CMS-3887-P-1

Because the referenced comment number does not pertain to the subject matter for CMS-3887-P, it is not included in the electronic public comments for this regulatory document.

CMS-3887-P-2

Because the referenced comment number does not pertain to the subject matter for CMS-3887-P, it is not included in the electronic public comments for this regulatory document.

CMS-3887-P-3

Submitter : **Dr. Jenkins Bush** **Date: 08/29/2007**

Organization : **Resurgen Orthopaedics**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Ambulatory Surgery Centers provide an invaluable means for patients to return to their families and workplaces while also providing with top-notch care.

Submitter : Catherine DiSabatino **Date:** 09/04/2007

Organization : Catherine DiSabatino

Category : Nurse

Issue Areas/Comments

Background

Background

ASC's should meet the same requirement as hospitals for reporting chosen quality measures.

GENERAL

GENERAL

Conditions for Coverage must be more specific in order to be followed.
1. Language to require the integration of QAPI/Risk Management activities. This is an accreditation standard.
2. Include language that requires the Governing Body to appoint(in writing) an appropriately trained indivudual,to be responsible for the implementation and oversight of the facility's QAPI program. In Florida, licensed risk managers are required in every ASC. Traditionally, the Risk Manager takes on the role of implementing and overseeing the Quality Improvement Plan.
3.Change language in CFP to be clearer regarding comprehensive history and physical assessment.
416.52(a)(1) Prior to scheduled surgery date and not more than 30 days before surgery date, each patient must have a comprehensive history and physical assessment completed by the pgysician who will be performing the procedure. If the physician delegates this responsibility to another physican, such as patient's PCP, the physician performing the procedure must review and authenticate the assessment prior to the scheduled surgery date. This ensures that the surgeon knows his patient's staus and risk associated with the procedure and allows for time for further labs and others studies to be completed and reviewed,if needed, prior to the date of procedure.
(2)The pre-surgical update is to be completed the date of the procedure prior to the patient being taken to the OR by the physician performing the procedure. This element cannot be delegated the the anessthesia provider.
(3) The patient's medical history and physical assessment must be placed in the patien's medical record prior to the patient being taken to the OR.

CMS-3887-P-5

Because the referenced comment number does not pertain to the subject matter for CMS-3887-P, it is not included in the electronic public comments for this regulatory document.

Submitter : **Dr. Scott Pacific** **Date: 09/12/2007**

Organization : **Summit Medical Group**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

Background

Background

Summit Medical Group is a 130+ MD multi-specialty group. We have a 6 OR ambulatory surgical center. We currently are able to provide our non-Medicare patients with Trans-esophageal echocardiography and cardioversions in our ASC with appropriate anesthesia and nursing care. This level of care cannot be duplicated in a physicians' office.
We have anesthesiologists and critical care nurses in our ASC.
Medicare currently reimburses for these procedure is performed in an office setting or a hospital.

GENERAL

GENERAL

Dr. Avi Kothovale and myself (Scott Pacific, M.D.), can be reached at the Summit Medical Group 908-273-4300. We look forward to ongoing discussions regarding this issue.
Sincerely,
Scott Pacific
Off: 908-277-8882
BP: 908-471-4221

Impact

Impact

see other fields

Provisions

Provisions

Having practiced Cardiac Anesthesia, I can tell you that the sub-set of Medicare patients who require cardioversions or transeaophageal echos cannot be safely performed in an office. I know of no cardiologists who practice in this manner. It seems illogieal that Medicare would reimburse for procedures that cannot be safely performed in an office setting, and yet not reimburse when they can be safely performed in an ASC, (at substantially less cost than in a hospital).

Submitter : Dr. Michael Chang **Date:** 09/12/2007

Organization : Muir Orthopaedics Specialists

Category : Physician

Issue Areas/Comments

Background

Background

please see attached

CMS-3887-P-7-Attach-1.DOC

#7

CMS-

Because the referenced comment number does not pertain to the subject matter for CMS- , it is not included in the electronic public comments for this regulatory document.

Submitter : **Mrs. kathy king** **Date: 09/20/2007**

Organization : **Surgery Center of Cincinnati**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

Background

Background

Have 29877 on our fee schedule. This procedure has been approved for ASC. CCI has a rule were you can not use 29877 w 29880/29881. Use G0289 instead. They both cover the same procedure.

GENERAL

GENERAL

Have tried to send twice, not sure it is getting rec? want to make sure I meet the deadline for 2008. The temprorary comment number for the 2nd time was 210946.
I don't think I added a email address or anything to hear a respond back (in case I need to do something else) so I am doing it again and trying to link them w giving the comment #.

Katherine King CPC
Biller/Coder
Surgery Center of Cincinnati
Kathy.King@docsgroup.com
Phone # 947-1130 Ext# 102
fax # 947-8541

Sorry, for the Redundancies.

Impact

Impact

ASC does not have G0289 on their fee schedule.

Provisions

Provisions

Would like to have G0289 added to ASC fee schedule. This will correspond with the CCI rule, and since we have been approved once already for this procedure as a 29877. I didn't think it would be a problem.

CMS-3887-P-8-Attach-1.DOC

CMS-3887-P-8-Attach-2.PDF

#8-1

To Whom It May Concern:

The purpose of this letter is to request that CPT code G0289 be added to the fee schedule for an Ambulatory Surgery Center in 2008. The National Correct Coding Institute (NCCI) rule of using G0289 instead of 29877 with 29880/29881 has raised this issue.

29877, a Chondraplasty, is on the fee schedule of an ASC. However, most of our procedures are 29880 or 29881 in addition to 29877. According to the bundling rule, 29877 cannot be used with these codes. The NCCI rule states to use the code G0289 instead of 29877, but G0289 is not on our fee schedule. **G0289 does the same thing as 29877, but because of the bundling rule we cannot code 29877 with our most commonly used procedures.**

The knee is considered to have three compartments and sometimes the Chondraplasty is done in two of those compartments. According to coding we must code everything that is being done and to its highest degree, please see example below:

~ A patient that had a Median Menisectomy, Lateral Chondroplasty and Pattlofemoral Chondraplasty would be coded as 29881 plus G0289 x 2

~A patient that had a Medial, Lateral Meniscetomy and Chondroplasty in all three compartments would be coded as 29880 plus G0289

Please add CPT code G0289 to the fee schedule of an ASC.

Thank you for your consideration,

Liberty Holt
Business Office Manager
Surgery Center of Cincinnati
4415 Aicholtz Rd
Cincinnati, OH 45245
513-947-1130

#8-2

Medicare

CMS

CENTERS for MEDICARE & MEDICAID SERVICES

2007

MEDICARE

PART B

AMBULATORY SURGICAL CENTER

FACILITY

FEE SCHEDULE

CLERMONT COUNTY

Revised: January 1, 2007

PALMETTO GBA
MEDICARE PART B OPERATIONS
P.O. BOX 182934 • COLUMBUS, OHIO 43218-2934
A CMS CONTRACTED INTERMEDIARY AND CARRIER

CLERMONT	45	29855	$617.26	Jan 1 2007 12:00AM
CLERMONT	45	29856	$617.26	Jan 1 2007 12:00AM
CLERMONT	45	29860	$617.26	Jan 1 2007 12:00AM
CLERMONT	45	29861	$617.26	Jan 1 2007 12:00AM
CLERMONT	45	29862	$1,311.92	Jan 1 2007 12:00AM
CLERMONT	45	29863	$617.26	Jan 1 2007 12:00AM
CLERMONT	45	29870	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29871	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29873	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29874	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29875	$617.26	Jan 1 2007 12:00AM
CLERMONT	45	29876	$617.26	Jan 1 2007 12:00AM
CLERMONT	45	29877 * G0289	$617.26	Jan 1 2007 12:00AM
CLERMONT	45	29879	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29880	$617.26	Jan 1 2007 12:00AM
CLERMONT	45	29881	$617.26	Jan 1 2007 12:00AM
CLERMONT	45	29882	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29883	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29884	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29885	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29886	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29887	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29888	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29889	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29891	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29892	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29893	$1,230.17	Jan 1 2007 12:00AM
CLERMONT	45	29894	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29895	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29897	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29898	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29899	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29900	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29901	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	29902	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	30115	$436.98	Jan 1 2007 12:00AM
CLERMONT	45	30117	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	30118	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	30120	$326.27	Jan 1 2007 12:00AM
CLERMONT	45	30125	$436.98	Jan 1 2007 12:00AM
CLERMONT	45	30130	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	30140	$436.98	Jan 1 2007 12:00AM
CLERMONT	45	30150	$499.69	Jan 1 2007 12:00AM
CLERMONT	45	30160	$617.26	Jan 1 2007 12:00AM
CLERMONT	45	30220	$454.76	Jan 1 2007 12:00AM
CLERMONT	45	30310	$326.27	Jan 1 2007 12:00AM
CLERMONT	45	30320	$436.98	Jan 1 2007 12:00AM

CHAPTOR 4-- NCCI

10. CPT codes 29874 (Surgical knee arthroscopy for removal of loose body or foreign body) and 29877 (Surgical knee arthroscopy for debridement/shaving of articular cartilage) should not be reported with other knee arthroscopy codes (29871-29889). Report G0289 (Surgical knee arthroscopy for removal of loose body, foreign body, debridement/shaving of articular cartilage at the time of other surgical knee arthroscopy in a different compartment of the same knee).

CMS-3887-P-9

Because the referenced comment number does not pertain to the subject matter for CMS-3887-P, it is not included in the electronic public comments for this regulatory document.

Submitter : **Regina McNally** **Date: 09/26/2007**

Organization : **Medical Society of the State of New York**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Impact

Impact

Re: CMS-3887-P
Provisions:
On Page 50472, it is indicated that ASCs that are Medicare certified may not keep patients beyond 11:59 PM on the day on which the surgical procedure is performed. This is not acceptable. There maybe situations when a procedure is scheduled late in the day and a patient needs the additional time for recovery. Furthermore, this rule runs counter to the emphasis on patient safety. Keeping patients overnight for monitoring after some of the more extensive procedures should be left to the clinical judgement of the physician be based on the patient's condition. Additionally, it would preclude the cost saving efforts of having a procedure provided in an ASC rather than the more costly hospital setting.

Submitter : **Dr. Scott Thellman** **Date: 09/27/2007**

Organization : **Lawrence Plastic Surgery**

Category : **Physician**

Issue Areas/Comments

Impact

Impact

See attachment

CMS-3887-P-11-Attach-1.DOC

#11

September 25, 2007
RE: CMS-3887-P

To Whom It May Concern:

I am writing in regard to proposed rules as published in the Federal Register of August 31, 2007. I have been made aware that among these proposed rule changes listed for the Department of Health and Human Services, Center for Medicare & Medicaid Services, 42CFR Part 416 [CMS-3887-P] are new proposed regulations for ASC patients concerning overnight stays following surgery. As written on pages 50471-2 in the "Definitions" section (416.2) no patients would be allowed to stay in a Medicare certified facility past 11:59 PM on the day of their operation. The reasons given for such a rule change are apparently related to cost and reimbursement policies as outlined in the Provider Reimbursement Manual, Part 1, section 2005, and seek to bring the reimbursement policies at an ASC in line with those used at hospitals. While this may be a reasonable clerical goal, I see the rule as proposed counterproductive to patient safety and potentially limiting to patient access.

As a plastic surgeon, I perform many operations at our local multispecialty ASC, jointly owned by physicians and our local hospital. As some of our operations are lengthy, with operating times at 4-6 hours, we keep many of these patients overnight for monitoring, discharging them on the following morning, less than 24 hours after their admission to our facility. These otherwise healthy patients undergoing long procedures are sent home the same day in some practices, but we feel it is better to err on the side of caution and monitor the patients overnight. At the national level, the American Society of Plastic Surgeons has been aggressively promoting better patient safety practices and has a strong dedication to educating the membership on proper measures to minimize patient risks. This includes overnight monitoring with trained nursing personnel following several common plastic surgical procedures (reconstructive breast surgery, abdominoplasty, body contouring, etc). This system has served us well for many years, allowing patients to receive excellent care in a convenient, safe, and cost efficient setting.

By eliminating overnight stays in an ASC following these procedures, patients will need to choose to have their operation at a hospital (which many healthy and/or cost minded patients will wish to avoid) or at a non-Medicare certified facility (which is the more likely choice). Of course, some "borderline" patients may be discharged home after a few hours, as they are not sick enough for hospital admission but do not have the option of staying at the ASC, despite the fact that this is the preference of the patient and/or physician. Therefore, going forward with this regulation will likely push patients into choosing a non-Medicare certified facility, or inappropriately early discharges. Both of these would clearly be <u>counterproductive to patient safety.</u>

A second consequence of this proposal may be that ASCs that currently hold Medicare certification may choose to give up that certificate so that they may continue to treat their non-Medicare patients in the safest possible manner. This would only further

limit the choices available to Medicare patients and their providers, ultimately leading to decreased access to the patient and physician's desired facility.

There is a final consequence of this proposed rule change. One can only assume that more procedures on Medicare patients would be done at hospitals, as certain procedures could not be consistently performed in a facility where an overnight stay is not permitted. In addition, if an ASC were to avoid Medicare certification to get past this rule, these patients also might be shifted to hospital care. Of course, Medicare payments for procedures performed at hospitals are substantially higher than for those same procedures performed in an ASC setting. Therefore, overall Medicare spending would increase, as cases move from an ASC reimbursement schedule to a hospital reimbursement schedule. Again, an undesired result of a small definition change intended only to clarify a billing and reimbursement issue.

As the proposed definition change is intended to only solve some inconsistencies in reimbursement language, I think great caution and consideration is called for before adopting this change. While these changes may reconcile some differences in reimbursement language, the unintended consequences could only have a negative impact on patient safety, patient access, and overall costs. Therefore, I would strongly urge that this rule change not be adopted. If it is inevitable that some changes in language take place, then this should only be applied to Medicare patients, and not the millions of others who would also potentially be affected by the unintentional impact of these changes.

I was disappointed that this issue was not addressed in any substantial way in the Regulatory Impact Analysis section. It seems this oversight may be significant, as it will directly affect the day to day operations of many surgery centers and the factors cited above deserve analysis when considering the impact of this change. While increased costs to the system as well as limitations in patient access are important, I think the most important consideration must always be patient safety. Adoption of this rule change will undoubtedly lead to worsening outpatient care, not better. I urge you not to adopt this change. As a physician, I always fall back on the first rule of medicine: "First, do no harm." Please let this be your guiding principle as well.

Scott Thellman, M.D.
Lawrence Plastic Surgery, P.A.
1112 W 6th St., Suite 210
Lawrence, KS 66044
sthellman@sunflower.com

Submitter : **Dr. Donathan Ivey** **Date: 09/29/2007**

Organization : **Specialty Surgery Center**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

Background

Background

Regarding need of surgeon to have admitting privledges at local hospital.

GENERAL

GENERAL

Consider allowing a surgeon to have an aggreement with a similar practitioner or have consulting privledges instead of admitting as these transfers are rare anyway.

Provisions

Provisions

This rule could allow hospitals to close down money saving surgery centers by revoking or denying privledges.

CMS-3887-P-13 **Medicare Program; Revisions to Conditions for Coverage for Ambulatory Surgical Centers**

Submitter : **Mr. Dodjie Guioa** **Date & Time:** **10/15/2007**

Organization : **CMS/RO VI**

Category : **Individual**

Issue Areas/Comments

Impact

CfC: Governing Body: Local hospital: this term needs to be clearly defined so that State surveyor will be able to assess compliance of the ASC. The vague definition of the term will be diffficult for the surveyors to assess comliance. I proposed that the term local hospital be defined as "a hospital, either Medicare or non-Medicare participating, that serves the same community as the ASC and has the resources to manage the patient's medical condition and any reasonably forseeable complications of that condition."

CfC: Patient Rights: Recieve care in a safe setting. The preamble mentioned the decision not to create a new list of emergency equipments which I agree. However, since the preamble anticipated that the lists of procedures that will potentially be done in an ASC will soon be expanded, it is crucial that the language in the current regulation at 416.44(c) be reviewed to ensure that patients receieve care in a safe setting. The current language at 416.44(c) is "Emergency equipment available to the operating rooms muct include at least the following...." ASCs has historically interpreted that so long as there these equipements in the OR, that it does not have to be available in the recovery areas of the ASCs. The fact is, post-operative emergencies frequently occurs at the recovery area. Therefore, I propose revising the language at 416.44(c) to read: " Emergency equipment available in the ASC to meet the emergency needs of patients must include at least the following........"

CMS-3887-P-14

Because the referenced comment number does not pertain to the subject matter for CMS-3887-P, it is not included in the electronic public comments for this regulatory document.

CMS-3887-P-15 **Medicare Program; Revisions to Conditions for Coverage for Ambulatory Surgical Centers**

Submitter : **Mrs. Jo Ann Dower, AVP** **Date & Time:** **10/22/2007**

Organization : **Virtua Health**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

See attachment

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

II Provisions of the Proposed Regulation

A. Definitions (§416.2)

ASC would mean any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring an overnight stay following the surgical services,
Overnight stay: beyond 11:59 p.m. of the day which the surgical procedure was preformed.

Comment:

We recommend a change in the definition of "Ambulatory Surgical Center" from the proposed definition to "ASC would mean any distinct entity that operates exclusively for the purpose of providing surgical services to patients requiring a stay following the surgical services that would not exceed 24 hours for facilities that are co-owned and co-managed, or owned in full by a hospital or healthcare system."

For facilities that are co-owned and co-managed or owned in full by a hospital or healthcare system, the definition of overnight stay using a time of 11:59 p.m. can safely we changed to a time frame of less than 24 hrs, regardless of the time on the clock.
In the centers that are co-owned/managed, or fully owned by hospitals, the oversight of quality outcomes, patient selection criteria and clinical appropriateness are reviewed on a routine bases. All clinical outcomes meet regulatory requirements, payer specifics and state regulations.
For a variety of procedures like lumbar discectomy, and total knee replacement, very specific patient selection criteria would be developed and monitored. This would include limiting patient selection to Anesthesia class I or II, patients having no significant medical co-morbidities, and ensuring the patients have the appropriate resources at home to support their recovery.

Allowing the change of definition of Ambulatory Surgery Center (ASC) would further help control costs and reduce the utilization of expensive resources.
At Virtua Health, some of our surgeons have been performing 23-hr quad sparing total knee replacements for the past three (3) years. [JoAnn – in what setting?] We have clearly demonstrated the quality outcomes of our program as evidenced by the Joint Commission certification for the total joint program we received last year and the re-certification for two (2) years obtained in 2007.

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CMS-3887-P-16

Submitter : **Wanda Wilson, CRNA,PhD** **Date: 10/30/2007**

Organization : **American Assoc. of Nurse Anesthetists**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

EPARTMENT OF HEALTH AND HUMAN SERVICES
ENTERS FOR MEDICARE AND MEDICAID SERIVICES
FFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

lease note: We did not receive the attachment that was cited in his comment. We are not able to receive attachments that have been repared in excel or zip files. Also, the commenter must click the ellow "Attach File" button to forward the attachment.

lease direct your questions or comments to 1 800 743-3951..

Submitter : **Wanda Wilson, CRNA,PhD** **Date: 10/30/2007**

Organization : **American Assoc. of Nurse Anesthetists**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-3887-P-17-Attach-1.PDF

#17

October 30, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G, Hubert H. Humphrey Bldg
200 Independence Ave., SW
Washington, DC 20201

ATTN: CMS-3887-P

Re: Comments on Medicare and Medicaid Programs: Ambulatory Surgical Centers, Conditions for Coverage (72 Fed. Reg. 50470, August 31, 2007).

I. **PROVISIONS**
   A. **Conditions for Coverage – Patient Admission, Assessment and Discharge (§416.52)**
   B. **Conditions for Coverage – Quality Assessment and Performance Improvement (§416.43)**

Dear Sir/Madam:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to comment on the proposed rule for the Medicare and Medicaid Programs; Ambulatory Surgical Centers, Conditions for Coverage *(72 Fed. Reg. 50470, August 31, 2007).* The AANA is submitting comments in the areas of Quality Assessment and Performance Improvement, and Patient Admission, Assessment and Discharge.

The AANA is the professional association for more than 36,000 Certified Registered Nurse Anesthetists (CRNAs) and student nurse anesthetists representing over 90 percent of the nurse anesthetists in the United States. CRNAs are advanced practice nurses who administer about 27 million anesthetics given to patients each year in the United States, according to the 2005 AANA Member Survey. Nurse anesthetists have provided anesthesia in the U.S. for over 125 years, and high quality, cost effective CRNA services continue to be in high demand. CRNAs are Medicare Part B providers and since 1986, have billed Medicare directly for 100 percent of the physician fee schedule amount for their services.

American Association of Nurse Anesthetists Office of Federal Government Affairs
412 First St., SE, Suite 12, Washington DC 20003 // 202-484-8400 // fax 202-484-8408 // www.aana.com

CRNA services include administering the anesthetic, monitoring and interpreting the patient's vital signs, and managing the patient throughout the surgery. CRNAs also provide assessment and evaluation for acute and chronic pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and are the sole anesthesia providers in almost two-thirds of rural hospitals, affording these medical facilities obstetrical, surgical, and trauma stabilization, and pain management capabilities. Nurse anesthesia predominates in Veterans Hospitals and in the U.S. Armed Forces. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers (ASCs), pain management units and the offices of dentists, podiatrists, and all varieties of specialty surgeons.

I. PROVISIONS

A. Conditions for Coverage – Patient Admission, Assessment and Discharge (§416.52)

- **ASC Conditions for Coverage should reflect current safe and effective anesthesia patient care.**

We appreciate CMS' efforts to amend the ASC Conditions for Coverage (CfC) to modernize the CfCs to be more aligned with today's ASC healthcare industry standards, and to reflect a more patient-centered approach that underscores essential steps to improve quality of care and patient outcomes.[1] In the area of patient admission, assessment and discharge, CMS' proposed rule addresses two CfCs that could impact anesthesia providers.

First, we understand that CMS intends on retaining the current CfC standard at 42 CFR §416.42(a) which requires a physician to evaluate each patient for anesthesia recovery before discharge. Generally, in day-to-day practice when a patient receives anesthesia or related services from a qualified anesthesia provider such as a CRNA or anesthesiologist, a physician meets this requirement by consulting with the qualified anesthesia provider as to the patient's anesthesia recovery before the physician discharges the patient. We argue that a post-anesthesia evaluation performed by a qualified anesthesia provider, or consultation with a qualified anesthesia provider, remain a critical element in a discharging physician determining a patient's anesthesia recovery. The unique expertise of a qualified anesthesia provider is crucial to the continued quality of anesthesia care patients receive before, during and after a surgical or other

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[1] 72 Fed.Reg. 50470, p. 50471, 50477

procedure requiring anesthesia or related services. Fundamentally, however, we advise the agency that a CRNA is qualified to determine anesthesia recovery. This service lies well within CRNAs' scope of practice. Permitting ASCs to have CRNAs determine anesthesia recovery ensures a qualified professional is making this determination for each patient in the interest of patient safety, while extending ASCs the flexibility to arrange their delivery of services in the most efficient manner compliant with the CfCs.

Second, CMS proposes to add a new section to the CfCs, 42 CFR §416.52 Conditions for coverage – Patient admission, assessment and discharge. Under the proposed §416.52(c)(3), the ASC must "(e)nsure each patient has a discharge order, signed by a physician or the 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* [emphasis added] anesthesia and medical recovery."[2] In this context, we understand "proper anesthesia recovery" to mean that though the patient could experience residual effects from the anesthesia, this does not mean that it is not appropriate for a physician or qualified provider to discharge the patient. Because the effects of anesthesia can last beyond the point at which a patient is discharged, patients are advised not to drive, sign important legal documents, etc. until the following day. However, the patient can still be safely discharged so he/she may return home and rest according to the post procedure instructions specific to that patient. To ensure appropriate and safe discharge of a patient it is important that a post-anesthesia evaluation by a qualified anesthesia provider, or consultation with a qualified anesthesia provider, remain a critical element in the discharging physician or provider determining a patient's anesthesia recovery and eventual discharge.

Additionally, we have a comment possibly in the nature of a technical correction to make. CMS' explanatory language in the proposed rule seems to state that the primary difference between the current CfC and the proposed CFC at 416.52 is that the current CfC allows *any* physician or qualified provider to sign the discharge order as opposed to the explanatory language in the proposed rule which requires that the discharge order be signed by "*the* physician or *the* qualified provider who actually performed the surgery or procedure unless specified by state law."[3] [Emphasis added.] However, the actual proposed CfC language for 416.52 states that "*a*

[2] Id. p.50487
[3] Id. p. 50478

physician or *the* qualified provider" [Emphasis added.] must sign the discharge order. This would seem to mean that *a* or *any* physician could sign the discharge order, or *the* qualified provider who performed the surgery or procedure could sign the discharge order. Which is reading is correct? Is it the explanatory language in which only "the physician or the qualified provider who performed the surgery or procedure" could sign the discharge order; or the proposed CfC language in which any physician or the qualified provider can sign the discharge order? Clarifying this difference would assist ASC's in appropriately developing staff schedules to accommodate this requirement.

B. Conditions for Coverage – Quality Assessment and Performance Improvement (§416.43)

- **CRNAs' Continued Contribution to Pay for Performance Quality Initiatives**

We appreciate Congress' and CMS' efforts to support the development of patient-centered, outcome-oriented efforts that focus on patient health and safety and to seek the expertise of all professional provider associations when developing quality and performance measures. CMS' objective is consistent with the AANA's mission to "advance patient safety and excellence in anesthesia, and we would welcome the opportunity to work with CMS and ASCs to develop and review anesthesia related measures for ASC Quality Assessment and Performance Improvement (QAPI) programs. For the agency to get a full picture, it is important for providers who are not physicians such as CRNAs to be able to participate in the development and measurement of these measures.

In particular, we appreciate CMS' use of the term "eligible professional" when referring to both physician and non-physician providers as healthcare professionals who can participate in the PQRI program. In our experience, exclusive use of the term "physician" when referring to both physicians and Medicare Part B providers who are not physicians, such as CRNAs, causes confusion among our members, other healthcare providers, healthcare facilities, and billing entities. This confusion can result in a delay in payment for CRNAs services and a bar to CRNAs participating in important CMS initiatives such as the PQRI. With CRNAs providing 27 million anesthetics annually, we want to ensure that CMS receives CRNAs' reporting data, data that is vital to accurately measuring quality and accountability in anesthesia, and that our

members are appropriately rewarded for their participation in the PQRI and future quality initiatives. CMS's continued use of the term "eligible professional" will assist in this effort.

To date, our work Pay for Performance initiatives has been multifaceted. In the policy arena, we have worked with members and committees of Congress to review and promote Pay for Performance provisions that place CRNAs and other healthcare providers who are not physicians on an equal footing with one another, and communicated our work and interest in the subject with senior CMS staff. In 2006, we hosted CMS' Dr. Thomas Valuck at a major AANA federal policy conference in Washington, DC, to discuss pay-for-performance systems. In related clinical and policy development venues, the AANA has played a partnership role with the Centers for Disease Control & Prevention's (CDC's) Surgical Care Improvement Project (SCIP) in the development and vetting of quality and performance measures. AANA continues to play an active role in the National Quality Forum (NQF), as the first major national anesthesia professional organization to serve as a member. At the suggestion of CMS staff, the AANA has been an active participant in the deliberations and decisions made by the AMA Physician Consortium on Performance Improvement (AMA-PCPI) Perioperative Work Group and more recently with its Anesthesiology Work Group. With the PCPI Perioperative Work Group we contributed to the development and deployment of the 2007 PQRI Perioperative measures listed in Table 16 of another CMS proposed rule related to the administration of an antibiotic prophylaxis.[4] As members of the PCPI Anesthesiology Work Group we have contributed to the development of the AMA/PCPI measures listed in Table 17 which include (1) Stress Ulcer Disease (SUD) Prophylaxis in Ventilated patients, (2) Prevention of Catheter-Related Bloodstream Infections (CRBSI) in Ventilated patients – Catheter Insertion Protocol, and (3) Perioperative Temperature Management for Surgical Procedures Under General Anesthesia.[5]

The AANA has also responded to requests from CMS contractor Quality Insights of Pennsylvania (QIP) to develop and vet quality measures appropriate for healthcare providers who are not physicians to use in ambulatory care settings, including measures listed in Table 18. Through this year, AANA has provided CRNAs as expert review panelists in the development of measures relating to universal documentation of medications, universal influenza vaccine screening and counseling, and universal weight screening and follow-up. The AANA also

[4] 72 Fed.Reg. 38122, July 12, 2007. p. 38200.
[5] id. p. 38201.

provided comments to QIP on its measures, provided a list of CRNAs for QIP to use in vetting the measures in the clinical setting, and participated in the promotion of the measures through the process established at AQA (formerly Ambulatory Care Quality Alliance).

Thus, CRNAs and the nurse anesthesia profession continue to play a leadership role in shaping legislation and in developing performance measures specific to anesthesia services. The 36,000 members of the AANA look forward to continued opportunities to extend to CMS our profession's longstanding commitment to improving anesthesia patient safety.

We thank you for the opportunity to comment on the proposed rule. Should you have any questions regarding these matters, please feel free to contact the AANA Senior Director of Federal Government Affairs, Frank Purcell, at 202.484.8400.

Sincerely,

Wanda Wilson, CRNA, PhD, MSN
AANA President

cc: Jeffery M. Beutler, CRNA, MS, AANA Executive Director
Frank Purcell, AANA Senior Director of Federal Government Affairs
Pamela K. Blackwell, JD - AANA Associate Director, Federal Regulatory Policy

Submitter : **Date: 10/30/2007**

Organization :

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

We support the proposed updates to the ASCs conditions for coverage. It demonstrates movement toward holding ASCs to the same standards that hospitals are held to when performing similar services. States vary in the licensing criteria for ambulatory surgery facilities and it is in the best interest of patients to require some standardized patient rights / quality focused measures in the certification process.

Submitter : **Dr. Christian Robertozzi** **Date: 10/30/2007**

Organization : **American Podiatric Medical Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3887-P-19-Attach-1.DOC

#19

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Fax: 301-530-2752
www.apma.org

October 30, 2007

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

RE: CMS–3887–P
Medicare and Medicaid Programs; Ambulatory Surgical Centers, Conditions for Coverage (72 Fed. Reg. 50470, Aug. 31, 2007)

[Submitted electronically at http://www.cms.hhs.gov/eRulemaking.]

Dear CMS:

The American Podiatric Medical Association (APMA), the national association representing more than 11,500 of America's foot and ankle physicians and surgeons, is pleased to comment on the proposed rule that revises the conditions for coverage ambulatory surgical centers (ASCs) must meet to participate in the Medicare and Medicaid programs. APMA acknowledges the need to update these conditions but cautions the Centers for Medicare & Medicaid Services (CMS) that some of the new conditions substantially increase administrative costs for facilities with no corresponding increase in reimbursement.

Provisions

Condition for Coverage – Governing Body and Management (42 CFR §416.41)
APMA understands the necessity for ASCs to have disaster preparedness plans. Nevertheless, we believe the condition proposed by CMS should be slightly modified. CMS should require ASCs to have a plan to provide for the emergency care only of the ASC's current patients in events that threaten their health and safety (§416.41(c)(1)). The language as proposed could be misinterpreted to require ASCs to provide emergency care for any and all persons in case of a natural disaster, a mandate that many ASCs, particularly small single-specialty facilities, might not be able to fulfill. This language can be corrected by simply inserting "its" in front of the word "patients" in the first reference to patients in §416.41(c)(1); this also would match the reference to "its patients" at the end of §416.41(c)(1). Services provided to the public at large in response to an emergency should be performed on a voluntary basis and in coordination with state and local agencies. The decision to act in the event of a disaster must be made by ASCs in consultation with local and state officials, rather than at the demand of CMS.

Condition for Coverage – Quality Assessment and Performance (42 CFR §416.43)
APMA agrees that quality assessment is an important task for an ASC, and we appreciate the flexibility CMS proposed. However, these requirements should be relaxed until they are more practical to implement. APMA believes ASCs want to demonstrate measurable improvement in

health outcomes, but few providers, if any, have the means to collect and study this information (§416.43(a)(1)). If this demonstration were simple, providers would have started these measurements long ago. CMS should not make this mandatory until the agency can provide detailed, specific guidance to ASCs about how to measure and analyze health outcomes data. In addition, if CMS wants ASCs to "measure, analyze, and track quality indicators," then CMS should reimburse facilities for this work (§416.43(a)(2)). CMS provides a small financial incentive to hospitals and physicians to report quality indicators in the Medicare program. Requiring ASCs to implement their own individual quality programs while limiting payments, under the new ASC payment policy, to just 65 percent of the hospital outpatient rate, is unfair. We ask CMS to either postpone such requirements or provide administrative and financial assistance to implement them.

Condition for Coverage – Patient Admission, Assessment and Discharge (42 CFR §416.52)
APMA strongly supports the proposed requirement for a physician, as defined in Section 1861(r) of the Social Security Act, to complete a comprehensive medical history and physical assessment (H&P) of each patient not more than 30 days before the date of scheduled surgery (§416.52(a)(1)). APMA believes this requirement appropriately matches the conditions of participation for Medicare hospitals and best reflects current medical practice and procedures.

Impact

APMA reminds CMS that many ASCs are small entities. In addition, many physician-owned ASCs are extensions of physician offices. APMA believes that the time and financial burden for small entities to meet these new conditions for coverage may be significantly higher than CMS estimates.

If you have any questions about these comments, please contact Tricia Bardon, the APMA Director of Health Policy and Practice, at tjbardon@apma.org or (301) 571-9200.

Sincerely,

Christian A. Robertozzi, DPM
President

Submitter : **Mrs. Deborah Bash** **Date: 10/30/2007**

Organization : **American Society of Plastic Surgeons**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-3887-P-20-Attach-1.DOC

#20

AMERICAN SOCIETY OF PLASTIC SURGEONS®

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847-228-9900
Fax: 847-228-9131
www.plasticsurgery.org

October 29, 2007

Herb Kuhn
Deputy Acting Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-3887-P
P.O. Box 8017
Baltimore, MD 21244-8017

Submitted Electronically

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

Dear Mr. Kuhn:

The American Society of Plastic Surgeons (ASPS) is the largest association of plastic surgeons in the world, representing surgeons certified by the American Board of Plastic Surgery. Plastic surgeons provide highly skilled surgical services that improve both the functional capacity and quality of life of patients. These services include the treatment of congenital deformities, burn injuries, traumatic injuries, and cancer. ASPS promotes the highest quality patient care, professional, and ethical standards and supports education, research and public service activities of plastic surgeons.

ASPS offers the following comments on the Center for Medicare and Medicaid Services (CMS) proposed rule for "Medicare and Medicaid Programs; Ambulatory Surgical Centers, Conditions for Coverage; CMS-3887-P" that was published in the Friday, August 31, 2007 *Federal Register*. As requested in the proposed rule, the relevant "issue identifier" that precedes the section we are commenting on is used as a sub-heading to assist the Agency in reviewing these comments.

Provisions

In the proposed rule, the Center for Medicare & Medicaid Services (CMS) assumes that it is reasonable to apply the same standard overnight definition to Ambulatory Surgical Centers (ASC)

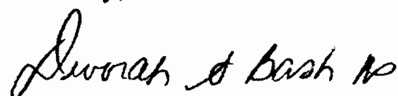
as is applied to hospital inpatient and skilled nursing facility patients. Specifically, the rule states that, "ASCs that are Medicare-certified may not keep patients beyond 11:59 p.m. of the day on which the surgical procedure was performed." However, we disagree with this standard as it applies to ASCs.

The aging population is driving significant growth in the demand for surgical services. As a result, ASCs are major sources of access to important diagnostic procedures and treatments frequently used by Medicare beneficiaries. ASCs have provided significant benefits to patients by decreasing patient wait time and scheduling delays. It is the hope of ASPS that ASCs will continue to play an important role in managing the increased need for surgical services as it arises in the years ahead.

The American Association of Ambulatory Surgery Centers (AAASC) states that Medicare saves approximately $464 million each year that procedures are done in ASCs instead of hospitals. Thus, ASCs are providing high quality, cost-effective alternatives to inpatient hospital care for surgical services.

Unfortunately, the proposed rule would limit Medicare patients' access to the important and needed services that ASCs deliver because of the possibility of unforeseen events that may result from any surgical procedure. To avoid circumstances that may lead to a violation of this regulation, physicians will perform more inpatient surgeries, which will create hospital overcrowding. Consequently, patients will have longer wait times for surgical procedures, and hospitals will see a significant decrease in operating room availability. Furthermore, Medicare will no longer see the cost savings that have resulted from surgical procedures being furnished in ASCs. We find it difficult to understand what, if any, benefits CMS will glean from implementation of this proposed regulation. Therefore, ASPS respectfully requests that CMS officials consider an alternative overnight standard in the ASC setting.

Sincerely,



Deborah Bash, MD
Chair, Payment Policy Committee

Submitter : **Carol Blanar** **Date: 10/30/2007**

Organization : **Indiana Federation of Ambulatory Surgical Centers**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

GENERAL

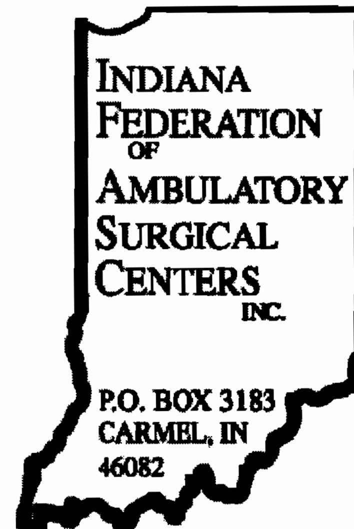
GENERAL

See Attachment

CMS-3887-P-21-Attach-1.DOC

#21

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:

416.50 Condition for coverage – Patient's Rights

Advance directives: ambulatory surgical centers perform elective surgery and if something goes wrong physiologically with the patient, our staff is directed to do everything within their power and training to make sure the patient doesn't die. Many of our member centers will refuse the patient access to the center and refer them to a hospital if they insist on "no resusitation." In addition, CMS's criteria for surgical procedures in the ASC setting excludes from payment those procedures determined to pose a significant risk to beneficiaries.

Also of concern is the condition that ASCs give the patient a copy of their rights. More paper wasted and left in our trash cans. The patient rights are already posted where the patient can read them. These conditions make the centers responsible for providing the following VERBALLY & IN WRITING to the patient who is coming in thirty (300 to ninety (90) minutes prior to surgery: a Privacy Statement; a Notice of Patient's Rights; and a Notice of Policy on Advance Directives. In addition to a consent form to read and sign and financial responsibility forms to read and sign (neither of which the patients want to read as it is). These documents could be made available for the patient to voluntarily take and read at their leisure.

The Privacy Notices that are given to patients now are either refused or thrown away. This condition may force ASCs to have to mail this information to the patient since it must be provided "prior to furnishing care" and "verbally." The ASC's costs will increase and their efficiency may be negatively affected because of the necessity to verbally give this information. It is adding stress to an already stressful situation for a patient or representative to have to read and listen to all this extraneous information on the day of surgery and thirty (30) to ninety (90) minutes preceding the start of the procedure. It may also require the patient to come to the center earlier thus creating a backup of patients in the waiting areas, who will then complain about having to be there so early. It may also cause some centers to have to hire additional staff just to handle this condition. By the time a patient comes in for surgery, they don't want to hear about this stuff. Several of our members have been surgical patients and agree that this is not the time or place to discuss these matters. In addition, the staff of the ASC will be reading and discussing

discharge instructions with the patient, which are more important to the patient's well-being. What an overload for the patient on the day of surgery when they are stressed out because of the surgery.

We would respectfully recommend that CMS publish all this information in the "*Medicare and You*" manual that is sent to the participants each year. This would save millions of dollars in time and materials for all healthcare providers.

Also, there is no statement of Patient Responsibility in these Conditions. The patient must be held accountable for their compliance with discharge instructions and doctor's orders.

416.52 Conditions for Coverage -- Patient admission, assessment, and discharge.

Of concern to our members is the condition that "ASCs must ... "ENSURE (guarantee or make certain) that the patient has a safe transition to home and that the postsurgical needs are met." Once the patient leaves the center, the ability of the ASC to ENSURE a safe transition to home and that the postsurgical needs are met is next to impossible unless we send a staff member home with them. And, what if they have a car accident on the way home? Is the center responsible? What if the patient tells us they have someone taking care of them and they do not and something happens to them? Is the center responsible? What is the interpretation of this condition?

Thank you for this opportunity to share our concerns about the Conditions for Coverage for ASCs.

Respectfully submitted,

Carol Blanar
Executive Director
The Indiana Federation of Ambulatory Surgical Centers
P.O Box 2299
West Lafayette, IN 47996-2299
765-474-7854
execdir@ifasc.com

Submitter : **Ms. Amy Nordeng** **Date: 10/30/2007**

Organization : **MGMA**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3887-P-22-Attach-1.PDF

#22

Medical Group Management Association

Defining Your Profession™

October 30, 2007

Acting Administrator Kerry Weems
Centers for Medicare & 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 - Proposed Changes to the Ambulatory Surgical Center Conditions for Coverage

Dear Acting Administrator Weems:

The Medical Group Management Association (MGMA) appreciates the opportunity to comment on the Proposed Changes to the Ambulatory Surgical Center (ASC) Conditions for Coverage (CfCs) in the above-referenced proposed rule.

MGMA is the nation's principal voice for medical group practice. MGMA's nearly 21,000 members manage and lead some 12,500 organizations, in which almost 270,000 physicians practice. MGMA's membership reflects the full range of physician organizational structures and includes group practices that perform surgical procedures in free standing offices, those structured as part of hospital outpatient departments (HOPDs) and those that own ASCs.

MGMA appreciates CMS's goal of updating the conditions for coverage to reflect today's current standards of practice. In fact, many MGMA members manage ASCs that are already accredited by one of the four Medicare-approved national accreditation standards. As a result, these facilities will likely already meet many of the increased standards in the proposed CfCs.

While these requirements may not necessarily present a hardship for currently-existing and accredited facilities, the impact on new facilities will be significant. Medicare certification is often the gateway to state licensure; any delay in certification can result in significant losses to an ASC. The new CfCs will require more complex surveys and more trained surveyors, both for the initial surveys and any re-surveys that will need to be completed. It is imperative that CMS prepare for this need and have the necessary resources available in order to prevent delays in the certifying process.

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fax: 202.293.2787

mgma.com

MGMA also has concerns about the definition of an "ambulatory surgery center or ASC" found at § 416.2. CMS defines an ASC as "any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring an overnight stay following the surgical services…." We recognize that CMS has chosen not to reimburse procedures where patients typically require active medical monitoring and care past midnight on the day of surgery. It is our understanding, however, that several states continue to allow ASCs to perform surgeries where active medical monitoring and care do not exceed 24 hours. If it adopts the proposed definition, CMS will be unnecessarily excluding facilities that perform these procedures (either for their private pay or self-pay patients) from the definition of the ASC.

In addition, MGMA also has concerns about the details of the proposed Quality Assessment and Performance Improvement (QAPI) program. To the extent that the QAPI requirements duplicate requirements imposed by the accrediting bodies, we ask that CMS work to minimize the burden of these requirements on ASCs.

Finally, MGMA is generally concerned that some of the proposed CfCs appear to be based on the needs of a hospital setting and do not reflect the realities of how smaller organizations handle patient issues. The formalization of certain requirements – for example, the need to adopt a grievance procedure or to have an infection-control officer – are not necessary in the smaller ASC setting, where a smaller staff and fluid work environment allow for a quick response to matters. Adding additional layers of bureaucracy may hinder the flexibility currently enjoyed by ASCs.

MGMA appreciates the opportunity to comment on these important matters. If you should have any questions or would like to discuss these matters further, please feel free to contact Amy Nordeng at MGMA at 202.293.3450.

Sincerely,

William F. Jessee, MD, FACMPE
President and Chief Executive Officer

Submitter : **Kay Gouwens** **Date: 10/30/2007**

Organization : **for Alaska Native Tribal Health Consortium**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

Impact

Impact

See attachment.

PARTMENT OF HEALTH AND HUMAN SERVICES
NTERS FOR MEDICARE AND MEDICAID SERIVICES
FICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

ease note: We did not receive the attachment that was cited in
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low "Attach File" button to forward the attachment.

ease direct your questions or comments to 1 800 743-3951..

Submitter : **Kay Gouwens** **Date: 10/30/2007**

Organization : **for Alaska Native Tribal Health Consortuim**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

Impact

Impact

See attachment.

Provisions

Provisions

See attachment.

CMS-3887-P-24-Attach-1.PDF

#24

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MARVIN J. SONOSKY (1909-1997)

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*ALASKA BAR
**ALASKA AND WASHINGTON BAR

October 30, 2007

Submitted Electronically at
http://www.cms.hhs.gov/eRulemaking

Mr. Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-3887-P

Re: Comments on file code CMS-3887-P, proposed rule on Medicare and Medicaid Programs, Ambulatory Surgical Centers, Conditions for Coverage.

Good Day:

We submit these comments on behalf of our client, the Alaska Native Tribal Health Consortium ("ANTHC"). ANTHC is a non-profit tribal organization created pursuant to federal law. Under the Indian Self-Determination and Education Assistance Act, Pub. L. 93-638, as amended, 25 U.S.C. 450 et seq. (ISDEAA), ANTHC and another tribal organization jointly operate the 155-bed Alaska Native Medical Center (ANMC) in Anchorage. ANMC is the only tertiary care tribal facility in Alaska, and serves Native patients from all across the State. Also pursuant to the ISDEAA, ANTHC has assumed most of the state-wide functions once carried out directly by the Alaska offices of the Indian Health Service (IHS), and in that capacity works with tribal providers across the State to deliver comprehensive health care services to Alaska Natives and other IHS beneficiaries.[1/]

1/ These services are provided pursuant to the ISDEAA, the Indian Health Care Improvement Act, other federal laws, and a health "Compact" and "funding agreements" between the Secretary of Health and Human Services and ANTHC.

Although ANMC is a hospital, it is interested in these proposed regulations for two reasons. First, under special Medicare and Medicaid reimbursement rules, a hospital operated by the IHS or a by tribal organization like ANTHC may be reimbursed at Ambulatory Surgical Center (ASC) rates for outpatient surgeries, instead of at the generally lower IHS outpatient hospital services per diem rate, provided it meets the ASC conditions for coverage.[2/] To the extent that they bill as ASCs, ANMC and other tribal hospitals will thus immediately and directly be affected by any rule changes to the conditions for ASC participation.[3/] Second, we understand that CMS may use any final rule on ASC participation as a template for future modifications to participation requirements for other facilities, including hospitals.

COMMENT ON PROVISIONS.

ANTHC appreciates the extent to which the proposed rule would generally allow facilities significant flexibility in designing required programs and procedures. However, in two significant areas the proposed rule would impose specific requirements that are of concern to ANTHC and we ask that these be modified. First, proposed requirements for radiology services are not appropriate for IHS and tribal facilities, given their extensive use of federally-employed health care providers, midlevel practitioners, and allied health professionals and para-professionals. Second, several of the proposed requirements for patient grievances are wasteful and counterproductive, and would actually make patient grievance policies a less effective tool for identifying and correcting a facility's shortcomings. We explain these concerns further below.

Comments on Subpart B. Specific Conditions for Coverage.

1. Laboratory and Radiologic Services (proposed 42 CFR § 416.49).

Delivering health care services in remote and far-flung Alaska Native villages, and on lower-48 Indian reservations, has special challenges. Among them is the difficulty of attracting

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2/ See the CMS "Medicare Claims Processing Manual," Chapter 19 - Indian Health Services – §§ 40.2.1, 100.6, and 100.6.; TrailBlazer Health Enterprises, LLC, "Medicare Part A Indian Health Services Manual. October 2003, pages 64 - 66; First Health Services Corporation, "Alaska Medical Assistance Program Indian Health Services (IHS)/Tribal Facility Services Provider Billing Manual (updated 04/15/-5), § D-9.

3/ Accordingly, the following statement in the "IMPACT" section of the notice of proposed rulemaking is *not accurate*:

> This regulation will not have a significant impact on the operations of a substantial number of small rural hospitals...

72 *Federal Register* 50480 (August 31, 2007).

and retaining the services of licensed health care professionals. Congress has taken many measures to help address this problem, including enacting laws authorizing federal health professionals to be assigned to work at tribal facilities[4/] and authorizing the training and use of allied professionals and para-professionals, such as "Community Health Aides" and "Community Health Representatives," in Alaska.[5/] To further address the shortage of physicians and contain health care costs, tribal providers also rely heavily on the services of mid-level professional practitioners, including physician assistants and nurse practitioners.

For these reasons, we are concerned by the proposal to require ASCs that provide radiological services to meet the same conditions for coverage that apply to providers of Portable X-Ray Services under 42 CFR §§ 486.100 through .110. Specifically, we are concerned by provisions that would require X-rays to be ordered only by physicians, and by provisions requiring physicians, staff, and equipment to be State-licensed.

The requirement that X-rays must be ordered only by physicians may prove very difficult for tribal hospitals because of their heavy reliance on the services of mid-level practitioners. Even ANMC, with its urban location, relies heavily on mid-level practitioners to provide these services. For the small tribal hospitals and other tribal providers with which ANMC works – including the small tribal hospitals in Bethel, Nome, and the United States' most northerly city, Barrow – this requirement would be a potentially crippling hardship. The requirement is also medically unnecessary, in our opinion. We simply see no reason why the Medicare rules should not allow X-rays to be ordered by qualified allied and mid-level practitioners acting within the scope of their licenses and professional training.

The various requirements for State licensure contained in the Conditions of Participation for Portable X-Ray Services are also uniquely problematic for tribal and IHS facilities, regardless of the facility's size or location. As we mentioned above, health professionals employed by the federal government, including Commissioned Corps Officers, may be assigned to work at tribal health facilities while retaining their federal employee status. Although these professionals are required by the federal government to hold a professional license from *some* State or other federal jurisdiction, in light of the fact that they may be reassigned to several different locations during the course of their careers, the government does not require that these professionals be licensed by the State where they are currently assigned. Given doctrines of federal supremacy and preemption, States lack the authority to require these federal health workers to hold licenses issued by them, and some (but not all) states' laws specifically recognize a licensing exemption for federal employees. Accordingly, ANMC's medical staff includes federal physicians and other federal health care providers who are licensed only in some other State. The same is true of dozens of other tribal facilities in Alaska and across the Nation.

4/ 25 U.S.C § 450 and 5 USC §§ 3371 - 3372.

5/ 25 U.S.C. §§1616 and 1616*l*.

For these reasons we ask that tribal and IHS facilities be exempted from the requirements discussed above. We suggest adding the following language:

> *Provided, however, that provisions that require personnel and facilities to be licensed by the State, and that require X-rays to be ordered only by physicians, shall not apply to a facility operated by the Indian Health Service or by a tribal organization carrying out programs of the Indian Health Service pursuant to the Indian Self-Determination and Education Assistance Act, Pub. L. 93-638, as amended, 25 U.S.C § 450 et seq.*

2. Patient Grievances (proposed 42 CFR § 416.50 (3)).

ANTHC supports patient grievance procedures and has had such procedures for many years. However, we have serious concerns about the specific requirements under consideration. As we explain below, we believe the proposed requirements would discourage the filing and thorough investigation of patient grievances, interfere with quality improvement and peer review activities, force facilities to waste resources documenting and investigating minor claims, inundate State agencies with reports of minor complaints, and require disclosure of confidential personnel action taken in response to patient grievances.

In ANTHC's view, a sound patient grievance policy has several characteristics. It encourages patients to express their concerns – both major and minor – by assuring patients that their privacy will be respected and that their complaints will be investigated as discretely and confidentially as possible. It promotes efficient resolution of complaints, by allowing minor complaints to be resolved quickly and by consent, without resort to a formal written report or a full-blown investigation. It encourages thorough and aggressive in-house investigation of more serious complaints, by allowing facilities to identify and correct their own short-comings before they trigger a complaint to, or investigation by, public authorities. And it allows facilities to respond to complaints with appropriate personnel actions against offending employees, without violating the employees' right to confidentiality.

Patient grievance policies would lose all these characteristics – and State agencies would be inundated with minor complaints and those that have already been resolved by the facility – if CMS adopts the current proposal.

Of particular concern is the proposal that "[a]ll allegations must be immediately reported to...the State and local bodies having jurisdiction. " (Proposed 42 CFR § 416.50(3)(ii).) ANTHC firmly believes that such a requirement would have a chilling effect on the reporting and investigation of patient grievances. Many patient complaints involve very private matters, and patients often don't want their care-givers to know of their complaint. If patients are informed that their complaint must be reported to State authorities (as, in fairness, they would have to be), the effect will often be to discourage them from making the complaint in the first place. And if a facility must immediately report all grievances to public authorities, its providers may not feel

comfortable engaging fully in crucial peer review and quality improvement activities, where protection from public scrutiny has proved so useful in promoting the degree of candor that is essential to an effective program. We agree that patients should be notified how to submit their complaints to appropriate public agencies if they wish to do so. But reporting all complaints would be counterproductive, and should not be the default rule.

We are also concerned by the proposed requirement that facilities must document and investigate virtually all patient grievances, regardless of their gravity.[6/] That requirement would make it impossible to efficiently and informally resolve the relatively minor complaints that typically comprise the majority of complaints filed. For example, many complaints deal with how quickly appointments are scheduled, how long patients wait to be seen once they arrive for their appointments, the comfort of waiting and recovery areas, staff demeanor, and other matters that – while of legitimate interest to patients – do not pose significant health or safety concerns. Often these complaints can be resolved orally and without further investigation. Requiring such complaints to be documented and investigated would bury facilities in pointless paperwork and divert their resources from the investigation of more serious concerns. And if all grievances must also be reported to State agencies, the agencies will be inundated with reports of minor concerns and those that have already been resolved by the facility, with no ready way to identify those few complaints that may warrant the State's involvement. We urge you to modify the rule to allow facilities more flexibility in structuring their patient grievance procedures and to prevent the patient grievance process from swallowing protected peer-review activities.

Finally, the proposed requirement that the facility must give the patient written notice of "the results of the grievance process" (proposed 42 CFR §416.50(3)(vi)) should be clarified to allow facilities to protect the confidentiality of personnel and peer review actions resulting from the grievance. ANTHC's current practice, when a patient complaint leads it to discipline or discharge of an employee, is to notify the patient only that "appropriate human resource actions have been taken with the involved employee(s)," without specifically identifying the employee or the exact action taken. In situations involving peer review and quality improvement activities, ANTHC also strives to provide appropriate information to affected patients about their own care while ensuring the review process is sufficiently confidential to elicit robust and candid evaluation by the peers participating in the process. We believe these practices strike a reasonable balance between the patient's interest in knowing the results of her complaint and ANTHC's other responsibilities. We urge you to modify the proposed rule to clearly allow these practices to continue.

6/ The proposed rule would require "[a]ll alleged violations/grievances relating, but not limited to, mistreatment...." to be fully documented, and would require investigation of "all grievances ... regarding treatment or care that is (or fails to be) given." (Proposed 42 CFR §516.50(3)(ii) and (v).) These quoted phrases are not further defined and could readily be interpreted to encompass virtually all aspects of a facility's dealings with patients, not just hands-on care. Some of our concerns could be addressed by precise and careful definition of key terms.

Thank you for the opportunity to comment.

Sincerely,

SONOSKY, CHAMBERS, SACHSE,
MILLER & MUNSON, LLP

/s/

By: Kay E. Maassen Gouwens
Myra M. Munson

cc: Valerie Davidson, ANTHC Senior Director of Legal and Inter-Governmental Affairs and Tribal Technical Advisory Group Chair
Nacole Heslep, ANTHC General Counsel
Karen MacClain, ANTHC Risk Manager
Dorothy Dupree, Center for Medicare and Medicaid Services Tribal Affairs Senior Policy Advisor, ddupree@cms.hhs.gov
Robert McSwain, Acting Director, Indian Health Service, Robert.McSwain@ihs.gov

CMS-3887-P-25

Submitter : **Dr. Patricia Linhardt** **Date: 10/30/2007**

Organization : **Wichita Clinic, PA**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

EPARTMENT OF HEALTH AND HUMAN SERVICES
ENTERS FOR MEDICARE AND MEDICAID SERIVICES
FFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

lease note: We did not receive the attachment that was cited in his comment. We are not able to receive attachments that have been repared in excel or zip files. Also, the commenter must click the ellow "Attach File" button to forward the attachment.

lease direct your questions or comments to 1 800 743-3951..

CMS-3887-P-26

Submitter : Dr. Patricia Linhardt

Date: 10/30/2007

Organization : Wichita Clinic, PA

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

EPARTMENT OF HEALTH AND HUMAN SERVICES
ENTERS FOR MEDICARE AND MEDICAID SERIVICES
FFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

lease note: We did not receive the attachment that was cited in his comment. We are not able to receive attachments that have been repared in excel or zip files. Also, the commenter must click the ellow "Attach File" button to forward the attachment.

lease direct your questions or comments to 1 800 743-3951.

Submitter : Dr. Patricia Linhardt

Date: 10/30/2007

Organization : Wichita Clinic, PA

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Dr. William Fishkind** **Date: 10/30/2007**

Organization : **OOSS and ASCRS**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3887-P-28-Attach-1.PDF

#28

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
OUTPATIENT OPHTHALMIC SURGERY SOCIETY

October 30, 2007

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, S.W.
Washington, D.C. 2021

RE: CMS-3887-P – Medicare and Medicaid Programs: Ambulatory Surgical Centers; Conditions for Coverage

Dear Acting Administrator Weems:

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical association representing over 1,000 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical services in cost-effective outpatient surgical environments, particularly ambulatory surgical centers (ASC).

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing over 10,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the vast majority of cataract procedures furnished annually in ASCs and hospitals.

The nation's 4,600 ASCs are committed to providing Medicare beneficiaries with access to the highest quality surgical care while lowering their cost-sharing obligations and assisting the Medicare program in the containment of health expenditures. Studies conducted by a multitude of federal agencies (including CMS; the Government Accountability Office; the Medicare Payment Advisory Commission; the Office of the Inspector General, HHS; and the Federal Trade Commission) have lauded the work of ASCs, recognizing that surgery centers provide care at levels of quality equal to or surpassing hospital outpatient departments (HOPD), at lower cost to the program and to beneficiaries, and in a patient-friendly and convenient environment that leads to the highest levels of patient satisfaction.

Cataract surgery in the ASC is emblematic of the phenomenon of the ASC becoming the choice of physicians and beneficiaries for site of surgery. More than 2.7 million patients receive cataract surgery each year; in consultation with their ophthalmic surgeons, more than 60 percent

of them select the ASC over the HOPD as their site of surgery. Simply stated, with respect to cataract surgery, the highest volume Medicare surgical procedure, the ASC is the predominant choice of the Medicare beneficiary because the quality of care provided is demonstrably high and the cost savings to the patient and the program are significant.

Generally, CMS is to be applauded for this proposal to revise the Medicare ASC Conditions of Coverage (CfC's) that have remained unchanged for the past 25 years. In most instances, the agency has struck a fair balance between the need to optimize quality of care and patient safety and reflect the needs and circumstances of an array of surgical providers that are diverse as to size, specialty, and type of patient. However, OOSS and ASCRS believe that the NPRM can be improved with respect to a number of provisions:

Definitions (Sec. 416.2)

We are concerned with the agency's decision to modify the current definition of an ASC. Current 42 C.F.R. §416.2 defines the ASC as an entity that operates exclusively for the purpose of providing surgical services to patients not requiring "hospitalization." By defining an ASC by reference to hospitalization, the current CfC rules permit overnight stays for *non-Medicare* patients, either in the ASC itself or in a certified or licensed recovery care unit that is distinct from the ASC and is not a hospital, *where such recovery care is permitted under state law.*

The proposal redefines the facility as one that operates exclusively for purposes of providing services to patients not requiring an "overnight stay" and further defines overnight stay as meaning recovery requiring monitoring beyond 11:59PM on the day of the procedure "regardless of whether it is provided in the ASC." This revision would have the effect of prohibiting an ASC from performing any procedures – including services furnished to non-Medicare patients – requiring active monitoring beyond midnight, even when such stays are permitted under state law. (Indeed, many states permit ASCs to retain patients for up to 23 or 24 hours, or to transfer patients to separately licensed or certified recovery care units for stays up to 24-72 hours.) This policy change could also jeopardize the planned transfer of patients to skilled nursing and rehabilitation facilities. For example, when a patient in a retirement community with an affiliated nursing facility undergoes cataract surgery, he may typically be admitted to the nursing facility for overnight observation following surgery. While this arrangement is permissible under current law because recovery in the nursing facility doesn't constitute hospitalization, the patient could not be transferred to the nursing facility under the proposed condition because recovery in the facility would represent an "overnight stay."

CMS provides no rationale for this change in policy. We do not believe that the agency should regulate, through the Medicare conditions of coverage, the services provided to non-Medicare patients, particularly when a state permits the provision of recovery care to its citizens. As such, OOSS and ASCRS recommend that CMS 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." In the alternative, an ASC could be defined as an entity that operates exclusively for the purpose of providing surgical services to patients whose recovery under normal circumstances will not require hospital inpatient care." Should CMS insist on defining

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ASC care by reference to overnight stays, we strongly recommend that the section be modified to preserve the right of ASCs to perform procedures involving overnight stays where permitted under applicable state law; this could be accomplished by modifying the definition as follows:

> *Ambulatory Surgical Center or ASC* means any distinct entity that operates 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 beyond 11:59 p.m. of the day on which the surgical procedure was performed.

Condition: Governing Body and Management (Sec. 416.41)

Our organizations recognize that the responsibility for the management of a high quality surgical facility rests at the top of the organization with the governing body and managers of the ASC. We generally support the expansion of this condition to mandate that the governing body assume direct oversight and accountability for the facility's quality assessment program and create and maintain a disaster preparedness plan.

With respect to the disaster preparedness plan, we have two concerns with the NPRM's language. §416.41(c)(2) requires that the ASC "coordinate" its plans with state and local agencies. We are concerned that surveyors or state officials could interpret this requirement to impose an affirmative duty on the ASC to integrate their facilities into state and local disaster relief efforts. CMS must recognize that ASCs provide limited services and that our facilities are neither staffed nor equipped to provide emergency care beyond its own patients. Indeed, our members have been most effective in these situations by making their staff available on-site or at local hospitals. We recommend that this provision be modified to require instead that "the ASC *communicates* the plan to State and local agencies, as requested or as required under applicable law."

Condition: Quality Assessment and Performance Improvement (Sec. 416.43)

For more than a decade, OOSS and ASCRS have advocated that the CfC's incorporate a less proscriptive and more proactive facility-specific approach to quality assessment and performance improvement. The proposal seems to recognize that a single-OR ophthalmic ASC is quite different from a large multi-specialty facility and that its quality of care challenges will vary as well. We are pleased that CMS appears to be providing to each ASC the flexibility to select its own quality indicators and performance measures, to establish its own priorities for program activities, and to develop performance improvement projects that reflect the scope and complexity of its services and operations.

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Condition: Patient Rights (Sec. 416.50)

The ASC industry has burgeoned because of its commitment to an optimal patient surgical experience. We fully recognize that this commitment encompasses all of the goals of this condition, including informing patients of their rights, treating them with respect and dignity, affording them privacy, appropriately managing their records, enabling them to participate in their care, and effectively responding to patient grievances and complaints. However, we believe that the proposal overreaches in several particulars and should be modified.

Written Notice of Rights. Proposed §416.50(a)(1) requires that all patients receive *written notice of their rights in a language they understand.* Our members embrace the proposition that ASCs should translate their notices of patient rights into the languages of non-English speaking groups that are frequently treated at our facilities. It is impracticable for an ASC located in an urban area serving patients who speak literally dozens of different languages to proffer full written translations to all of their patients; it is often more effective for patients to be offered meaningful translations or written summaries. We suggest that ASCs be afforded the flexibility to develop their own processes for ensuring that patients are fully apprised of their rights.

Disclosure of Physician Ownership. §416.50(a)(1)(ii), which mandates that written ownership disclosure information be furnished to patients *prior to* the first visit to the ASC, embodies the potential to needlessly disrupt patient care and inconvenience our patients. We are not opposed to the disclosure of ASC ownership information to our patients: many of our members disclose this information on their own volition; some states and all private accreditation organizations require it; and, federal anti-kickback safe harbor protection is contingent upon it. However, the decision as to the appropriate site of surgery rests, we believe, with the patient and his surgeon. Indeed, prior notice from the facility to the patient may not be practicable because surgery may be scheduled on short notice or on an urgent basis. To the extent that a duty to disclose is to be mandated, it should appropriately rest with the physician, as many states require in their medical practice acts. We recommend that CMS adopt instead the accreditation standard that ownership information be made "available" to patients upon request, or, in the alternative, that it be posted or otherwise furnished to patients at the facility.

Advance Directives. We believe that the advanced directive requirements, in §416.50(a)(2), are unduly burdensome with respect to ASCs and should be modified. Virtually all of the services performed in our members' facilities involve elective day surgery where, as a practical matter, advance directives are inapplicable. As such, ASCs typically implement a policy under which they are not honored, or that they must be suspended for purposes of their treatment in the ASC. OOSS and ASCRS recommend that the proposal be modified to incorporate the accreditation standard that "information be made available to patients and staff concerning . . . advanced directives, as required by state or federal law or regulations."

Condition: Infection Control (Sec. 416.51)

Because of the ASC industry's commitment to the adoption of state-of-the-art infection prevention measures and the extensive education and training of our professionals, freestanding centers enjoy an exemplary record in infection control. Indeed, a 2006 Rand Health study commissioned by the Medicare Payment Advisory Commission, *Further Analyses of Medicare Procedures Provided in Multiple Ambulatory Settings,* concluded that rates of post-cataract endophthalmitis were significantly lower in the ASC than in the hospital. We are pleased that CMS appears to be delegating to the individual ASC the responsibility to develop and implement its own infection control program.

Condition: Patient Admission, Assessment, and Discharge (Sec. 416.52)

History and Physical Assessment. Proposed §416.52(a)(1) mandate the conduct of a "comprehensive" history and physical assessment no more than 30 days prior to surgery. While an appropriate and current pre-surgical assessment is essential, these might not necessarily be accomplished through a comprehensive exam during the 30-day window. If, for example, repetitive or bilateral procedures, such as cataract extraction for both eyes, are scheduled, a comprehensive exam may be appropriate prior to the first procedure while a more limited update of the first exam may typically be sufficient prior to the second procedure to determine whether there have been any significant changes in the patient's physical condition. Under the proposal, if the bilateral procedures are separated by several weeks – or if the original surgery needed to be rescheduled – the patient would be required to undergo additional and unnecessary comprehensive exams. We recommend that CMS adopt the accreditation standard that the assessment include "an appropriate and current history, including a list of current medications, and dosages if known, physical examination, and pre-operative diagnostics . . . incorporated into the patient's medical record prior to surgery."

Discharge. Proposed §416.52(c)(2) requires the ASC to "ensure the patient has a safe transition home." This overly broad standard suggests that the ASC has requisite control over the patient, his mode of transportation home, and the patient's post-discharge recovery environment. This language should be deleted and CMS should retain the existing requirement that "all patients are discharged in the company of a responsible adult." We also object to §416.52(c)(3), which could be interpreted to require that the physician who performed the surgery must not only sign the discharge order but also remain in the facility and evaluate the patient for proper anesthesia and recovery prior to discharge. In many facilities, it is appropriate for either the surgeon or the anesthesiologist to write the discharge order. This section should be modified to clarify that the discharge order must be signed by "a physician or other qualified practitioner unless otherwise specified by State law."

Proposed Modification to Existing Condition: Environment (Sec. 416.44)

Existing §416.44, which sets forth the CfC for the Environment, requires that an ASC be able to provide mechanical ventilator assistance, including a ventilator. We note that current Advanced Cardiac Life Support (ACLS) guidelines do not even reference ventilator use. Many ASCs, including ophthalmic facilities, provide surgical care without the use of general anesthesia. In facilities that do not perform cases requiring the administration of general

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anesthesia, the requirement that a ventilator be present is unnecessary. Moreover, given the lack of knowledge and expertise of the clinical staff in such a facility in the proper use of a jet ventilator, the patient could be placed at risk if such equipment were utilized. In these facilities, should a patient require respiratory assistance, it would be most appropriate to utilize an Ambu-bag. We recommend that §416.44 be modified to clarify that ASCs that do not administer general anesthesia are not required to have a ventilator in the facility.

*****

Thank you for providing our organizations with the opportunity to present our comments on the proposed rule. Should you have any questions, please do not hesitate to contact our Washington representatives: Michael Romansky, Washington Counsel, OOSS at mromansky@ooss.org or at 301.332.6474; or Emily Graham, RHIT, CCS-P, CPC, ASCRS Associate Director of Regulatory Affairs at egraham@ascrs.org or 703.591.2220.

Sincerely,

Richard L. Lindstrom, MD
President, ASCRS

William Fishkind, MD
President, OOSS

Submitter : **Dr. Patricia Linhardt** **Date: 10/30/2007**

Organization : **Wichita Clinic, PA**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

GENERAL

GENERAL

October 30, 2007
RE: CMS-3887-P

Centers for Medicare & Medicaid Services, Department of Health and Human Services:

I am writing as the Medical Director of the Wichita Clinic, PA s Ambulatory Surgery Center in regards to proposed rules published in the Federal Register of August 31, 2007. Our organization has been made aware that among these proposed rule changes listed for the Department of Health and Human Services, Center for Medicare & Medicaid Services, 42CFR Part 416 [CMS-3887-P] are new proposed regulations for ASC patients concerning overnight stays following surgery.

As written on pages 50471-2 in the Definitions section (416.2) no patients would be allowed to stay in a Medicare certified facility past 11:59 PM on the day of their operation. Historically, Medicare has not reimbursed for those procedures requiring a 23 hour stay in an ASC setting. However, other commercial payers recognize the value of a quality, cost effective alternative for the provision of surgical services. We are concerned the proposed Medicare language would extend this midnight standard to the ASC conditions for coverage (CfC) so as to 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 in which the ASC is licensed.

If Medicare does not reverse the proposed rule to re-define 23 hour stay in an ASC as part of their conditions for participation, it is of great concern that this will have an adverse effect within our organization as well as other health care institutions within our medical community. Our organization and others may be forced to re-assess our Medicare certification status, potentially resulting in access concerns for Medicare beneficiaries.

It appears to us that there may be an oversight in the proposed language as ASCs have been proven in their ability to provide safe, efficient, quality care and the language as proposed is counterproductive to the continuation of this level of care. While we understand Medicare has not allowed reimbursement for 23 hour stays for Medicare beneficiaries in the past, we find the proposal to apply those restrictions to all other patient populations to be completely unacceptable.

In summary, we request that the proposed language be applicable to Medicare beneficiaries only and not expand the scope to non-Medicare beneficiaries.

Patricia W. Linhardt, MD
Medical Director
Wichita Clinic, PA Ambulatory Surgery Centers
1947 Founders Circle
Wichita, KS 67206
LinhardtPW@wichitaclinic.com

Submitter : **Dr. Michael Repka** **Date: 10/30/2007**

Organization : **American Academy of Ophthalmology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3887-P-30-Attach-1.PDF

#30

Suite 700
1101 Vermont Avenue NW
Washington, DC 20005-3570

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http://www.aao.org

Federal Affairs Department

October 30, 2007

SENT VIA ELECTRONIC MAIL
Kerry Weems, 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, S.W.
Washington, D.C. 2021

RE: CMS-3887-P – Medicare and Medicaid Programs: Ambulatory Surgical Centers; Conditions for Coverage

Dear Administrator Weems:

On behalf of the American Academy of Ophthalmology (Academy) I am writing to comment on the proposed Medicare Ambulatory Surgical Centers (ASC) Conditions for Coverage (CfC). The Academy is the world's largest organization of eye physicians and surgeons, with more than 27,500 members. Over 16,000 of our members are in active practice in the United States. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule.

The Academy generally supports the work of CMS in updating this important regulatory structure. The ASC setting is now by far the site of service choice for ophthalmologists providing surgical care to their patients. In our just released bi-annual member survey, 65% of ophthalmologists now operate in the ASC setting. This is due in large part to the fact that such a setting provides high quality of care while being both cost effective for Medicare and the beneficiaries our members treat.

With a new Medicare payment system about to go into effect on January 1, 2008, we believe now is the right time to bring the CfCs more in line with the practices of today's ASCs. Thus, we urge CMS to adopt the changes put forth by the Academy and the ASC community as a whole and implement the revised CfCs without undue delay. In general the Academy supports the changes being suggested by the Federated Ambulatory Surgical Association (FASA) and the Ophthalmic Outpatient Surgery Society (OOSS).

The Academy joins FASA and OOSS in objecting strongly to 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."

We are extremely troubled by these new definitions because they 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 Medicare ASC payment system already prohibits coverage of procedures requiring an overnight stay for Medicare

beneficiaries, we agree with the ASC community that there is no reason for this unwarranted intrusion into the authority of the states to regulate the provision of services for non-Medicare patients.

ASCs throughout the country have invested time, money, and resources in developing recovery care programs for non-Medicare patients that may be jeopardized by the CfC proposed rule. According to FASA, at least 14 states permit ASCs to retain patients for up to 23 or 24 hours of overnight recovery care. In addition, a number of states permit extended recovery stays of up to 24, 48 and, in some cases, 72 hours in separately licensed or certified recovery care units affiliated with nursing homes or extended care facilities.

Therefore, because of these concerns about 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 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 Academy would like to again thank you for providing us with the opportunity to comment and looks forward to the CMS response to our comments in the final rule. If you have any questions or need additional information from the AAO regarding any of these issues, please feel free to contact us.

Sincerely,

Michael X. Repka, M.D.
Secretary of Federal Affairs

Submitter : Dr. Jason Ormsby

Date: 10/30/2007

Organization : The Joint Commission

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Impact

Impact

CMS-3887-P-31-Attach-1.DOC

CMS-3887-P-31-Attach-2.DOC

#31

October 29, 2007

Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services (DHHS)
CMS-3887-P
P.O. Box 8017
Baltimore, MD 21244-8017

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

The Joint Commission welcomes the opportunity to comment on the Ambulatory Surgical Centers, Conditions for Coverage (CfC) Proposed Rule, released August 31, 2007. Established in 1951, The Joint Commission is an independent, not-for-profit organization that evaluates and accredits approximately 15,000 healthcare organizations in the United States. In addition to accrediting over 700 ambulatory surgical centers (ASCs), representing nearly 1,200 sites, other Joint Commission-accredited organizations include hospitals; laboratories; behavioral healthcare; home care; hospice and other long term care organizations. Although accreditation is voluntary, a variety of federal and state government regulatory bodies recognize and rely upon Joint Commission accreditation decisions and findings for Medicare and state licensure purposes across all of the Joint Commission's accreditation programs.

The Joint Commission commends CMS for a much needed, and long-awaited, update of the ASC CfCs. The revisions generally reflect current practices and align with current Joint Commission ASC standards. Below, are a few specific comments organized by CFR notation that The Joint Commission offers for CMS's consideration.

CFR 416.2 – Revised Definitions

Proposed: Conditions for Coverage - Definitions.

A. An ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring an overnight stay following the surgical services, 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.

B. Overnight stay means the patient's 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.

The Joint Commission's Comment

CMS' revised definition of an ASC clarifies the term "overnight stay," and includes an accompanying definition of overnight stay. The arbitrary 11:59 p.m. cutoff may pose problems for the field for those patients who experience complications following an ambulatory surgical procedure. To ensure consistency with the approach outlined in the preamble, The Joint Commission believes that the definition should be revised to read: "Any distinct entity that operates exclusively for the purpose of providing surgical services to patients for which the patient will not be expected to require active medical monitoring and care at midnight following the procedure, 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." Use of this definition could also lessen instances in which patients with late afternoon surgery would be unsafely discharged to meet an arbitrary cutoff time.

There are other problems that exist under the current definition and are not addressed by this proposed revision. Specifically, the new definition retains the term "exclusively," which in the past has been compromised by CMS policy to allow for different procedures and treatments for Medicare and non-Medicare patients in the same Medicare-approved facility. Can we assume that by retaining the term "exclusively," CMS will now require that the same standard for procedures and overnight stays will apply to all patients, regardless of the payment source? Additionally, The Joint Commission recommends that CMS include a definition for "distinct entity," which is another term in the definition that has caused confusion over the years.

CFR 416.41(a)

Proposed: Conditions for Coverage – Governing body and management.

The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation; has oversight and accountability for the quality assurance and performance improvement program; and ensures that facility policies and programs are administered so as to provide quality health care in a safe

environment, and creates and maintains a disaster preparedness plan. (a) Standard: Contract services. When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner.

The Joint Commission's Comment

In the areas involving governing bodies and management, most of CMS's proposed CfCs match the Joint Commission's standards in these areas. However, The Joint Commission would like to take this opportunity to inform CMS of our plans to extensively update Joint Commission ASC governance standards, which will then exceed CMS's proposed requirements in this area.

CFR 416.43 (a)(1)

Proposed: Conditions for Coverage—Quality assessment and performance improvement. The ASC must develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program. (a) Standard: Program scope. (1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.

The Joint Commission's Comment

Overall, The Joint Commission commends CMS for emphasizing performance improvement within the CfCs. Joint Commission standards, however, go beyond CMS's and require facilities to collect data on performance improvement priorities identified by leadership; integrate information from leadership, staff and patients; and promote avenues of accountability. CMS should pursue similar priorities to promote a "systems" approach to quality improvement, which integrates all areas of the organization. Additionally, CMS should emphasize the need for ASCs to understand the underlying causes of sentinel events and promote the identification of systemic prevention and process improvement remedies to reduce the likelihood of repeat events.

CFR 416.43 (a)(2)

Proposed: Conditions for Coverage—Quality assessment and performance improvement.

(a) Standard: Program scope. (2) The ASC must measure, analyze, and track quality indicators, including adverse patient events, infection control and other aspects of performance that includes processes of care and services furnished in the ASC.

The Joint Commission's Comment

CMS should consider requiring facilities to collect data on priorities identified by leadership; integrate information from leadership, staff and patients; and promote ASCs to focus on the causes of sentinel events. ASCs should be required to understand what systems failures lead to the adverse events they experience and should identify where process and systems redesign will reduce the likelihood of a repeat event.

CFR 416.43 (b)(1)

Proposed: Conditions for Coverage—Quality assessment and performance improvement.

(b) Standard: Program data. (1) The program must incorporate quality indicator data including patient care and other relevant data regarding services furnished in the ASC into its QAPI program.

The Joint Commission's Comment

The Joint Commission urges facilities to better integrate the efforts of leaders, staff and patients in the quality assessment and improvement process. Additionally, The Joint Commission's standards require facilities to focus on high risk areas (e.g., medication management, blood product use and/or restraint use).

CFR 416.43 (b)(2)

Proposed: Conditions for Coverage—Quality assessment and performance improvement.

(b) Standard: Program data. (2) The ASC must use the data collected to— (i) Monitor the effectiveness and safety of its services, and quality of its care.

The Joint Commission's Comment

CMS should incorporate language into the CfCs that better integrates leadership into quality monitoring and that adds accountability. Also, under the Joint Commission standards (LD.4.70 (EP 3)), leadership is required to assess resources allocated to performance improvement activities. Because of problems that arise from obvious resource constraints, CMS should consider language that makes leadership more accountable for the assessment of performance improvement. Finally, the Joint Commission standards address specific high risk topics, and although CFR 416.43(c)(1)(i) promotes high risk areas when setting performance improvement priorities, The Joint Commission suggests that CMS specifically focus on high risk areas in any other quality assessment activities within the CfCs.

CFR 416.43 (c)(1)(i)

Proposed: Conditions for Coverage—Quality assessment and performance improvement.

(c) *Standard: Program activities.* (1) The ASC must set priorities for its performance improvement activities that— (i) Focus on high risk, high volume and problem-prone areas.

The Joint Commission's Comment

CMS should consider emphasizing that performance improvement activities be more proactive, therefore preventing problems by consistently examining points of high risk the delivery process. In addition, CMS should consider integrating leadership in the QAPI process to better promote accountability.

CFR 416.43 (d)(2)

Proposed: Conditions for Coverage—Quality assessment and performance improvement.

(d) *Standard: Performance improvement projects.* (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.

The Joint Commission's Comments

The Joint Commission has an issue with the use of the word "annually", when referencing "distinct" improvement projects. Does this mean that there needs to be a set of separate and distinct projects every year? The Joint Commission believes that important systemic issues,

which have been proven to cause medical errors and impact safety, take longer than one year to (1) assess, (2) identify and implement improvement activities, and (3) conduct an evaluation to ascertain whether the improvement activities were successful. Additionally, The Joint Commission has a concern about CMS's use of "number" of improvement projects. This could be subject to wide surveyor interpretation. The Joint Commission suggests striking the word "number", to keep the focus on the scope, which also implies number.

<u>**CFR 416.43 (e)(4)**</u>

Proposed: Conditions for Coverage—Quality assessment and performance improvement.

(e) *Standard: Governing body responsibilities.* The governing body must ensure that the QAPI—
(4) Program expectations for safety are clearly established.

The Joint Commission's Comments

Although CMS must be commended for QAPI efforts, The Joint Commission suggests that CMS consider enhancing the CfCs in the area of governance, stressing the importance of an integrated patient safety program.

<u>**CFR 416.43 (e)(5)**</u>

Proposed: Conditions for Coverage—Quality assessment and performance improvement.

(e) *Standard: Governing body responsibilities.* The governing body must ensure that the QAPI—
(5) Resources are adequately allocated for implementing the facility's program.

The Joint Commission's Comments

The Joint Commission suggests that CMS consider enhancing the definition of "resources" to include specific references to staff, time, information systems and training.

<u>**CFR 416.50 (a)(1)(i)**</u>

Proposed: Conditions for Coverage— Patients' rights.

The ASC must inform the patient or the patient's representative of the patient's rights, and must protect and promote the exercise of such rights. (a) *Standard: Notice of rights.* (1) The ASC must provide the patient or the patient's representative with verbal and written notice of the patient's rights prior to furnishing care to the patient and in a language and manner that the patient or

patient representative understands. In addition, the ASC must- (i) Post the written notice of patient rights in a place or places within theASC likely to be noticed by patients (or their representative, if applicable) waiting for treatment. Notice of rights must include the name, address, and telephone number for a representative in the State agency to whom patients can report complaints about ASCs, as well as the Web site.

The Joint Commission's Comment

The Joint Commission recommends the deletion of the term "post the written notice", and encourages broader interpretation of "informing the patient or patient representative" (e.g., material provided in advance, provided on organization's web site, etc.)

<u>CFR 416.50 (a)(1)(ii)</u>

Proposed: Conditions for Coverage— Patients' rights.

The ASC must inform the patient or the patient's representative of the patient's rights, and must protect and promote the exercise of such rights. (a) *Standard: Notice of rights.* (1) The ASC must provide the patient or the patient's representative with verbal and written notice of the patient's rights prior to furnishing care to the patient and in a language and manner that the patient or patient representative understands. In addition, the ASC must- must— (ii) Disclose, if applicable, physician financial interests or ownership in the ASC facility in accordance with part 420 of this subchapter. Disclosure information must be in writing and furnished to the patient prior to the first visit to the ASC.

The Joint Commission's Comments

The Joint Commission believes that CMS should re-evaluate these provisions because they may be too prescriptive, and create administrative burdens which would negatively affect care delivery.

<u>CFR 416.51 (a)</u>

Proposed: Conditions for Coverage—Infection control.

The Ambulatory Surgical Center (ASC) must maintain an infection 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.

The Joint Commission's Comments

The Joint Commission believes that infections present one of the greatest risks in healthcare today, which is why our standards require: expertise, planning an evaluation; systems for communication; systems for reporting, and: systems for investigating outbreaks.

CFR 416.52 (a)(2)

Proposed: Conditions for Coverage—Patient admission, assessment and discharge.

(a) Standard: *Admission and presurgical assessment.* (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.

The Joint Commission's Comments

The proposed CMS revision includes a statement that documentation would include the patient's mental ability to undergo the surgical procedure. In the proposed CfCs, the term "ability" is vague. CMS should explain whether this means the patient has the "coping skills" to undergo a surgical procedure, or has a history of mental illness or impaired cognitive function?. Additionally, CMS should define what level of practitioner would be necessary to determine "mental ability."

CFR 416.52 (c)(3)

Proposed: Conditions for Coverage—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 unless otherwise specified by State law. The discharge order must indicate that the patient has been evaluated for proper anesthesia and medical recovery.

The Joint Commission's Comments

This requirement might be considered too prescriptive, and goes beyond the standard of care which enables the use of a qualified physician to sign the discharge order.

Submitter : Dr. Jason Ormsby

Date: 10/30/2007

Organization : The Joint Commission

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3887-P-32-Attach-1.DOC

#32

October 29, 2007

Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services (DHHS)
CMS-3887-P
P.O. Box 8017
Baltimore, MD 21244-8017

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

The Joint Commission welcomes the opportunity to comment on the Ambulatory Surgical Centers, Conditions for Coverage (CfC) Proposed Rule, released August 31, 2007. Established in 1951, The Joint Commission is an independent, not-for-profit organization that evaluates and accredits approximately 15,000 healthcare organizations in the United States. In addition to accrediting over 700 ambulatory surgical centers (ASCs), representing nearly 1,200 sites, other Joint Commission-accredited organizations include hospitals; laboratories; behavioral healthcare; home care; hospice and other long term care organizations. Although accreditation is voluntary, a variety of federal and state government regulatory bodies recognize and rely upon Joint Commission accreditation decisions and findings for Medicare and state licensure purposes across all of the Joint Commission's accreditation programs.

The Joint Commission commends CMS for a much needed, and long-awaited, update of the ASC CfCs. The revisions generally reflect current practices and align with current Joint Commission ASC standards. Below, are a few specific comments organized by CFR notation that The Joint Commission offers for CMS's consideration.

CFR 416.2 – Revised Definitions

Proposed: Conditions for Coverage - Definitions.

A. An ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring an overnight stay following the surgical services, 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.

B. Overnight stay means the patient's 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.

The Joint Commission's Comment

CMS' revised definition of an ASC clarifies the term "overnight stay," and includes an accompanying definition of overnight stay. The arbitrary 11:59 p.m. cutoff may pose problems for the field for those patients who experience complications following an ambulatory surgical procedure. To ensure consistency with the approach outlined in the preamble, The Joint Commission believes that the definition should be revised to read: "Any distinct entity that operates exclusively for the purpose of providing surgical services to patients for which the patient will not be expected to require active medical monitoring and care at midnight following the procedure, 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." Use of this definition could also lessen instances in which patients with late afternoon surgery would be unsafely discharged to meet an arbitrary cutoff time.

There are other problems that exist under the current definition and are not addressed by this proposed revision. Specifically, the new definition retains the term "exclusively," which in the past has been compromised by CMS policy to allow for different procedures and treatments for Medicare and non-Medicare patients in the same Medicare-approved facility. Can we assume that by retaining the term "exclusively," CMS will now require that the same standard for procedures and overnight stays will apply to all patients, regardless of the payment source? Additionally, The Joint Commission recommends that CMS include a definition for "distinct entity," which is another term in the definition that has caused confusion over the years.

CFR 416.41(a)

Proposed: Conditions for Coverage – Governing body and management.

The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation; has oversight and accountability for the quality assurance and performance improvement program; and ensures that facility policies and programs are administered so as to provide quality health care in a safe

environment, and creates and maintains a disaster preparedness plan. (a) Standard: Contract services. When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner.

The Joint Commission's Comment

In the areas involving governing bodies and management, most of CMS's proposed CfCs match the Joint Commission's standards in these areas. However, The Joint Commission would like to take this opportunity to inform CMS of our plans to extensively update Joint Commission ASC governance standards, which will then exceed CMS's proposed requirements in this area.

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The Joint Commission's Comment

Overall, The Joint Commission commends CMS for emphasizing performance improvement within the CfCs. Joint Commission standards, however, go beyond CMS's and require facilities to collect data on performance improvement priorities identified by leadership; integrate information from leadership, staff and patients; and promote avenues of accountability. CMS should pursue similar priorities to promote a "systems" approach to quality improvement, which integrates all areas of the organization. Additionally, CMS should emphasize the need for ASCs to understand the underlying causes of sentinel events and promote the identification of systemic prevention and process improvement remedies to reduce the likelihood of repeat events.

CFR 416.43 (a)(2)

Proposed: Conditions for Coverage—Quality assessment and performance improvement.

(a) Standard: Program scope. (2) The ASC must measure, analyze, and track quality indicators, including adverse patient events, infection control and other aspects of performance that includes processes of care and services furnished in the ASC.

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CMS should consider requiring facilities to collect data on priorities identified by leadership; integrate information from leadership, staff and patients; and promote ASCs to focus on the causes of sentinel events. ASCs should be required to understand what systems failures lead to the adverse events they experience and should identify where process and systems redesign will reduce the likelihood of a repeat event.

CFR 416.43 (b)(1)

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(b) Standard: Program data. (1) The program must incorporate quality indicator data including patient care and other relevant data regarding services furnished in the ASC into its QAPI program.

The Joint Commission's Comment

The Joint Commission urges facilities to better integrate the efforts of leaders, staff and patients in the quality assessment and improvement process. Additionally, The Joint Commission's standards require facilities to focus on high risk areas (e.g., medication management, blood product use and/or restraint use).

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CFR 416.43 (c)(1)(i)

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(c) *Standard: Program activities.* (1) The ASC must set priorities for its performance improvement activities that— (i) Focus on high risk, high volume and problem-prone areas.

The Joint Commission's Comment

CMS should consider emphasizing that performance improvement activities be more proactive, therefore preventing problems by consistently examining points of high risk the delivery process. In addition, CMS should consider integrating leadership in the QAPI process to better promote accountability.

CFR 416.43 (d)(2)

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(d) *Standard: Performance improvement projects.* (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.

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The Joint Commission has an issue with the use of the word "annually", when referencing "distinct" improvement projects. Does this mean that there needs to be a set of separate and distinct projects every year? The Joint Commission believes that important systemic issues,

which have been proven to cause medical errors and impact safety, take longer than one year to (1) assess, (2) identify and implement improvement activities, and (3) conduct an evaluation to ascertain whether the improvement activities were successful. Additionally, The Joint Commission has a concern about CMS's use of "number" of improvement projects. This could be subject to wide surveyor interpretation. The Joint Commission suggests striking the word "number", to keep the focus on the scope, which also implies number.

<u>CFR 416.43 (e)(4)</u>

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Although CMS must be commended for QAPI efforts, The Joint Commission suggests that CMS consider enhancing the CfCs in the area of governance, stressing the importance of an integrated patient safety program.

<u>CFR 416.43 (e)(5)</u>

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The Joint Commission suggests that CMS consider enhancing the definition of "resources" to include specific references to staff, time, information systems and training.

<u>CFR 416.50 (a)(1)(i)</u>

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The Joint Commission recommends the deletion of the term "post the written notice", and encourages broader interpretation of "informing the patient or patient representative" (e.g., material provided in advance, provided on organization's web site, etc.)

CFR 416.50 (a)(1)(ii)

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The Joint Commission believes that CMS should re-evaluate these provisions because they may be too prescriptive, and create administrative burdens which would negatively affect care delivery.

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The Joint Commission's Comments

The Joint Commission believes that infections present one of the greatest risks in healthcare today, which is why our standards require: expertise, planning an evaluation; systems for communication; systems for reporting, and: systems for investigating outbreaks.

<u>**CFR 416.52 (a)(2)**</u>

Proposed: Conditions for Coverage—Patient admission, assessment and discharge.

(a) Standard: *Admission and presurgical assessment.* (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.

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<u>**CFR 416.52 (c)(3)**</u>

Proposed: Conditions for Coverage—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 unless otherwise specified by State law. The discharge order must indicate that the patient has been evaluated for proper anesthesia and medical recovery.

The Joint Commission's Comments

This requirement might be considered too prescriptive, and goes beyond the standard of care which enables the use of a qualified physician to sign the discharge order.

Submitter : **Dr. John Dooley** **Date: 10/30/2007**

Organization : **Mississippi Valley Surgery Center**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3887-P-33-Attach-1.DOC

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 is the hallmark 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 our 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,

John B. Dooley, M.D.

Administrator