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

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

Dear Administrator Weems:

FASA is pleased to submit these comments on the proposed rule to modify the Medicare and Medicaid conditions for coverage (CfCs) for ambulatory surgery centers (ASCs). FASA is the nation's largest ASC organization, representing more than 2,200 ASCs, the professionals who provide care in such centers and the patients who receive high quality and cost-effective ASC services. FASA's members include all types of ASCs – small and large; for profit and non-profit; single-specialty and multi-specialty; physician-owned, joint ventures between hospitals and physicians, joint ventures between physicians and management companies and hospital-owned surgery centers.

FASA shares CMS's stated goal of modernizing the Medicare ASC requirements to be "more closely aligned with today's ASC health care industry standards" and to "focus on a patient-centered, outcome-oriented process that promotes patient care foremost." That said, we believe the proposed rule reflects a missed opportunity to truly update and modernize the CfCs. In fact, other than the long overdue adoption of standards to require a forward-looking quality assessment and performance improvement program for ASCs – which has been standard practice in the ASC industry for almost three decades – there is very little in the proposed rule that will have a meaningful impact on enhancing the quality of care delivered in today's ASCs.

To the contrary, a number of provisions in the proposed rule actually would turn back the clock on ASC regulation and needlessly limit access to high quality surgical care. In particular, we are very troubled by the proposals to prohibit overnight recovery care for non-Medicare patients and to require compliance with portable x-ray conditions by ASCs that provide imaging guidance

and therapeutic radiology services. We especially urge CMS to seriously reconsider its approach in these two critically important areas.

Other sections of the rule set forth proposed standards that will be impractical for ASCs to meet or that are out of step with generally accepted medical practices, particularly in the areas of patient rights and patient admission, assessment and discharge. Our concern is that if implemented as proposed, these revised conditions would significantly increase the regulatory burdens on ASCs, without any indication that improved care would result. Thus, in the comments that follow we have tried, whenever possible, to suggest alternative approaches that we believe would produce more practical standards without compromising patient safety or quality of care.

We would welcome the opportunity to meet with CMS to discuss our concerns and comments on the CfC proposed rule in greater detail. Because of the serious impact that the proposed rule could have on the delivery of care in ASCs, we urge CMS to take the time necessary to fully evaluate the comments that follow and others the agency will receive from the ASC community.

A. Definitions (§ 416.2)

We begin with perhaps the most troubling aspect of the CfC proposed rule – the proposal to redefine an ASC as a distinct entity that operates "exclusively" for the purpose of providing surgical services to patients not requiring an "overnight stay." An "overnight stay," in turn, is a newly defined term meaning recovery requiring active medical monitoring beyond 11:59 p.m. (i.e., midnight) on the day of the procedure, "regardless of whether it is provided in the ASC." We are extremely troubled by these new definitions because they apparently would prohibit Medicare-certified ASCs from performing *any* procedures – including procedures for non-Medicare patients – requiring active medical monitoring beyond midnight, *even if such stays are permitted for non-Medicare patients in the state where the ASC is licensed*. Given that the Medicare ASC payment system already prohibits coverage of procedures requiring an overnight stay for Medicare beneficiaries, we see no reason for this unwarranted federal intrusion into the authority of the states to regulate the provision of services for non-Medicare patients. If Medicare-participating facilities are no longer able to provide overnight recovery care to non-Medicare patients, tens and perhaps hundreds of millions of dollars that has been invested in the development of this care model over the past three decades could be effectively wiped out – a consequence that is not even remotely addressed in the proposed rule's regulatory impact analysis. In fact, that analysis wrongly states that this rule "has no Federalism implications."¹

Since CMS has been aware of the provision of overnight recovery care by ASCs for non-Medicare patients for many years, we believe the agency has a heavy burden to justify this abrupt change in policy and the severe consequences that likely will result if the redefinition of ASC is adopted as proposed. Yet, the proposed rule offers no real explanation for why it is necessary – or even desirable – to change the current CfC definition of an ASC as an entity that

¹ 72 Federal Register 50469, 50480 (Aug. 31, 2007).

operates for the purpose of providing surgical services to patients not requiring “hospitalization.” See 42 C.F.R. § 416.2. The origins of this regulatory definition can be found in Section 1833(i)(1)(A) of the Social Security Act, which establishes the ASC benefit and provides Medicare coverage for “those surgical procedures...performed on an inpatient basis *in a hospital* but which also can be performed safely on an ambulatory basis in an ambulatory surgical center” (emphasis supplied). In other words, the Medicare statute envisions ASCs as a surgical alternative for patients *not requiring hospitalization*, which is how ASCs have been defined since Medicare coverage was first established for ASC services in 1982.

By defining an ASC by reference to hospitalization, rather than overnight stay, the current CfC rules allow overnight stays for non-Medicare patients, either in the ASC itself or in a licensed or certified recovery care unit that is distinct from the ASC and not a hospital, where such recovery care is permitted under state law.² In reliance on the current policy, ASCs throughout the country have invested countless amounts of time, money, and resources in developing recovery care programs for non-Medicare patients that may be needlessly jeopardized by the CfC proposed rule. As of 1999, when FASA last did a comprehensive survey on this topic, extended recovery care centers existed in 34 states (plus Puerto Rico) and approximately nine percent of ASCs nationwide.³

Because Medicare prohibits planned overnight stays for its beneficiaries, the patients served in ASC-affiliated recovery care centers tend to reflect a younger, relatively healthy patient population that prefers a non-hospital setting for mostly elective, non-emergent surgery. The kinds of procedures most commonly performed in these facilities include orthopedic and cosmetic surgery, where more costly inpatient hospital care is not necessary. As the Medicare Payment Advisory Commission (MedPAC) observed in 2000, these recovery care centers “make up a distinct class of health care facilities that provide limited medical and nursing care to people who require short-term inpatient observation or overnight lodging for services that include pain control, drug administration and fluid maintenance.”⁴ In other words, these facilities provide mostly observation and monitoring services, rather than emergency care. According to MedPAC, “[o]ver the past two decades, these facilities have increased in number and in private-sector use as technological advances have allowed more types of surgeries to be safely performed in an ambulatory setting.”⁵

² The licensure laws in approximately 14 states allow ASCs to retain patients for up to 23 or 24 hours of overnight recovery care in the ASC itself. A number of other states permit extended recovery stays of up to 24, 48 and, in some cases, 72 hours in separately licensed or certified recovery care units. Under the Medicare CfCs, these latter units are required to be legally and operationally distinct from a Medicare-certified ASC and may not share staff, space or equipment with an ASC during concurrent hours of operation.

³ Federated Ambulatory Surgery Association, *Post-Surgical Recovery Care Survey* at 4 and 6 (2000).

⁴ Medicare Payment Advisory Commission, *Medicare Payment for Post-Surgical Recovery Care Centers* at 3 (November 2000).

⁵ *Id.* at v.

Patient safety in these facilities is overseen by state licensure laws that strictly regulate things like staffing levels and credentials, emergency equipment requirements and maximum lengths of stay. By focusing on surgical recovery and employing experienced nurses and other staff with specialized expertise in post-operative treatment, extended recovery care in ASCs may be of higher quality of care than the typical general acute care hospital. According to the FASA survey noted above, 74 percent of ASCs require all of their extended recovery care nurses to be advanced cardiac life support (ACLS) certified, and another 17 percent require some nurses to be ACLS certified. In addition, the nurse-to-patient ratio in extended recovery care centers offered by ASCs (ranging from 0.84 to 1.20, according to the FASA survey) is often better than in a hospitals. At the same time, the risks of cross-infections and other complications inherent to the hospital environment are greatly reduced in recovery care facilities.

These benefits have been confirmed in studies finding non-hospital recovery care to be safe and desirable to patients and to health care professionals. For example, a decade-long study released in 2000 by the California Office of Statewide Health Planning and Development concluded that recovery care is safe for patients and that “there was substantial interest [among] both patients and professional staff in short-stay recovery periods, pleasant surroundings, home-like settings, and hotel-like services.”⁶ Because they are more cost-effective than hospitals, recovery care centers also are attractive option for many commercial insurers.

In light of these benefits, it is difficult to understand why CMS would choose now – 25 years after the Medicare ASC benefit was first established and after an entire industry has been built around the current regulatory framework – to redefine an ASC in a way that would eliminate the ability of Medicare-participating facilities to continue providing this beneficial care option to non-Medicare patients. Because the proposed rule does not offer a rationale for this far reaching change in Medicare policy, we must presume it somehow relates to patient safety concerns with the provision of overnight care in ASCs. Yet, because Medicare does not cover overnight recovery care, that concern can relate only to the safety of non-Medicare patients, which historically has been the province of the states. Indeed, the licensure and regulation of health care facilities and the protection of patient health, safety and welfare are classic state responsibilities, and we cannot fathom why this administration, in particular, would choose to intrude on the ability of states to define for themselves what kinds of post-surgical recovery care can be provided to non-Medicare patients. That decision should continue to be left to the states, without unwarranted intrusion from the federal government that, in this case, threatens to destroy a model of care delivery that has worked to benefit patients for almost 30 years without any notable patient safety or quality of care concerns.

Another possible consequence of the proposed redefinition of ASC could be reduced access to ASCs for Medicare beneficiaries. Indeed, if faced with the choice of retaining Medicare certification under the proposed definition of ASC or forgoing the provision of recovery care services to non-Medicare patients, a significant number of facilities simply may choose to opt

⁶ California Office of Statewide Health Planning and Development, *Postsurgical Recovery Care Demonstration Project Report 2000*.

out of Medicare. The likely result would be to needlessly limit beneficiary access to many innovative and high quality surgery centers.

We also note that the proposed restriction on recovery requiring “active monitoring” beyond midnight also puts at risk planned transfers to skilled nursing facilities, rehabilitation facilities, correctional institutions and other non-hospital facilities for overnight observation and monitoring following surgery. This is permitted under the current definition of ASC because recovery in these kinds of facilities is not “hospitalization.” If the proposed definition is adopted, however, it appears that such observation care would be prohibited. As a result, more procedures may need to be performed on an inpatient basis at hospitals, thus resulting in higher costs to the Medicare program. Before adopting a change that could have such a broad impact, more study is warranted.

In sum, if the concern is that overnight recovery care may not be appropriate for Medicare’s elderly patient population, that issue already has been addressed by the ASC payment system rules prohibiting Medicare coverage for any services that routinely require an overnight stay. However, the same restrictions should not be extended to the general patient population served by ASCs, whose safety is adequately overseen by state licensure laws.

Therefore, to avoid needlessly restricting access to appropriate recovery care and intruding on the traditional role of the states to regulate health care facilities for patient health and safety, we strongly urge CMS to retain the current CfC definition of an ASC by reference to patients not requiring *hospitalization*. In addition, we have always considered the requirement that ASCs operate “exclusively” for purposes of providing surgical services to be overly restrictive and an unnecessary hindrance to the efficient delivery of patient care services. We believe an ASC would be sufficiently distinguished from other provider types if it operated primarily for the purpose of providing surgical services to patients, and thus suggest modifying the existing definition of ASC as follows:

Ambulatory Surgical Center or ASC means any distinct entity that operates ~~exclusively~~primarily for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

Recognizing that hospitalization is a somewhat imprecise term, another acceptable alternative would be a definition along the lines of the following, which would continue to permit overnight stays for non-Medicare patients where permitted under state law:

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

Another acceptable alternative would be to define an ASC by reference to the provision of “outpatient” care, which would seem to require language, such as the following, to help distinguish an ASC from a hospital outpatient department:

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

Finally, if despite the concerns outlined above, CMS remains intent on defining ASC by reference to overnight stays for non-Medicare patients, we urge you to preserve the right of ASCs to perform procedures involving overnight stays, where permitted under state law, by modifying the proposed rule’s definition as follows:

Ambulatory Surgical Center or ASC means any distinct entity that operates exclusively primarily for the purpose of providing surgical services to patients not requiring an overnight stay in the ASC following the surgical services (except where permitted under applicable state law), has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

* * *

Overnight stay means the patient’s normal course of recovery requires active monitoring by qualified medical personnel, ~~regardless of whether it is provided in the ASC,~~ beyond 11:59 p.m. of the day on which the surgical procedure was performed.

B. Specific Conditions for Coverage

1. Governing Body and Management (§ 416.41)

FASA believes it is appropriate for the governing body, as the proposed rule provides, to (1) assure direct oversight and accountability for the quality assessment program, and (2) create and maintain a disaster preparedness plan. We believe an effective quality assessment program and disaster preparedness plan are essential to promoting quality care and patient safety, so that responsibility for their development and implementation appropriately resides with the governing body.

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

- First, we are concerned that requiring ASCs to “coordinate” their plans with state and local agencies, as currently proposed in § 416.41(c)(2), could be broadly construed as

imposing an affirmative duty on all ASCs to integrate their facilities into state and local disaster relief efforts. This may be appropriate for some ASCs, and in some locales ASCs have demonstrated their interest in, and ability to provide, disaster relief services. Many ASCs, however, are neither staffed nor equipped to handle the kind of trauma care that disasters often require (although many of these facilities have performed admirably in making their staff available to support disaster relief efforts, as many FASA members did in response to the September 11 attacks and Hurricane Katrina). Therefore, we believe CMS should make clear that the Medicare standard is limited to disaster preparedness planning for the care of an ASC's own patients, and leave any broader role for ASCs to the facilities themselves and to state and local authorities.

- Second, while FASA supports the requirement for periodic drills on the disaster preparedness plan, we believe the proposed standard in § 416(c)(3) that corrective action in response to those drills be implemented “immediately” is unrealistic and counterproductive. In some cases, meaningful corrective action takes time to implement; the most immediate fix is not always the best or most effective. At the same time, undue delay in addressing known short comings with a disaster preparedness plan should not be tolerated either. Thus, we believe the right balance here is struck with a requirement for “prompt” or “timely” corrections, rather than “immediate action.”⁷ Through this minor change in word choice, we believe the standards would be improved by providing time for appropriate reflection and planning, without compromising the need for prompt and timely action.

2. Quality Assessment and Performance Improvement (§ 416.43)

Quality assessment and performance improvement have been cornerstones of the ASC industry for the past 30 years. Thus, FASA supports the proposal to revise the existing quality assessment standard to require a proactive quality assessment and performance improvement (QAPI) program. Our members already address quality improvement prospectively, through focused projects designed to reduce errors and address problems before patients are adversely affected. To the extent there are outliers in the ASC industry who have not adopted that approach, the proposed rule may help move the industry closer to universal compliance.

At the same time, we also recognize that the quality of care challenges for a single operating room eye surgery center, for example, are very different from those facing large multi-specialty facilities. Thus, we appreciate that the proposed rule does not try to prescribe a “one-size-fits-all” QAPI program but, instead, provides ASCs with the flexibility to select their own quality indicators and performance measures, to set their own priorities for program activities and to design performance improvement projects that reflect the scope and complexity of each ASC's own services and operations.

⁷ “As soon as practical” is another alternative that would be preferable to the current proposal.

In short, we agree that ASCs should be able to determine how best to implement a QAPI program appropriate for improving the processes and outcomes relevant to the services they provide and the patients they serve. It is our fervent hope that this philosophy will be honored in the field by the surveyors tasked with reviewing QAPI programs, and urge CMS to implement a proactive training program for state surveyors to ensure that happens.

3. Laboratory and Radiologic Services (§ 416.49)

We are most concerned that proposed changes to this section could severely – and it appears unintentionally – restrict the ability of ASCs to perform procedures requiring imaging guidance. To understand why this may be the case, it is helpful to begin with the current ASC conditions for coverage, which provide that laboratory and radiology services – including intraoperative imaging services, such as fluoroscopy – must be obtained from a Medicare-approved facility. In the *Guidance to Surveyors* contained at Appendix L of the State Operations Manual, this requirement is interpreted, for radiology services, to mean that if the ASC itself provides directly for all radiological services, it must meet either the Medicare conditions of participation for hospitals as they relate to radiological services (42 C.F.R. § 482.26) or the conditions for coverage for portable x-ray services (42 C.F.R. §§ 486.100-486.110).⁸

In the proposed rule, however, CMS revises the standards for radiology to say that all radiological services, whether furnished directly or under arrangements, must be furnished in accordance with the portable x-ray conditions – thus in effect, dropping the alternative option of complying with the hospital conditions for radiology. The problem with this change is the portable x-ray conditions are aimed exclusively at *diagnostic* imaging services, and a close look at their requirements reveals a number of significant problems for the typical ASC providing *intraoperative* imaging guidance, rather than diagnostic services:

- First, § 486.102(b) of the portable x-ray conditions states that portable x-ray services must be provided under the supervision of a licensed physician “who is qualified by advanced training and experience in the use of x-rays for diagnostic purposes” (emphasis supplied) – essentially meaning a radiologist. In ASCs, however, intraoperative imaging services typically are performed under the direct supervision of a surgeon, not a radiologist. Indeed, a radiologist’s supervision would be neither practical nor useful in performing such services, since the radiology services are being performed to aid and guide the surgeon, not for diagnostic purposes.
- Second, § 486.104(a) of the portable x-ray conditions requires formal training in x-ray technology through an accredited program, college or university for all operators of portable x-ray equipment. However, many of the personnel who assist surgeons in the provision of imaging guidance services in ASCs do not meet these requirements, which

⁸ According to the *Guidance to Surveyors*, when the ASC fails to meet either the radiology requirements for hospitals or the portable x-ray standards, then all radiology services must be obtained from a Medicare-approved facility.

are aimed at technologists performing the technical component of diagnostic radiology services without the physician being present when the services are furnished. By contrast, imaging guidance in ASCs is provided under the direct, personal supervision of the surgeon performing the procedure, who remains fully accountable for the services. Thus, extensive formal training in x-ray technology generally is neither necessary nor practical for the personnel who assist physicians in surgery.

- Third, § 486.106 of the portable x-ray conditions requires a written physician's order specifying "the reason an x-ray test is required, the area of the body to be exposed, the number of radiographs to be obtained, and the views needed," as well as documentation in the patient's record of "a description of the procedures ordered and performed, the referring physician, the operator(s) of the portable x-ray equipment who performed the examination, the physician to whom the radiograph was sent, and the date it was sent." Such order and documentation requirements have practical utility for diagnostic imaging procedures, but are mostly irrelevant to intraoperative imaging guidance services.

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

It does not appear that this is an intended consequence of the proposed rule. Indeed, the preamble indicates that the revisions to § 416.49 are intended merely to divide the radiology standards from the laboratory standards, and to make clear that the radiology standards apply both to services provided directly by the ASC and to services furnished under arrangement. There is no hint that sweeping new restrictions on procedures involving imaging guidance were intended. Moreover, in the final rule for the new ASC payment system published on August 2, 2007, CMS provides for coverage of radiology services integral to the performance of surgical procedures, stating that "appropriate radiology services may be necessary for the safe performance of covered surgical procedures that are provided to Medicare beneficiaries in ASCs."⁹ This expansion would be rendered illusory, however, if ASCs performing intraoperative radiology services are required to comply with the supervision and documentation requirements of the portable x-ray conditions. Instead, these procedures would need to be performed at hospitals at higher cost to the Medicare program. Similarly, the portable x-ray conditions should not be applied to therapeutic radiology services, such as brachytherapy, that will be covered under the new ASC payment system when integral to a covered surgical procedure.

Fortunately, there is a simple solution to this apparent oversight – retain the current option of allowing ASCs to furnish radiology services in accordance with the hospital conditions of participation pertaining to radiology services at 42 C.F.R. § 482.26. Unlike the portable x-ray

⁹ 72 Federal Register 42469, 42496 (Aug. 2, 2007).

conditions, the hospital conditions countenance the provision of intraoperative and therapeutic radiology services by providing more flexible supervision, personnel and documentation requirements. Specifically, the hospital conditions only require general supervision of “ionizing radiology services” by a “qualified full-time, part-time, or consulting radiologist.”¹⁰ Moreover, a radiologist is needed to “interpret only these radiologic tests that are determined by the medical staff to require a radiologist’s specialized knowledge.”¹¹ As a result, surgeons are able to oversee the provision of non-ionizing radiology services (including ultrasound) without needlessly involving a radiologist, and ASCs are required to consult with radiologists only where truly needed. In addition, the hospital conditions allow the facility medical staff to designate the qualifications of radiology technicians and contain less prescriptive ordering and documentation standards more suitable to the provision of intraoperative and therapeutic radiology services.¹² ASCs that provide radiology services are familiar with the hospital conditions and have been safely operating in accordance with those requirements for many years.

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

4. Patient Rights (§ 416.50)

ASCs have been leaders in safeguarding patient rights, and FASA and its members are fully committed to continuing that tradition. We also understand this commitment begins with informing patients of their rights, and is implemented by treating patients with respect, consideration and dignity, providing appropriate privacy, handling patient records and information confidentially, giving patients the opportunity to participate in decisions involving their health care and responding appropriately to patient grievances and complaints. With these ideals firmly in mind, and with support for the notion of including a patient rights provision in the conditions for coverage, we believe the proposed standards at § 416.50 are flawed in a number of respects.

- First, the requirement in proposed § 416.50(a)(1) that all patients receive written notice of their rights in a language they understand sets an unreasonably high standard for ASCs that treat diverse patient populations speaking multiple languages. Certainly, FASA supports the idea that ASCs should translate their notices of patient rights into the languages of non-English speaking groups frequently encountered at their facilities. However, the burden of providing written translations should not apply in all cases. Rather, as the Department of Health and Human Services observed in its 2003 *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*, some

¹⁰ 42 C.F.R. § 482.26(c)(1).

¹¹ *Id.*

¹² *Id.* at § 482.26(b)(4), (c)(2) and (d).

flexibility is needed in addressing the needs of limited English proficient (LEP) patient populations:

The languages spoken by the LEP individuals with whom the recipient has contact determine the languages into which vital documents should be translated. A distinction should be made, however, between languages that are frequently encountered by a recipient and less commonly-encountered languages. Some recipients may serve communities in large cities or across the country. They regularly serve LEP persons who speak dozens and sometimes over 100 different languages. To translate all written materials into all of those languages is unrealistic. Although recent technological advances have made it easier for recipients to store and share translated documents, such an undertaking would incur substantial costs and require substantial resources....As a result, the extent of the recipient's obligation to provide written translations of documents should be determined by the recipient on a case-by-case basis..."¹³

We note that the hospital conditions of participation merely require that hospitals "inform" patients of their rights,¹⁴ and believe similar flexibility should be applied in the ASC conditions for participation. Thus, we suggest applying the hospitals conditions to ASCs or, alternatively, deleting the reference to "verbal and written" notice in proposed § 416.50(a)(1), so that ASCs are able to determine the most effective means of notifying patients of their rights. In accordance with the *HHS LEP Guidance*, in appropriate cases this may include, for example, providing "written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of...written materials, free of cost," rather than a full written translation.¹⁵ It also would include posting signs and providing information in patient brochures, which have ASCs have found to be effective means of communicating information to patients.

- Second, we believe the requirement in proposed § 416.50(a)(1)(ii) that written ownership disclosure information be furnished to patients *prior to* the first visit to an ASC could needlessly disrupt patient care and inconvenience patients. To be clear, we are not opposed to making ownership information available to patients, which already is required by the private accreditation organizations and by the anti-kickback statute safe harbor regulations.¹⁶ The decision as to where surgery is performed, however, is between the physician and his or her patient, and so if there is to be a requirement for prior disclosure of a physician's ownership interest in an ASC, that duty properly should rest with the

¹³ 68 Federal Register 47311, 47319 (Aug. 8, 2003).

¹⁴ 42 C.F.R. § 482.13(a)(1).

¹⁵ 68 Fed. Reg. at 47319.

¹⁶ 42 C.F.R. § 1001.952(r).

physician, as many states currently require in their medical practice acts.¹⁷ Moreover, prior notice from the facility is not practical when surgery is scheduled on short notice or on an urgent basis. We do not believe it benefits patient care to have ASCs turn patients away because they did not receive an ownership disclosure notice prior to arriving at the facility. We also wonder about the practical limits of the proposed standard – if ownership disclosure is not made prior to the first visit, does that mean the patient is forever barred from choosing that facility? Given these practical problems, we suggest that CMS adopt the accreditation standard that ownership information simply is made “available” to patients upon request¹⁸ or, alternatively, that it be posted or otherwise furnished to patients at the facility. We also believe the same disclosure rules should apply to other facilities that have physician investors or employees, including hospitals.

- Third, we believe the advance directives requirements in proposed § 416.50(a)(2) are unduly burdensome and inappropriate for ASCs. Indeed, the vast majority of procedures performed at ASCs involve elective day surgery, where advance directives do not apply as a practical matter. As a result, most ASCs adopt a policy that advance directives to limit care generally are not honored. To the extent a patient has executed a “do not resuscitate” or similar order, the patient has the choice of either suspending that order for their treatment at the ASC or having their surgery performed at a facility that honors such directives. Requiring disclosure of that policy should be sufficient to protect patient rights. That being the case, we believe the proposal to require that ASCs provide verbal and written information concerning its policies on advance directives is likely to be confusing and unnecessarily alarming to patients. Moreover, a requirement for “verbal information” draws health care providers into discussions with patients about the complicated legal issues surrounding advance directives. Smaller facilities cannot be expected to make a lawyer available to every patient to answer the questions that will inevitably arise from these discussions. We also believe the proposal to require “prominent” documentation of advance directives is unnecessary, given their limited application to ASCs. Again, we believe that accreditation standards provide a more practical approach; that is, we recommend replacing the current proposed § 416.50(a)(2) with the accreditation standard that “information is made available to patients and staff concerning...advance directives, as required by state or federal law or regulations.”¹⁹

¹⁷ For example, see California Business and Professions Code § 650.01(f) (a physician who makes a referral to “an organization in which the [physician] has a financial interest, shall disclose the financial interest...in writing, at the time of the referral or request for consultation”). In addition to California, at least 20 other states require physicians to disclose ownership interests to patients, including Arizona, Connecticut, Florida, Georgia, Hawaii, Kansas, Louisiana, Maryland, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia and West Virginia.

¹⁸ See Accreditation Association for Ambulatory Health Care, Inc., *Accreditation Handbook for Ambulatory Health Care* at 22 (2007).

¹⁹ *Id.* at 19.

- Fourth, we suggest rephrasing the grievance reporting requirement at proposed § 416.50(a)(3)(iii), which currently provides as follows: “*All allegations* must be *immediately* reported to a person in authority in the ASC, the State and local bodies having jurisdiction, and the State survey agency *if warranted*” (emphasis supplied). Since it is not clear what the phrase “if warranted” is intended to modify (i.e., the allegations or just the authorities to whom allegations must be reported), to ensure compliance with this requirement, it appears that “all” allegations, no matter how trivial, would need to be reported to state and local officials as soon as they are received (i.e., “immediately”). Since we presume the intent here was not to inundate government officials with immaterial and unsubstantiated patient complaints, we recommend revising this provision to require something along the lines of the following:

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

- Finally, we believe the confidentiality of clinical records standard at proposed § 416.50(d) creates unnecessary confusion with the more comprehensive HIPAA privacy standards applicable to ASCs. More specifically, the proposed rule provides that “[a]ccess to or release of patient records is permitted only with written consent of the patient or the patient’s representative or as authorized by law.” While this is not inconsistent with the HIPAA standards, we note that the HIPAA standards permit routine disclosures *without* patient consent for purposes of payment, treatment and health care operations.²⁰ Rather than having surveyors perform this two-step analysis, which has the potential to generate a significant amount of confusion over time, we believe it would be far better if the ASC conditions stuck with one standard and simply cross-referenced the HIPAA standards; i.e., access to or release of patient information and clinical records is permitted only in accordance with the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Part 164.

5. Infection Control (§ 416.51)

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

²⁰ See 45 C.F.R. §§ 164.502 and 164.506.

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

6. Patient Admission, Assessment and Discharge (§ 416.52)

The proposed rule's standards on patient admission, assessment and discharge include four provisions that are inconsistent either with accepted medical practices or with applicable legal standards of care and, thus, would interfere with the efficient delivery of patient care or impose undue burdens on ASCs, in each case without any measurable benefits for patient safety.

- The first is a requirement in proposed § 416.52(a)(1) for a "comprehensive" history and physical assessment no more than 30 days prior to surgery. While an *appropriate and current* pre-surgical assessment is unquestionably essential, that does not always need to be accomplished via a comprehensive exam within a 30-day window. Consider, for example, the common situation of repetitive or bilateral procedures, such as cataract removal for both eyes or carpal tunnel repair in both wrists. Although a comprehensive exam may be appropriate in advance of the first procedure, a more limited update of that exam typically is sufficient in advance of the second surgery to determine whether there have been any significant changes in the patient's condition. Yet, under the proposed rule, if the initial exam occurred outside of the 30-day window – which it often would because bilateral procedures normally are separated by a number of weeks – the patient would need to undergo an additional and unnecessary comprehensive exam just to meet Medicare requirements. Similar problems with a strict 30-day comprehensive exam requirement would be encountered when surgeries are rescheduled. To avoid this waste of health care resources and inconvenience to Medicare beneficiaries, we suggest the following, more practical accreditation standard for pre-surgical assessments:

An appropriate and current history, including a list of current medications, and dosages if known, physical examination, and pre-operative diagnostic studies are incorporated into the patient's medical record prior to surgery.²¹

- The second cause for concern in this section is a requirement in proposed § 416.52(a)(2) that the pre-surgical assessment include documentation to determine the patient's "mental ability" to undergo the surgical procedure. Imposing this duty on ASCs seems to interfere with the doctor-patient relationship and the rights of patients to control their own medical decisions, rather than have physicians or ASCs substitute their judgment for

²¹AAAHC *Handbook*, supra note 14 at 48.

that of the patient. Notably, this fundamental right of self-determination is expressly recognized in the patient rights provision of the proposed rule at § 416.50(b). Indeed, the well-established legal framework here places a duty *on the physician* to (1) discuss the necessity and appropriateness of the proposed surgery, as well as available alternative treatments, with the patient prior to scheduling surgery, and (2) obtain informed consent of the patient or, if applicable, of the patient's representative, before the procedure is performed. In other words, the decision to undergo a surgical procedure goes to the heart of the doctor-patient relationship,²² and ultimately is a decision reserved by law to the patient or to his or her representative – not to the physician, and certainly not to the ASC. Thus, we strongly believe that CMS should not interfere with that legal framework by imposing a separate regulatory duty in the CfCs to assess the patient's subjective "mental ability" to undergo surgery, especially where such an assessment conflicts with the legal right of patients to make their own health care decisions or to have those decisions made by their designated representatives, rather than by health care providers.

- The third cause for concern in this section is a requirement in proposed § 416.52(c)(2) that the ASC must "ensure the patient has a safe transition to home." Of course, unless this is supposed to mean that ASCs are obligated to assume full responsibility for actually transporting patients to their homes using ambulances or other extraordinary precautions, there is no way for ASCs to "ensure" against care accidents or other intervening events outside of their control that could interfere with a patient's safe transition to home. Rather, the proper standard here is to preserve the current legal standard of reasonable care, along with the existing requirement at § 416.42(c) that "all patients are discharged in the company of a responsible adult."
- The final cause for concern in this section is the current phrasing of proposed § 416.52(c)(3), which could be read to require that the physician who performed the surgery must not only sign the discharge order (an appropriate requirement that we support), but also must remain in the facility and evaluate the patient for proper anesthesia and recovery prior to discharge. At present, it is common practice for surgeons to sign discharge orders indicating that a patient should be "discharged when stable," and then delegate authority for that final assessment to another physician – often an anesthesiologist with specialized training and experience in proper anesthesia recovery – who remains present at the facility, while the surgeon is on call and available if needed. It is not clear whether CMS intended to upset that established medical practice, especially since we are not aware of any compelling medical need for requiring that the physician who performed the surgery also be the physician who evaluates for final anesthesia recovery. To the contrary, anesthesiologists generally are better suited for this role. Because the proposed language is ambiguous, however, we suggest clarifying that the standard remains as currently contained at § 416.42(a), which provides that before

²² To the extent that physician's do not appropriately perform this function, that is properly addressed through the ASC medical staff and its peer review and credentialing processes.

discharge from an ASC, each patient must be evaluated by *a physician* – not necessarily the performing physician – for proper anesthesia recovery.

C. Updates Not Included in the Proposed Rule

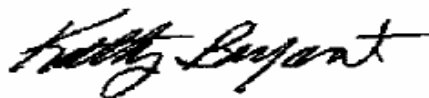
Finally, we recommend that CMS address a couple of long-standing areas of concern for ASCs in the environment standards:

- The first is amending the language in existing § 416.44(a)(2), which currently states that ASCs must have a separate recovery “room” and waiting “area.” We have never understood the need for a separate waiting area and believe that requirement should be eliminated. In addition, on occasion our members have had to deal with surveyors who believe the CfC’s use of the terms “room” and “area” reflects a meaningful distinction and that a recovery “room” must have a door and be completely separate from other areas of the facility, even though this impedes effective nursing care. CMS officials have informally confirmed for us that the CfCs do not require a door and that the primary reason for requiring a “separate recovery room” is to ensure that ASCs do not share their recovery space with hospitals, clinics or physician offices. To avoid this confusion in the future, we recommend amending § 416.44(a)(2) as follows: “The ASC must have a recovery area that is separate from any other facility.” We note that a proposal similar to this recommendation was included as part of the CfCs circulated by the agency for informal comments in 2000.
- We also suggest that CMS consider eliminating the requirement at existing § 416.44(c)(3) that all ASCs have a mechanical ventilator.

* * *

Thank you for your consideration of our comments. We look forward to continuing to work with CMS to strengthen and modify the ASC conditions for coverage.

Sincerely,



Kathy J. Bryant
President