above rules is consistent with EPA's definition in 40 CFR 51.100(s). EPA is proposing to approve this revision.

The March 20, 2009 version incorporates changes to sections 21.1 and 21.5 that require owners/operators of VOC stationary storage tanks with floating roofs to provide additional emission information concerning roof landing operations.

EPA evaluated New Jersey's revisions for consistency with the Act, EPA regulations, and EPA policy and proposes to approve them.

II. Conclusion

Both Subchapters 16 and 19 contain provisions which require case-by-case RACT determinations to be submitted as SIP revisions. These case-by-case RACT determinations are needed to fulfill the RACT requirement of section 182 of the Act. The State is in the process of evaluating these determinations for approval and therefore has not yet submitted them as SIP revisions. EPA would normally propose to conditionally approve this SIP revision as meeting the RACT requirement pending New Jersey's submission and EPA's approval of the case-by-case RACT determinations. However, based on information provided by New Jersey, the quantity of NO_X and VOC emissions relevant to these determinations is below 5 percent of the stationary source baseline of emissions which is what EPA considers to be de minimis. Therefore, pursuant to EPA guidance,[5] EPA is proposing to approve Subchapters 16 and 19. The remaining element needed to fulfill the VOC RACT requirement is New Jersey's Subchapter 26, which New Jersey submitted to EPA on April 9, 2009, as a SIP revision and which EPA is currently reviewing.

Therefore, EPA evaluated New Jersey's submittal for consistency with the Act, EPA regulations and policy. The proposed new control measures will strengthen the SIP by providing additional NO_X, SO_2, fine particulate, and VOC emission reductions. Accordingly, EPA is proposing to approve the revisions to Subchapters 4, 10, 16, 19 and related revisions to Subchapter 21, as adopted on March 20, 2009, except that EPA is continuing to not act, for the reasons explained above in this rulemaking, on the phased compliance plans by repowering and innovative control technology in sections 19.21 and 19.23, respectively. In addition, EPA is proposing to delete 40 CFR 52.1576, relating to a prior finding that NO_X RACT was not included in the New Jersey SIP.

[5] "Approval Options for Generic RACT Rules Submitted to Meet the non-CTG VOC RACT Requirement and Certain NO_X RACT Requirements," November 7, 1996.

III. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: April 14, 2010.

Judith A. Enck,

Regional Administrator, Region 2.

[FR Doc. 2010–9463 Filed 4–22–10; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Service

42 CFR Part 416

[CMS–3217–P]

RIN 0938–AP93

Medicare Program; Ambulatory Surgical Centers, Conditions for Coverage

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise one of the existing conditions for coverage (CfC) that ambulatory surgical centers (ASCs) must meet in order to participate in the Medicare program. The proposed revision would modify the current CfC for patient rights to include an exception that would allow an ASC to provide patients or the patients' representative or surrogate with required patient rights information on the day of the procedure when the procedure must, to safeguard the health of the patient, be performed on the same day as the physician's referral. In addition, we are proposing some other minor changes to the CfC for patient right requirements.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. EST on June 22, 2010.

ADDRESSES: In commenting, please refer to file code CMS–3217–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3217–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3217–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Joan A. Moliki, (410) 786–5526, Jacqueline Morgan, (410) 786–4282, Steve Miller, (410) 786–6656, or Jeannie Miller, (410) 786–3164.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Legislative and Regulatory Authority for the Ambulatory Surgical Centers, Conditions for Coverage

As the single largest payer for health care services in the United States, the Centers for Medicare & Medicaid Services (CMS) has a critical role in promoting high quality care for Medicare beneficiaries. CMS is responsible for ensuring that the conditions for coverage (CfCs) of Ambulatory Surgical Center (ASC) services, and enforcement of those conditions, are adequate to protect the health and safety of the individuals treated in such ASCs. Any regulatory changes that we contemplate must 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 requirements 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 perform procedures covered by Medicare. Under the agreement, the ASC agrees to accept the standard Medicare amount determined under section 1833(i)(2) of the Act as full payment for services, and to accept assignment of benefits as described in section 1842(b)(3)(B)(ii) of the Act for payment for all services furnished by the ASC to enrolled individuals. Substantive requirements are set forth in 42 CFR part 416 subpart B and subpart C of our regulations. The regulations at 42 CFR part 416 subpart B describe the general conditions and requirements for ASCs, and the regulations at 42 CFR part 416 subpart C describe the specific CfCs for ASCs.

B. Updates and Revisions to the Ambulatory Surgical Centers Conditions for Coverage

On August 31, 2007, we published a proposed rule (72 FR 50470) in the **Federal Register** entitled, "Medicare and Medicaid Programs; Ambulatory Surgical Centers, Conditions for Coverage," in which we proposed to update the ASC CfCs by revising some of the definitions and the CfCs regarding governing body and management, and laboratory and radiologic services, to reflect current ASC practices. In addition, we proposed to add several new CfCs regarding quality assessment and performance improvement; patient rights; infection control; and patient admission, assessment and discharge. We proposed these CfCs in order to promote and protect patient health and safety.

In the proposed rule at § 416.50, we proposed to divide the patient rights CfC into four standards. Under the first standard, § 416.50(a)(1), "Notice of rights," we proposed that ASCs be required to provide the patient or the patient's representative with verbal and written notice of the patient's rights in a language and manner the patient understood in advance of providing care to the patient. In addition, we set out what information would be required and where the ASC would have to post the information for the patient to see while waiting for treatment.

On November 18, 2008, we published a final rule (73 FR 68502), entitled "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates". The final rule, among other changes, finalized the new CfC for patient rights in ASCs. In response to the proposed patient rights provision, several commenters expressed concern about the amount of paperwork patients would be required to complete on the day of the procedure and stated that patients would benefit from reviewing pertinent information before they arrived at the ASC for the procedure (see 73 FR 68718). Therefore, in response to comments, we revised our proposed requirement for patient rights at § 416.50(a)(1), (a)(1)(ii) and (a)(2)(i), to specify that ambulatory surgical centers (ASCs) provide patient rights information to patients or the patient's representative in advance of the date of the procedure.

When we published the final rule for the ASC CfCs on November 18, 2008, we specified at § 416.50(a)(1) that patient rights information was to be provided by the ASC in advance of the date of the procedure. It was, and continues to be, our intent to require that ASCs provide patients or the patient's representative or surrogate with information we believe they need in order to make an informed choice about the facility where their procedure will be performed. Likewise, we continue to believe that this information should be imparted in advance of the date of the procedure.

The patient's representative or surrogate, who could be a family member or friend that accompanies the patient, may act as a liaison between the patient and the ASC to help the patient communicate, understand, remember, and cope with the interactions that take place during the visit, and explain any instructions to the patient that are delivered by the ASC staff. If a patient is unable to fully communicate directly with the ASC staff, then the ASC may give patient rights information to the patient's representative or surrogate. The patient has the choice of using an interpreter of his or her own, or one supplied by the ASC. A professional interpreter is not considered to be a patient's representative or surrogate. Rather, it is the professional interpreter's role to pass information from the ASC to the patient. In following translation practices, we recommend, but do not propose requiring, that a written translation be provided in languages that non-English speaking clients can read, particularly for languages that are most commonly used by non-English-speaking clients of the ASC. We note that there are many hundreds of languages (not all written) that are used by one or more residents of the United State, but that in most geographic areas the most common non-English language, by far, is Spanish.

While we propose this standard under the authority of title 18, section 1832(a)(2)(F)(i), there are other legal requirements, most notably, those under title VI of the Civil Rights Act of 1964. Our proposed requirement has been designed to be compatible with recent guidance on title VI. The Department of Health and Human Services' (HHS) guidance related to Title VI of the Civil Rights Act of 1964, "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons" (August 8, 2003, 68 FR 47311) applies to those entities that receive federal financial assistance from HHS, including ASCs. This guidance may assist ASCs in ensuring that patient rights information is provided in a language and manner the Medicare patient understands.

In the November 18, 2008, ASC regulation, we also specified at § 416.50(a)(1)(ii) (physician financial interest or ownership), and § 416.50(a)(2)(i) (Advance directives) that ASCs are also required to provide this information to patients in advance of the date of the procedure. We believe that the current organization of § 416.50 is confusing relative to the need for ASCs to furnish information to patients prior to the date of the procedure. Therefore, we are proposing to revise this section.

II. Provisions of the Proposed Regulation

As stated above, the November 18, 2008 final rule finalized the patient's right provision at § 416.50, to require ASCs to provide specific patients' rights information to patients in advance of the date of the procedure. We believed this modification would alleviate provider concerns while at the same time afford patients sufficient time to review pertinent information before undergoing a procedure. However, since the publication of the final rule, it has come to our attention that a few ASCs sometimes provide same-day procedures on an emergency basis. Therefore, the current patient rights CfC requirement has been problematic for those ASCs that perform procedures on the same day they receive physician referrals (for example, a patient is referred to an ASC due to severe eye trauma).

ASCs contemplating providing services to a patient on the same day he or she receives a referral must either refuse serving the patient for fear of violating Medicare requirements or accept the patient for service and be out of compliance with Medicare patient rights requirements. ASCs that serve same-day patients would like to continue to serve this constituency; however, potential non-compliance with the current Medicare requirement is a deterrent.

This rule proposes to establish an exception when an ASC is providing services to a patient on the same day he or she receives a physician referral for the ASC service(s) and when a delay in providing the service(s) would adversely affect the patient's health. In general, the ASC would continue to be required to provide information as specified at § 416.50. However, the proposed exception would apply only if: (1) The written referral was signed and dated by the physician on the date the patient was presented at the ASC for the service(s); and (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. This proposed exception attempts to balance our responsibility to promote the health and safety of ASC patients with undue burden on facilities.

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) and (a)(2) 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.

The current provisions at § 416.50(a), (b), and (c) require that an ASC provide verbal and written notice of patient rights to the patient or the patient's representative. This encompasses the posting of rights, disclosure of physician financial interest or ownership, the provision of advance directives, the submission and investigation of grievances, the exercise of rights, privacy and safety, and the confidentiality of clinical records. We are proposing to reorganize § 416.50(a), (b), and (c) by creating separate standards for provisions that are currently required in these paragraphs. Specifically, we are proposing to retitle and reorganize the requirements of § 416.50, "Patient rights," as follows: (a) *Standard:* Notice of rights; (b) *Standard:* Disclosure of physician financial interest or ownership; (c) *Standard:* Advance directives; (d) *Standard:* Submission and investigation of grievances; (e) *Standard:* Exercise of rights and respect for property and person; (f) *Standard:* Privacy and safety; (g) *Standard:* Confidentiality of medical records; and (h) *Standard:* Exception to the timing of the notice of patient rights. We believe this reorganization would eliminate confusion about the patient rights information to be provided to patients. We note that these are not new requirements.

In addition, as stated above, we are proposing to add a new exception to § 416.50 (proposed Standard (h)) that would allow an ASC in the case of an emergency procedure, and when it was not feasible to provide notice of patient rights information in advance of the date of the procedure, to provide this information to the patient or the

patient's representative or surrogate on the day of treatment before the procedure.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comments on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Proposed § 416.50 (h)(1) and (h)(2) would require an ASC facility to furnish information as specified when an ASC accepts a patient for a procedure that must be performed on the same day as a physician referral. Specifically, proposed § 416.50(h)(2) states that a physician in the ASC or the referring physician must communicate in writing and the ASC must document in the medical record that the procedure be performed as soon as possible to safeguard the health of the patient. The burden associated with this requirement is the time and effort necessary for an ASC physician or a referring physician to make the aforementioned written communication and documentation.

We believe the burden associated with this requirement in proposed § 416.50 constitutes a usual and customary business practice as defined in 5 CFR 1320.3(b)(2). The medical record requirement at § 416.47, which remains unchanged, also specifies that ASCs must maintain complete, comprehensive and accurate medical records to ensure adequate patient care. A physician referral letter is considered part of the patient's medical history and is always part of the medical record.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–3217–P, Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.eop.gov*.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), 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 (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 RFA requires agencies to analyze options for regulatory relief of small businesses. 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 5,100 Medicare Participating ASCs with average admissions of approximately 1,240 patients per ASC (based on the number of patients seen in ASCs in 2008). Most ASCs are considered to be small entities, either by nonprofit status or by having revenues of $7 million to $34.5 million in any 1 year. For purposes of burden estimates, we are unable to accurately determine the exact number of ASCs that provide services to patients on the same day as referral by their physicians. However, one national ASC chain informed us in September 2009 that approximately 3 percent of its ASCs provide services to patients on the same day as referral by their physicians. Using this percentage, we estimate that 153 ASCs overall perform these same day services. Due to this small percentage, we have determined that the ASC industry on average will experience a slightly reduced burden associated with mailing out patient rights informational packets to patients prior to providing the service(s). Instead, a small percentage of patients would be informed in person on the day of the procedure. Thus, we believe this exception rule should have little or no effect on the benefit cost of ASC services.

In addition, section 1102(b) of the 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 603 of the RFA. However, this proposed 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 2010, that threshold level is approximately $135 million. This proposed rule is not expected to reach this spending threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed 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 proposes to amend 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 to 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.* Except as set forth in paragraph (h) of this section, an ASC must, in advance of the date of the procedure, provide the patient or the patient's representative or surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient or the patient's representative or surrogate understands 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 whom 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.

(c) *Standard: Advance directives.* The ASC must comply with the following requirements:

(1) Provide the patient or, as appropriate, the patient's representative or surrogate with written information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms.

(2) Inform the patient or, as appropriate, the patient's representative or surrogate of the patient's right to make informed decisions regarding the patient's care.

(3) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.

(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) Allegations of neglect, mistreatment, sexual or physical abuse must be immediately reported to a person in authority in the ASC.

(3) Only substantiated allegations of neglect, mistreatment, sexual or physical abuse must be reported to the applicable 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 or the patient's representative or 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 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

(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 health and safety 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.

(f) *Standard: Privacy and safety.* The patient has the right to the following:

(1) Personal privacy.

(2) Receive care in a safe setting.

(3) Be free from all forms of abuse or harassment.

(g) *Standard: Confidentiality of medical records.* The ASC must comply with the Department's rules for the privacy and security of individually identifiable health information, as specified at 45 CFR parts 160 and 164.

(h) *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.

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

Dated: *January 21, 2010.*

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: *April 5, 2010.*

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–8903 Filed 4–22–10; 8:45 am]

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