or investment. In such a situation, a dedicated professional may be more effective than an individual in each facility because their exposure to the experiences in multiple facilities may speed the dissemination of best practices and coordinate the collection and reporting of infection control data through the QAPI program.

We appreciate the agency's flexibility in allowing ASCs to determine the method of cleaning and sterilization of equipment utilized in ASC procedures. ASCs have long recognized that the proper cleaning and sterilization of equipment used in multiple patient encounters is critical to ensuring the health of their patients and staff.

6. Patient admission, assessment, and discharge (§ 416.52)

CMS has proposed a new condition that would impose additional requirements for pre-surgical and post-surgical assessments and discharge. The agency has stated that its rationale for proposing these requirements rests on the expansion of the list of procedures for which CMS will provide payment in ASCs and the greater risks faced by older patients undergoing surgical procedures. CMS states that the agency seeks "to ensure that accurate and thorough assessments are conducted."

We question the rationale for this new condition. CMS has indeed expanded the number of procedures that will be eligible for Medicare reimbursement in the ASC setting, but has done so only after subjecting each new procedure not only to detailed review by its medical advisors, but also to public comment as a means of ensuring that every one of them can indeed be safely performed for Medicare beneficiaries in the ASC setting. In short, CMS has already thoroughly and rather exhaustively evaluated the safety risks of performing these procedures in the ASC setting, and has done so with full consideration of the general medical condition of the typical Medicare beneficiary.

Further, analysis of the procedures that are newly eligible for Medicare payment in the ASC setting reveals that the more than two-thirds are procedures that CMS considers to be office-based because they are performed in physician offices more than half the time. The remaining procedures are already performed in the hospital outpatient setting for Medicare beneficiaries and are clearly appropriate ambulatory services. Outdated Medicare coverage standards have been the principal barrier to ASC access for these services. The recent revisions in these standards will merely allow Medicare beneficiaries the option of having these services performed in an ASC – a choice that has been available to privately insured individuals in the ASC setting for years. Imposing additional conditions because these outpatient procedures will now be covered by Medicare in the ASC is not justified, particularly since CMS has deemed them safe.

We know of no evidence demonstrating that the current standards have been ineffective in safeguarding Medicare beneficiaries. Before imposing additional clinical and administrative requirements on the ASC provider community, CMS should reveal any evidence it has concerning systemic issues that would necessitate these additional requirements.

Pre-surgical and post-surgical assessments

The existing standard for a pre-surgical assessment at §416.42 (a) adequately addresses this important prerequisite to ASC services, by requiring that "[a] physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed." Several additional requirements included in §416.52 should be reconsidered and revised:

- The proposed pre-surgical assessment standard adds a new requirement to determine the patient's mental ability to undergo the procedure. This new requirement is not consistent with currently accepted medical practice patterns. Requiring determination of a patient's mental ability to undergo the procedure appears to invoke a requirement for a psychological and/or psychiatric assessment in the immediate preoperative period, after the patient has already arrived at the ASC. This is not the appropriate time or place for such an assessment, which, if necessary, is arranged under the direction of the physician as part of the process of determining whether the patient is a surgical candidate. When indicated, this type of assessment is performed well in advance of scheduling the procedure at the ASC, while treatment options are still being considered.

- Also of concern is the proposed standard for a post-surgical assessment, which would include a requirement that a "thorough assessment of the patient's post-surgical condition must be completed and documented in the medical record." The preamble to this proposed rule suggests that in order to complete a "thorough" assessment, the physician would need to assess all body systems. CMS has moved beyond standard practice to propose requirements that are not medically necessary. Consider the examples of cataract surgery, gastrointestinal endoscopies and pain management injections, which are some of the most commonly performed procedures for Medicare beneficiaries in the ASC setting. It is not necessary for a physician to perform a post-operative assessment of *all* body systems for these services. There is no evidence-based clinical rationale for such a broad requirement. Physicians are highly trained professionals capable of determining which body systems require review in their post-operative assessments, which are by nature variable according to the procedure performed. The proposed requirement does not acknowledge this.

- We agree that the postoperative condition of the patient should be assessed and documented in the medical record. This is consistent with current standards of medical practice. However, we propose that the requirement for a post-operative assessment be revised to state, "The patient's post-surgical condition must be documented in the medical record by a qualified practitioner." This would assure documentation of the post-operative assessment, while still allowing the practitioner sufficient flexibility to determine the assessment appropriate to the nature and scope of the procedure performed as well as the specific medical condition of the individual patient.

Discharge orders

We are also concerned with the new requirements with respect to discharge orders. The existing requirement at §416.62 (a), "[b]efore discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery," is appropriate and should be retained. However, we find that the current language is flawed in limiting the evaluation to "proper anesthesia recovery," which excludes patients that may not have had anesthesia. This standard should be

moved to the newly created discharge standard and revised to read, "Before discharge from the ASC, each patient must be evaluated by a physician."

- With respect to the proposed requirements proposed under the discharge standard, we agree that providing written discharge instructions is appropriate and reflective of standard medical practice. However, the language requiring that the ASC "ensure the patient has a safe transition to home and that the post-surgical needs are met" is overly broad. Requiring an ASC to ensure a "safe transition to home" assumes that the ASC has control over the patient after he or she leaves the ASC, that the ASC has control over the automobile or other vehicle used to transport the patient, and that the ASC has control over the environs the patient encounters after they have left the confines of the ASC. It further assumes that the patient is returning home, when this may not be the case, either because the patient does not live at home in the first place or because the patient has made arrangements to stay in another location following their procedure. We are also concerned by the requirement that ASCs are to ensure "that the post-surgical needs are met." This is very broad, and as currently written, beyond the scope of the ASC. The patient may have post-surgical needs that are not within the scope of services provided by the ASC, but rather by the physician performing the procedure or another provider, such as a physical therapist. The ASC should not be put in the position of having to ensure the patient's care by other providers. We favor retention of the current discharge standard at §416.62 (d) which requires that, "[a]ll patients are discharged in the company of a responsible adult, except those exempted by the attending physician." This standard is appropriate and has been a sufficient safeguard for decades. The proposed language at §416.52 (c)(2) should be abandoned.

- The requirement for a discharge order, signed by a physician or the other qualified practitioner who performed the surgery or procedure indicating that the patient has been evaluated for proper anesthesia and medical recovery should be revised. While it is appropriate to require a discharge order from a physician, the proposed language is overly restrictive and does not recognize current practice patterns. In many facilities anesthesiologists are available to care for patients once the procedure has been completed, and the patient has been moved to the recovery area. In such facilities, it is accepted medical practice for either the surgeon or the anesthesiologist to write the discharge order once the patient has recovered satisfactorily. Therefore the proposed language at §416.52 (c)(3) should be revised to read, "Each patient must have a discharge order, signed by a physician or other qualified practitioner unless otherwise specified by State law."

Finally, we note the lack of similar standards for pre-operative assessments, post-operative assessments and discharge requirements for surgical services provided to Medicare beneficiaries in a hospital. Although Medicare pays HOPDs for procedures with much higher associated risk, there are no comparable conditions requiring assessments or dictating the manner in which the patient is to be discharged in those facilities. Further, the conditions proposed here are much more stringent than those that have been developed by independent accrediting bodies, which are generally regarded as the appropriate standard setting bodies for health care providers. These

organizations have recognized expertise in developing provider-specific standards and guidelines that are appropriate and effective in ensuring safe delivery of patient care without being unduly burdensome.

In summary, CMS should retain the current standards at §416.42 (a) and §416.42 (d) as there is no evidence that revision is needed. The expansion of the ASC list to include additional procedures that CMS has deemed safe for Medicare beneficiaries in the ASC setting is not a satisfactory rationale for imposing additional provider burdens, many of which are not consistent with current standards of medical practice and are marked by unnecessary inflexibility. The recommendations we are making with respect to the standards and conditions in §416.52 are complicated. To summarize our suggestions, we have attached Table 1, which illustrates how the standards and conditions in this section should be revised.

***

Thank you for your consideration of our comments on the proposed Conditions for Coverage.

Sincerely,

Joseph Banno, MD
President
American Association of Ambulatory Surgery Centers

Kathy Bryant
President
FASA

Ken P. McDonald
Immediate Past President
AmSurg Corp.

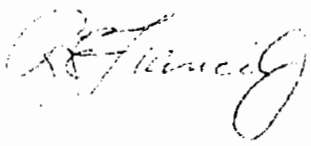
David Shapiro, M.D.
Florida Society of Ambulatory Surgery Centers

Joseph T. Clark
Executive Vice President and Chief Operating Officer
Surgical Care Affiliates

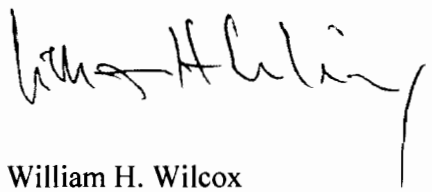
Randy Leffler
Executive Director
Ohio Association of Ambulatory Surgery Centers

Richard D. Pence
Chief Operating Officer
National Surgical Care

Thomas Hall
President and Chief Executive Officer
NovaMed, Inc.



Richard Francis
Chairman and Chief Executive Officer
Symbion, Inc.



William H. Wilcox
President & Chief Executive Officer
United Surgical Partners International

Table 1. Summary of Current, CMS Proposed and ASC Community Proposed Conditions for Coverage

Current Conditions for Coverage	Conditions for Coverage Proposed by CMS	Conditions for Coverage Proposed by ASC Coalition
§416. 42 (a) Standard: Anesthetic risk and evaluation. A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.	§416.52 (a) Standard: Admission and pre-surgical assessment. (1) Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with State law and ASC policy. (2) Upon admission, each patient must have a pre-surgical assessment that includes, at a minimum, an updated medical record entry documenting an examination for any changes in the patient's condition since the most recently documented medical history and physical assessment. The assessment must include documentation to determine the patient's physical and mental ability to undergo the surgical procedure, and any allergies to drugs and biologicals. (3) The patient's medical history and physical assessment must be placed in the patient's medical record before the surgical	§416.52 (a) Standard: Admission and pre-surgical assessment. (1) Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with State law and ASC policy. (2) The patient's history and physical must be placed in the patient's medical record before the surgical procedure is started. (3) A qualified practitioner must document any allergies to drugs and biologicals in the patient's medical record. (4) A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.

	procedure is started.	
	§416.52 (b) Standard: Post-surgical assessment. (1) A thorough assessment of the patient's post-surgical condition must be completed and documented in the medical record. (2) Post-surgical needs must be addressed and included in the discharge notes.	§416.52 (b) Standard: Post-surgical assessment. (1) The patient's post-surgical condition must be documented in the medical record by a qualified practitioner.
§416. 42 (d) Standard: Discharge. All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.	§416.52 (c) Standard: Discharge. The ASC must - (1) Provide each patient with written discharge instructions. (2) Ensure the patient has a safe transition to home and that the post-surgical needs are met. (3) Ensure each patient has a discharge order, signed by a physician or the other qualified practitioner who performed the surgery or procedure unless otherwise specified by State law. The discharge order must indicate that the patient has been evaluated for proper anesthesia and medical recovery.	§416.52 (c) Standard: Discharge. (1) The ASC must provide each patient with written discharge instructions. (2) Before discharge from the ASC, each patient must be evaluated by a physician. (3) Each patient must have a discharge order, signed by a physician or other qualified practitioner unless otherwise specified by State law. (4) All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.

ASC Quality Collaboration

October 30, 2007

VIA HAND DELIVERY

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3887-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3887-P; Background

Dear Acting Administrator Weems:

On behalf of the ASC Quality Collaboration, a cooperative effort of organizations and companies interested in ensuring that ambulatory surgical center (ASC) quality data is appropriately developed and reported, please accept the following comments regarding CMS-3887-P, Section I. Background as it pertains to quality measures appropriate to ambulatory surgical centers (ASCs). Early in 2006, the ASC Quality Collaboration came together to initiate the process of developing standardized ASC quality measures. The organization's stakeholders include ASC corporations, ASC associations, professional societies, accrediting bodies and government entities. We are pleased that Section 109 of the Tax Relief and Health Care Act of 2006 (TRHCA) will afford ASCs the opportunity to share standardized quality indicators with CMS and the public.

In this proposed rule, CMS solicits comments on quality measures appropriate to ASCs. Specifically, CMS has requested information regarding the extent to which ASCs are currently using quality measures, the data sources for those measures, and the extent to which data are maintained electronically. CMS also expressed an interest in how the measures were developed and why they are appropriate to measure the care provided to Medicare patients in ASCs. We appreciate this opportunity to share our knowledge of these matters with the agency.

I. Use of Quality Measures

Approximately 4600 ASCs are certified by the Medicare program. As certified providers, these ASCs maintain internal programs designed to assess the quality of care provided. These programs must monitor key indicators of quality and appropriateness on an ongoing basis and the information gathered is to be used to improve patient care.

In addition to being certified, many ASCs are also accredited by organizations such as the Accreditation Association for Ambulatory Health Care, the American Osteopathic Association

and The Joint Commission. Participation in this voluntary activity gives ASCs an opportunity for ongoing independent third party assessments of quality and performance against nationally recognized standards. Accreditation requirements include participation in quality improvement and benchmarking activities.

ASCs also have the opportunity to participate in clinical benchmarking programs offered by ASC industry associations such as FASA and the American Association of Ambulatory Surgery Centers; professional societies such as the Association of Perioperative Registered Nurses; and non-profit organizations, such as the AAAHC Institute for Quality Improvement . Participation allows ASCs to compare clinical indicators with their peers and identify opportunities for improvement.

While ASCs currently use a broad variety of programs and measures to assess quality and performance, these are not standardized across the industry.

II. Development of Outpatient Surgical Facility Quality Measures by the ASC Quality Collaboration

The quality of facility services for outpatient surgery is most appropriately evaluated by measures specifically designed to assess processes or outcomes of care germane to the specific services rendered by facilities that provide these services. It is crucial that measures selected for the evaluation of facility quality reflect processes or outcomes of care that are attributable to and reasonably the responsibility of the facility itself -- its staff, the equipment, the environment of care offered to its patients, and its roles in the delivery of patient care.

When the ASC Quality Collaboration was formed, we undertook a detailed evaluation of existing nationally endorsed quality measures to determine which could be directly applied to the outpatient surgery facility setting. Though several existing measures addressed surgical care, none had been developed specifically for the ASC setting. In fact, many of these measures are specific to procedures that are either uncommonly performed in outpatient facilities, or not performed at all for Medicare beneficiaries in the outpatient surgical setting. Other measures expressly exclude patients with a stay of less than 24 hours, effectively eliminating the entire ASC patient population. Still other measures focus on processes of care that are specific responsibilities of physicians, such as the selection and ordering of antibiotics.

Finding no nationally endorsed measures designed for public reporting and accountability specific to facilities performing outpatient surgery, the ASC Quality Collaboration developed a number of facility-level measures of ASC quality. These measures were based on those already commonly used by the ASC community for internal quality assessment and external benchmarking. After refining these standardized measures, the ASC Quality Collaboration piloted them in a sample of twenty ASCs and was able to confirm their feasibility and usability. To date, these measures have been reviewed by a technical advisory panel and a steering committee of the National Quality Forum (NQF). As a result of these evaluations, five measures have been recommended for endorsement. Public and NQF member comment on these five measures closed in September and NQF member voting is currently in progress. We anticipate that final action on these measures could be taken as early as November 2007.

One of the principles that guided the ASC Quality Collaboration was harmonization – the idea that the measures developed through our efforts should be applicable to all facilities offering ambulatory surgery, allowing comparison of quality across sites of service. The ASC measures currently under consideration for endorsement by the NQF are appropriate for other outpatient surgical settings, effectively addressing the need to harmonize quality measures whenever possible.

Of the five measures, four are outcome measures that have applicability to all outpatient surgical facilities and thereby ensure broad facility participation regardless of case mix. These measures focus on 1) patient falls, 2) patient burns, 3) hospital transfer/admission and 4) wrong site/wrong side/wrong patient/wrong procedure/wrong implant. The fifth measure is a process measure which evaluates the timing of the administration of intravenous antibiotics for prophylaxis of surgical site infection. This prophylactic antibiotic timing measure has been specifically designed to harmonize with, and be complementary to, similar measures (see, for example, PQRI #20 and PQRI #30) developed to evaluate physician performance in this area. Please see Attachment A for detailed information on the five outpatient surgical facility-specific quality measures.

The prophylactic antibiotic timing measure also addresses the statutory requirement under TRHCA for evaluation of medication errors. In their recent *MEDMARX® Data Report: A Chartbook of Medication Error Findings from the Perioperative Settings from 1998-2005*, the U.S. Pharmacopeia detailed the various types of medication errors in outpatient surgery, one of which was "wrong time." The report specifically recommended "[d]eveloping strategies to ensure that medications, especially antimicrobial agents, are administered at the correct time."

As of this writing, we are not aware of any other measures specifically addressing facility quality in the delivery of outpatient surgical services that have either been nationally endorsed for public reporting and accountability or are in the process of evaluation for endorsement. Therefore, we strongly recommend CMS consider these five facility-specific measures for ASC reporting, if they are endorsed by the NQF.

III. Appropriateness of ASC Quality Collaboration Measures

As noted above, the measures developed by the ASC Quality Collaboration were based on those commonly used by the ASC community for internal quality assessment and external benchmarking. As such, they measure processes or outcomes of care that are appropriate to the ASC setting. The specific rationale and applicability of each of the five measures that are currently in process for potential NQF endorsement are discussed in more detail below.

A. Patient Burn

There are numerous case reports in the literature regarding patient burns in the surgical and procedural setting. The diversity of the causative agents underscores the multitude of potential risks that must be properly mitigated to avoid patient burns.

The literature on burns suggests that electrosurgical burns are most common. In 2000, a Joint Commission Sentinel Alert indicated "burns from electrocautery used with a flammable prep solution" as one of the seven most frequent operative and postoperative complications.[1] A survey of members of the American College of Surgeons found that 18% of respondents had personally experienced an electrosurgical burn to their patient during laparoscopy.[2] A recent publication from the ECRI highlights the increased risk of burns with newer surgical devices that apply higher currents at longer activation times.[3]

Although electrical burns are most prevalent, other mechanisms of burn injury are frequently reported in case studies and case series. For example, a case series of 19 patients with intraoperative burn accidents severe enough to require subsequent surgical treatment found that although 13 were caused by electrical burns, five were caused by chemical burns and one had an unclear etiology.[4] A closed claims analysis of 3000 claims found that of 54 burns, 28 were caused by patient warming devices.[5]

Surgical fires are rare; however, their consequences can be grave, killing or seriously injuring patients and surgical staff. The risk of surgical fires is present whenever and wherever surgery is performed, whether in an operating room, a physician's office, or an outpatient clinic.[6,7] Based on anecdotal evidence, there are at least 20-30 surgical patient fires each year in the United States.[8]

Recognizing the diversity of mechanisms by which a patient could sustain an unintentional burn in the ASC setting, the ASC Quality Collaboration chose a broad definition of burn, encompassing all six recognized means by which a burn can occur - scalds, contact, fire,

---

[1] Joint Commission. Joint Commission Sentinel Event Alert. Issue 12, February 4, 2000. Operative and Postoperative Complications: Lessons for the Future. Chicago, IL

[2] Tucker R. Laparoscopic electrosurgical injuries: survey results and their implications. *Surg Laparosc Endosc.* 1995;5(4):311-7.

[3] ECRI. Higher currents, greater risks: preventing patient burns at the return-electrode site during high-current electrosurgical procedures. *Health Devices.* 2005;34(8):273-9.

[4] Demir E, O'Dey D, and Pallua N. Accidental burns during surgery. *J Burn Care Res.*. 2006 ;27(6):895-900.

[5] Cheney F, Posner K, Caplan R, and Gild W. Burns from warming devices in anesthesia. A closed claims analysis. *Anesthesiology.* 1994;80(4):806-10.

[6] Barker S and Polson J. Fire in the operating room: a case report and laboratory study. *Anesth Anal.* 2001;93:960-965.

[7] Agency for Healthcare Research and Quality (AHRQ). A clinician's guide to surgical fires: how they occur, how to prevent them, how to put them out. Available at: http://www.guideline.gov/summary/summary.aspx?doc_id=3688&nbr=002914&string=surgery+AND+burns. Last accessed October 4, 2007.

[8] ECRI. Devastation of patient fires. *Health Devices.* 1992;21:3-39.

chemical, electrical, or radiation. This will allow stakeholders to develop a better understanding of the incidence of these events and further refine means to ensure prevention.

B. Patient Fall

"Falls per 100,000 patient days" has been endorsed as a serious reportable event by the NQF.[9]

According to the Agency for Healthcare Research and Quality's *Prevention of Falls in Acute Care* guideline, patient falls may be reduced by following a four-step approach: 1. evaluating and identifying risk factors for falls in the older patient; 2. developing an appropriate plan of care for prevention; 3. performing a comprehensive evaluation of falls that occur in the hospital; and 4. performing a post-fall revision of plan of care as appropriate.[10]

This measure serves as an indirect assessment of adherence to these guidelines by quantifying the outcome of a patient fall.

While ASCs have been demonstrated to have a relatively low incidence of adverse events in general, information regarding the incidence of patient falls is not currently available. However, stakeholders have expressed a general interest in ASC oversight and the public reporting of such adverse events.[11] Due to the use of anxiolytics, sedatives, and anesthetic agents as adjuncts to procedures, patients undergoing outpatient surgery are at increased risk for falls.

C. Hospital Transfer / Admission

The need for transfer/admission is an unanticipated outcome and could be the result of insufficient rigor in patient or procedure selection. Hospital transfers/admissions also result in unplanned cost and time burdens that must be borne by patients and payors.

While ambulatory surgery has been shown to have good outcomes, routine procedures can still result in complications.[11] A recent study on same-day surgical patients demonstrated that of the 20,817 ambulatory surgical patients evaluated, 1,195 (5.7 percent) returned to the hospital within 30 days or were admitted directly after surgery. Of those unanticipated admissions and readmissions, 313 (1.5 percent) were directly related to the original procedure. Pain was the

---

[9] National Quality Forum. *Serious Reportable Events in Healthcare.* Washington, DC: NQF, 2002.

[10] Agency for Healthcare Research and Quality. National Guideline. Preventing Falls in Acute Care. Available at: http://www.guideline.gov/summary/summary.aspx?doc_id=3510&nbr=002736&string=patient+AND+falls. Last accessed October 4, 2007.

[11] Department of Health and Human Services, Office of Inspector General. *Quality Oversight of Ambulatory Surgical Centers.* Available at: http://www.oig.hhs.gov/oei/reports/oei-01-00-00452.pdf. Last accessed October 4, 2007.

most commonly reported reason for return, occurring in 120 (38 percent) of the admitted patients.[12]

Selected states have expressed an interest in the public reporting of such events[13,14,15,16,17]. While hospital transfers and admissions undoubtedly represent good patient care when necessary, high rates of transfer and/or admission may be an indicator that practice patterns are in need of review.

D. Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

"Surgery performed on the wrong body part", "surgery performed on the wrong patient", and "wrong surgical procedure performed on a patient" have all been endorsed as serious reportable surgical events by NQF.[9]

This outcome measure serves as an indirect measure of providers' adherence to the Joint Commission's "Universal Protocol" guideline for eliminating wrong site, wrong procedure, wrong person surgery. The Universal Protocol is based on the consensus of experts and is endorsed by more than forty professional medical associations and organizations.[18]

The Agency for Healthcare and Research Quality's *Making Healthcare Safer* evidence report includes the following statements regarding the incidence of wrong site surgery:[19]

---

[12] Coley K et al. Retrospective evaluation of unanticipated admissions and readmissions after same day surgery and associated costs. *J Clin Anesth.* 2002;14:349-353.

[13] Florida Agency for Health Care Administration. *Ambulatory Surgical and Emergency Department Data.* Available at: http://www.fdhc.state.fl.us/SCHS/apdunit.shtml. Last accessed October 4, 2007.

[14] Indiana State Department of Health. *Reporting a Complaint.* Available at: http://www.in.gov/isdh/regsvcs/asc_index.htm. Last accessed October 4, 2007.

[15] New York State Department of Health. *Statewide Planning and Research Cooperative System.* Available at: http://www.health.state.ny.us/statistics/sparcs/. Last accessed April 30, 2007.

[16] Commonwealth of Pennsylvania, Patient Safety Authority. Available at: http://www.psa.state.pa.us/psa/cwp/view.asp?a=1165&q=441808&psaNav=|. Last accessed October 4, 2007.

[17] Texas Department of State Health Services. Available at: http://www.dshs.state.tx.us/HFP/safety.shtm. Last accessed April 30, 2007.

[18] Joint Commission. *Universal Protocol For Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery.* Available at: www.jointcommission.org/NR/rdonlyres/E3C600EB-043B-4E86-B04E-CA4A89AD5433/0/universal_protocol.pdf. Last accessed October 4, 2007.

[19] Agency for Healthcare Research and Quality (AHRQ). *Making Healthcare Safer. A Critical Analysis of Patient Safety Practices. Chapter 43.2 – Strategies to Avoid Wrong Site Surgery.* Available at: http://www.ahrq.gov/clinic/ptsafety/chap43b.htm. Last accessed October 4, 2007.

"From January 1995 to March 2001, JCAHO reviewed voluntary reports of 1,152 'sentinel events'. Wrong-site surgery accounted for 114 (9.9%) of these reports and included procedures in neurosurgery, urology, orthopedics, and vascular surgery. Despite the high profile of JCAHO's Sentinel Event Policy, it is believed that under-reporting by healthcare organizations apparently affects these statistics. Only 66 percent of the 1,152 total events were self-reported by the institutions involved. The remainder came from patient complaints, media stories and other sources. Using a mandatory reporting system, the New York State Department of Health received 46 reports of wrong-site surgery from 1998 through 2004 compared with the 114 cases JCAHO received nationally over a period three times longer, suggesting that voluntary incident reporting may underestimate the true incidence by a factor of 20 or greater.

The Physicians Insurers Association of America (PIAA) reviewed claims data from 22 malpractice carriers representing 110,000 physicians from 1985 to 1995. These claims included 331 cases of wrong-site surgery. The complete PIAA database documents almost 1,000 closed malpractice claims involving wrong-site surgery. However, this figure also underestimates the prevalence of wrong-site surgery, as every case does not result in a claim. Most wrong-site surgeries involve relatively minor procedures such as arthroscopy, rather than limb amputations or major neurosurgical procedures. Consequently sequelae are minimal. The State Volunteer Mutual Insurance Company (Tennessee) released a series of 37 wrong-site surgery claims from 1977 to 1997. Performing the correct procedure on the wrong side constituted the most common error (e.g., arthroscopic knee surgery on the wrong knee in 15 of the 37 cases). Twenty-six of the patients experienced no sequelae beyond a scar, and only three patients suffered permanent disability. Given the rarity of significant harm, estimates of the incidence of wrong-site surgery derived from litigation data likely underestimate the true prevalence of this problem, as do estimates based on incident reports."

In order to encompass the outcomes of all key identification verifications, the ASC Quality Collaboration's measure incorporates not only wrong site, wrong side, wrong patient and wrong procedure, but also wrong implant in its specifications.

E. Prophylactic Intravenous Antibiotic Timing

The CMS Surgical Infection Prevention performance measure states the following:[20]

"Surgical site infections occur in 2-5 percent of clean extra-abdominal surgeries and up to 20 percent of intra-abdominal surgeries.[21] Each infection is estimated to increase a

[20] Centers for Medicare and Medicaid Services (CMS). 7th Statement of Work. Quality of care measure specifications: surgical infection prevention. Baltimore, MD: Centers for Medicare and Medicaid Services; 2002 Aug 1. Various p. Available at: http://www.qualitymeasures.ahrq.gov/summary/summary.aspx?ss=1&doc_id=9513&string=. Last accessed October 4, 2007.

[21] Horan T, Culver D, Gaynes R, Jarvis W, Edwards J, and Reid C. Nosocomial infections in surgical patients in the United States, January 1986-June 1992. National Nosocomial Infections Surveillance (NNIS) System. Infect Control Hosp Epidemiol. 1993;14(2):73-80.

hospital stay by an average of 7 days and add over $3,000 in charges (1992 data).[22] *Patients who develop surgical site infections are 60 percent more likely to spend time in an ICU, five times more likely to be readmitted to the hospital, and have twice the incidence of mortality.*[23] *Despite advances in infection control practices, surgical site infections remain a substantial cause of morbidity and mortality among hospitalized patients. Studies indicate that appropriate preoperative administration of antibiotics is effective in preventing infection. Systemic and process changes that promote compliance with established guidelines and standards can decrease infectious morbidity.*[23]

The goal of pre-surgical antibiotic prophylaxis is to establish bactericidal tissue and serum levels at the time of skin incision. In a recent study of 2,847 surgery patients at Latter-Day Saints Hospital in Salt Lake City, it was demonstrated that the lowest incidence of post-operative infection was associated with antibiotic administration one hour prior to surgery."[24]

There is no literature available on variation in adherence to recommended prophylactic IV antibiotic timing among ASC providers. However, variability in the accuracy of timing of administration has been demonstrated in other settings.[24]

IV. Data Sources

Most ASCs use medical records, various clinical logs and occurrence/incident reports as the data sources for their quality assessment and improvement projects. Typically these are paper-based tools for data charting, although selected centers have the ability to generate certain forms as electronic documents in formats such as Microsoft Word.

V. Extent of Electronic Data

Few ASCs have electronic medical records. Hospital-owned ASCs are the most likely to have electronic databases and electronic medical records, however this ownership structure is the least common in the industry.

Selected states have implemented ASC data reporting requirements. The data elements required and means of reporting are quite variable, but most reporting is internet-based. In many cases the data is reported in a summary format, though a few states require patient-level data.

---

[22] Marton W, Jarvis W, Culver D, and Haley R. Incidence and nature of endemic and epidemic nosocomial infections. In: Bennett J, Brachman P, editor(s). Hospital infections. 3rd ed. Boston, MA: Little, Brown and Co.; 1992. 577-596.

[23] Kirkland K, Briggs J, Trivette S, Wilkinson W, and Sexton D. The impact of surgical-site infections in the 1990s: attributable mortality, excess length of hospitalization, and extra costs. Infect Control Hosp Epidemiol. 1999;20(11):725-30.

[24] Burke J. Maximizing appropriate antibiotic prophylaxis for surgical patients: an update from LDS Hospital, Salt Lake City. Clin Infect Dis. 2001;33(Suppl 2):S78-83.

Depending on the state, the ASC may be required to prepare an electronic file in a specific format (such as XML) for uploading to the state website or may directly enter data into the state website.

VI. Quality Reporting Methodology for ASCs

To date, CMS has implemented a number of quality reporting systems that employ a variety of methods to collect patient-level quality data. Most of these systems require that data be submitted electronically to a repository. As recently proposed, hospital outpatient departments would adopt the same methodology currently used by hospitals for inpatient reporting. That process requires abstraction of clinical data based on chart review, followed by compilation and submission in specific XML format to an approved data submission vendor. This vendor then transmits the data to the QIO Clinical Warehouse.

On the other hand, under the CMS Physician's Quality Reporting Initiative (PQRI), physicians report patient-level quality data using administrative claims. Using either HCPCS Level II G codes or AMA Category II CPT codes adopted specifically for quality reporting, the physician is able to submit quality data in conjunction with codes for services rendered on the CMS-1500. Given the administrative burden of medical record extraction, physicians are likely to continue using a claims-based approach to quality reporting in the future.

We have carefully evaluated these approaches, taking into account the characteristics and resources of the typical ASC. Though there is significant variability, CMS data indicates a median of two operating/procedure rooms per facility (mean = 2.5). FASA's 2006 ASC Salary & Benefits Survey shows that the majority (62.2%) of ASCs have 20 or fewer full time equivalents, including both clinical and non-clinical staff. It is unusual for an ASC to have a medical records department staffed with multiple individuals.

Our evaluation of alternative reporting methodologies has focused on their complexity, staff resources needed for implementation, requirements for hardware and software, training requirements, and additional expenses, particularly related to contracting with data submission vendors. In all these areas, we find the administrative claims data approach to be the most practical, feasible and economical solution for ASCs.

The administrative and financial burden of reporting quality measures should be fully considered. CMS has estimated that approximately 73 percent of ASCs would be considered small businesses according to the Small Business Administration (SBA) size standards (see 72 Fed. Reg. 42538 (August 2, 2007) and 72 Fed. Reg. 42812 (August 2, 2007)). In this respect, ASCs more closely resemble individual physician practices than hospitals.

Further, ASCs will continue submitting their Medicare claims using the CMS-1500 at least through 2008. Therefore, ASCs are in a position to report quality data in the same manner as physicians, which will allow CMS to leverage the processes it has already developed under PQRI. If ASCs move to the UB-04 in the future (a change we support), these codes can continue to be reported on the new form and comparisons across multiple years would remain feasible.

We request CMS work with ASC leaders to develop HCPCS Level II G codes that would allow facility-level quality measures to be reported using a claims-based approach. Reporting data on the claim form using HCPCS codes is achievable across ambulatory settings and can be accommodated on both the CMS-1500 and the UB-04.

VII. Public Display of Quality Data

The ASC Quality Collaboration supports the development of transparency regarding health care information and welcomes a fair presentation of ASC cost and quality information to assist consumers in making decisions.

The success of transparency efforts is closely linked to how effectively information is shared with the public. A data reporting infrastructure should allow patients and payers to compare quality across Medicare's payment silos when a service or procedure can be delivered in multiple ambulatory settings.

Consumers should be able to access quality and cost information on websites that are organized to allow easy comparisons, while also protecting the rights of providers to assure the information is correct, up-to-date, and clearly presented. Specifically, web-based presentation of quality and cost data should address or incorporate the following principles.

1) Information should be presented on all available sites of service so consumers can compare a hospital outpatient department and an ASC for a procedure that could be performed in both locations.

2) There should be a mechanism for providers to raise concerns with any information to be posted prior to its public presentation.

3) There should be a provider narrative section for each provider-specific item presented to the consumer. This narrative box would allow the provider to advise the consumer of any concerns the provider has regarding the reliability or accuracy of the information presented.

4) In addition to reporting quality measures, other useful information such as accreditation status, state licensure and Medicare certification should be made available.

We request more detailed consideration and expanded description on this vital matter from CMS in future rulemaking.

VIII. Summary of Recommendations

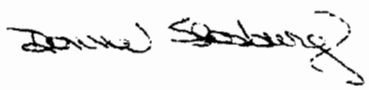
The ASC Quality Collaboration fully supports public reporting of facility-level quality measures that evaluate outcomes or processes of care specific to the facility services rendered in the outpatient surgical setting. CMS should adopt facility-level quality measures that have been endorsed by the NQF specifically for ASC reporting. The five measures developed by the ASC Quality Collaboration that are currently being considered for NQF endorsement are all important indicators of the quality of care ASCs provide to Medicare beneficiaries.

Given the limited electronic capabilities and the manual processes required for quality assessment in ASCs, CMS should implement a claims-based reporting system for ASCs, similar to the quality reporting system the agency has implemented for physicians. Such a system would allow patient-level data collection without undue financial and administrative burden.

Presentation of quality data deserves careful consideration to achieve the most effective communication of information. At a minimum, the method CMS selects for sharing data should allow interested parties to directly compare measures of outpatient surgical facility services across facility types.

Thank you for considering these comments. I would be happy to assist with questions or provide additional information at your request.

Sincerely,



Donna Slosburg, BSN, LHRM, CASC
Executive Director
ASC Quality Collaboration
727-867-0072
donnaslosburg@ascquality.org

Appendix A

ASC Quality Collaboration Measures "*Recommended for Endorsement*" by the National Quality Forum (NQF)

PLEASE NOTE: These measures are subject to change pending additional action by the NQF.

Patient Burn	
Intent	To capture the number of admissions (patients) who experience a burn prior to discharge
Numerator/Denominator	Numerator: Ambulatory Surgery Center (ASC) admissions experiencing a burn prior to discharge Denominator: All ASC admissions
Inclusions/Exclusions	Numerator Inclusions: ASC admissions experiencing a burn prior to discharge Numerator Exclusions: None Denominator Inclusions: All ASC admissions Denominator Exclusions: None
Suggested Data Sources	ASC operational data, including administrative records, medical records, incident/occurrence reports and quality improvement reports
Data Element Definition and Allowable Values	Admission: completion of registration upon entry into the facility; Allowable values: The count for this data element would be represented by any whole number 0 or greater Burn: Unintended tissue injury caused by any of the six recognized mechanisms: scalds, contact, fire, chemical, electrical or radiation, (e.g. warming devices, prep solutions, electrosurgical unit or laser); Allowable values: The count for this data element would be represented by any whole number 0 or greater

Prophylactic IV Antibiotic Timing	
Intent	To capture whether antibiotics given for prevention of surgical site infection were administered on time
Numerator/Denominator	Numerator: Number of Ambulatory Surgery Center (ASC) admissions with an order for a prophylactic IV antibiotic for prevention of surgical site infection who received the prophylactic antibiotic on time Denominator: All ASC admissions with a preoperative order for a prophylactic IV antibiotic for prevention of surgical site infection
Inclusions/Exclusions	Numerator Exclusions: None Denominator Exclusions: ASC admissions with a preoperative order for a prophylactic IV antibiotic for prevention of infections other than surgical site infections (e.g. bacterial endocarditis); ASC admissions with a preoperative order for a prophylactic antibiotic not administered by the intravenous route
Suggested Data Sources	ASC operational data, including administrative records, medical records, incident/occurrence reports and quality improvement reports
Data Element Definition and Allowable Values	Admission: completion of registration upon entry into the facility; Allowable values: The count for this data element would be represented by any whole number 0 or greater Antibiotic administered on time: Antibiotic infusion is initiated within one hour prior to the time of the initial surgical incision or the beginning of the procedure (e.g., introduction of endoscope, insertion of needle, inflation of tourniquet) or two hours prior if vancomycin or fluoroquinolones are administered; Allowable values: 0 minutes to 24 hours reporting in military time format from 0:00 to 23:59; hours from 00 to 23 and minutes from 00 to 59. If unable to determine (UTD), "UTD" is assigned. Prophylactic antibiotic: an antibiotic prescribed with the intent of reducing the probability of an infection related to an invasive procedure. For purposes of this measure, the following antibiotics are considered prophylaxis for surgical site infections: Ampicillin/sulbactam, Aztreonam, Cefazolin, Cefmetazole, Cefotetan, Cefoxitin, Cefuroxime, Ciprofloxacin, Clindamycin, Erythromycin, Gatifloxacin, Gentamicin, Levofloxacin, Metronidazole, Moxifloxacin, Neomycin and Vancomycin

Patient Fall in the ASC

Intent	To capture the number of admissions (patients) who experience a fall within the ASC
Numerator/Denominator	Numerator: Ambulatory Surgery Center (ASC) admissions experiencing a fall within the confines of the ASC Denominator: All ASC admissions
Inclusions/Exclusions	Numerator Inclusion: ASC admissions experiencing a fall within the confines of the ASC Numerator Exclusion: ASC admissions experiencing a fall outside the ASC Denominator Inclusion: All ASC admissions Denominator Exclusion: ASC admissions experiencing a fall outside the ASC
Suggested Data Sources	ASC operational data, including administrative records, medical records, incident/occurrence reports and quality improvement reports
Data Element Definition and Allowable Values	Admission: completion of registration upon entry into the facility; Allowable values: The count for this data element would be represented by any whole number 0 or greater Fall: a sudden, uncontrolled, unintentional, downward displacement of the body to the ground or other object, excluding falls resulting from violent blows or other purposeful actions. (National Center for Patient Safety)

Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant

Intent	To capture any ASC admissions (patients) who experience a wrong site, side, patient, procedure or implant
Numerator/Denominator	Numerator: All Ambulatory Surgery Center (ASC) admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure or wrong implant Denominator: All ASC admissions
Inclusions/Exclusions	Numerator Inclusions: All ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure or wrong implant Numerator Exclusions: None Denominator Inclusions: All ASC admissions Denominator Exclusions: None
Suggested Data Sources	ASC operational data, including administrative records, medical records, incident/occurrence reports, quality improvement reports
Data Element Definition and Allowable Values	Admission: completion of registration upon entry into the facility; Allowable values: The count for this data element would be represented by any whole number 0 or greater Wrong: not in accordance with intended site, side, patient, procedure or implant; Allowable values: The count for this data element would be represented by any whole number 0 or greater

Hospital Transfer/Admission

Intent	To capture any ASC admissions (patients) who are transferred or admitted to a hospital prior to discharge from the ASC
Numerator/Denominator	Numerator: Ambulatory Surgery Center (ASC) admissions requiring a hospital transfer or hospital admission upon discharge from the ASC Denominator: All ASC admissions
Inclusions/Exclusions	Numerator Inclusions: ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC Numerator Exclusions: None Denominator Inclusions: All ASC admissions Denominator Exclusions: None
Suggested Data Sources	ASC operational data, including administrative records, medical records, incident/occurrence reports and quality improvement reports
Data Element Definition and Allowable Values	Admission: completion of registration upon entry into the facility; Allowable values: The count for this data element would be represented by any whole number 0 or greater Hospital transfer/admission: any transfer/admission from an ASC directly to an acute care hospital including hospital emergency room; Allowable values: The count for this data element would be represented by any whole number 0 or greater Discharge: occurs when the patient leaves the confines of the ASC

October 30, 2007

Kerry Weems, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3887-P
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3887-P – Ambulatory Surgical Centers Conditions for Coverage

Dear Administrator Weems:

On behalf of the undersigned state associations, we submit these comments on the proposed rule to update the Medicare conditions for coverage (CfCs) for ambulatory surgery centers (ASCs). More specifically, the below-listed associations all represent ASCs in states that permit overnight post-surgical recovery care, either in ASCs themselves or in separately licensed or certified recovery care units. We write to express the collective dismay of our members at the proposal to redefine what is an "ambulatory surgery center" for purposes of the CfCs in a way that apparently would prohibit Medicare-certified ASCs from performing *any* procedures – including procedures for non-Medicare patients – requiring active medical monitoring beyond midnight, *even if such stays are permitted for non-Medicare patients in the state where the ASC is licensed.*

For the past 29 years, ASCs in our states have invested countless amounts of time, money and resources in the development of state-of-the-art recovery care units. As of 1999, extended recovery care centers existed in 34 states (plus Puerto Rico) and approximately nine percent of ASCs nationwide.* On the whole, ASCs provide superb post-surgical recovery care at significantly lower costs than hospitals, making them an extremely attractive care option for both patients and payers in our states. Thus, we cannot understand why CMS would choose now – 25 years after the Medicare ASC benefit was first established and after an entire industry has been built around the current regulatory framework – to redefine an ASC in a way that would eliminate the ability of Medicare-participating facilities to continue providing this beneficial care option to non-Medicare patients.

We also want to make sure you appreciate that if Medicare-participating facilities are no longer able to provide overnight recovery care, millions of dollars that has been invested in the development of this care model over the past two decades could be effectively wiped out. Given that CMS has been aware of the provision of overnight recovery care by ASCs for non-Medicare patients for many years, we believe the agency has a heavy burden to justify this abrupt change in policy and the severe consequences that likely will result if the redefinition of ASC is adopted as proposed.

* Federated Ambulatory Surgery Association, *Post-Surgical Recovery Care Survey* (2000).

Because the proposed rule does not offer a rationale for this far reaching change in Medicare policy, we must presume it somehow relates to patient safety concerns with the provision of overnight care in ASCs. Yet, because Medicare does not cover overnight recovery care, that concern can relate only to the safety of non-Medicare patients, which historically has been the province of the states. Indeed, the licensure and regulation of health care facilities and the protection of patient health, safety and welfare are classic state responsibilities, and we cannot fathom why this administration, in particular, would choose to intrude on the ability of states to define for themselves what kinds of post-surgical recovery care can be provided to non-Medicare patients. That decision should continue to be left to the states, without unwarranted intrusion from the federal government that, in this case, threatens to destroy a model of care delivery that has worked for almost 30 years to benefit patients in our states.

To help further inform the agency's thinking on this rule, we offer the following observations and perspectives on our experiences with post-surgical recovery care in our states:

- Because Medicare prohibits planned overnight stays for its beneficiaries, the patients served in post-surgical recovery care centers in or affiliated with ASCs tend to reflect a younger, relatively healthy patient population that prefers a non-hospital setting for mostly elective, non-emergent surgery. The kinds of procedures most commonly performed in these facilities include orthopedic and cosmetic surgery, where inpatient hospital care is not necessary. This extended care is not for emergency care but, rather, less intensive monitoring for things like pain control, nausea, drug administration and fluid maintenance.

- Patient safety in these facilities is overseen by state licensure laws that strictly regulate things like staffing levels and credentials, emergency equipment requirements and maximum lengths of stay. The regulatory standards are rigorous. As a result, the patient care facilities and capabilities of recovery care centers tend to resemble hospitals much more than the average ASC.

- Although these facilities are capable, they also are cost-effective, especially when compared to inpatient hospital care.

- By focusing on surgical recovery and employing experienced nurses and other staff with specialized expertise in post-operative treatment, extended recovery care in ASCs may be of higher quality of care than the typical general acute care hospital. According to the FASA survey noted above, 74 percent of ASCs require all of their extended recovery care nurses to be advanced cardiac life support (ACLS) certified, and another 17 percent require some nurses to be ACLS certified. In addition, the nurse-to-patient ratio (ranging from 0.84 to 1.20, according to the FASA survey) in extended recovery care centers offered by ASCs is often better than in a hospitals.

- The risks of cross infections and other complications inherent to the hospital environment are greatly reduced in recovery care facilities.

- Recovery care centers are extremely popular with the patients they serve. Patients especially appreciate the professionalism, personal attention and non-institutional approach that are the hallmarks of these facilities.

In light of these benefits, we strongly urge CMS to reconsider its proposal to adopt a definition of ASC for the CfCs that would prevent Medicare-certified facilities from providing overnight recovery care to non-Medicare patients. These facilities have become a vital part of the care continuum in our states and are adequately regulated by the state health departments. We also believe that if faced with the choice of retaining Medicare certification under the proposed definition of ASC or forgoing the provision of recovery care services to non-Medicare patients, a significant number of facilities in our states simply may choose to opt out of Medicare, thus needlessly limiting beneficiary access to large numbers of high-quality providers. With all due respect, there is simply no justification for Medicare to override state laws in this area.

We understand that in their comments on the CfC rule, FASA, AAASC and the ASC Coalition will suggest alternative definitions of an ASC that we commend to your attention. For us and for our members who, for the past three decades, have advanced the quality of surgical care in our states by developing and operating high quality recovery care centers, the bottom line is that CMS not overstep its authority to regulate the Medicare program but, instead, preserve the right of ASCs to continue performing procedures involving overnight stays for non-Medicare patients where permitted under state law.

Thank you for your consideration of our comments.

Sincerely,

Alabama Association of Ambulatory Surgery Centers
Ambulatory Surgery Center Association of Illinois
California Ambulatory Surgery Association
Colorado Ambulatory Surgery Center Association
Georgia Society of Ambulatory Surgery Centers
Indiana Federation of Ambulatory Surgical Centers
Iowa Association of Ambulatory Surgery Centers
Kentucky Ambulatory Surgery Center Association
Mississippi Ambulatory Surgery Association
New Jersey Association of Ambulatory Surgery Centers
Ohio Association of Ambulatory Surgery Centers
Utah Ambulatory Surgery Center Association
Washington Ambulatory Surgery Center Association

Attachment #13

Meeting America's Surgical Needs

1012 Cameron Street
Alexandria, VA 22314

703.836.8808
(fax) 703.549.0976

www.fasa.org
FASA@fasa.org

October 30, 2007

Kerry Weems, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3887-P
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3887-P – Ambulatory Surgical Centers Conditions for Coverage

Dear Administrator Weems:

FASA is pleased to submit these comments on the proposed rule to modify the Medicare and Medicaid conditions for coverage (CfCs) for ambulatory surgery centers (ASCs). FASA is the nation's largest ASC organization, representing more than 2,200 ASCs, the professionals who provide care in such centers and the patients who receive high quality and cost-effective ASC services. FASA's members include all types of ASCs – small and large; for profit and non-profit; single-specialty and multi-specialty; physician-owned, joint ventures between hospitals and physicians, joint ventures between physicians and management companies and hospital-owned surgery centers.

FASA shares CMS's stated goal of modernizing the Medicare ASC requirements to be "more closely aligned with today's ASC health care industry standards" and to "focus on a patient-centered, outcome-oriented process that promotes patient care foremost." That said, we believe the proposed rule reflects a missed opportunity to truly update and modernize the CfCs. In fact, other than the long overdue adoption of standards to require a forward-looking quality assessment and performance improvement program for ASCs – which has been standard practice in the ASC industry for almost three decades – there is very little in the proposed rule that will have a meaningful impact on enhancing the quality of care delivered in today's ASCs.

To the contrary, a number of provisions in the proposed rule actually would turn back the clock on ASC regulation and needlessly limit access to high quality surgical care. In particular, we are very troubled by the proposals to prohibit overnight recovery care for non-Medicare patients and to require compliance with portable x-ray conditions by ASCs that provide imaging guidance and therapeutic radiology services. We especially urge CMS to seriously reconsider its approach in these two critically important areas.

Other sections of the rule set forth proposed standards that will be impractical for ASCs to meet or that are out of step with generally accepted medical practices, particularly in the areas of patient rights and patient admission, assessment and discharge. Our concern is that if implemented as proposed, these revised conditions would significantly increase the regulatory burdens on ASCs, without any indication that improved care would result. Thus, in the comments that follow we have tried, whenever possible, to suggest alternative approaches that we believe would produce more practical standards without compromising patient safety or quality of care.

We would welcome the opportunity to meet with CMS to discuss our concerns and comments on the CfC proposed rule in greater detail. Because of the serious impact that the proposed rule could have on the delivery of care in ASCs, we urge CMS to take the time necessary to fully evaluate the comments that follow and others the agency will receive from the ASC community.

A. Definitions (§ 416.2)

We begin with perhaps the most troubling aspect of the CfC proposed rule – the proposal to redefine an ASC as a distinct entity that operates "exclusively" for the purpose of providing surgical services to patients not requiring an "overnight stay." An "overnight stay," in turn, is a newly defined term meaning recovery requiring active medical monitoring beyond 11:59 p.m. (i.e., midnight) on the day of the procedure, "regardless of whether it is provided in the ASC." We are extremely troubled by these new definitions because they apparently would prohibit Medicare-certified ASCs from performing *any* procedures – including procedures for non-Medicare patients – requiring active medical monitoring beyond midnight, *even if such stays are permitted for non-Medicare patients in the state where the ASC is licensed.* Given that the Medicare ASC payment system already prohibits coverage of procedures requiring an overnight stay for Medicare beneficiaries, we see no reason for this unwarranted federal intrusion into the authority of the states to regulate the provision of services for non-Medicare patients. If Medicare-participating facilities are no longer able to provide overnight recovery care to non-Medicare patients, tens and perhaps hundreds of millions of dollars that has been invested in the development of this care model over the past three decades could be effectively wiped out – a consequence that is not even remotely addressed in the proposed rule's regulatory impact analysis. In fact, that analysis wrongly states that this rule "has no Federalism implications."[1]

Since CMS has been aware of the provision of overnight recovery care by ASCs for non-Medicare patients for many years, we believe the agency has a heavy burden to justify this abrupt change in policy and the severe consequences that likely will result if the redefinition of ASC is adopted as proposed. Yet, the proposed rule offers no real explanation for why it is necessary – or even desirable – to change the current CfC definition of an ASC as an entity that operates for the purpose of providing surgical services to patients not requiring "hospitalization." *See* 42 C.F.R.§ 416.2. The origins of this regulatory definition can be found in Section 1833(i)(1)(A) of the Social Security Act, which establishes the ASC benefit and provides

[1] 72 Federal Register 50469, 50480 (Aug. 31, 2007).

Medicare coverage for "those surgical procedures...performed on an inpatient basis *in a hospital* but which also can be performed safely on an ambulatory basis in an ambulatory surgical center" (emphasis supplied). In other words, the Medicare statute envisions ASCs as a surgical alternative for patients *not requiring hospitalization*, which is how ASCs have been defined since Medicare coverage was first established for ASC services in 1982.

By defining an ASC by reference to hospitalization, rather than overnight stay, the current CfC rules allow overnight stays for non-Medicare patients, either in the ASC itself or in a licensed or certified recovery care unit that is distinct from the ASC and not a hospital, where such recovery care is permitted under state law.[2] In reliance on the current policy, ASCs throughout the country have invested countless amounts of time, money, and resources in developing recovery care programs for non-Medicare patients that may be needlessly jeopardized by the CfC proposed rule. As of 1999, when FASA last did a comprehensive survey on this topic, extended recovery care centers existed in 34 states (plus Puerto Rico) and approximately nine percent of ASCs nationwide.[3]

Because Medicare prohibits planned overnight stays for its beneficiaries, the patients served in ASC-affiliated recovery care centers tend to reflect a younger, relatively healthy patient population that prefers a non-hospital setting for mostly elective, non-emergent surgery. The kinds of procedures most commonly performed in these facilities include orthopedic and cosmetic surgery, where more costly inpatient hospital care is not necessary. As the Medicare Payment Advisory Commission (MedPAC) observed in 2000, these recovery care centers "make up a distinct class of health care facilities that provide limited medical and nursing care to people who require short-term inpatient observation or overnight lodging for services that include pain control, drug administration and fluid maintenance."[4] In other words, these facilities provide mostly observation and monitoring services, rather than emergency care. According to MedPAC, "[o]ver the past two decades, these facilities have increased in number and in private-sector use as technological advances have allowed more types of surgeries to be safely performed in an ambulatory setting."[5]

Patient safety in these facilities is overseen by state licensure laws that strictly regulate things like staffing levels and credentials, emergency equipment requirements and maximum lengths of stay. By focusing on surgical recovery and employing experienced nurses and other staff with specialized expertise in post-operative treatment, extended recovery care in ASCs may be of

---

[2] The licensure laws in approximately 14 states allow ASCs to retain patients for up to 23 or 24 hours of overnight recovery care in the ASC itself. A number of other states permit extended recovery stays of up to 24, 48 and, in some cases, 72 hours in separately licensed or certified recovery care units. Under the Medicare CfCs, these latter units are required to be legally and operationally distinct from a Medicare-certified ASC and may not share staff, space or equipment with an ASC during concurrent hours of operation.

[3] Federated Ambulatory Surgery Association, *Post-Surgical Recovery Care Survey* at 4 and 6 (2000).

[4] Medicare Payment Advisory Commission, *Medicare Payment for Post-Surgical Recovery Care Centers* at 3 (November 2000).

[5] Id. at v.

higher quality of care than the typical general acute care hospital. According to the FASA survey noted above, 74 percent of ASCs require all of their extended recovery care nurses to be advanced cardiac life support (ACLS) certified, and another 17 percent require some nurses to be ACLS certified. In addition, the nurse-to-patient ratio in extended recovery care centers offered by ASCs (ranging from 0.84 to 1.20, according to the FASA survey) is often better than in a hospitals. At the same time, the risks of cross-infections and other complications inherent to the hospital environment are greatly reduced in recovery care facilities.

These benefits have been confirmed in studies finding non-hospital recovery care to be safe and desirable to patients and to health care professionals. For example, a decade-long study released in 2000 by the California Office of Statewide Health Planning and Development concluded that recovery care is safe for patients and that "there was substantial interest [among] both patients and professional staff in short-stay recovery periods, pleasant surroundings, home-like settings, and hotel-like services."[6] Because they are more cost-effective than hospitals, recovery care centers also are attractive option for many commercial insurers.

In light of these benefits, it is difficult to understand why CMS would choose now – 25 years after the Medicare ASC benefit was first established and after an entire industry has been built around the current regulatory framework – to redefine an ASC in a way that would eliminate the ability of Medicare-participating facilities to continue providing this beneficial care option to non-Medicare patients. Because the proposed rule does not offer a rationale for this far reaching change in Medicare policy, we must presume it somehow relates to patient safety concerns with the provision of overnight care in ASCs. Yet, because Medicare does not cover overnight recovery care, that concern can relate only to the safety of non-Medicare patients, which historically has been the province of the states. Indeed, the licensure and regulation of health care facilities and the protection of patient health, safety and welfare are classic state responsibilities, and we cannot fathom why this administration, in particular, would choose to intrude on the ability of states to define for themselves what kinds of post-surgical recovery care can be provided to non-Medicare patients. That decision should continue to be left to the states, without unwarranted intrusion from the federal government that, in this case, threatens to destroy a model of care delivery that has worked to benefit patients for almost 30 years without any notable patient safety or quality of care concerns.

Another possible consequence of the proposed redefinition of ASC could be reduced access to ASCs for Medicare beneficiaries. Indeed, if faced with the choice of retaining Medicare certification under the proposed definition of ASC or forgoing the provision of recovery care services to non-Medicare patients, a significant number of facilities simply may choose to opt out of Medicare. The likely result would be to needlessly limit beneficiary access to many innovative and high quality surgery centers.

---

[6] California Office of Statewide Health Planning and Development, *Postsurgical Recovery Care Demonstration Project Report 2000.*

We also note that the proposed restriction on recovery requiring "active monitoring" beyond midnight also puts at risk planned transfers to skilled nursing facilities, rehabilitation facilities, correctional institutions and other non-hospital facilities for overnight observation and monitoring following surgery. This is permitted under the current definition of ASC because recovery in these kinds of facilities is not "hospitalization." If the proposed definition is adopted, however, it appears that such observation care would be prohibited. As a result, more procedures may need to be performed on an inpatient basis at hospitals, thus resulting in higher costs to the Medicare program. Before adopting a change that could have such a broad impact, more study is warranted.

In sum, if the concern is that overnight recovery care may not be appropriate for Medicare's elderly patient population, that issue already has been addressed by the ASC payment system rules prohibiting Medicare coverage for any services that routinely require an overnight stay. However, the same restrictions should not be extended to the general patient population served by ASCs, whose safety is adequately overseen by state licensure laws.

Therefore, to avoid needlessly restricting access to appropriate recovery care and intruding on the traditional role of the states to regulate health care facilities for patient health and safety, we strongly urge CMS to retain the current CfC definition of an ASC by reference to patients not requiring *hospitalization*. In addition, we have always considered the requirement that ASCs operate "exclusively" for purposes of providing surgical services to be overly restrictive and an unnecessary hindrance to the efficient delivery of patient care services. We believe an ASC would be sufficiently distinguished from other provider types if it operated primarily for the purpose of providing surgical services to patients, and thus suggest modifying the existing definition of ASC as follows:

> *Ambulatory Surgical Center or ASC* means any distinct entity that operates ~~exclusively~~primarily for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

Recognizing that hospitalization is a somewhat imprecise term, another acceptable alternative would be a definition along the lines of the following, which would continue to permit overnight stays for non-Medicare patients where permitted under state law:

> *Ambulatory Surgical Center or ASC* means any distinct entity that operates ~~exclusively~~primarily for the purpose of providing surgical services to patients whose recovery under normal circumstances will not require inpatient hospital care, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

Another acceptable alternative would be to define an ASC by reference to the provision of "outpatient" care, which would seem to require language, such as the following, to help distinguish an ASC from a hospital outpatient department:

> *Ambulatory Surgical Center or ASC* means any distinct entity that is not provider-based, as defined in § 413.65 of this chapter, and that operates ~~exclusively~~primarily for the purpose of providing surgical services on an outpatient basis, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

Finally, if despite the concerns outlined above, CMS remains intent on defining ASC by reference to overnight stays for non-Medicare patients, we urge you to preserve the right of ASCs to perform procedures involving overnight stays, where permitted under state law, by modifying the proposed rule's definition as follows:

> *Ambulatory Surgical Center or ASC* means any distinct entity that operates ~~exclusively~~primarily for the purpose of providing surgical services to patients not requiring an overnight stay in the ASC following the surgical services (except where permitted under applicable state law), has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.
>
> * * *
>
> *Overnight stay* means the patient's normal course of recovery requires active monitoring by qualified medical personnel~~, regardless of whether it is provided in the ASC,~~ beyond 11:59 p.m. of the day on which the surgical procedure was performed.

B. Specific Conditions for Coverage

1. Governing Body and Management (§ 416.41)

FASA believes it is appropriate for the governing body, as the proposed rule provides, to (1) assure direct oversight and accountability for the quality assessment program, and (2) create and maintain a disaster preparedness plan. We believe an effective quality assessment program and disaster preparedness plan are essential to promoting quality care and patient safety, so that responsibility for their development and implementation appropriately resides with the governing body.

That said, we have two concerns with the language used in the proposed disaster preparedness plan standard at § 416.41(c):

- First, we are concerned that requiring ASCs to "coordinate" their plans with state and local agencies, as currently proposed in § 416.41(c)(2), could be broadly construed as imposing an affirmative duty on all ASCs to integrate their facilities into state and local disaster relief efforts. This may be appropriate for some ASCs, and in some locales ASCs have demonstrated their interest in, and ability to provide, disaster relief services. Many ASCs, however, are neither staffed nor equipped to handle the kind of trauma care

that disasters often require (although many of these facilities have performed admirably in making their staff available to support disaster relief efforts, as many FASA members did in response to the September 11 attacks and Hurricane Katrina). Therefore, we believe CMS should make clear that the Medicare standard is limited to disaster preparedness planning for the care of an ASC's own patients, and leave any broader role for ASCs to the facilities themselves and to state and local authorities.

- Second, while FASA supports the requirement for periodic drills on the disaster preparedness plan, we believe the proposed standard in § 416(c)(3) that corrective action in response to those drills be implemented "immediately" is unrealistic and counterproductive. In some cases, meaningful corrective action takes time to implement; the most immediate fix is not always the best or most effective. At the same time, undue delay in addressing known short comings with a disaster preparedness plan should not be tolerated either. Thus, we believe the right balance here is struck with a requirement for "prompt" or "timely" corrections, rather than "immediate action."[7] Through this minor change in word choice, we believe the standards would be improved by providing time for appropriate reflection and planning, without compromising the need for prompt and timely action.

2. Quality Assessment and Performance Improvement (§ 416.43)

Quality assessment and performance improvement have been cornerstones of the ASC industry for the past 30 years. Thus, FASA supports the proposal to revise the existing quality assessment standard to require a proactive quality assessment and performance improvement (QAPI) program. Our members already address quality improvement prospectively, through focused projects designed to reduce errors and address problems before patients are adversely affected. To the extent there are outliers in the ASC industry who have not adopted that approach, the proposed rule may help move the industry closer to universal compliance.

At the same time, we also recognize that the quality of care challenges for a single operating room eye surgery center, for example, are very different from those facing large multi-specialty facilities. Thus, we appreciate that the proposed rule does not try to prescribe a "one-size-fits-all" QAPI program but, instead, provides ASCs with the flexibility to select their own quality indicators and performance measures, to set their own priorities for program activities and to design performance improvement projects that reflect the scope and complexity of each ASC's own services and operations.

In short, we agree that ASCs should be able to determine how best to implement a QAPI program appropriate for improving the processes and outcomes relevant to the services they provide and the patients they serve. It is our fervent hope that this philosophy will be honored in the field by the surveyors tasked with reviewing QAPI programs, and urge CMS to implement a proactive training program for state surveyors to ensure that happens.

---

[7] "As soon as practical" is another alternative that would be preferable to the current proposal.

3. Laboratory and Radiologic Services (§ 416.49)

We are most concerned that proposed changes to this section could severely – and it appears unintentionally – restrict the ability of ASCs to perform procedures requiring imaging guidance. To understand why this may be the case, it is helpful to begin with the current ASC conditions for coverage, which provide that laboratory and radiology services – including intraoperative imaging services, such as fluoroscopy – must be obtained from a Medicare-approved facility. In the *Guidance to Surveyors* contained at Appendix L of the State Operations Manual, this requirement is interpreted, for radiology services, to mean that if the ASC itself provides directly for all radiological services, it must meet **either** the Medicare conditions of participation for hospitals as they relate to radiological services (42 C.F.R. § 482.26) **or** the conditions for coverage for portable x-ray services (42 C.F.R. §§ 486.100-486.110).[8]

In the proposed rule, however, CMS revises the standards for radiology to say that all radiological services, whether furnished directly or under arrangements, must be furnished in accordance with the portable x-ray conditions – thus in effect, dropping the alternative option of complying with the hospital conditions for radiology. The problem with this change is the portable x-ray conditions are aimed exclusively at *diagnostic* imaging services, and a close look at their requirements reveals a number of significant problems for the typical ASC providing *intraoperative* imaging guidance, rather than diagnostic services:

- First, § 486.102(b) of the portable x-ray conditions states that portable x-ray services must be provided under the supervision of a licensed physician "who is qualified by advanced training and experience in the use of x-rays for diagnostic purposes" (emphasis supplied) – essentially meaning a radiologist. In ASCs, however, intraoperative imaging services typically are performed under the direct supervision of a surgeon, not a radiologist. Indeed, a radiologist's supervision would be neither practical nor useful in performing such services, since the radiology services are being performed to aid and guide the surgeon, not for diagnostic purposes.

- Second, § 486.104(a) of the portable x-ray conditions requires formal training in x-ray technology through an accredited program, college or university for all operators of portable x-ray equipment. However, many of the personnel who assist surgeons in the provision of imaging guidance services in ASCs do not meet these requirements, which are aimed at technologists performing the technical component of diagnostic radiology services without the physician being present when the services are furnished. By contrast, imaging guidance in ASCs is provided under the direct, personal supervision of the surgeon performing the procedure, who remains fully accountable for the services. Thus, extensive formal training in x-ray technology generally is neither necessary nor practical for the personnel who assist physicians in surgery.

---

[8] According to the *Guidance to Surveyors*, when the ASC fails to meet either the radiology requirements for hospitals or the portable x-ray standards, then all radiology services must be obtained from a Medicare-approved facility.

- Third, § 486.106 of the portable x-ray conditions requires a written physician's order specifying "the reason an x-ray test is required, the area of the body to be exposed, the number of radiographs to be obtained, and the views needed," as well as documentation in the patients record of "a description of the procedures ordered and performed, the referring physician, the operator(s) of the portable x-ray equipment who performed the examination, the physician to whom the radiograph was sent, and the date it was sent." Such order and documentation requirements have practical utility for diagnostic imaging procedures, but are mostly irrelevant to intraoperative imaging guidance services.

In short, mandatory compliance with the portable x-ray conditions would be impractical for the intraoperative radiology services most commonly performed in ASCs today, including fluoroscopic and ultrasonic guidance. This, in turn, would make it difficult, if not impossible, for most ASCs to perform procedures requiring imaging guidance – procedures that now are routinely performed in ASCs at lower cost than in hospital outpatient departments.

It does not appear that this is an intended consequence of the proposed rule. Indeed, the preamble indicates that the revisions to § 416.49 are intended merely to divide the radiology standards from the laboratory standards, and to make clear that the radiology standards apply both to services provided directly by the ASC and to services furnished under arrangement. There is no hint that sweeping new restrictions on procedures involving imaging guidance were intended. Moreover, in the final rule for the new ASC payment system published on August 2, 2007, CMS provides for coverage of radiology services integral to the performance of surgical procedures, stating that "appropriate radiology services may be necessary for the safe performance of covered surgical procedures that are provided to Medicare beneficiaries in ASCs."[9] This expansion would be rendered illusory, however, if ASCs performing intraoperative radiology services are required to comply with the supervision and documentation requirements of the portable x-ray conditions. Instead, these procedures would need to be performed at hospitals at higher cost to the Medicare program. Similarly, the portable x-ray conditions should not be applied to therapeutic radiology services, such as brachytherapy, that will be covered under the new ASC payment system when integral to a covered surgical procedure.

Fortunately, there is a simple solution to this apparent oversight – retain the current option of allowing ASCs to furnish radiology services in accordance with the hospital conditions of participation pertaining to radiology services at 42 C.F.R. § 482.26. Unlike the portable x-ray conditions, the hospital conditions countenance the provision of intraoperative and therapeutic radiology services by providing more flexible supervision, personnel and documentation requirements. Specifically, the hospital conditions only require general supervision of "ionizing radiology services" by a "qualified full-time, part-time, or consulting radiologist.[10] Moreover, a radiologist is needed to "interpret only these radiologic tests that are determined by the medical

[9] 72 Federal Register 42469, 42496 (Aug. 2, 2007).

[10] 42 C.F.R. § 482.26(c)(1).

staff to require a radiologist's specialized knowledge."[11] As a result, surgeons are able to oversee the provision of non-ionizing radiology services (including ultrasound) without needlessly involving a radiologist, and ASCs are required to consult with radiologists only where truly needed. In addition, the hospital conditions allow the facility medical staff to designate the qualifications of radiology technicians and contain less prescriptive ordering and documentation standards more suitable to the provision of intraoperative and therapeutic radiology services.[12] ASCs that provide radiology services are familiar with the hospital conditions and have been safely operating in accordance with those requirements for many years.

Therefore, absent any evidence of patient safety or quality of care concerns with radiology services now routinely performed in ASCs, we urge CMS to retain the option of compliance with the hospital conditions of participation for radiology services.

4. Patient Rights (§ 416.50)

ASCs have been leaders in safeguarding patient rights, and FASA and its members are fully committed to continuing that tradition. We also understand this commitment begins with informing patients of their rights, and is implemented by treating patients with respect, consideration and dignity, providing appropriate privacy, handling patient records and information confidentially, giving patients the opportunity to participate in decisions involving their health care and responding appropriately to patient grievances and complaints. With these ideals firmly in mind, and with support for the notion of including a patient rights provision in the conditions for coverage, we believe the proposed standards at § 416.50 are flawed in a number of respects.

- First, the requirement in proposed § 416.50(a)(1) that all patients receive written notice of their rights in a language they understand sets an unreasonably high standard for ASCs that treat diverse patient populations speaking multiple languages. Certainly, FASA supports the idea that ASCs should translate their notices of patient rights into the languages of non-English speaking groups frequently encountered at their facilities. However, the burden of providing written translations should not apply in all cases. Rather, as the Department of Health and Human Services observed in its 2003 *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*, some flexibility is needed in addressing the needs of limited English proficient (LEP) patient populations:

  > The languages spoken by the LEP individuals with whom the recipient has contact determine the languages into which vital documents should be translated. A distinction should be made, however, between languages that are frequently encountered by a recipient and less commonly-encountered

[11] Id.

[12] Id. at § 482.26(b)(4), (c)(2) and (d).

> languages. Some recipients may serve communities in large cities or across the country. They regularly serve LEP persons who speak dozens and sometimes over 100 different languages. To translate all written materials into all of those languages is unrealistic. Although recent technological advances have made it easier for recipients to store and share translated documents, such an undertaking would incur substantial costs and require substantial resources....As a result, the extent of the recipient's obligation to provide written translations of documents should be determined by the recipient on a case-by-case basis..."[13]

We note that the hospital conditions of participation merely require that hospitals "inform" patients of their rights,[14] and believe similar flexibility should be applied in the ASC conditions for participation. Thus, we suggest applying the hospitals conditions to ASCs or, alternatively, deleting the reference to "verbal and written" notice in proposed § 416.50(a)(1), so that ASCs are able to determine the most effective means of notifying patients of their rights. In accordance with the *HHS LEP Guidance*, in appropriate cases this may include, for example, providing "written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of...written materials, free of cost," rather than a full written translation.[15] It also would include posting signs and providing information in patient brochures, which have ASCs have found to be effective means of communicating information to patients.

- Second, we believe the requirement in proposed § 416.50(a)(1)(ii) that written ownership disclosure information be furnished to patients *prior to* the first visit to an ASC could needlessly disrupt patient care and inconvenience patients. To be clear, we are not opposed to making ownership information available to patients, which already is required by the private accreditation organizations and by the anti-kickback statute safe harbor regulations.[16] The decision as to where surgery is performed, however, is between the physician and his or her patient, and so if there is to be a requirement for prior disclosure of a physician's ownership interest in an ASC, that duty properly should rest with the physician, as many states currently require in their medical practice acts.[17] Moreover, prior notice from the facility is not practical when surgery is scheduled on short notice or

---

[13] 68 Federal Register 47311, 47319 (Aug. 8, 2003).

[14] 42 C.F.R. § 482.13(a)(1).

[15] 68 Fed. Reg. at 47319.

[16] 42 C.F.R. § 1001.952(r).

[17] For example, see California Business and Professions Code § 650.01(f) (a physician who makes a referral to "an organization in which the [physician] has a financial interest, shall disclose the financial interest...in writing, at the time of the referral or request for consultation"). In addition to California, at least 20 other states require physicians to disclose ownership interests to patients, including Arizona, Connecticut, Florida, Georgia, Hawaii, Kansas, Louisiana, Maryland, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia and West Virginia.

on an urgent basis. We do not believe it benefits patient care to have ASCs turn patients away because they did not receive an ownership disclosure notice prior to arriving at the facility. We also wonder about the practical limits of the proposed standard – if ownership disclosure is not made prior to the first visit, does that mean the patient is forever barred from choosing that facility? Given these practical problems, we suggest that CMS adopt the accreditation standard that ownership information simply is made "available" to patients upon request[18] or, alternatively, that it be posted or otherwise furnished to patients at the facility. We also believe the same disclosure rules should apply to other facilities that have physician investors or employees, including hospitals.

- Third, we believe the advance directives requirements in proposed § 416.50(a)(2) are unduly burdensome and inappropriate for ASCs. Indeed, the vast majority of procedures performed at ASCs involve elective day surgery, where advance directives do not apply as a practical matter. As a result, most ASCs adopt a policy that advance directives to limit care generally are not honored. To the extent a patient has executed a "do not resuscitate" or similar order, the patient has the choice of either suspending that order for their treatment at the ASC or having their surgery performed at a facility that honors such directives. Requiring disclosure of that policy should be sufficient to protect patient rights. That being the case, we believe the proposal to require that ASCs provide verbal and written information concerning its policies on advance directives is likely to be confusing and unnecessarily alarming to patients. Moreover, a requirement for "verbal information" draws health care providers into discussions with patients about the complicated legal issues surrounding advance directives. Smaller facilities cannot be expected to make a lawyer available to every patient to answer the questions that will inevitably arise from these discussions. We also believe the proposal to require "prominent" documentation of advance directives is unnecessary, given their limited application to ASCs. Again, we believe that accreditation standards provide a more practical approach; that is, we recommend replacing the current proposed § 416.50(a)(2) with the accreditation standard that "information is made available to patients and staff concerning...advance directives, as required by state or federal law or regulations."[19]

- Fourth, we suggest rephrasing the grievance reporting requirement at proposed § 416.50(a)(3)(iii), which currently provides as follows: "*All allegations* must be *immediately* reported to a person in authority in the ASC, the State and local bodies having jurisdiction, and the State survey agency *if warranted*" (emphasis supplied). Since it is not clear what the phrase "if warranted" is intended to modify (i.e., the allegations or just the authorities to whom allegations must be reported), to ensure compliance with this requirement, it appears that "all" allegations, no matter how trivial, would need to be reported to state and local officials as soon as they are received (i.e.,

[18] See Accreditation Association for Ambulatory Health Care, Inc., *Accreditation Handbook for Ambulatory Health Care* at 22 (2007).

[19] Id. at 19.

"immediately"). Since we presume the intent here was not to inundate government officials with immaterial and unsubstantiated patient complaints, we recommend revising this provision to require something along the lines of the following:

> All allegations must be promptly reported to a person in authority at the ASC and, if determined to constitute a violation of applicable laws, regulations or health care program requirements, to appropriate federal, state or local authorities as required by law.

- Finally, we believe the confidentiality of clinical records standard at proposed § 416.50(d) creates unnecessary confusion with the more comprehensive HIPAA privacy standards applicable to ASCs. More specifically, the proposed rule provides that "[a]ccess to or release of patient records is permitted only with written consent of the patient or the patient's representative or as authorized by law." While this is not inconsistent with the HIPAA standards, we note that the HIPAA standards permit routine disclosures *without* patient consent for purposes of payment, treatment and health care operations.[20] Rather that having surveyors perform this two-step analysis, which has the potential to generate a significant amount of confusion over time, we believe it would be far better if the ASC conditions stuck with one standard and simply cross-referenced the HIPAA standards; i.e., access to or release of patient information and clinical records is permitted only in accordance with the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Part 164.

5. Infection Control (§ 416.51)

Significantly lower risk of infection is one of the primary advantages of ASCs over hospital-based surgery. The exemplary infection control record of the ASC industry, as a whole, has been hard-earned through proactive and widespread use of state-of-the-art preventive measures, as well as extensive education and training. For the most part, this success has been achieved without prescriptive regulatory standards, and we appreciate that the proposed infection control condition does not mandate any specific set of infection control guidelines and allows flexibility for ASCs to determine how to meet the objectives of preventing, controlling and investigating infections. As with the proposed QAPI program standards, we believe the most effective infection control programs are those tailored to the unique needs of each individual facility.

Towards that end, we ask that CMS confirm that the requirement in proposed § 416.51(b)(1) that an ASC's infection control program be directed by a "qualified professional who has training in infection control" should not be read as mandating any particular infection control credentials or certification. Rather, consistent with the general approach in this section, we believe this statement includes the flexibility for each ASC to determine the qualifications and training needs for its infection control director. However, we also believe it would be helpful to have confirmation of that interpretation in the final rule.

---

[20] See 45 C.F.R. §§ 164.502 and 164.506.

6. Patient Admission, Assessment and Discharge (§ 416.52)

The proposed rule's standards on patient admission, assessment and discharge include four provisions that are inconsistent either with accepted medical practices or with applicable legal standards of care and, thus, would interfere with the efficient delivery of patient care or impose undue burdens on ASCs, in each case without any measurable benefits for patient safety.

- The first is a requirement in proposed § 416.52(a)(1) for a "comprehensive" history and physical assessment no more than 30 days prior to surgery. While an *appropriate and current* pre-surgical assessment is unquestionably essential, that does not always need to be accomplished via a comprehensive exam within a 30-day window. Consider, for example, the common situation of repetitive or bilateral procedures, such as cataract removal for both eyes or carpal tunnel repair in both wrists. Although a comprehensive exam may be appropriate in advance of the first procedure, a more limited update of that exam typically is sufficient in advance of the second surgery to determine whether there have been any significant changes in the patient's condition. Yet, under the proposed rule, if the initial exam occurred outside of the 30-day window – which it often would because bilateral procedures normally are separated by a number of weeks – the patient would need to undergo an additional and unnecessary comprehensive exam just to meet Medicare requirements. Similar problems with a strict 30-day comprehensive exam requirement would be encountered when surgeries are rescheduled. To avoid this waste of health care resources and inconvenience to Medicare beneficiaries, we suggest the following, more practical accreditation standard for pre-surgical assessments:

  > An appropriate and current history, including a list of current medications, and dosages if known, physical examination, and pre-operative diagnostic studies are incorporated into the patient's medical record prior to surgery.[21]

- The second cause for concern in this section is a requirement in proposed § 416.52(a)(2) that the pre-surgical assessment include documentation to determine the patient's "mental ability" to undergo the surgical procedure. Imposing this duty on ASCs seems to interfere with the doctor-patient relationship and the rights of patients to control their own medical decisions, rather than have physicians or ASCs substitute their judgment for that of the patient. Notably, this fundamental right of self-determination is expressly recognized in the patient rights provision of the proposed rule at § 416.50(b). Indeed, the well-established legal framework here places a duty *on the physician* to (1) discuss the necessity and appropriateness of the proposed surgery, as well as available alternative treatments, with the patient prior to scheduling surgery, and (2) obtain informed consent of the patient or, if applicable, of the patient's representative, before the procedure is performed. In other words, the decision to undergo a surgical procedure goes to the heart

[21] *AAAHC Handbook*, supra note 14 at 48.

of the doctor-patient relationship,[22] and ultimately is a decision reserved by law to the patient or to his or her representative – not to the physician, and certainly not to the ASC. Thus, we strongly believe that CMS should not interfere with that legal framework by imposing a separate regulatory duty in the CfCs to assess the patient's subjective "mental ability" to undergo surgery, especially where such an assessment conflicts with the legal right of patients to make their own health care decisions or to have those decisions made by their designated representatives, rather than by health care providers.

- The third cause for concern in this section is a requirement in proposed § 416.52(c)(2) that the ASC must "ensure the patient has a safe transition to home." Of course, unless this is supposed to mean that ASCs are obligated to assume full responsibility for actually transporting patients to their homes using ambulances or other extraordinary precautions, there is no way for ASCs to "ensure" against care accidents or other intervening events outside of their control that could interfere with a patient's safe transition to home. Rather, the proper standard here is to preserve the current legal standard of reasonable care, along with the existing requirement at § 416.42(c) that "all patients are discharged in the company of a responsible adult."

- The final cause for concern in this section is the current phrasing of proposed § 416.52(c)(3), which could be read to require that the physician who performed the surgery must not only sign the discharge order (an appropriate requirement that we support), but also must remain in the facility and evaluate the patient for proper anesthesia and recovery prior to discharge. At present, it is common practice for surgeons to sign discharge orders indicating that a patient should be "discharged when stable," and then delegate authority for that final assessment to another physician – often an anesthesiologist with specialized training and experience in proper anesthesia recovery – who remains present at the facility, while the surgeon is on call and available if needed. It is not clear whether CMS intended to upset that established medical practice, especially since we are not aware of any compelling medical need for requiring that the physician who performed the surgery also be the physician who evaluates for final anesthesia recovery. To the contrary, anesthesiologists generally are better suited for this role. Because the proposed language is ambiguous, however, we suggest clarifying that the standard remains as currently contained at § 416.42(a), which provides that before discharge from an ASC, each patient must be evaluated by *a physician* – not necessarily the performing physician – for proper anesthesia recovery.

C. Updates Not Included in the Proposed Rule

Finally, we recommend that CMS address a couple of long-standing areas of concern for ASCs in the environment standards:

---

[22] To the extent that physician's do not appropriately perform this function, that is properly addressed through the ASC medical staff and its peer review and credentialing processes.

- The first is amending the language in existing § 416.44(a)(2), which currently states that ASCs must have a separate recovery "room" and waiting "area." We have never understood the need for a separate waiting area and believe that requirement should be eliminated. In addition, on occasion our members have had to deal with surveyors who believe the CfC's use of the terms "room" and "area" reflects a meaningful distinction and that a recovery "room" must have a door and be completely separate from other areas of the facility, even though this impedes effective nursing care. CMS officials have informally confirmed for us that the CfCs do not require a door and that the primary reason for requiring a "separate recovery room" is to ensure that ASCs do not share their recovery space with hospitals, clinics or physician offices. To avoid this confusion in the future, we recommend amending § 416.44(a)(2) as follows: "The ASC must have a recovery area that is separate from any other facility." We note that a proposal similar to this recommendation was included as part of the CfCs circulated by the agency for informal comments in 2000.

- We also suggest that CMS consider eliminating the requirement at existing § 416.44 (c)(3) that all ASCs have a mechanical ventilator.

* * *

Thank you for your consideration of our comments. We look forward to continuing to work with CMS to strengthen and modify the ASC conditions for coverage.

Sincerely,

Kathy J. Bryant
President

AMERICAN COLLEGE OF GASTROENTEROLOGY

6400 Goldsboro Road, Suite 450, Bethesda, Maryland 20817-5846; P: 301-263-9000; F: 301-263-9025

October 31, 2007

Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-3887-P
P.O. Box 8017
Baltimore, Maryland 21244-8017

Re: *Conditions for Coverage (CfCs) for Ambulatory Surgery Centers Participation in the Medicare and Medicaid Programs, CMS-3887P*

Dear Mr. Weems:

The American College of Gastroenterology is pleased to provide these comments with respect to CMS' proposed conditions for coverage for ambulatory surgery centers (ASCs) (42 CFR Part 416) participating in the Medicare and Medicaid program as published in the *Federal Register* on August 31, 2007.

INTRODUCTION

The American College of Gastroenterology is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, the College currently numbers more than 10,000 physicians among its membership of health care providers of gastroenterology specialty care. Although the vast majority of these physicians are gastroenterologists, the College's membership also includes surgeons, pathologists, hepatologists, and other specialists in various aspects of the overall treatment of digestive diseases and conditions. The College has chosen to focus its activities on clinical gastroenterology – the issues confronting the gastrointestinal specialist in treatment of patients. The primary activities of the College have been, and continue to be, educational efforts directed at promoting and optimizing quality care.

In addition to the College's comments, which follow, we also wish to endorse specifically the comments submitted jointly in this matter by the American College of Gastroenterology, the American Society for Gastrointestinal Endoscopy, and the American Gastroenterological Association. The comments below are meant to add to the record in addition to the jointly submitted comments referenced above.

ASCs are a key site of service for gastrointensinal care, and thus these proposed regulations are of vital importance. The existing regulations are twenty-five years old, and it is essential that the proposed changes support continued innovation in the delivery of high-quality, patient-centric care while meeting well-established criteria for cost-effectiveness.

Regulatory Impact Analysis

We commend CMS for completing the required regulatory impact analysis and analysis of the effect of this proposal on small businesses, as the majority of endoscopy centers are small businesses. Given that the final ASC payment rule will result in significant and unwarranted payment cuts to endoscopy centers over a four-year period, it is more important than ever for the cost-benefit analysis of new regulations affecting such centers to be rigorous and accurate and that these requirements lead to improvements in care and quality. While patient safety and protection must be paramount, in a time of declining reimbursement, there is little room for error in crafting new requirements. Ambulatory surgery centers, including endoscopy centers, often have certificate of need restrictions – as well as facing architectural realities—that will keep them for offering other services to make up for the decline in GI revenues. Surveys of our members indicate that under the proposed ASC payment rule, as many as one-third of GI ASCs would stop seeing Medicare patients or close, and a Deutsche Bank analysis found that any GI ASC that provides fewer than 3,500 procedures per year will be put out of business. Lack of access to care is the ultimate lack of patient protection.

Conditions for Coverage—Patient Rights

CMS's new proposal would require ASCs to notify patients of their rights, provide for the exercise of rights, establish the right of privacy and safety, and maintain the confidentiality of clinical records. To ensure quality care patients should be notified not only of their rights but also of their responsibilities so that patients can be full partners in their care. Included in the notice of patient rights should be an explicit section on patient responsibilities that notes, for example, that patients should comply with all pre- and post-procedure instructions; should treat all staff and fellow patients respectfully; keep appointments; and understand and fulfill all payment responsibilities. Fulfillment of such responsibilities will lead to greater patient and provider satisfaction and higher quality care. A notice that includes responsibilities can serve as an important patient education tool. Evaluating patient grievances in light of patient adherence to their responsibilities can also serve as a helpful evaluation prism.

Condition for Coverage—Patient Admission, Assessment and Discharge

This section states that CMS would propose that "each patient must have a comprehensive medical history and physical assessment completed not more than 30 days before the date of scheduled surgery by a physician (as defined in section 1861(r) of the Act), or other qualified practitioner in accordance with State law and ASC policy." The ACG finds it ironic that the new CfCs require a pre-surgical assessment within 30 days of the scheduled surgery given that the agency refuses to cover such a pre-assessment prior to screening colonoscopies. The literature is clear that given the number of co-morbidities in the Medicare population and the importance of understanding the procedure and adhering to preparation instructions to quality colonoscopy, that such assessment are vital. It is particularly troublesome that Medicare does not cover such an assessment when such assessments are covered for a diagnostic colonoscopy which is the same procedure, performed only for a different indication. In light of the new CfC requirements, we urge the agency to reconsider its policy on pre-assessment physicals for

screening colonoscopies, particularly since the major accreditation bodies require such assessments for any procedure – such as colonoscopy -- involving sedation.

Conclusion

We are deeply concerned that the cumulative cuts from the SGR, and the pending reform to the ambulatory surgery payment system will drive many gastroenterology practices and ASCs out of the Medicare system and/or out of business and compromise their ability to continue to provide gastroenterology specialty care to Medicare beneficiaries. We appreciate the opportunity to submit our comments on this CfC proposal.

Respectfully submitted,

Amy Foxx-Orenstein, DO, FACG
ACG President

Scott Tenner, MD, FACG
Chair, National Affairs Committee

October 30, 2007

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: 42 CFR Part 416; Medicare and Medicaid Programs; Ambulatory Surgical Centers, Conditions for Coverage; Proposed Rule

Dear Mr. Weems:

On behalf of the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE) who jointly represent over 15,000 physicians specializing in digestive diseases, we are pleased to have the opportunity to comment on the proposed regulations 42 CFR Part 416; Medicare and Medicaid Programs; Ambulatory Surgical Centers, Conditions for Coverage.

The Conditions for Coverage (CFCs) were originally issued in 1982. In the ensuing twenty years, significant innovations in ASC patient care delivery, safety, and quality assessment have emerged. Our societies support the Agency's efforts to continue to promote high-quality care in the ASC setting by updating the ASC CFCs.

We are in agreement with most of the proposed conditions for coverage and find them generally consistent with accreditation requirements already imposed on ASCs by other entities such as the Joint Commission or the Accreditation Association for Ambulatory Health Care (AAAHC). However, as indicated below, we have concerns with several of the proposed conditions.

We have a broad concern with the Agency's ability to provide the increased support these additional regulations will require.

At present, a newly established ASC can experience significant delays in certification, with further delays generated if a follow-up survey is required. Delays in initial Medicare certification can be economically unsustainable for a smaller single specialty center, particularly for individually owned ASCs in comparison to ASCs owned by larger commercial entities. In anticipation of a survey, the center must be prepared to function by being fully staffed and supplied, but cannot perform any cases except those allowed by the surveyor. An ASC can wait weeks in this situation waiting for the availability of the contractor. This can result in enormous financial burdens for the ASC and cause significant delays in beneficiaries accessing services.

We anticipate that the regulations will result in a more complex survey process; yet, we are not confident that CMS will have the resources needed to support the demands implied by a survey that incorporates the complexity, detail and scope necessary for the implementation of these proposed regulations. We do not want to see even greater delays in the survey process emerge as a result of these new regulations.

While the survey process may be critical to certify an ASC, we do not believe that ASCs should be penalized with further delays generated where quality and safety criteria are met, but administrative details are lacking.

Based on these concerns, our societies recommend that prior to implementation of these new regulations, CMS take steps to assure that adequate resources are in place to assure timely surveys and resurveys so as to minimize delays in the participation or continued participation of ASCs. In this connection, we trust that CMS and its contractors will apply a *rule of reason* to assure that minor deficiencies in administrative conditions (e.g., provision of translator services or definition of grievance) are not considered as the same level of deficiency as a basic health and safety requirement. We hope that CMS will *conditionally* certify or recertify ASCs found out of compliance with a minor or technical condition and provide a period of time to meet the specific standard.

ASCs are an important source of high quality care for Medicare beneficiaries. While these proposed CFCs will support the on-going provision of this high-quality care, we would be disappointed to see their implementation causing delayed access to care for Medicare beneficiaries.

These proposed CFCs will not only increase the administrative demand on CMS, but also substantially increase the administrative burden on ASC operations. While overall we support the Agency's efforts and believe that the new requirements will help in the provision of good patient care, we observe the inconsistency inherent in decreasing Medicare payments for ASCs providing important gastroenterology services to Medicare beneficiaries as the Agency introduces parallel increases in costly administrative requirements.

Condition for Coverage—Quality Assessment and Performance Improvement (QAPI)
With the proposed Quality Assessment and Performance Improvement (QAPI) requirement, CMS has raised the bar for all participating ASCs. In contrast to the traditional retroactive, problem-oriented approach, currently required by CMS, the QAPI program will require the development, implementation, and maintenance of an ongoing quality improvement program that aims to proactively reduce errors and address omissions of care *prior* to performing a procedure. We agree with CMS that this model of on-going monitoring of quality versus the traditional problem-oriented model is better supported by available evidence. In fact we believe that most accredited ASCs already have such programs in place, in accordance with processes implied by the accreditation process.

The gastroenterology community fully supports the implementation of QAPI programs in ASCs. We believe that such programs demonstrate improvement in patient health outcomes, improve patient safety and help decrease medical errors. While we support the concept of instituting the requirement of a QAPI program, we strongly disagree with the estimated staff support and expense suggested by the Proposed Rule, with special reference to the number of hours needed for development and implementation. CMS estimated that fifty-two hours annually per ASC are required for this process. In fact, our experience would suggest that this is a gross underestimate

of staff time. To properly conduct a program of the scope and breadth described in the proposed regulations *at least* one full-time employee (FTE) would be needed for a typical ASC. Further, the scope of this project would require the expertise of an RN level staff member. Given that the majority of gastroenterology ASCs are small employers, this will be a substantial un-reimbursed expense for these practices.

We request that in the final regulations CMS include a more accurate estimate of the number of labor hours required to develop and implement a QAPI program. We recommend an estimate of one FTE (2,000 hours) annually per ASC to support a QAPI program.

Conditions for Coverage—Patient Rights

CMS's new proposal would require ASCs to notify patients of their rights, provide for the exercise of rights, establish the right of privacy and safety, and maintain the confidentiality of clinical records. Based on our review, we found the requirements proposed in this section to be reasonable.

Written policies that detail the rights of patients protect both the facility and the patient and encourage the provision of safe and high quality care. However, we urge CMS to assist us in this endeavor by providing additional detail and clarification on issues surrounding the concept of grievances. In the daily operation of an ASC, administrators, staff, and providers receive a variety of feedback from patients and their family or caregivers that is both positive and negative in nature. Such negative comments may be trivial (e.g., the color of the gown, the temperature in the room) or important (e.g., a concern about privacy). The proposed regulations require ASCs to investigate, document and respond to all grievances, no matter how trivial. We do not believe that CMS meant to imply that every patient complaint rises to the level of a grievance. *The societies request that CMS provide a definition of grievance in the final regulations to provide both surveyors and ASCs with better guidance in terms of what types of situations would fall within the grievance category.*

Beyond more detail on grievances, we ask CMS to provide more detail on the Agency's expectations for dealing with grievances and situations where there is a difference in interpreting compliance. As currently stated, the requirement is too general and requires an inordinate subjective interpretation. A Medicare contractor conducting an ASC survey will have significant influence on interpreting the regulations. We believe that it is in the best interest of both the patient and the ASC if there is less reliance on individual contractor interpretation of these regulations and more national consistency in implementation. *The societies urge CMS to provide more detailed discussion of these issues in the final regulations.*

Condition for Coverage—Patient Admission, Assessment and Discharge

The proposed new requirement in this section would augment current regulations with the proposal for an admission and pre-surgical assessment, post-surgical assessment and a discharge. A discharge protocol with written discharge instructions containing elements delineated in the proposed regulations is the current standard in the industry. However, we request that CMS provide additional clarification on certain of the elements proposed. For example, under the proposed regulations, it is unclear who the responsible individual is for preparing the discharge. Accredited ASCs require that patients meet well-defined criteria for discharge after sedation, and these discharge criteria are delineated in the standard operating procedures for the ASC. Accredited ASCs require pre-operative evaluation of certain organ systems prior to the procedures and after the procedure. The proposed regulations (in the preamble) suggest that an evaluation of *all* organ systems will be required prior to discharge. This requirement would be atypical for discharge from any procedure in any facility. For example, an ophthalmologic

examination is not typically performed prior to patient discharge after an endoscopic procedure. The actual standard specifies that the discharge order signed by a physician must indicate that the patient has been evaluated for proper anesthesia and medical recovery. We think the judgment as to which organ systems need to be reviewed for compliance with this standard should be left to the judgment of the ASC governing body. *The societies recommend that CMS remove or substantially modify this requirement in the final regulations.*

Thank you for the opportunity to submit these comments. If we may provide additional information, you may contact Sheila Madhani, Consultant to ASGE at 202-833-0007, Anne Marie Bicha, AGA Director of Regulatory Affairs, at 240-482-3223, or Julie Cantor-Weinberg, ACG Vice President of National Affairs, at 301-263-9000.

Sincerely,

Amy Foxx-Orenstein, DO, FACG
President, American College of Gastroenterology

Mark Donowitz, MD

Mark Donowitz, MD, AGAF
Chair, American Gastroenterological Association

Grace H. Elta, M.D.

Grace H. Elta, MD, FASGE
President, American Society for Gastrointestinal Endoscopy