

HEALTH LAW UPDATE

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

Ambulatory Surgical Centers – CMS Issues New Guidance on Shared Waiting Rooms and Proposes Modification to Same-Day Surgery Disclosure Rules

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The Centers for Medicare & Medicaid Services (“CMS”) has recently issued new guidance clarifying the agency’s policy on Ambulatory Surgical Centers (“ASCs”) that share waiting rooms with other entities such as physician offices. CMS also recently proposed rules on disclosures to ASC patients who receive same-day surgery. Both of these issues have caused concern for many ASCs over the past year because of ambiguities that arose after CMS issued new ASC regulations and interpretive guidelines in May 2009.

Shared Waiting Rooms

On May 21, 2010, CMS issued a memorandum that clarified the agency’s position on ASCs sharing waiting rooms with other entities such as physician groups.¹ A number of ASCs in the U.S. are located in buildings with other tenants such as physician offices, and in some cases the ASC and the physician office may share a waiting room. In the past there has been ambiguity regarding whether or not this practice was consistent with CMS regulations, and this ambiguity was heightened after CMS changed the wording of its interpretive guidelines on May 15, 2009.²

In the May 21, 2010 memorandum, CMS takes a firm position that ASCs may *not* share space with another entity when the ASC is open. *However*, CMS also directs that *existing* ASCs that already share a waiting area with other building occupants may be eligible for a waiver from the rule.

To be eligible for a waiver, an existing ASC must ensure that ASC patients and visitors using the waiting area are separated from other occupants in a shared waiting area by a temporary partition, and the partition must meet certain specific fire safety standards.³ In addition, signage must be posted that clearly identifies the distinct ASC waiting area. Existing ASCs that do not currently have a shared waiting area are not permitted to introduce a shared waiting area. Moreover, ASCs applying for a new Medicare agreement are not eligible for a waiver (this includes situations where ASCs have undergone a change of

¹ The memorandum, titled “ASC Waiting Area Separation Requirements” (S&C-10-20-ASC), is directed to State Survey Agency Directors and State Fire Authorities, but is publicly available to enable ASCs to prepare for survey issues. <http://www.ascmember.org/upload/waitingroom.pdf>

² These interpretive guidelines for ASC are contained in State Operations Manual, Appendix L – Guidance for Surveyors: Ambulatory Surgical Centers. Revised interpretive guidelines were issued May 15, 2009, three days in advance of the effective date of new ASC regulations – the “Conditions for Coverage” for ASCs which went into effect May 18, 2009. The interpretive guidelines were further refined on December 30, 2009.

³ Temporary partitions are not necessary if the ASC is “temporally distinct” from the other entity – i.e. the other tenant only uses the waiting room when the ASC is closed.

ownership and the new owner applies for a new Medicare agreement rather than assuming the old owner's agreement).

The May 21, 2010 memorandum from CMS outlines the process for obtaining a waiver, which includes preparation of a plan of correction after a shared waiting room has been identified as a deficiency in a survey. The waiver request must specify the unreasonable hardship necessitating a waiver (i.e. unreasonable structural change would be needed⁴), and must verify that the waiver will not result in any adverse health and safety impact. A waiver re-application will have to be submitted as part of the plan of correction for each subsequent survey. Any subsequent renovation, alteration or modernization of the ASC space may cause the ASC to lose its waiver and necessitate that a separate waiting room meeting life safety code requirements be established. Because this guidance is not a proposed regulation but is rather a clarification of CMS's interpretation of the existing rule, CMS has not requested any comments.

Proposed Modification to Disclosure Rules

CMS has also recently proposed changes to its regulations on written disclosures that must be given to ASC patients. The ASC Conditions for Coverage that became effective May 18, 2009 added a requirement that ASCs make certain written disclosures to patients "in advance of the date of the procedure." Three different disclosures are required under the rule: (i) information on patient rights, (ii) where applicable, disclosure of physician financial interest or ownership in the ASC, and (iii) the ASC's policies on advance directives.

Since its adoption, this new rule has created a concern for many ASCs because sometimes patients are scheduled for same-day surgery, in which case it would not be possible to provide notice prior to the date of surgery. CMS became aware of this concern and issued interpretive guidelines to address the issue on May 15, 2009, three days before the rule became effective. The guidelines stated that, with respect to patient rights, ASCs can give the required notices on the same day of surgery if (a) the referral is made on that same date, and (b) the referring physician indicates in writing that it is medically necessary for the patient to have the surgery on the same day and that surgery in an ASC setting is suitable for that patient. On December 30, 2009, CMS further revised the interpretive guidelines to clarify that this exception applies not only to the patient rights disclosure, but also to the other two categories of required disclosure – physician ownership disclosure and advance directives.

In its most recently proposed rule on this topic, issued in April 2010, CMS attempts to provide clarification and to incorporate a slightly modified version of this exception into the text of the regulation itself. Unfortunately the proposed language may lead to additional confusion. It appears from the language of the preamble of this most recently proposed rule that CMS intended the new regulations to generally track the December 30, 2009 interpretive guidelines, i.e., all three categories of notices would be required in advance of the date of the procedure, but all three categories would also be eligible for an exception in cases of medical necessity. However, the actual text of the proposed new regulation only imposes the "in advance of the date" requirement on the patient rights component, and also only makes the exception available to that component as well. Based on apparent discrepancies between the actual text of the proposed regulation and the preamble commentary, it is possible that the actual text represents an error or oversight on CMS' part.⁵

⁴ CMS did not specify what level of structural change would be considered "unreasonable."

⁵ The preamble states: "In addition to modifying §416.50 to provide for an exception for same-day procedures, we are proposing minor revisions to this section. Currently § 416.50(a)(1) [patient rights and physician ownership] and (a)(2) [advance directives] require disclosure of information to be made in advance of the date of the procedure. We are proposing to eliminate this specific requirement from these sections and add this requirement to the stem statement at § 416.50 since the stem statement applies to all of the proposed requirements at § 416.50." 78 Fed. Reg. 21209 (Apr. 23, 2010). However, notwithstanding this comment, CMS did *not* add this language to the stem statement, but instead put it only in the patient rights section. And the exception, as drafted, only applies to the patient rights portion as well. *Id.* at p. 21211. CMS removed the "in advance of the date" language from the

Although the proposed rule creates ambiguities in some areas, it does clearly modify the specific circumstances under which the “patient rights” component can be provided on the same day as a procedure. Whereas the previous guidelines allowed for an exception when “medically necessary for the patient to have the surgery on the same day,” the proposed new rule allows for an exception for “emergency” procedures that “must be performed as soon as possible to safeguard the health of the patient.” This new proposed language appears to be more stringent and provide somewhat less flexibility for performing same-day procedures than the previously issued interpretive guidelines. The full text of the exception as set forth in the proposed rule states:

“Standard: Exception to the timing of the notice of patient rights. In the case of an emergency procedure, when it is not feasible to inform the patient or the patient’s representative or surrogate of the patient’s rights in advance of the date of the procedure, the ASC may provide the required notice and disclosures to the patient or the patient’s representative or surrogate immediately before the procedure only if the following conditions are met:

- (1) The signed physician referral is in writing, is dated the day the patient presents at the ASC, and is placed in the patient’s medical record prior to the procedure.
- (2) A physician in the ASC or the referring physician communicates in writing and the ASC documents in the medical record that the procedure must be performed as soon as possible to safeguard the health of the patient.”

CMS is accepting comments on the proposed rule until June 22, 2010. It remains to be seen whether the final rule will address the uncertainties and possible drafting error described above.

If you have any questions about the ASC rules or other matters discussed in this *Health Law Update*, please do not hesitate to contact any of the attorneys in our Healthcare Practice Group listed below.

other two sections (physician ownership and advance directives) which means that, as drafted, under this proposal the required written notice of physician ownership and advance directives can apparently be provided at any time. However, this discrepancy may be clarified in the final rule.

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