

2012 OCT 24 PM 5:20

OFFICE OF THE
S. GRAY

VINCENT C. GRAY
MAYOR

OCT 24 2012

The Honorable Phil Mendelson
Chairman, Council of the District of Columbia
The John A. Wilson Building
1350 Pennsylvania Avenue, N.W., Suite 504
Washington, D.C. 20004

Dear Chairman Mendelson:

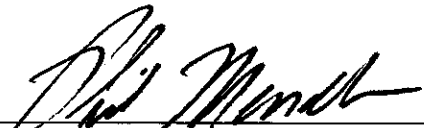
Attached for your review and approval are proposed regulations on ambulatory surgical facilities and the "Ambulatory Surgical Facility Licensing Resolution of 2012." The regulations are drafted in accordance with the Health-Care and Community Residence Facility, Hospice and Home Care Licensure Act of 1983, D.C. Law 5-48, D.C. Official Code § 44-501, et seq. (hereinafter "the Act"). The proposed regulations contain updated standards on regulating and operating ambulatory surgical facilities.

The proposed regulations clarify and expand on many of the Medicare certification requirements with which some existing facilities must now comply. The rulemaking provides, among other things, a list of allowable surgical procedures (as required by the Act); detailed standards on medical and nursing services as well as the duties of the governing body; and specific policies and procedures that the facilities must develop and implement. Operation of the facilities will be subject to the licensing and enforcement provisions of 22 DCMR Chapter 31, which are also applicable to other health-care facilities.

If you need further information, please contact Kenneth Campbell, General Counsel, Department of Health at 442-5970.

Sincerely,

A handwritten signature in black ink that reads "Vincent C. Gray".
Vincent C. Gray


Chairman Phil Mendelson
at the request of the Mayor

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34

A PROPOSED RESOLUTION

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

Chairman Phil Mendelson, at the request of the Mayor, introduced the following resolution, which was referred to the Committee on _____.

To approve the proposed rules on ambulatory surgical facility licensing standards.

RESOLVED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, That
this resolution may be cited as the "Ambulatory Surgical Facility Licensing Resolution of 2012".

Sec. 2. Pursuant to section 5(j) of the Health-Care and Community Residence Facility, Hospice and Home Care Licensure Act of 1983, effective February 24, 1984 (D.C. Law 5-48; D.C. Official Code § 44-504(j)), the Council of the District of Columbia approves the proposed rules to create regulations to license ambulatory surgical facilities.

Sec. 3. Fiscal Impact Statement. The Council adopts the fiscal impact statement submitted in conjunction with this resolution.

Sec. 4. The Secretary of the Council of the District of Columbia shall transmit a copy of this resolution, upon its adoption, to the Mayor of the District of Columbia.

Sec. 5. This resolution shall take effect immediately.

DEPARTMENT OF HEALTH

NOTICE OF PROPOSED RULEMAKING

The Director of the Department of Health, pursuant to the authority set forth in section 5(a) of the Health-Care and Community Residence Facility, Hospice and Home Care Licensure Act of 1983, effective February 24, 1984, D.C. Law 5-58, D.C. Official Code § 44-504(a)(2005 Repl.) (hereinafter "the Act"), and in accordance with Mayor's Order 98-137, dated August 20, 1998, hereby gives notice of the intent to adopt the following licensure, construction and operating standards for ambulatory surgical facilities in not less than thirty (30) days from the publication of this notice in the D.C. Register and upon completion of the forty-five (45) day Council review period if the Council does not act earlier to adopt a resolution approving the rules.

These proposed rules create operating standards for ambulatory surgical facilities in the District of Columbia, and address such areas as patient care, qualifications of staff, and recordkeeping.

There shall be a new chapter 102 added to Title 22 of the District of Columbia Municipal Regulations which shall read as follows:

CHAPTER 102 AMBULATORY SURGICAL FACILITIES

10200 GENERAL PROVISIONS

- 10200.1 This chapter applies to all freestanding ambulatory surgical facilities, but shall exclude freestanding maternity centers and freestanding kidney dialysis centers.
- 10200.2 In the absence of requirements in this chapter or in other applicable regulations, the management and operation of each ASF shall be in accordance with Joint Commission standards and good medical and public health practices, and the following:
- (a) Pharmaceutical services, Title 42 of the Code of Federal Regulations (hereinafter "CFR") § 416.48;
 - (b) Laboratory and radiological services, 42 CFR § 416.49;
 - (c) Infection control, 42 CFR § 416.51;
 - (d) Surgical services, 42 CFR § 416.42;
 - (e) Anesthesia services, 42 CFR § 416.42(a); and

(f) Emergency services, 42 CFR § 416.44(c)-(d).

10200.3 If an ambulatory surgical facility delivers services through a contract with a business that is licensed by another jurisdiction, the ASF shall be responsible for delivery of services in compliance with the laws of the District of Columbia.

10200.4 Each ASF shall be licensed and shall comply with the requirements set forth in this Chapter and with those set forth in Chapter 31 of Title 22 of the District of Columbia Municipal Regulations (DCMR), which contains provisions on inspections, licensing and enforcement actions pertaining to ASFs and other facilities authorized under the Health-Care and Community Residence Facility, Hospice and Home Care Licensure Act of 1983.; 22 DCMR 1502.1; and 22 DCMR 1503.2.10200.5 The ASF shall comply with section 9 of the Act (D.C. Official Code § 44-508) with regard to clinical privileges.

10200.6 A license is nontransferable.

10200.7 The following facilities are not required to obtain a license under this chapter: an office of a licensed physician, dentist or podiatrist at which outpatient surgery is not the primary medical service provided ; a licensed nursing home or a licensed hospital.

10200.8 If a person or facility is unsure about whether licensing under this chapter is required, a written claim for exemption, including all documentation supporting the exemption claim, may be submitted to the Director. The Director shall evaluate the claim and issue a decision within a reasonable period.

10200.9 Each ASF shall apply for District of Columbia licensure no later than 180 days after the effective date of this chapter.

10200.10 The ASF's license shall be posted in a conspicuous place in the ASF within the public's view.

10200.11 Each facility shall meet the minimum requirements for insurance as appropriate for the number and types of beds in the facility and the number and types of services available as determined by the Director.

10200.12 Allowable surgical procedures are listed in accordance with section 10208 of this Chapter.

10201 ADDITIONAL LICENSING PROCEDURES FOR AMBULATORY SURGICAL FACILITIES

10201.1

Any person desiring to operate an ASF shall:

- (a) Be designated by a distinctive name, which shall not be changed without notifying the Director and receiving approval in writing. Duplication of an existing facility's name is prohibited;
- (b) Be in compliance with all local and federal laws, including the District's Fire and Life Safety Code;
- (c) Submit a written description of its quality assurance program that meets the requirements of this chapter;
- (d) Provide the following:
 - (i) The governing body's bylaws, rules and regulations, or other written organizational plan;
 - (ii) The name, District of Columbia license number, and license expiration date of the medical director;
 - (iii) The number of physicians, dentists, podiatrists and advance practice nurses on staff;
 - (iv) Staffing plans for medical, nursing, allied health and behavioral health services;
 - (v) The name, District of Columbia license number, and license expiration date of the nursing director;
 - (vi) The number of surgical suites and recovery rooms; and
 - (vii) Written fire and emergency plans and procedures.
- (e) In cases of an ASF applying for first licensure after purchase, and previously licensed under other ownership, the licensure application shall include:
 - (i) A signed agreement with the Director to correct any deficiencies listed in the most recent licensure inspection report;
 - (ii) A copy of the closing documents, which must include an effective date and the signatures of the buyer and seller; and

- (iii) Evidence of payment of, or arrangement to pay, any money owed to the District by the ASF.

10201.2 There shall be disclosure of ASF ownership. If owned by an individual, partnership or trust, the names and ownership percentages of such individuals, partners or trustees must be provided, except that, in the case of a limited partnership, such information shall be provided only for those owning 10% or more of the partnership interest and the general partner. If owned by a for-profit corporation, the names of all stockholders with more than 10% interest shall be disclosed. If owned by a not-for-profit corporation, the names of the members and directors of the corporation shall be disclosed. Any changes in or additions to any information in the ownership control document shall be reported to the Director 30 days prior to the change in ownership.

10202 SEPARATE LICENSE

10202.1 A separate license shall be required for ASFs maintained on separate premises although operated under the same management. A separate license is not required for separate buildings on the same grounds or within the same complex of buildings.

10202.2 A hospital that has a separate ASF that is located outside the grounds of the licensed hospital is required to have a separate license for that facility.

10203 LICENSE ISSUANCE AND FEE

10203.1 No person may establish or operate an ASF without obtaining a license from the Director.

10203.2 Each application for a license or license renewal shall be accompanied by a license fee of \$700.

10203.3 Every license shall state the name and address of the ASF, the number of surgical suites and recovery rooms, the period of licensure, and the services the ASF provides.

10203.4 Each license shall be returned to the Director immediately upon change of ownership or voluntary cessation of services, or when the license is suspended or revoked.

10203.5 Each license shall be renewed annually in accordance with 22 DCMR 3102 and 3104.

10203.6 An ASF shall submit an application for licensure renewal to the Director no later than ninety (90) days before the expiration date of the current license. The facility shall submit the license fee with the application.

10204 ADMINISTRATION AND OPERATION

10204.1 The ASF must have a governing body that sets policy and assumes full legal responsibility for the operation of the ASF.

10204.2 The responsibilities of the governing body shall include the following:

- (a) Determining the mission, goals, and objectives of the ASF;
- (b) Assuring that facilities and personnel are adequate and appropriate to carry out the mission;
- (c) Establishing an organizational structure and specifying functional relationships among the various components of the ASF;
- (d) Adopting written bylaws and/or written policies for the orderly operation development and management of the ASF;
- (e) Assuring that the quality of care is evaluated and that problems are identified and addressed;
- (f) Reviewing all legal and ethical matters concerning the ASF and its staff and, when necessary, responding appropriately;
- (g) Maintaining effective communication throughout the ASF;
- (h) Establishing a system of financial management and accountability that includes an audit appropriate to the ASF;
- (i) Developing, implementing, and enforcing a written policies on the rights of patients;
- (j) Approving all major contracts or arrangements affecting the medical care provided, including, but not limited to, those concerning:
 - (i) The employment of health care practitioners;
 - (ii) Effective procedures and agreements with a local hospital for transfer of patients if necessary in an emergency or for care beyond the capability of the ASF;

- (iii) The use of external laboratories;
- (iv) An effective procedure for obtaining emergency laboratory, radiology, and pharmaceutical services if laboratory, X-ray, and pharmacy services are not provided on site;
- (v) The provision of education to students and postgraduate trainees if the ASC participates in such programs;
- (k) Formulating long-range plans in accordance with the mission, goals, and objectives of the ASF;
- (l) Operating the ASF without limitation because of race, creed, sex, or national origin;
- (m) Assuring that all marketing and advertising concerning the ASF do not imply that it provides care or services which it is not capable of providing;
- (n) Developing a system of risk management appropriate to the ASF including, but not limited to:
 - (i) Periodic review of all litigation involving the ASF, its staff, and health care practitioners regarding activities in the ASF;
 - (ii) Periodic review of all incidents reported by staff and patients;
 - (iii) Review of all deaths, trauma, or adverse reactions occurring on the premises; and
 - (iv) Evaluation of patient complaints;
- (o) Providing for the initial appointment, reappointment, assignment or the curtailment of privileges and practice for physicians and non-physicians; and
- (p) Developing policies and procedures on reporting unusual incidents to the licensing agency. An unusual incident may include, but may not be limited to, an event that results in death, wrong-site surgery, an accident, injury drug error, abuse or neglect.

10204.3

An ASF shall have a formal organizational plan with written by-laws, rules and regulations or their equivalent. These shall clearly set forth the

organization of the ASF, and the duties, responsibilities, accountability and relationships of professional staff and other personnel.

10204.4 The by-laws, rules and regulations, or their equivalent, shall include at least the following:

- (a) A statement of the purpose, mission and goals of the ASF;
- (b) A description of the functions and duties of the governing body;
- (c) A statement of authority and responsibility delegated to an administrator and the medical staff; and
- (d) Provision of guidelines for relationships among the governing body the administrator, and medical staff.

10204.5 A governing body shall meet at least annually and keep minutes or records as necessary for the orderly conduct of the ASF. .

10204.6 If an ASF's governing body elects, appoints or employs officers to carry out any of its directives, the authority, responsibility and functions of all such positions shall be clearly defined and written.

10204.7 The responsibility for the daily administration and management of the ASF shall be vested in an administrator, who shall be appointed by the governing body, and whose qualifications, authority and duties shall be defined in a written statement adopted by the governing body . The administrator's duties shall include, but not be limited to:

- (a) Implementing the facility's policies and coordinating the provision of services;
- (b) Organizing and coordinating administrative functions;
- (c) Establishing procedures for the accountability of personnel involved in patient care;
- (d) Training staff on the facility's policies and procedures, and on applicable local and federal law;
- (e) Participating in the development of organizational and fiscal planning for the ASF;
- (f) Participating in the development, negotiation and implementation of agreements or contracts to which the ASF is a party;

- (g) Ensuring that all personnel receive orientation and have sufficient experience to perform the duties of the job for which they were hired; and
- (h) Ensuring that all personnel are licensed or certified as appropriate under District law.

10204.8 The administrator, in consultation with other professional staff as necessary including but not limited to the medical and nursing directors, shall develop and implement policies and procedures governing the operation of the facility. The administrator shall ensure that policies and procedures are reviewed by staff at least annually and revised as necessary. The governing body shall approve all policies and procedures and any revisions thereto.

10204.9 Required policies of the ASF shall include the following:

- (a) A description of the type, scope and delivery of services provided by the ASF either directly or through contractual arrangements;
- (b) The granting of clinical privileges to physicians, podiatrists, physician assistants and advanced practice nurses in accordance with D.C. Official Code 44-507;
- (c) Personnel policies delineating functional responsibility and authority and job descriptions, requiring appropriate licensure, and specifying the responsibilities and privileges of employment;
- (d) Methods of communication among personnel to provide for the orderly flow of information;
- (e) The types of anesthesia that may be used;
 - (v) Admissions and discharges, including criteria for evaluating the patient before admission and at discharge, and providing aftercare plans;
 - (vi) Protocols for providing surgical and medical care and in emergencies;
 - (vii) Preoperative testing and postoperative recovery and care; Handling of pharmaceuticals;
 - (viii) Transfer and referral of patients who require emergency services or services not provided by the facility;

- (ix) Written informed consent of the patient prior to any medical procedure;
- (x) Maintenance, disposal and transport of medical waste and pharmaceuticals;
- (xi) Maintenance of equipment to ensure proper safety and operation;
- (xii) Regulation of the use, removal, handling and storage of any radioactive material;
- (xiii) Precautions against electrical, mechanical or radiation hazards;
- (xiv) Safe storage and use of anesthetics and medical gases;
- (xv) Patient rights; and
- (r) Written policies and procedures for decontamination, disinfection, sterilization and storage of sterile supplies shall be developed, implemented and enforced. The policies shall include the receiving, cleaning, decontaminating, disinfecting, preparing, and sterilization of critical items (reusable items), as well as for the assembly, wrapping, storage, distribution and the monitoring and control of sterile items and equipment.

10204.10 The administrator shall ensure that policies and procedures are available at all times for staff inspection and use, and that appropriate personnel implement all policies and procedures as adopted.

10204.11 Policies and procedures shall be made available to the Director upon request.

10205 PERSONNEL

10205.1 The administrator shall ensure that all personnel:

- (a) Have sufficient experience to demonstrate competency to perform assigned duties, and shall document such experience;
- (b) Are licensed and certified by all appropriate licensing boards to practice in the District, if required by law;

- (c) Comply with criminal background check requirements (D.C. Official Code 44-551), and all applicable federal and local employment laws;
- (d) Have malpractice insurance, if applicable;
- (e) Practice in accordance with applicable state law and federal and conform to the standards and ethics of their profession;
- (f) Comply with the following:
 - (i) Each person, other than a physician, involved in the performance of duties involving direct patient care shall have an occupational health screening by a physician or other qualified health professional within thirty (30) calendar days prior to entering active status or within thirty (30) calendar days after entering, and at least once every two (2) years thereafter. Each physician shall have a health examination performed by another physician or other qualified health care professional at the time of appointment and once every two (2) years thereafter.
 - (ii) Each health screening shall include a medical history, physical examination, intradermal tuberculin test and any indicated laboratory work.
 - (iii) Preventative measures, testing and frequency of testing for tuberculosis shall be in accordance with standards and guidelines developed by the Centers for Disease Control and Prevention.
 - (iv) A report, signed by an examining physician or other qualified health professional, shall be made of each examination.
 - (v) The report of each examination shall be kept on file in the ASF, or shall be immediately available, and shall be open to inspection by the Director.
 - (vi) In lieu of the pre-employment intradermal tuberculin test required by this subsection, the examining physician may accept a written report of the test or x-ray made by a qualified person within twelve (12) months prior to the date of the reexamination.
 - (vii) Each person who is involved in direct patient care and who

has been absent from duty because of an illness required to be reported to the Director in accordance with requirements related to communicable diseases shall, prior to returning to duty, obtain certification from a physician or other qualified health professional, as provided for in the ASF's policies, that he or she may return to duty without apparent danger of transmitting the cause of the illness to any patient.

- (viii) A copy of each certification as required in subsection (vii) above shall be kept on file and made available for examination by the Director.
- (ix) Immunization against communicable disease shall be required of all employees and all other persons who routinely come in contact with patients or patient areas. Immunizations shall be in accordance with current standards and guidelines developed by the Centers for Disease Control and Prevention.

- 10205.2 The administrator shall ensure that the ASF has a sufficient number of qualified staff to ensure the safe operation of the ASF in accordance with nationally accepted standards of practice.
- 10205.3 The administrator shall ensure that the ASF has on file job descriptions for all personnel.
- 10205.4 The administrator shall ensure that each employee sign an employment agreement, an offer letter or job description, and maintain copies of each signed document on file. The administrator shall also ensure that a current copy of any required license, or a printout from a professional licensing website, is maintained in each file.
- 10205.5 The ASF shall notify the Director in writing within 30 days of any personnel changes in the medical director, nursing director or administrator positions.
- 10205.6 The administrator shall ensure that all personnel are provided with orientation and training to familiarize them with the ASF's policies, procedures and facilities.
- 10205.7 Credentials including education and experience, certifications, licenses, and registrations shall be reviewed and verified for every person providing medical services. Clinical privileges for each such person shall be clearly defined and written, and a copy of the clinical privileges shall be kept in each person's personnel file.

- 10205.8 The ASF shall have a formal written credentialing process for physicians, dentists and podiatrists. As part of the credentialing process, the administrator, in consultation with the medical director, shall collect, review and document the following information:
- (a) The physician's, dentist's and podiatrist's education, professional experience, board certifications and post-graduate training;
 - (b) Any licenses or registrations to practice a health occupation;
 - (c) Any suspensions or revocations of any health occupation license;
 - (d) The name of any hospital where any dentist, podiatrist and physician on staff was employed, the number of years worked there, any privileges held and any disciplinary actions taken or voluntary surrenders;
 - (e) The name of all professional liability insurance carriers for the past five years. The ASF shall document the current carrier; current limits on coverage; current types of coverage; and any restrictions on coverage;
 - (f) Any claims made against the dentist, podiatrist or physician in the last five years, and the status of that claim;
 - (g) Reasonable efforts made to identify any physical or mental condition that currently impairs the physician's, dentist's or podiatrist's ability to exercise privileges; and
 - (i) Any data on the dentist, podiatrist or physician in the National Practitioners Databank.
- 10205.8 The administrator shall establish a procedure for the reappointment of any physician, podiatrist or dentist at least biannually, and shall consider the factors in sections 10205.7 and 10205.9 upon reappointment.
- 10205.9 The performance of any person on staff who provides medical services shall be evaluated at least annually, and shall consider: the medical service provider's involvement in any complaints against the ASF; malpractice claims filed against the medical service provider; adherence to policies, bylaws and procedures; any assessments through the quality assurance program.

10205.10 Whenever a licensed health-care professional is terminated as a result of a job-related incident, the hospital shall refer a report of the incident to the appropriate professional health-care board which shall review the report in accordance with the District of Columbia Health Occupations Revision Act of 1985 (D.C. Law 6-99).

10206 MEDICAL SERVICES GENERALLY

10206.1 All medical services performed in the ASF shall be limited to those procedures that are approved by the governing body upon the recommendation of qualified medical personnel. Surgical procedures to be performed in the ASF shall be reviewed periodically as part of the peer review portion of the ASF's quality assurance program.

10206.2 Medical services shall be supervised by a medical director, who shall be responsible for the quality of such services and for the overall medical care provided by the ASF. The Medical Director shall advise and consult with facility staff on all medical issues relating to the services provided by the facility.

10206.3 The medical director shall be a physician licensed to practice surgery in the District.

10206.3 The medical director shall develop protocols for the management of surgical patients and emergency situations, including staffing and supervision of surgery, which shall be approved by the governing body. The protocols shall be available on site at all times for reference. The medical director shall review the protocols at least annually and revise them as necessary. Any revisions shall be approved by the governing body.

10206.4 At least one physician shall be present at the ASF whenever medical services are provided and until all patients have been discharged.

10206.5 Licensed nurses and other personnel assisting in the provision of medical services shall be appropriately trained and supervised and shall be available in sufficient numbers for the medical care provided.

10206.6 No medication or treatment shall be given except on the signed order of a person lawfully authorized to order treatment or medication by District law. As specified in ASF policies and procedures, emergency telephone and other verbal orders shall be signed within a reasonable time not to exceed 48 hours by the person giving the order or, when such person is not available, cosigned by another physician or other person authorized to give the order.

10206.7 Only physicians and registered nurses shall administer blood and blood products.

10207 SURGICAL SERVICES

10207.1 Each ASF shall provide adequate supervision of all services offered and provided at the facility.

10207.2 Protocols for the implementation of surgical services shall include but not be limited to: personnel, preoperative testing and examinations, surgical procedures, post-anesthesia care and evaluation, discharge planning, emergency care, informed consent, and safety.

10207.3 Surgical procedures shall be performed by a physician, podiatrist or dentist licensed to perform such procedures in the District and who has been granted privileges to perform such procedures after review of the practitioner's documented education, training, experience and competence.

10207.4 An appropriate physical history, physical examination, and pertinent preoperative diagnostic studies, including a pre-anesthesia evaluation, shall be incorporated into the patient's medical record prior to surgery.

10207.5 Sufficient time shall be allowed between any examination, testing or studies and any procedure to permit the reporting and review of the exam, testing or studies by the responsible physicians. Where medical evaluation, examination, and referrals are made from a private physician's office, or another hospital, clinic or medical service, pertinent records therefrom shall be obtained and incorporated into the patient's medical record at the time the patient is admitted to the outpatient surgical hospital.

10207.6 In outpatient hospitals that provide abortion services, the diagnosis of pregnancy shall be the responsibility of the physician performing the abortion procedure.

10207.7 If any of the assessments required in section 10207.4 are performed before the day of surgery, a qualified health practitioner shall on the day of surgery reassess and document any change in the patient's clinical status that could have an effect on the surgical procedure to be performed and the anesthesia to be used.

10207.8 The necessity or appropriateness of any proposed surgery, as well as any alternate treatment, shall be discussed with the patient prior to scheduling the patient for surgery.

- 10207.9 A description of the findings and techniques of an operation shall be accurately and completely written or dictated immediately after the procedure by the practitioner who performed the procedure. If the description was dictated, an accurate written summary shall be immediately available to the health care practitioners providing care and becomes part of the patient's medical record.
- 10207.10 A safe environment for treating surgical patients, including adequate safeguards to protect the patient from cross-infection, shall be assured through the provision of adequate space, equipment and personnel.
- 10207.11 Each patient shall be evaluated for post-operative complications under the direct supervision of a physician.
- 10207.12 Written protocols shall be established for instructing patients in self-care after surgery.

10208 ALLOWABLE SURGICAL PROCEDURES

- 10208.1 In accordance with section 5(h) of the Act, this section lists outpatient surgical procedures which, if not performed in a hospital or, when appropriate, a maternity center, may be performed only in a facility licensed as an ambulatory surgical facility.
- 10208.2 The District of Columbia hereby adopts as allowable outpatient surgical procedures the procedures listed as "Final ASC Covered Surgical Procedures" by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS).
- 10208.3 The list of allowable outpatient surgical procedures is extensive and is updated quarterly at the end of the months of January, April, July and October.
- 10208.4 The list of allowable outpatient surgical procedures appears on the website of CMS and can be accessed as follows;
- (a) Go to
http://www.cms.gov/apps/ama/license.asp?file=/ascpayment/downloads/Jan_2012_ASC_addenda_extenders.zip
 - (b) Click "Accept" at bottom of page.
 - (c) "File Download" appears. Click "Open".

- (d) Allowable outpatient surgical procedures are listed in the first column, entitled "Addendum AA".

10208.5 Instructions for access is also published on the D.C. Department of Health website, link to "Health Regulation and Licensing Administration", then "Health Care Facilities".

10208.6 Any change in format or instruction shall be published on the D.C. Department of Health website, link to "Health Regulation and Licensing Administration", then "Health Care Facilities".

10209 NURSING SERVICES

102098.1 Each ASF shall retain a sufficient number of nurses qualified to provide the nursing services necessary for the type of care the ASF provides in keeping with generally accepted nursing standards of practice. The number and type of nursing personnel, including registered nurses, licensed practical nurses, and supplementary staff, shall be based upon the needs of the patients and types of services performed, and shall be documented in writing in the ASF's policies and procedures.

10209.2 Nursing services shall be under the direction of a nursing director, who shall be a registered nurse licensed in the District and who shall be responsible for the quality of nursing services.

10209.3 At least one registered nurse with current certification in basic life support shall be on duty at all times when the ASF is in use and whenever a patient is on the premises.

10209.4 There shall be a written plan of administrative authority for all nursing services addressing responsibilities and a written delineation of functions, qualifications, and patient care responsibilities for all categories of nursing personnel.

10209.5 A registered nurse shall assign nursing care of patients to other personnel in accordance with patient needs and the qualifications of available nursing staff.

10209.11 Recovery room nurses shall have specialized training in resuscitation techniques and other emergency procedures consistent with policies and procedures of the ASF for designated special units.

10210 ANESTHESIA SERVICES

- 10210.1 Anesthesia services in the ASF shall be limited to those that are approved by the governing body.
- 10210.2 Anesthesia services shall be under the direction of a physician approved by the governing body and licensed in the District of Columbia. The physician is responsible for the supervision of all persons administering anesthesia, the review of all complications, and the development of policies and procedures related to anesthesia care in consultation with medical staff.
- 10210.3 The physician identified in section 10210.2 shall, in conjunction with medical staff, develop written practice guidelines for the anesthesia service, which shall be approved, implemented and enforced by the governing body. In developing the guidelines, the ASF must consider the applicable standards and guidelines of the American Society of Anesthesiologists, the American Association of Nurse Anesthetists, and the licensing rules and standards applicable to those categories of licensed professionals qualified to administer anesthesia.
- 10210.4 The following practitioners may administer anesthesia in accordance with their education and training:
- (a) An anesthesiologist;
 - (b) A physician, dentist, oral surgeon or podiatrist who is qualified under District law and has education, training and experience in the type of anesthesia being administered; and
 - (c) Certified registered nurse anesthetist practicing in accordance with rules and regulations promulgated by the D.C. Board of Nursing.
- 10210.5 Medications for conscious sedation may be administered by a registered nurse in accordance with the requirements set out by the Board of Nursing.
- 10210.6 If anything other than an un-supplemented local anesthetic is needed to accomplish a surgical procedure, the practitioner providing anesthesia shall conduct a pre-anesthesia evaluation and document the anesthetic risk to the patient. If the assessment was performed prior to the day of surgery, a qualified health professional shall on the day of surgery reassess and document any changes in the patient's clinical status that could have an effect on the surgical procedure to be performed and the anesthesia to be used.
- 10210.7 The person administering the anesthesia shall ensure that the patient's

condition is documented during the procedure, at recovery, and at discharge, and such documentation shall be incorporated into the patient's record.

- 10210.8 Patients who have received anesthesia shall be evaluated for proper recovery by the operating surgeon or the person who administered the anesthesia prior to discharge. The person administering the anesthesia shall be available until all his or her patients have been discharged.
- 10210.9 Patients who have received local anesthesia shall only be allowed to leave the facility in the company of a responsible adult.
- 10210.10 Emergency equipment and supplies appropriate for the type of anesthesia services provided shall be maintained and accessible to staff at all times.
- 10210.11 Functioning equipment and supplies which are required for each ASF shall include:
- (a) Suctioning equipment, including a source of suction and suction catheters in appropriate sizes for the population being served;
 - (b) Source of compressed gases;
 - (c) Basic airway management equipment, including oral and nasal airways, face masks and self-inflating breathing bag valve sets;
 - (d) Blood pressure monitoring equipment; and
 - (e) Emergency medications specified by the medical staff and appropriate to the type of surgical procedures and anesthesia services provided by the ASF.
- 10210.12 In addition to the equipment and supplies required above, each ASF that provides moderate sedation/analgesia, deep sedation/analgesia, regional analgesia and/or general anesthesia shall provide the following:
- (a) Intravenous equipment, including catheters, tubing, fluids, dressing supplies, and appropriately sized needles and syringes;
 - (b) Advanced airway management equipment, including laryngoscopes and an assortment of blades, endotracheal tubes and stylets in appropriate sizes for the population being served;

- © A mechanism for monitoring blood oxygenation, such as pulse oximetry;
- (d) Electrocardiographic monitoring equipment;
- (e) Cardiovertor-defibrillator; and
- (f) Pharmacologic antagonists as specified by the medical staff and appropriate to the type of anesthesia services provided.

10210.13 There shall be written procedures, approved by the physician identified in section 10210.2, for the safe storage and use of inhalation anesthetics and medical gases.

10211 PHARMACEUTICAL SERVICES

10211.1 The ASF shall provide drugs and biologics in a safe and effective manner in accordance with professional practices and in compliance with all District and federal laws and regulations. The ASF shall be licensed as required by the Pharmaceutical Control Division of the Health Regulation and Licensing Administration, and shall comply with all applicable pharmaceutical services regulations.

10211.2 The medical director or his or her licensed designee shall be responsible for the provision of pharmaceutical services in compliance with applicable District of Columbia and federal regulations.

10211.3 Pharmaceutical services may be made available by the ASF through a contractual agreement in accordance with the same ethical and professional practices and legal requirements that would be required if the ASF were providing the service.

10211.4 Each ASF shall obtain a criminal record check in accordance with 22 DCMR Chapter 47 for any compensated employee not licensed by the Board of Pharmacy whose job it is to provide access to controlled substances within the ASF.

10211.5 Drugs shall only be provided under the direction of an authorized prescriber.

10211.6 Staff shall prepare and administer drugs in accordance with ASF policies and procedures and acceptable standards of practice.

10211.7 Adverse reactions to drugs shall be reported immediately to the patient's health care practitioner and documented in the patient's medical record.

10211.8 Any oral drug order shall be immediately reduced to writing and signed by the authorized prescriber within twenty-four (24) hours. The order shall include:

- (a) The full name, of the practitioner;
- (b) The date and time of the order;
- (c) The full name and strength of the drug, directions for use; and
- (d) The name of the practitioner who received the verbal order.

10211.9 Each ASF providing pharmaceutical services shall comply with the following:

- (a) Drugs shall be obtained from suppliers licensed or registered as required by federal and District law.
- (b) A current and complete list of all medications in inventory shall be maintained by the ASF
- (c) All areas where drugs are stored shall be dry, well lighted, well ventilated, maintained at a temperature safe for the storage of drugs as specified by the United States Pharmacopoeia/National Formulary (USP/NF) or the United States Food and Drug Administration (USFDA) and maintained in a clean and orderly condition.
- (d) Drug storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their use as stipulated by the United States Pharmacopoeia /National Formulary (USP/NF) and/or the manufacturer's or distributor's labeling unless otherwise indicated by the Pharmaceutical Control Division.
- (e) Each ASF shall provide refrigeration facilities exclusively for the storage of drugs requiring cold storage with a thermometer controlling the interior temperature to keep it maintained between thirty-six degrees Fahrenheit (36°F) and forty-six degrees Fahrenheit (46°F).
- (f) The drug storage area shall be separately enclosed and secured in such a manner as to prevent diversion and unauthorized access.

- (g) Access to the drug storage area shall be limited to persons who require entry for the purpose of discharging a job-related duty and to persons legally entitled to engage in inspection, enforcement or other regulatory duty.
- (h) Medications shall not be kept or displayed in an area that is accessible to the public.
- (i) Each ASF shall maintain current drug information reference sources consistent with the scope of practice at the location of the ASF.
- (j) Each ASF shall define procedures for proper management of drug recalls which may include, where appropriate, contacting patients to whom the recalled drug product(s) has been dispensed.
- (k) Each ASF shall ensure that discontinued and outdated drugs, and containers with worn, illegible or missing labels are maintained separately from current drug stock.
- (l) Each ASF shall develop and implement policies and procedures for disposal of drugs that is in compliance with District and Federal laws.
- (m) Medications designated as high alert medications as defined by standard setting bodies, such as Joint Commission and the Institute for Safe Medication Practices, shall be stored, handled and administered with precautions and safeguards consistent with the standards of practice associated with these medications.
- (n) Medications in multi-use vials shall base beyond-use dating on the stability information available from the manufacturer or other published studies using the same pharmaceutical contents. In the absence of stability information, the beyond-use date can be determined as follows:
 - i. For non-aqueous liquids and solids made using commercially manufactured products, the beyond-use date shall be no greater than 25% of the time remaining on the commercial product or a maximum of six months, whichever is less.
 - ii. For aqueous solutions made from solids obtained from commercially manufactured drug products, the beyond-use date is 14 days when stored at a cold temperature.

- iii. For all other formulations, the beyond-use date is not later than the intended duration of therapy or 30 days, whichever is earlier.

10211.10 ASFs providing pharmaceutical services shall comply with the following with respect to controlled substances:

- (a) Controlled substances shall be ordered by the DEA registrant or licensed person noted on a delegation of authority.
- (b) Only designated, licensed health care persons who are authorized by written facility policy to handle controlled substances shall have access to controlled substances.
- (c) Schedule II controlled substances shall be ordered using a DEA-222 form or electronic equivalent.
- (d) Upon receipt of Schedule II Controlled Substances, the DEA 222 form must be properly executed (date, quantity & initialed by receiver).
- (e) Invoices for controlled substances shall be filed separately from other invoices, shall be readily retrievable and maintained for 5 years.
- (f) A separate double locked cabinet, permanently affixed compartment box or drawer within a locked cabinet shall provide for the storage of each substance that is controlled by the D.C. Uniform Controlled Substance Act, effective August 5, 1981, D.C. Law 4-29, D.C. Code Official Code § 33-501 *et seq.*, and other drugs subject to abuse
- (g) A perpetual inventory of all controlled substances shall be completed daily and must be signed by a person authorized to handle the controlled substances. The perpetual inventory must be documented in a separately maintained log book or similar recordkeeping instrument
- (h) Any discrepancies in inventory must be reconciled immediately.
- (i) A complete inventory of controlled substances must be taken at minimum every (2) two years. This inventory shall be identified as the biennial inventory, signed by the authorized handler, dated and indicate time (opening or closing of business) when inventory was taken.

- (j) All thefts, losses and unusual occurrences must be reported to the Pharmaceutical Control Division within 48 hours of discovery.
- (k) A DEA Theft/Loss Report (Form 106) must be completed in the event of theft or loss of a controlled substance. A copy of the DEA Theft/Loss Report must be filed with the DEA and the Pharmaceutical Control Division.
- (l) Controlled substances records must be maintained for five (5) years. The most recent two years must be maintained on the premise. The later 3 years may be kept off-site, but must be retrievable within three (3) business days.
- (m) Controlled substance disposal shall be handled in accordance with District and Federal Pharmaceutical Waste Disposal laws and regulations.

10211.11 An ASF shall maintain on a complete and accurate record of all drugs received, administered or otherwise disposed of for a period of five (5) years. The most recent two years of records shall be maintained on site and the remaining three years of records may be maintained off site as long as the records can be retrieved within three (3) business days of a request.

10211.12 An ASF shall develop, maintain and implement a policy and procedure manual for pharmaceutical services that will be reviewed annually.

10211.13 The medical director or designee shall inspect any areas where medications are stored and maintained quarterly and make appropriate written records and notations of those inspections as part of a Quality Assurance Program.

10212 RADIOLOGY AND X-RAY SERVICES

10212.1 Radiology and x-ray services shall be provided for and made available when appropriate to meet the needs of the patients and shall adequately support the ASF's clinical capabilities.

10212.2 Radiological and x-ray services may be made available to the ASF through a contractual agreement in accordance with the same ethical and professional practices and legal requirements that would be required if the ASF were providing the service.

10212.3 A radiologist shall authenticate all examination reports, except reports of specific procedures that may be authenticated by physicians who are not radiologists but who have been granted privileges by the governing body

or its designee to authenticate such reports. All reports shall be made a part of the patient's medical record.

- 10212.4 Radiology and x-ray services shall be provided only upon the written order of a physician, dentist, advanced practice nurse or other authorized healthcare practitioner (such orders must be accompanied by a concise statement of the reason for the service).
- 10212.5 The ASF shall limit the use of any radioactive sources to physicians who have been granted privileges for such use on the basis of their training, experience and current competence.
- 10212.6 Radiographic equipment shall be licensed in accordance with any federal and local requirements. The ASF shall develop and implement safety programs, requirements for education, credentialing and training of personnel, and a requirement that all personnel working with radiographic equipment be adequately trained in the safety and use of all equipment.

10213 PATHOLOGY AND CLINICAL LABORATORY SERVICE

- 10213.1 Laboratory facilities shall be approved under the Clinical Laboratory Improvement Act (CLIA), and any other federal or local laws as applicable.
- 10213.2 Pathology and clinical services shall be provided, or made available in accordance with the same ethical and professional practices and legal requirements that would be required if the ASF were providing the service, when appropriate to meet the needs of the patients and adequately support the ASF clinical capabilities.
- 10213.3 Pathology and clinical laboratory services shall include, but are not limited to:
- (a) Conducting laboratory procedures that are appropriate to the needs of the patients;
 - (b) Performing tests in a timely manner;
 - (c) Distributing routine and non-critical test results within twenty-four (24) hours after completion of a test and maintaining a copy of the results in the laboratory; and
 - (d) Performing and documenting appropriate quality assurance procedures, including but not limited to, instrument maintenance

and quality control testing, and validating test results through use of standardized control specimens or laboratories.

- 10213.4 Preoperative laboratory procedures may be required as follows:
- (a) It shall be at the discretion of the Medical Director or the governing body upon the recommendation of the medical staff to require preoperative laboratory orders. Discretion shall be primarily consistent with standard medical practice.
 - (b) Other laboratory work shall be performed only on the order of a physician, podiatrist, dentist, or advanced practice registered nurse and written on the patient's chart.
- 10213.5 These services shall be provided either directly by the ASF or through an effective contract arrangement with a CLIA-certified laboratory.
- 10213.6 The contractual agreement with the reference laboratory shall provide for routine and stat work to include pathology, clinical, and blood bank services, if blood is authorized by the ASF, and shall be available for review.
- 10213.7 The patient may be instructed to go directly to the reference laboratory, or the specimen may be collected on the ambulatory surgical center's premises and then referred to the Medicare-approved reference laboratory.
- 10213.8 If the specimens are collected on the premises only, the following shall be maintained:
- (a) Procedures and policies governing the approved reference laboratory specimen requirements; identification, collection, labeling, storage, and transportation of the specimen, and preventive maintenance of equipment used in processing and storage of specimen; and
 - (b) A log book which shall include patient name and identification number, doctor's name, date the specimen was drawn and sent to the Medicare-approved reference laboratory, laboratory tests ordered, date the final report came back from the reference laboratory, and condition of the specimen. The final report shall be on the patient's chart, with copies kept in the ASF's laboratory.
- 10213.9 If laboratory tests are performed on the premises, the following shall be maintained:

- (a) Procedures governing identification, collection, labeling, and storage of specimens;
- (b) A log book, which shall include patient name and identification number, practitioner's name, date the specimen was drawn, tests ordered, and results;
- (c) Procedures for each test performed by the laboratory, including source of reagents, standards, and calibration procedures, and information concerning the basis for the tested normal ranges;
- (d) Procedures and documentation of performed maintenance on equipment used to process laboratory work;
- (e) Dated reports of all examinations performed and made a part of the patient's medical record; and
- (f) Proficiency testing as appropriate for the type of testing performed.

- 10213.10 Quality control of the laboratory shall be monitored through the quality assurance committee.
- 10213.11 The ASF can allow laboratory work to be performed and brought in from other reference laboratories or practitioners' offices, and the reports shall be on the patient's charts before surgery.
- 10213.12 Written criteria describing the length of time tests can be done prior to surgery shall be developed by the medical staff and approved by the governing body.
- 10213.13 Laboratory work shall be performed in a reference laboratory or in the patient's healthcare practitioner's office. This shall be written in a policy accepted by the medical staff and governing body.
- 10213.14 If the ASF performs surgery which incorporates the removal of a tissue specimen or the freezing of a tissue specimen, the specimen shall be submitted to a reference laboratory.
- 10213.15 Pathology tissue reports and positive cytology reports shall have the authorized signature of the pathologist interpreting the report.
- 10214 **MEDICAL WASTE AND HANDLING OF TISSUE**
- 10214.1 Each ASF shall dispose of medical waste in accordance with section 3 of the Illegal Dumping Enforcement Act (D.C. Official Code § 8-902).

10214.2 Each ASF shall maintain and store tissue and waste in accordance with section 10204.9(l) of this Chapter.

10215 DISCHARGES

10215.1 Each ASF shall have a program to provide discharge planning to patients. Discharge planning shall include, but is not limited to:

- (a) A system for timely evaluation of any discharge planning needs Of patients;
- (b) Identification of staff responsible for the program;
- (c) Development of a discharge plan, including medication review, with the patient or representative when need is identified;
- (d) Provision of documentation regarding follow-up care and medication review with the patient or representative;
- (e) Contact information in the event of an emergency or complications; and
- (f) Maintenance of a complete and accurate list of community-based services, resources and facilities to which patients can be referred.

10216 PATIENT RIGHTS

10216.1 The ASF shall have written protocols for ensuring patient rights that are consistent with the following requirements.

10216.2 Patients shall be treated with respect, consideration and dignity.

10216.3 Patients shall be provided with adequate privacy.

10216.4 Patient records shall be treated confidentially and, except when prevented by law, patients shall be given the opportunity to approve or refuse their release.

10216.5 Patients shall be provided, to the extent known, appropriate information concerning their diagnosis, treatment and prognosis. When it is medically inadvisable to provide such information to the patient, the information shall be provided to an authorized representative.

- 10216.6 Patients have the right to participate in decisions involving their health care, except when such participation is contraindicated for medical reasons. Patients shall have the right to refuse to participate in experimental research.
- 10216.7 Information shall be available to patients and staff concerning:
- (a) Patient rights;
 - (b) Patient conduct and responsibilities;
 - (c) Services provided at the ASF;
 - (d) Provisions for after-hours and emergency care;
 - (e) Fees for services;
 - (f) Payment policies;
 - (g) Patients' right to refuse to participate in experimental research; and
 - (h) Grievance procedures.
- 10216.8 Each Patient shall be given a written copy of his or her rights and responsibilities prior to or upon admission to the ASF.
- 10216.9 Patients shall be entitled to copies of their records upon request. The ASF shall provide copies of records within 10 business days of the request. The ASF may charge a reasonable fee for the copying of records.
- 10217 PATIENT SAFETY GOALS**
- 10217.1 Each ASF shall have a Patient Safety Program that shall ensure that the ASF complies with the National Patient Safety Goals published by the American Association for Accreditation of Ambulatory Surgical Facilities, the Accreditation Association for Ambulatory Health Care, the Joint Commission on Accreditation of Healthcare Organizations or another accrediting body for ambulatory surgical facilities which is approved by the Director..
- 10217.2 The ASF must develop, adopt and implement an effective, on-going Patient Safety Program.

10217.3 The Patient Safety Program must be in writing, approved by the governing body and made available for review by the Director. It must include the following components:

- (a) The definition of medical errors, and adverse and reportable events;
- (b) The process for internal reporting of medical errors and adverse and reportable events;
- (c) A list of events and occurrences which staff are required to report internally;
- (d) Time frames for internal reporting of errors and events;
- (e) Consequences for failing to report events;
- (f) Mechanisms for preservation and collection of data;
- (g) The process for conducting and completing an investigation to determine the cause of the event;
- (h) The development of an action plan within forty-five (45) days of the event or error designed to reduce the risk of events or errors in the future;
- (i) The process for communication of action plans; and
- (j) The process for feedback to staff of root cause analyses and action plans.

10217.4 The ASF must make the root cause analysis and action plan available to the Director for review.

10217.5 The ASF must provide patient education and training to staff. Training must include all components of the Patient Safety Program.

10217.6 The ASF must designate one or more individuals to be responsible for the management of the Patient Safety Program.

10218 QUALITY ASSURANCE PROGRAM

10218.1 The administrator shall ensure that the facility develops and maintains a quality assurance program. Quality assurance includes:

- (a) The identification and selection of appropriate staff and concomitant responsibilities for the program;
- (b) Ongoing review of clinical responsibilities and authority;
- (c) Peer review and supervision of all professional and technical activities;
- (d) Monitoring and evaluation of the Patient Safety Program;
- (e) The maintenance of medical records; and
- (f) Quality controls for all diagnostic and other technical services provided.

10218.2 The professional and administrative staff shall understand and support the quality assurance program.

10218.4 Quality assurance activities shall be conducted by a Quality Assurance Committee, which is composed of the specific clinical disciplines within the ASF. The committee shall meet not less than quarterly.

10218.5 The ASF shall have a peer review process that shall include a mechanism to evaluate the clinical performance of each health care practitioner on a continuous basis, but not less than annually; and a written annual evaluation of each health care practitioner.

10218.6 The administrator shall ensure that the ASF develop a quality control procedure to monitor the safety and performance of all biomedical equipment. In considering such procedure, the administrator shall consider Food and Drug Administration recommendations and the equipment manufacturer's recommendations.

10218.7 A written description of the ASF's quality assurance program shall be submitted with the initial application for licensure. The facility shall submit any changes to its quality assurance program at the time of renewal.

10219 EMERGENCY CARE

10219.1 Each employee shall be trained and certified, if appropriate, in emergency procedures, disaster plans and fire evacuation plans.

10219.2 Each ASF shall maintain the ability to provide emergency services as necessary. An ASF shall at a minimum have the following equipment available in the operating rooms:

- (a) An emergency call system;
- (b) Oxygen;
- (c) Mechanical ventilator assistance, including airways;
- (d) Manual breathing bags and ventilator;
- (e) Cardiac defibrillator;
- (f) Cardiac monitoring equipment;
- (g) Tracheostomy set;
- (h) Laryngoscopes and endotracheal tubes;
- (i) Suction equipment; and
- (j) Any other equipment and supplies specified by the medical director.

10219.3 A written agreement which ensures emergency transportation to a licensed general hospital shall be executed with an ambulance service.

10219.4 A written agreement shall be executed with a general hospital, no further than fifteen (15) minutes away, to ensure that any patient of the outpatient surgical hospital shall receive needed emergency treatment. The agreement shall be with a hospital capable of providing full surgical, anesthesia, clinical laboratory, and diagnostic radiology service on 15 minutes' notice and which has a physician in the hospital available for emergency service at all times.

10219.5 Each ASF shall have a written plan and procedures for emergency transfers, including a mechanism for notifying a hospital of a pending emergency transfer and a procedure for transferring any medical records.

10220 MEDICAL RECORDS

10220.1 The ASF shall maintain a complete, comprehensive and accurate medical record for each patient, and develop and maintain a system for the collection, processing, maintenance, storage, retrieval and distribution of patient medical records.

10220.2

The record or chart shall contain sufficient information to identify the patient, the diagnosis, any need for medical or surgical service and shall, as applicable, include but not be limited to, the following:

- (a) Patient identification;
- (b) Admitting information, including patient history and results of physical examinations;
- (c) Signed consents;
- (d) Confirmation of pregnancy, if applicable;
- (e) Preoperative diagnostic studies (if any);
- (f) Allergies;
- (g) Physician orders;
- (h) Laboratory tests and results;
- (i) Anesthesia records;
- (j) Operative records;
- (k) Medications and treatments;
- (l) Recovery room notes;
- (m) Physician and nurse progress notes;
- (n) Condition at the time of discharge;
- (o) Patient instructions;
- (p) Names of referral physicians or agencies;
- (q) Discharge instructions; and
- (r) Emergency contact numbers provided to patients.

10220.3

All relevant patient information shall be incorporated into the chart in a timely manner. Medical advice given to a patient by telephone shall be entered into a patient's record and signed by the person giving the advice.

- 10220.4 The content and format of medical records shall be uniform, except as otherwise required by law.
- 10220.5 All clinical information relevant to a patient shall be made available to all practitioners involved in the care of that patient.
- 10220.6 Entries shall be legible to clinical personnel and shall be accurate and completed promptly.
- 10220.7 When necessary for patient care, summaries or photocopies of the records of a patient who was treated elsewhere shall be obtained.
- 10220.8 All final tissue and abnormal cytology reports shall be signed by a pathologist.
- 10220.9 The ASF shall send a copy of the medical record with the patient on referral to another health care provider or on transfer to a hospital.
- 10220.10 Provisions shall be made for the safe storage of medical records or accurate and legible productions thereof. Such storage shall comply with the Health Insurance Portability and Accountability Act (42 U.S.C. sec. 1320d *et seq.*)
- 10220.11 All medical records shall be kept for a minimum of five (5) years. Records of minor patients shall be kept for 5 years after the patient reaches the age of eighteen (18).

10221 PHYSICAL ENVIRONMENT

- 10221.1 The ASF shall meet all applicable guidelines of the Building Officials and Code Administrators, and all federal and local laws, ordinances and regulations for construction.
- 10221.2 The ASF shall meet all safety requirements of the National Fire Protection Association (NFPA) 101 "Life Safety Code 2000."
- 10221.3 Each operating room shall be designed and equipped so that the types of services provided can be performed in a manner that protects the lives and assures the physical safety of all persons in the area. Treatment rooms, including operating rooms, shall have a minimum clear floor area sufficient to permit removal of a patient by stretcher.
- 10221.4 A safe environment for treating patients, including adequate safeguards to protect each patient from cross-infection, shall be assured through the provision of adequate space, equipment and personnel.

- 10221.5 Provisions shall be made for the isolation or immediate transfer of persons with communicable diseases.
- 10221.6 All persons entering the operating room shall be properly attired.
- 10221.7 Acceptable aseptic techniques shall be used by all persons in the surgical area.
- 10221.8 Only authorized personnel shall be allowed in the surgical area.
- 10221.9 The ASF shall maintain suitable equipment for high-speed and routine sterilization that ensure that operating room materials are sterile. Performance records for all sterilizers shall be maintained for six (6) months.
- 10221.10 Operating rooms shall be appropriately cleaned before, during and after each operation.
- 10221.11 Illumination at the examination tables and in the surgical areas shall provide at least one hundred (100) foot candles of light.
- 10221.12 Emergency power adequate for the types of surgery performed shall be available in the operative and post-operative areas in accordance with NFPA 99, NFPA 101 and NFPA 110.
- 10221.13 All parts of the ASF and its premises shall be kept clean and neat and free of litter and rubbish.
- 10221.14 Hazardous cleaning solutions, compounds and substances shall be labeled, stored in a safe place, and kept in an enclosed section separate from other materials.
- 10221.15 Adequate space shall be provided for accumulated waste. Such waste, including all contaminated sharps, dressings or similar infectious waste, shall be disposed of in a manner compliant with the Occupational Safety and Health Administration and Centers for Disease Control guidelines.
- 10221.16 Each ASF shall make provisions for the cleaning of all linens. There shall be separate areas for the storage and handling of clean and soiled linens. All soiled linens shall be placed in closed containers prior to transportation.
- 10221.17 Adequate provisions shall be maintained for the processing, sterilizing, storing and dispensing of clean and sterile supplies and equipment. Written procedures shall be established for the appropriate disposal of pathological and other potentially infectious waste and supplies.

10221.18 The ASF shall comply with all guidelines for infection control promulgated by the Association for Professionals in Infection Control and Epidemiology, Inc.

10221.19 The ASF shall ensure that all medical equipment operates in accordance with the manufacturer's standards, and shall perform preventative maintenance in accordance with the manufacturer's recommendations and generally accepted standards. All equipment shall be periodically tested as appropriate to ensure proper functioning. Maintenance records for equipment shall be maintained by the ASF for at least three (3) years.

10222 DIETARY SERVICE

10222.1 If the program calls for dietary service, serving of snacks or other food, adequate space, equipment, and supplies shall be provided. Applicable local laws pertaining to the receipt, storage, refrigeration, preparation, and serving of food shall be followed.

10222.1 Any food service offered or provided to patients of the ASF shall be in accordance with the District of Columbia laws and regulations on food, Title 25 of the DCMR, Subtitles A and B.

10223 CONSTRUCTION

10223.1 All ASFs shall be designed, constructed, and maintained in a manner that is safe, clean, and functional for the type of care and treatment to be provided. The standards for the facilities are set forth below.

10223.2 New construction and renovations shall comply with the following codes and guidelines to provide a safe and accessible environment that is conducive to the care and treatment to be provided:

- (a) Building Officials and Code Administrators (BOCA);
- (b) National Fire Protection Association, Life Safety Code
- (c) National Fire Protection Association 99, Health Care Facilities;
- (d) American Institute for Architects (AIA) Guidelines for Design and Construction of Hospitals and Health Care Facilities;
- (e) National Electrical Code; and
- (f) Uniform Federal Accessibility Standards.

10224 INCIDENT REPORTS

- 10224.1 Each facility shall maintain and keep for three (3) years from the date of occurrence a summary and analysis of each unusual incident that occurs within the facility, on the premises and in regard to a person's status as a patient, visitor or employee of the facility.
- 10224.2 A summary and analysis of each incident shall be completed immediately and reviewed within forty-eight (48) hours of the incident by the Medical Director or the Director of Nursing and shall include the following:
- (a) The date, time and description of the incident;
 - (b) The name of all witnesses;
 - (c) The statement of the victim;
 - (e) A statement indicating whether there is a pattern of occurrence; and
 - (e) A description of the corrective action taken.
- 10224.3 Summaries and analyses of incidents shall be reviewed at least monthly by the administrator or designee in order to identify and correct health and safety hazards and patterns of occurrence.
- 10224.4 Each incident shall be documented in the patient's records and reported to the Director within two (2) business days of occurrence, except that an incidents or accident that results in harm to a patient shall be reported within twenty-four (24) business hours of occurrence.
- 10225 GRIEVANCE PROCEDURES**
- 10225.1 Each ASF shall develop written procedures that assure prompt and complete investigations of all grievances that are filed against any ASF staff. The procedures will be made available to the Director upon request.
- 10225.2 Each ASF's procedures shall include, at a minimum, a senior staff person to investigate grievances; establishment of a reporting procedure so that the senior staff person receives the grievance within 24 hours; and a written process for investigation.
- 10225.3 Each ASF shall maintain a grievance file that includes the original report of the complaint; the investigation process and any findings of the investigation; the outcome of the investigation; and any actions taken.

- 10225.4 The grievance file shall be available for inspection by the Director.
- 10225.5 If the Director receives a grievance regarding patient care or safety, the Director may inspect the ASF at any time. If the Director receives a grievance regarding the performance of a health care practitioner or standards of practice, the Director shall refer the grievance to the board that licenses or certifies the practitioner.
- 10225.6 The Director shall conduct investigations of complaints in accordance with 22 DCMR Chapter 31.

10226.7 EVACUATION PLAN

Each ASF shall develop a written evacuation plan to assure reasonable precautions are taken to protect patients, employees and visitors from fire and other disasters. The evacuation plan shall provide a program to familiarize personnel with evacuation procedures. The evacuation plan shall be available to the Director upon request.

10299 DEFINITIONS

Administrator--A person who is a physician, is a registered nurse, has a baccalaureate or postgraduate degree in administration or a health-related field, or has at least three (3) years of administrative experience in a health care setting.

Advanced Practice Nurse - An individual licensed by the D.C. Board of Nursing and authorized to practice as an advanced practice nurse in the District of Columbia.

ASF (Ambulatory Surgical Facility) - any facility, other than a hospital or maternity center, including an office-based facility, whose primary practice is outpatient surgical and related procedures on patients for whom there is no planned overnight stay.

Certified registered nurse anesthetist (CRNA)--A registered nurse who has current certification from the Council on Certification of Nurse Anesthetists and who is currently authorized to practice as an advanced practice registered nurse by the District of Columbia Board of Nursing.

Dentist--A person who is currently licensed under the laws of this state to practice dentistry.

Director- the Director of the Department of Health and his or her designee.

Direct supervision- supervision in which the supervisor is immediately available on the premises and within vocal communication either directly or by a communication device.

Freestanding – independent and not part of or affiliated with an existing hospital, maternity center or other health care facility licensed in accordance with D.C. Law 5-48.

Governing body – the entity that is designated full responsibility for determining, implementing, and monitoring policies governing the operation of the ASF's.

Healthcare practitioner- anyone who provides medical services at the ASF and is authorized to do so by the Health Occupations Revisions Act, D.C. Law 6-99, D.C. Official Code §3-1201, *et seq.*.

Licensed practical nurse --A person who is currently licensed by the D.C. Board of Nursing as a licensed vocational nurse.

Medical services- the diagnoses or treatment of any patient for a medical condition. Medical services shall include but not be limited to surgical services.

Outpatient is any patient who remains in a facility less than 24 hours. The 24-hour period begins with the induction of anesthesia.

Registered nurse (RN)--A person who is currently licensed by the D.C. Board of Nursing as a registered nurse.

Physician--An individual licensed by the D.C. Medical Board and authorized to practice medicine in the District of Columbia.

Podiatrist- An individual licensed by the D.C. Medical Board and authorized to practice podiatry in the District of Columbia.

Physician's Assistant - An individual licensed by the D.C. Medical Board and authorized to practice as a physician's assistant in the District of Columbia.

For the purposes of determining compliance with the ASC definition, CMS relies, with minor modification, upon the definition of surgery developed by the American College of Surgeons (www.facs.org/fellows_info/statements/st-11.html.) Accordingly, the following definition is used to determine whether or not a procedure constitutes surgery:

Surgery – In accordance with the American College of Surgeons, (1) structurally altering the human body by the incision or destruction of tissues; (2) the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles; or (3) the injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system. The tissue can be cut, burned, vaporized, frozen, sutured, probed or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means.

Unusual incident - an unexpected occurrence or accident resulting in death, life-threatening or serious injury, or the risk thereof, to a patient, visitor or employee of the facility. An unusual includes, but is not limited to, an incident resulting in the abuse of a patient, wrong-site, accidents, injuries, drug errors, abuse, and neglect.

Comments on this proposed rulemaking should be submitted, in writing, to Feseha Woldu, Ph.D., Senior Deputy Director, Health Regulation and Licensing Administration, Department of Health, at 899 North Capitol Street, N.E., 2nd Floor, Washington, DC 20002, within 30 days of the date of publication of this notice in the D.C. Register. Additional copies of this rulemaking are available at the above address.

RULEMAKING TRANSMITTAL FORM

TYPE OF RULEMAKING ACTION: EMERGENCY RULES

 FINAL RULES X PROPOSED RULES COMBINED

AGENCY: Department of Health

AGENCY REPRESENTATIVE: Kenneth B. Campbell, General Counsel

ADDRESS: 899 North Capitol Street, NE, 5th Floor, Washington, D.C. 20002 TELEPHONE: (202) 442-5970

TITLE AND DESCRIPTION OF RULES: Rules for the licensing and operation of ambulatory surgical facilities

If this rulemaking action will amend or repeal existing rules, give a complete citation to the rules being amended or repealed: N/A

FINAL RULES ONLY: Give the D.C. REGISTER citation and date of publication of the Notice of Proposed Rulemaking for these rules: DCR DATE:

COMPLETE CITATION to the statute, regulation, or other legal authority which specifically authorizes the issuance of the substance of these rules: Section 5(a) of the Health-Care and Community Residence Facility, Hospice and Home Care Licensure Act of 1983, effective February 24, 1984, D.C. Law 5-48, D.C. Official Code, § 44-504(a) and Mayor's Order 98-137, dated August 20, 1998.

LEGAL CERTIFICATION: I certify that I have reviewed the attached rulemaking and, in my opinion, the substance of the text of the rules is legally sufficient.

<input checked="" type="checkbox"/> FINAL	<input type="checkbox"/> CONDITIONAL
---	--------------------------------------

SIGNED: Janet M. Robins PHONE: 202-724-5524
NAME: Janet M. Robins TITLE: Deputy, Legal
 Counsel Division

PROMULGATOR: Name and title of the person legally authorized to adopt and promulgate these rules (or the name of the board or other body authorized to adopt rules by vote):

 Mohammad Akhter, MD TITLE: Director

COMPLETE CITATION to the statute, regulation, order, or other legal authority that specifically authorizes this person or agency to adopt and promulgate these rules: Section 5(a) of the Health-Care and Community Residence Facility, Hospice and Home Care Licensure Act of 1983, effective February 24, 1984, D.C. Law 5-48, D.C. Official Code, § 44-504(a) and Mayor's Order 98-137, dated August 20, 1998,

SIGNATURE OF THE PERSON AUTHORIZED TO ADOPT RULES OR ATTEST TO THE ADOPTION OF RULES

DATE OF APPROVAL OR VOTE: <u> June 11, 2012 </u>	APPROVAL OR ATTEST: _____
TITLE: _____	PHONE: <u> (202) 442-5955 </u>

Office of Documents use only:
THIS NOTICE PUBLISHED AT: VOL. DCR DATE: