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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
LITTERA SCRIPTA MANET
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FEDERAL REGISTER

Vol. 76 Monday,
No. 205 October 24, 2011

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Service

42 CFR Chapter IV

Medicare and Medicaid Programs; Changes to the Ambulatory Surgical Centers Patient Rights Conditions for Coverage; Reform of Hospital and Critical Access Hospital Conditions of Participation; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Final Rule and Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Service

42 CFR Part 416

[CMS–3217–F]

RIN 0938–AP93

Medicare Program; Changes to the Ambulatory Surgical Centers Patient Rights Conditions for Coverage

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the ambulatory surgical centers (ASCs) conditions for coverage (CfC) to allow patient rights information to be provided to the patient, the patient's representative, or the patient's surrogate prior to the start of the surgical procedure. In addition, we made minor changes to the CfC for patient rights requirements, as specified in the proposed rule. This final rule reflects the Centers for Medicare and Medicaid Services' (CMS') commitment to the general principles of the President's Executive Order 13563 released January 18, 2011, entitled ''Improving Regulation and Regulatory Review.''

DATES: *Effective Date:* These regulations are effective December 23, 2011.

FOR FURTHER INFORMATION CONTACT:

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I. Background

This final rule reflects the Centers for Medicare and Medicaid Services' (CMS') commitment to the general principles of the President's Executive Order 13563 released January 18, 2011, entitled ''Improving Regulation and Regulatory Review.'' As the single largest payer for health care services in the United States, CMS has a critical role in promoting high quality care for Medicare beneficiaries. CMS is responsible for ensuring that the conditions for coverage (CfCs) for Ambulatory Surgical Centers (ASCs) are adequate to protect and promote the health and safety of the individuals treated in ASCs. Any regulatory changes that we contemplate consider patient health and safety along with the administrative burden placed on Medicare-participating facilities.

Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) specifies that an ASC must meet health, safety, and other standards specified by the Secretary of Health and Human Services (HHS) (the Secretary) in regulation if it has an agreement in effect with the Secretary to accept payment by Medicare as payment in full for Medicare-covered services.

Substantive requirements are set forth in 42 CFR part 416 subparts B and C of our regulations. The regulations at 42 CFR part 416 subpart B describe the general conditions and requirements for ASCs. The regulations at 42 CFR part 416 subpart C describe the specific CfCs for ASCs, which include the health and safety provisions.

II. Provisions of the Proposed Regulation

On April 23, 2010, we published a proposed rule (75 FR 21207) in the **Federal Register** entitled, ''Medicare Programs; Ambulatory Surgical Centers, Conditions for Coverage,'' (hereinafter referred to as ''ASC patient rights proposed rule'') in which we proposed to revise one of the existing CfCs that ASCs must meet in order to participate in the Medicare program. The ASC patient rights proposed rule was based on feedback received after the publication of the November 18, 2008 Hospital Outpatient PPS Update for CY 2009 final rule (73 FR 68502), which contained a CfC requiring an ASC to provide notice of patient rights in advance of the date of a procedure. We were subsequently informed that the CfC notice of patient rights requirement in the November 18, 2008 rule presented problems for ASCs that provided same-day procedures on an emergency basis. In order to address those problems, we proposed in the ASC patient rights proposed rule, to establish an exception to that CfC that would permit notice of patient rights to be provided on the date of the procedure, if an ASC provided services to a patient on the same day he or she received a physician referral for the ASC service(s), and if a delay in providing the service(s) would adversely affect the patient's health. Since publishing the ASC patient rights proposed rule on April 23, 2010, we have learned that a number of ASCs routinely perform surgeries on the same day they receive physician referrals from their patients. ASCs that routinely serve same-day patients would like to continue doing so, whether the service is being performed on an emergency or non-emergency basis. Because we believe scheduling decisions should be between the patient and the ASC, rather than dictated by CMS, we are finalizing a different policy than we proposed.

In our ASC patient rights proposed rule at § 416.50(h) ''Standard: Exception to the timing of the notice of patient rights,'' we proposed to include an exception that would allow an ASC, in the case of an emergency procedure, when it was not feasible to inform the patient or the patient's representative of the patient's rights in advance of the date of the procedure, to provide this information to the patient or the patient's representative on the day of treatment, immediately before the procedure, but only if (1) the signed physician referral was in writing, was dated the day the patient presents at the ASC, and was placed in the patient's medical record prior to the procedure; and (2) a physician in the ASC or the referring physician communicated in writing and the ASC documented in the medical record that the procedure had to be performed as soon as possible to safeguard the health of the patient.

In addition to proposing to add § 416.50(h) to provide for an exception for same day procedures, we proposed other minor revisions to § 416.50. Because both § 416.50(a)(1) and (a)(2) include the requirement that disclosure of information be made in advance of the date of the procedure, we proposed to eliminate this specific requirement from these sections and to include it instead in the stem statement, which would apply to all of the requirements in § 416.50.

Further, we proposed to reorganize § 416.50(a), (b), and (c) by creating separate standards for provisions that are currently required in these paragraphs. Specifically, we proposed to retitle and reorganize the requirement of § 416.50, ''Conditions for coverage—Patient rights.''

III. Analysis of and Responses to Public Comments

We received 10 comments on the ASC patient rights proposed rule that addressed various issues regarding patient rights in ASCs. Approximately 7 comments were from ASCs and 3 comments were received from groups representing ASCs. A summary of the major issues and our responses follow:

Comment: Several commenters applauded CMS' recognition of the need to address the importance of communicating patients' rights information when an ASC is providing services to a patient on the same day the patient is referred to the ASC.

Response: We appreciate the recognition of our intent to ensure that important quality of care issues are addressed in our regulations.

Comment: Several commenters stated the exception is too intrusive in requiring that surgeries performed on the same day as the physician's referral must be for emergency procedures only.

These commenters also stated that the restriction could create patient scheduling inconveniences and patient travel issues. They believe the CfC should be expanded so that urgent (nonemergency) procedures can be performed on the same day as the physician referral of the patient.

Response: We agree with these commenters. The restrictive patient rights exception could create patient scheduling inconveniences and patient travel issues. After considering the public comments and the potential negative impact of the proposed exception on ASC patients, their families and ASC operations, we have revised the patient rights CfC. In this final rule, we have eliminated proposed § 416.50(h) and, at 416.50(a), we have amended the patient rights CfC to specify that patient rights information can be provided to the patient prior to the start of the surgical procedure. With this new requirement, ASCs will have ample time to give the patient and/or the patient's representative patient rights information. This revision will provide the patient, the patient's provider of transportation, and the ASC with the flexibility of having the surgical procedure completed on the same day the notice of patient rights is provided, when appropriate. This policy promotes ASC health and safety standards by allowing the use of optimal scheduling practices that address the routine, urgent and emergent needs of ASCs and their patients without compromising patient safety.

Comment: Some commenters stated that there were several urgent procedures for which patients (many of whom may not have a primary-care physician) self-refer to ASCs. In such instances, under the proposed rule, these patients would be unable to have the procedure completed on the same day they present at the ASC.

Response: We agree with these commenters. There are times when patients visit ASCs for urgent matters even though these patients do not have primary care physicians to provide them with referrals. Patients such as these are seen in some ASCs across the country to obtain the necessary urgent care, sometimes on the same day they contact the ASC. We agree that the ASC patient rights proposed rule could negatively impact the patient's receipt of care in those situations. The revisions we have made in this final rule, reflected in § 416.50(a), will allow for the completion of such urgent procedures within the timeframes that best meet the schedules of the patient and the ASC.

Comment: Some commenters believe that implementing the proposed limited exception for same day surgeries will unreasonably disadvantage ASCs in the services they can provide to patients compared to the services that can be provided at hospital outpatient departments. The commenters also believe that these restrictions could have the consequence of increasing health care costs to the Medicare program and limiting the choices of those patients who prefer to receive care in the ASC.

Response: We agree that placing limitations on the types of surgeries an ASC can perform on the same day patients present at the ASC with physician referrals is unduly restrictive and that ASCs could be unreasonably disadvantaged compared to hospital outpatient departments. We agree with these commenters that these restrictions could limit patient access to non-emergent procedures at ASCs and limit patient choices, create patient scheduling inconveniences, and create patient travel issues. Therefore, in this final rule, we are revising the ASC patient rights proposed rule at § 416.50(a) to allow ASCs to continue providing services based on the criteria determined by applicable ASC patient scheduling standards and policies that were in effect prior to implementing the patient rights final rule published on November 18, 2008. We are confident that our latest revisions will ensure that ASCs are in a position to continue serving the needs and promoting the health and safety of their patients.

Comment: Several commenters stated that the requirement to have the patient obtain a written referral is an unrealistic expectation to meet when a patient is presenting to the ASC for an immediate procedure.

Response: We do not believe that the requirement of obtaining a referral would be a burden for most patients who generally seek an opinion and obtain a referral from their primary physician. However, we are eliminating the proposed requirement at § 416.50(h), which includes the provision that a patient must obtain a written referral. Instead, ASCs should continue to use their current referral policies for such procedures. We have taken this approach because we believe ASCs are in the best position to know whether it is appropriate to require patients to bring referrals for procedures performed on the same day the patient comes to the ASC for treatment.

Comment: One commenter stated that the guidelines for surveyors in the State Operations Manual have recognized the appropriateness of surgical procedures performed on the same day that a referral is made when medical necessity is documented.

Response: We regard the interpretive guidelines as a tool to assist ASCs in determining when ''same day'' surgeries are appropriate. The policy currently set out in our regulation is still binding until the effective date of this rule.

Comment: Several commenters stated that the ASC may be hesitant to document in the medical record that a procedure was an emergency which needed to be performed as soon as possible to safeguard the health of the patient, because a plaintiff's attorney could use the documentation in the medical record against the ASCs or physician in an attempt to demonstrate negligence.

Response: Standard medical practice requires the ASC surgeon to systematically document the patient's medical record with information concerning the illness, injury or condition that brought the patient to the ASC, as well as the care and services received by the patient while at the ASC. Since medical records are legal documents and are subject to State and Federal laws, the documentation thereof must be complete, comprehensive, and accurate to ensure adequate patient care. ASCs continue to be responsible for determining if a surgical procedure can be performed safely at the ASC. Additionally, we do not have any control over how a medical record may be used in a legal proceeding.

Comment: Several commenters stated that patient notice requirements should be applied equally in all provider settings.

Response: We agree with these commenters. We reviewed the conditions set out for other providers and suppliers when finalizing this rule. The patient rights requirement for ASCs is now comparable to other CMS providers and suppliers, as appropriate.

IV. Provisions of the Final Regulation

In this final rule, we are adopting the provisions as set forth in the April 23, 2010 proposed rule with the following revisions:

- We revised § 416.50(a)(1) to delete the reference to the timing of the notice of patient rights exception. We are making a conforming change to § 416.50(a)(2)(i) (redesignated as § 416.50(c)(1) in this final rule).
- We revised § 416.50(a)(1) to change the timing of the notice of patient rights from ''in advance of the date of the procedure'' to ''prior to the start of the surgical procedure.''
- We revised § 416.50(d)(6) to specify that the ASC must provide ''the patient, the patient's representative, or the

patient's surrogate'' with written notice of a grievance decision. The proposed rule only included the ''patient.'' Although this change was not proposed in the proposed rule, we are making it because it is a minor technical correction to bring this provision into accordance with the other notice provisions for ASCs as well as other providers.

- We revised § 416.50(e)(2) to delete the words ''health and safety'' because competency is not a ''health and safety'' law. This is a technical correction and makes no change in established policy.
- We removed the exceptional requirement at § 416.50(h) which allowed an ASC in the case of an emergency to provide patients rights information in advance of the date of the procedure.

V. Waiver of Notice Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. In completing this final rule, we determined that there were two instances in the proposed rule which were incorrectly stated. These two statements have been corrected in this final rule, as follows:

In the proposed rule, at § 416.50(d)(6), we did not specify that the patient's representative (if applicable) should also be provided with written notice of its grievance decision. However, throughout the preamble portion of the rule, we indicated that the patient or the patient's representative should receive patient rights information. The omission from § 416.50(d)(6) was an oversight, which did not in any way reflect our intent to include the representative in all instances where patient rights information was provided. Additionally, in the proposed rule, at § 416.50(e)(2), we proposed that if a patient was adjudged incompetent under applicable State health and safety laws by a court of proper jurisdiction, the rights of the patient would be exercised by the person appointed under State law to act on the patient's behalf. However, State laws that address a patient's competency are not health and safety laws. Therefore, in this final rule, we have deleted the words ''health and safety''. The deletion of these words in no way impact the intent or the protection of patient's rights in the ASC. Because of the nontechnical nature of both of these corrections, and in accordance with the Administrative Procedure Act, we find it unnecessary to provide notice and comment to correct these omissions. Therefore, we are waiving notice of proposed rulemaking and an opportunity to comment on the nontechnical corrections in this rule.

VI. Collection of Information Requirements

The information collection and recordkeeping requirements for the ASC Patient Rights CfC were previously accounted for in the November 18, 2008 final rule entitled ''Changes to the Ambulatory Surgical Center Conditions for Coverage.'' This ASC Patient Rights final rule does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VII. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The rule does, however, create substantial savings for both patients and facilities. In 2009, there were approximately 7 million ASC admissions. Of this amount, we estimate that approximately one in five (which would ordinarily require two medical visits, one on each of two separate days) would be reduced to one visit by allowing ASCs to perform surgical procedures on the same day a patient is referred to the ASC. As a result, about 1,400,000 visits can be avoided. We estimate that the average visit to an ASC requires two and one half hours of patient time (30 minutes to get to the ASC, a 30 minute wait to be seen, 60 minutes for the visit, and 30 minutes to return home). We value patient time at $10 an hour. We therefore project a savings in patient time of about 35 million dollars a year from 1,400,000 trips avoided because of ASCs performing procedures on the same day patients are referred to the ASC. We also project that the average provider cost for the visit eliminated is about $20, which includes 15 minutes of doctor's time, 15 minutes of a nurse's time and 15 minutes of clerical processing time, to provide the patient with an assortment of forms and informational materials (including patient rights). Taking into account time spent on patients' rights at the remaining visit, we believe that the net time saving would be about $10. We project that this will result in 17.5 million dollars a year in provider cost savings. On average, a facility would realize savings of about $3,500, assuming that one-fifth of 1,400 visits were avoided. These savings would be slightly offset by additional time spent on mailing costs. We did not, however, calculate the cost for mailing out patient rights information because these documents would be included in the informational packets that ASCs typically mail to their patients.

The RFA requires agencies to analyze options for regulatory relief of small businesses in cases were rules would impose a ''significant economic impact on a substantial number of small entities.'' For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We estimate there are approximately 5,200 Medicare participating ASCs with average admissions of approximately 1,432 patients per ASC (based on the number of patients seen in ASCs in 2009). Many ASCs are considered to be small entities, by having annual revenues of less than $7 million. Based on our

estimate that on average facilities would save about $3,500, we do not believe that this would be an ''economically significant'' amount. Accordingly, we have determined that this rule does not require a regulatory flexibility analysis.

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. However, this final rule only affects ambulatory surgical centers and not hospitals. As a result, we are not preparing an analysis for section 1102 (b) of the Act because we believe and the Secretary has determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year by State, local or tribal governments, in the aggregate, or by the private sector of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold level is approximately $136 million. This final rule will not reach this spending threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule has no Federalism implications and does not impose any costs on State or local governments. Therefore, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 416 as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

■ 1. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Specific Conditions for Coverage

■ 2. Section 416.50 is revised as follows:
■ a. Redesignate paragraph (d) as paragraph (g).
■ b. Redesignate paragraph (c) as paragraph (f).
■ c. Redesignate paragraph (b) as paragraph (e).
■ d. Revise newly designated paragraph (e).
■ e. Redesignate paragraph (a)(3) as paragraph (d).
■ f. Revise newly designated paragraph (d).
■ g. Redesignate paragraphs (a)(2) introductory text, (a)(2)(i), (a)(2)(ii) and (a)(2)(iii) as paragraphs (c) introductory text, (c)(1), (c)(2), and (c)(3) respectively.
■ h. Amend newly redesignated paragraph (c)(1) by removing the words ''in advance of the date of the procedure, with information'' and replacing it with ''with written information''.
■ i. Redesignate paragraph (a)(1)(ii) as paragraph (b).
■ j. Revise the newly designated paragraph (b).
■ k. Revise paragraph (a).
■ m. Revise the introductory text.

The revisions read as follows:

§ 416.50 Condition for coverage—Patient Rights.

The ASC must inform the patient or the patient's representative or surrogate of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.

(a) *Standard: Notice of Rights.* An ASC must, prior to the start of the surgical procedure, provide the patient, the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.

(b) *Standard: Disclosure of physician financial interest or ownership.* The ASC must disclose, in accordance with Part 420 of this subchapter, and where applicable, provide a list of physicians who have financial interest or ownership in the ASC facility. Disclosure of information must be in writing.

* * * * *

(d) *Standard: Submission and investigation of grievances.* The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. The following criteria must be met:

(1) All alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse, must be fully documented.

(2) All allegations must be immediately reported to a person in authority in the ASC.

(3) Only substantiated allegations must be reported to the State authority or the local authority, or both.

(4) The grievance process must specify timeframes for review of the grievance and the provisions of a response.

(5) The ASC, in responding to the grievance, must investigate all grievances made by a patient, the patient's representative, or the patient's surrogate regarding treatment or care that is (or fails to be) furnished.

(6) The ASC must document how the grievance was addressed, as well as provide the patient, the patient's representative, or the patient's surrogate with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the result of the grievance process and the date the grievance process was completed.

(e) *Standard: Exercise of rights and respect for property and person.* (1) The patient has the right to the following:

(i) Be free from any act of discrimination or reprisal.

(ii) Voice grievances regarding treatment or care that is (or fails to be) provided.

(iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed.

(2) If a patient is adjudged incompetent under applicable State laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf.

(3) If a State court has not adjudged a patient incompetent, any legal representative or surrogate designated by the patient in accordance with State

law may exercise the patient's rights to the extent allowed by State law.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 11, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 7, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–27171 Filed 10–18–11; 11:15 am]

BILLING CODE 4120–01–P