**Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

**Subtitle 07 HOSPITALS**

**Chapter 01 Acute General Hospitals and Special Hospitals**

**Authority: Health-General Article, §§19-307.2, 19-308, 19-308.6, 19-308.8, 19-318—19-320, 19-323, and 19-349.1; Insurance Article, Title 4, Subtitle 4; Public Safety Article, §14-110.1; Annotated Code of Maryland**

*10.07.01.01*

**.01 Definitions.**

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Accredited hospital" means a hospital accredited by The Joint Commission or other accreditation organization approved by the Department.

(2) "Accredited special rehabilitation hospital" means a hospital that is accredited by the Commission on Accreditation of Rehabilitation Facilities for providing comprehensive physical rehabilitation services.

(2-1) "Accreditation organization" means a private entity that conducts inspections and surveys of health care facilities based on nationally recognized and developed standards.

(3) "Administrative day" means a day of care rendered to a patient who no longer requires the level of care the hospital is licensed to provide.

(4) "Admission" means the formal acceptance by a hospital of a patient who is to be provided with room, board, and medical services.

(5) "Agent" means the individual or individuals, or organization that shall conduct utilization review activities in fulfillment of a hospital's responsibilities under these regulations. The agent may be a hospital employee or employees, or it may be an independent group or organization.

(6) "Appointment" means designation of a physician to have staff privileges at the hospital.

(6-1) "Calculated licensed bed capacity" means the total number of inpatient beds recalculated annually as 140 percent of a general hospital's average daily census as determined by the Health Services Cost Review Commission for the most recent 12-month period.

(7) "Claim" means a written demand for damages as a result of alleged professional malpractice.

(8) "Commission on Accreditation of Rehabilitation Facilities" means the private, nonprofit organization formed in 1966 which has established standards of quality for rehabilitation services and accredits those who provide the services.

(9) "Comprehensive physical rehabilitation services" has the same meaning as defined in Health-General Article, §19-1201(b), Annotated Code of Maryland.

(10) "Credentialing process" means the process by which a hospital:

(a) Verifies qualifications of a physician;

(b) Delineates clinical privileges of a physician; and

(c) Monitors performance of a physician.

(11) "Department" means the Department of Health and Mental Hygiene.

(12) "Elective", when applied to admission or to a health care service, means an admission or service that can be delayed without substantial risk to the health of the individual.

(12-1) "Healthcare-associated infection" means an infection that:

(a) Develops in a patient who is cared for in any setting where healthcare is delivered; and

(b) Was not incubating or present at the time the healthcare was provided.

(13) "Hospital" means an institution that:

(a) Has a group of at least five physicians who are organized as a medical staff for the institution;

(b) Maintains facilities to provide, under the supervision of the medical staff, diagnostic and treatment services for two or more unrelated individuals; and

(c) Admits or retains the individuals for overnight care.

(14) "Incident" means any circumstance or occurrence that may be injurious to a patient or that may result in an adverse outcome to a patient.

(15) "The Joint Commission" means the voluntary national healthcare accreditation service recognized for Medicare certification purposes by Public Law 89-97 and for Maryland State licensure purposes by Health-General Article, §19-2302, Annotated Code of Maryland.

(16) "License" means a license issued by the Secretary to operate a hospital in this State.

(17) "Long-term care" means, for the purpose of this chapter, care provided in a hospital, but is designed to treat conditions requiring treatment at a level below that of acute hospital care.

(18) "Maryland Medical Assistance Program" means the program administered by the State under Title XIX of the Social Security Act which provides comprehensive medical and other health-related care for eligible categorically and medically needy persons. For the purpose of this chapter, this shall include those persons provided care under the program administered and financed by the State for eligible needy persons who do not meet the technical requirements of federally funded Medical Assistance.

(19) "Medicare Program" means the federal program of health insurance for the aged and disabled established pursuant to 42 U.S.C. §1395 et seq.

(20) "Nonaccredited hospital" means a:

(a) Hospital not accredited by The Joint Commission or other accreditation organization approved by the Department; or

(b) Special rehabilitation hospital not accredited by The Joint Commission.

(21) "Nonelective", when applied to admission or to a health care service, means an admission or service that cannot be delayed without substantial risk to the health of the individual.

(22) "Physician" has the meaning stated under Health Occupations Article, §14-101(j), Annotated Code of Maryland.

(23) "Plan" means a thorough written specification of how the elements of review required by these regulations shall be performed.

(24) "Privilege" means the authority granted to a physician by a hospital to:

(a) Admit patients to the hospital; or

(b) Perform specific procedures or treatments on patients at the hospital.

(25) "Secretary" means the Secretary of Health and Mental Hygiene.

(26) "Specialized rehabilitation program" has the meaning stated in Health-General Article, §19-1201(e), Annotated Code of Maryland.

(26-1) Telemedicine.

(a) “Telemedicine” means the use of interactive audio, video, or other telecommunications or electronic technology by a physician in the practice of medicine outside the physical presence of the patient.

(b) “Telemedicine” does not include:

(i) An audio only telephone conversation between the physician and patient;

(ii) An electronic mail message between a physician and a patient; or

(iii) A facsimile transmission between a physician and a patient.

(27) "Unexpected adverse outcomes" means unanticipated negative outcomes related to a patient’s medical treatment and not related to the natural course of the patient’s illness or underlying disease condition.

(27-1) “Uniform standard credentialing form” means:

(a) The form designated by the Department through COMAR 10.07.01.24C(6) for credentialing physicians who seek to be employed by or have staff privileges at a hospital; or

(b) The uniform credentialing form that the Insurance Commissioner designates under Insurance Article, §15–112.1, Annotated Code of Maryland.

(28) "Utilization review" means a system for reviewing the appropriate and efficient allocation of hospital resources and services given or proposed to be given to a patient or group of patients.

(29) "Utilization review plan" means a description of the standards governing utilization review activities performed by a private review agent or hospital utilization review agent.

*10.07.01.02*

**.02 Incorporation by Reference.**

The Guidelines for the Design and Construction of Hospitals and Outpatient Facilities, The Facilities Guidelines Institute (2014 Edition), is incorporated by reference, with the following exceptions:

A. 2.3 Specific Requirements for Freestanding Emergency Department, pp. 211—213;

B. 3.3 Specific Requirements for Freestanding Outpatient Diagnostic and Treatment Facilities, pp. 295—296;

C. 3.4 Specific Requirements for Freestanding Birthing Center, pp. 297—302;

D. 3.5 Specific Requirements for Freestanding Urgent Care Centers, pp. 303—306; and

E. 3.6 Specific Requirements for Freestanding Cancer Treatment Facilities, pp. 307—309.

*10.07.01.03*

**.03 Hospital Classification.**

A. General Hospital. A hospital shall be classified as a general hospital if the hospital at least has the facilities and provides the services that are necessary for the general medical and surgical care of patients.

B. Special Hospital. A hospital shall be classified as a special hospital if the hospital:

(1) Defines a program of specialized services, such as obstetrics, mental health, tuberculosis, orthopedy, chronic disease, or communicable disease;

(2) Admits only patients with medical or surgical needs within the program; and

(3) Has the facilities for and provides those specialized services.

C. Special Rehabilitation Hospital. A hospital shall be classified as a special rehabilitation hospital if the hospital provides or holds itself out as providing comprehensive physical rehabilitation services.

*10.07.01.04*

**.04 Licensure Application Procedure.**

A. A person desiring to open a hospital, to continue the operation of an existing hospital, or to change the classification of an existing hospital shall file an application with the Secretary, on a form provided by the Secretary. An application shall state the classification of hospital for which a license is sought.

B. Applications on behalf of a corporation, association, or governmental unit or agency shall be made by two officers of the corporation, association, or governmental unit or agency and names of their Board members shall be submitted. Ownership of property, real estate, and equipment shall be disclosed if it is other than the licensee's. The names of persons holding 2 percent or more of the stock or assets shall be disclosed.

C. License Renewal. An application for the renewal of the license shall be made:

(1) By a nonaccredited hospital at least 60 days before expiration of the issued license; or

(2) By an accredited hospital within 30 calendar days of the exit date of the triennial survey conducted by an accreditation organization approved by the Department.

D. License Fees.

(1) All applications shall be accompanied by the fee established by the Secretary.

(2) Accredited hospitals shall submit a $3,000 nonrefundable license fee per accreditation period, payable to the Department.

(3) Nonaccredited hospitals shall submit a $1,000 nonrefundable annual license fee, payable to the Department.

E. In order to ensure that the hospital's licensure information is current, the hospital shall immediately notify the Department in writing of any change in the hospital's:

(1) Name;

(2) Administrator; or

(3) Contact information such as mailing address and telephone number.

F. In order to ensure the completion of any review or inspection by the Department of any major renovations, construction of patient care areas, or the establishment of a medical service as defined under Health-General Article, §19-120, Annotated Code of Maryland, and not previously provided by the hospital, the hospital shall notify the Department 60 days before its occupancy or operation.

*10.07.01.05*

**.05 Duration of License.**

A. The Secretary shall issue a license to an accredited hospital or special rehabilitation hospital for the term of the facility's accreditation.

B. The Secretary shall issue a license to a nonaccredited hospital for a term not to exceed 1 year.

*10.07.01.06*

**.06 Separate License Required.**

A. Separate licenses are required for institutions maintained on separate premises, even though both institutions are operated under the same management.

B. Separate licenses are not required for separate buildings on the same grounds.

*10.07.01.06-1*

**.06-1 Licensed Bed Capacity.**

A. On or before July 1, 2000, and each July 1 thereafter, the Secretary shall determine the authorized licensed bed capacity for each hospital classified as a general hospital.

B. Methodology for Calculating Total Authorized Licensed Bed Capacity.

(1) The average daily census for each general hospital shall be obtained from the most current Health Services Cost Review Commission inpatient utilization data for a 12-month period.

(2) The calculation of average daily census shall include the utilization of inpatient medical-surgical, gynecology, obstetric, pediatric, and acute psychiatric service beds. Newborn services are excluded from the calculation of average daily census.

(3) The total licensed bed capacity for each general hospital shall equal 140 percent of the calculated average daily census for all inpatient acute care hospital services.

C. Application for Designation of Licensed Bed Capacity by Service.

(1) The Secretary shall annually forward to each general hospital its calculated total licensed bed capacity for the next licensure period and the current allocation of beds by major service category.

(2) In a format specified by the Secretary, each general hospital shall notify the Department of its designation of total beds by major service category for the next licensure period.

(3) The Maryland Health Care Commission shall review and approve the designation of total beds by major service category.

(4) This section does not permit a general hospital to reallocate bed capacity in a manner inconsistent with applicable statute and regulations.

D. On or before July 1, 2000, and each July 1 thereafter, the Secretary shall delicense any licensed hospital beds determined to be excess bed capacity under Regulation .07B of this chapter.

E. Temporary Adjustments to Calculated Licensed Bed Capacity.

(1) If necessary to adequately meet demand for services, a general hospital may exceed its calculated licensed bed capacity if:

(a) On average for the 12-month period, the hospital does not exceed its licensed bed capacity based on the annual calculation; and

(b) The hospital includes in its monthly report to the Health Services Cost Review Commission the following information:

(i) The number of days in the month the hospital exceeded its licensed bed capacity, and

(ii) The number of beds that were in excess on each of those days.

(2) A hospital exceeding its calculated licensed bed capacity shall notify the Department within 5 business days of the effective dates of the change in a format specified by the Secretary.

*10.07.01.07*

**.07 Inspections.**

A. New Hospitals. A hospital that began initial operation on or after July 1, 1982, shall be inspected for compliance with the safety and sanitation components of the regulations promulgated by the Department until the hospital receives accreditation by an accreditation organization approved by the Department. If the hospital has not applied for accreditation by an accreditation organization approved by the Department within 1 year after beginning operation or has had its application for accreditation rejected, the Department shall inspect the hospital for compliance with the standards adopted under this subtitle.

B. Accredited Hospitals and Accredited Special Rehabilitation Hospitals. An accredited hospital and an accredited special rehabilitation hospital shall be subject to inspection under this chapter by the Department to:

(1) Determine compliance with a quality requirement;

(2) Follow up on any serious problem identified by an accreditation organization approved by the Department;

(3) Investigate a complaint; or

(4) Validate the findings of an accreditation organization approved by the Department.

C. Nonaccredited Hospitals. Nonaccredited hospitals shall be subject to at least two inspections per year by the Department.

D. Inspection by Secretary. The Secretary may inspect any:

(1) Hospital record or record of any utilization review agent of a hospital pertaining to review activities under the utilization review plan of the hospital to enforce the provisions of Regulations .13—.22 of this chapter;

(2) Physician credentialing record to enforce the provisions of Regulation .24 of this chapter; and

(3) Hospital patient safety record, patient complaint record, or hospital patient record pertaining to review activities under a hospital's patient safety program to enforce the provisions of COMAR 10.07.06.

*10.07.01.08*

**.08 Complaint Investigations.**

A. Notwithstanding any other provisions of this subtitle, each hospital and residential treatment center shall be open to inspections by the Department to investigate and resolve any complaint concerning patient care, safety, medical and nursing supervision, physical environment, sanitation, or dietary matters.

B. Complaints.

(1) To resolve expeditiously a complaint that alleges the existence of any non-life-threatening deficiency, the Department shall refer the complaint directly to the hospital.

(2) If appropriate, issues relating to the practice of medicine or the licensure or conduct of a health professional shall be referred to the hospital and may be referred to the appropriate licensure Board for resolution.

(3) If the Department determines that the hospital has not satisfactorily addressed the referred complaint or if the complaint alleges the existence of a life-threatening deficiency, the Department shall conduct an independent investigation. When conducting its independent investigation, the Department shall use:

(a) For an accredited hospital, the standards of review of The Joint Commission;

(b) For an accredited special rehabilitation hospital, the standards of review of the Commission on Accreditation of Rehabilitation Facilities; or

(c) For a nonaccredited hospital, the standards adopted by the Secretary under this subtitle.

*10.07.01.09*

**.09 Service Standards — Nonaccredited Hospitals.**

A. Acute General Hospitals and Special Hospitals.The 2013 Hospital Accreditation Standards (July Update, The Joint Commission, One Renaissance Blvd., Oakbrook, Illinois 60181), is incorporated by reference.

B. Waiver Authority. The Secretary may, for good cause, waive compliance with the incorporated Joint Commission standards. The hospital shall justify the need for the waiver in the manner prescribed by the Department.

*10.07.01.10*

**.10 Service Standards — Special Rehabilitation Hospitals.**

A. Before a special rehabilitation hospital can provide or hold itself out as providing comprehensive physical rehabilitation services, the special rehabilitation hospital shall:

(1) Except as otherwise provided in this regulation, be accredited by the Commission on Accreditation of Rehabilitation Facilities; and

(2) Meet the standards of the Commission on Accreditation of Rehabilitation Facilities as set forth in the Medical Rehabilitation Standards Manual, which is incorporated by reference under COMAR 10.07.18.05.

B. Waiver of Accreditation.

(1) To allow a special rehabilitation hospital to achieve accreditation by the Commission on Accreditation of Rehabilitation Facilities as required under this regulation, the accreditation requirement shall be waived for any special rehabilitation hospital that has submitted an appropriate application for accreditation.

(2) The waiver under this section shall be effective for not more than 2 years from the later of:

(a) July 1, 1986; or

(b) The date on which the facility begins operations.

*10.07.01.11*

**.11 Special Rehabilitation Programs — Hospitals.**

A. Except as otherwise provided in this regulation, before a hospital can provide or hold itself out as providing any specialized rehabilitation program, the hospital shall be accredited by the Commission on Accreditation of Rehabilitation Facilities to provide the program.

B. The requirement that a hospital be accredited by the Commission on Accreditation of Rehabilitation Facilities before the hospital can provide any specialized rehabilitation program shall be waived if the hospital has applied for accreditation for the program, for not more than 2 years from the later of:

(1) July 1, 1986; or

(2) The date on which the hospital begins operation of the specialized rehabilitation program.

*10.07.01.12*

**.12 Records and Reports — Inspection.**

Licensees shall keep such records and make reports in the manner and form as the Secretary shall prescribe by regulation, and all these records shall be open to inspection by the Secretary.

*10.07.01.13*

**.13 Utilization Review Plan.**

A. Before October 1, 1985, each hospital shall submit a proposed utilization review plan to the Secretary.

B. Effective October 1, 1985, each hospital shall have in effect a utilization review plan approved by the Secretary pursuant to this chapter.

C. The purpose of the hospital's utilization review program, as defined by the plan, shall be to determine for patients included in the hospital's review responsibilities the:

(1) Reasonableness and medical necessity of care given or proposed to be given at the hospital;

(2) Quality of care given at the hospital; and

(3) Appropriateness of the level of care proposed or given, including whether the care could be or could have been provided appropriately and more economically on an outpatient basis or in a facility that provides a lower level of care.

D. A utilization review plan shall:

(1) Identify the designated utilization review agent;

(2) Describe the criteria to be used in evaluating proposed or delivered hospital care;

(3) Delineate the types and kinds of cases that the agent will review and the circumstances under which either some or all patients in the hospital, or within specific diagnostic groups, will be selected;

(4) Make provisions for the collecting, storing, and reporting of data;

(5) Define measures by which the agent can evaluate the effectiveness of its program;

(6) Make provisions for screening medical records pertaining to patients for which the agent has review responsibility in order to identify and verify problems in the quality of care;

(7) Establish a mechanism through which patients, physicians, or third-party payers may seek reconsideration of decisions made by the utilization review agent;

(8) Detail how each of the following elements is to be performed by the agent:

(a) Pre-admission review of elective admissions;

(b) Post-admission review of nonelective admissions;

(c) Concurrent or retrospective review of admissions;

(d) Pre-authorization of certain selected procedures proposed to be performed on an inpatient basis;

(e) Institution of an objective second surgical opinion protocol to evaluate the desirability of performing selected surgical procedures on an elective basis;

(f) Discharge planning review;

(g) Continued stay review; and

(h) Re-admission review;

(9) Meet all other requirements for utilization review promulgated by the Secretary.

*10.07.01.14*

**.14 Utilization Review Agent.**

A. Each hospital shall appoint a utilization review agent to carry out the requirements of the utilization review plan. When the agent is composed of hospital related personnel the hospital's plan shall expressly designate the positions and the organizational structure within the hospital that constitute the utilization review agent for that institution.

B. Each utilization review plan shall set forth the manner in which the agent:

(1) Utilizes the services of doctors of medicine or osteopathy and other practitioners capable of admitting patients, who are representative of practicing physicians in the area in which the hospital is located.

(2) Has available the services of sufficient numbers of physicians and dentists to assure the adequate review of medical specialty and subspecialty cases.

(3) Utilizes the services of registered nurses, medical records technicians, or similarly qualified persons supported and supervised by physicians in carrying out its review activities.

(4) Uses only a doctor of medicine, osteopathy, or dentistry to make a final determination that care rendered or to be rendered was, is, or may be medically inappropriate.

(5) Makes direct comparisons with professionally developed, objective criteria to determine the appropriateness of admission and continued stay. The criteria should:

(a) Be nationally recognized and accepted, unless a special exception is granted by the Secretary;

(b) Be capable of being utilized to define the type and extent of services which are to be considered as within the range of appropriate diagnosis and treatment for a given condition;

(c) Identify the level of care at which the services can appropriately and economically be rendered; and

(d) Recognize that for many conditions more than one mode or site of treatment or diagnosis may be medically acceptable.

(6) Collects information relevant to its function, maintains records, and reports to the Department as required. The hospital's utilization review plan shall outline the method by which patient confidentiality shall be maintained.

C. A member of the agent's staff, or any person that the agent may delegate or employ, may not review or make a determination of appropriateness for care that that person was directly responsible for providing, or which was provided by or to a member of that person's family.

*10.07.01.15*

**.15 Performance Standards for Utilization Review.**

The hospital's program shall apply to all patients with the exceptions of those noted in Regulation .17, below. Except when noted for certain types of review, the program may delineate certain types and kinds of cases to be reviewed, so as to most efficiently carry out the purposes of these regulations. As a minimum, the hospital utilization review program shall satisfy the following performance standards:

A. Pre-admission Review.

(1) A review of those elective admissions identified under the plan shall be performed by the agent in advance of the proposed admission.

(2) The purpose of this review shall be to determine the reasonableness and medical necessity of the admission, and the appropriateness of the level of proposed care.

(3) In conducting the review, the agent may supplement the information provided by the hospital through discussion with the patient's physician.

(4) The agent, using specific medical criteria, shall render a decision as to whether the admission is medically appropriate within 3 working days of the time it receives the case, except in those circumstances when responding within this period would not permit sufficient consultation or discussion to render a responsible opinion.

B. Post-admission Review.

(1) For those categories of emergency admissions identified for review in the hospital's plan, the agent shall carry out a review to ascertain the:

(a) Reasonableness and medical necessity of the admission;

(b) Appropriateness of the level of care provided; and

(c) Justification for the non-elective nature of the admission.

(2) The agent shall be notified by the hospital within 24 working hours of the admission and the agent shall carry out the review within 3 working days of notification, except in cases when appropriate consultation cannot be carried out in this period of time.

C. Concurrent or Retrospective Review.

(1) For patients included in the plan the agent shall determine whether each day of the patient's hospitalization was medically necessary and appropriate based upon nationally recognized criteria. The agent shall also designate those days of hospitalization caused by administrative requirements including days on which patients await appropriate placement or equipment needed after discharge.

(2) The review may be concurrent with the patient's stay or take place after the patient is discharged.

(3) Days designated as administrative shall be found appropriate only if approved under discharge planning review, as discussed in §F.

D. Pre-authorization Review.

(1) The agent shall review prospectively all elective admissions in which one or more of the plan designated procedures is the principal procedure being performed for that admission.

(2) The procedures for which pre-authorization is required are set forth in Regulation .21.

(3) The agent may approve inpatient treatment for the listed procedures only if there is documentation that equivalent outpatient treatment would not be medically appropriate for the patient.

(4) All non-elective admissions that have not been pre-authorized and that subsequently involve performance of one or more of the plan designated procedures shall be reviewed concurrently or retrospectively by the agent.

E. Objective Second Opinion.

(1) Before an elective admission for a surgical procedure designated below, the patient shall obtain an objective second opinion.

(2) The procedures for which a second opinion is required are set forth in Regulation .22.

(3) The second opinion may be rendered by any physician of the patient's choosing except a physician having any financial relationship with the patient's original physician.

(4) Should a voluntary admission not take place within 6 months of the rendering of the second opinion, then another opinion shall be sought before admission.

(5) The agent may waive the requirement for obtaining a second opinion because:

(a) Obtaining the second opinion would impose a hardship on the patient; or

(b) The patient's medical insurance does not cover second opinions, and was:

(i) Issued and delivered in another state, and

(ii) Not intended to cover persons living or working in Maryland.

F. Discharge Planning.

(1) The utilization review plan shall set forth the hospital's discharge planning procedures.

(2) The agent shall review the effectiveness of the hospital's discharge planning.

(3) The agent shall review those days of care which have been designated to be administrative as a result of the agent's concurrent or retrospective review.

(4) Administrative days may be approved as necessary and appropriate only if evidence can be found that the hospital has developed and implemented a discharge plan at the earliest possible time and there is evidence that appropriate placement efforts have been made.

G. Continued Stay Review. For patients in beds licensed for long term care, the agent shall periodically review and certify as appropriate the level of care and placement, and the medical necessity of treatment prescribed.

H. Re-admission Review. The agent shall review the appropriateness of the previous discharge and the indications for admission for hospitalizations occurring shortly after a previous discharge.

*10.07.01.16*

**.16 Protection of Patients — Patient Liability.**

A. Charges for any days disallowed as a result of retrospective review by the agent or by a payer conducting utilization review under these regulations shall be deducted from the gross charges in the bill to the patient as a contractual allowance unless the patient refuses or has refused to leave the hospital when it is medically appropriate to do so, and the disallowed days occur:

(1) After the hospital has notified the patient in writing of the potential disallowance; or

(2) As a direct result of the noncompliance by the patient to treatment or hospital regulations.

B. If a bill is generated before the receipt of the results of retrospective review, a subsequent adjustment to the bill, if required under § A, above, shall be issued by the hospital. The final bill shall demonstrate all procedures, services, or days of care found to be inappropriate.

C. In cases when a form of review other than retrospective review was performed, each patient bill generated by the hospital shall clearly demonstrate all procedures, services, or days of care which have been found to be inappropriate or have been disallowed by the hospital's utilization review agent or any other reviewer or payer conducting utilization review.

D. The utilization review agent shall be responsible for establishing a process by which physicians and patients may request clarification and reconsideration of review decisions. These clarifications or reconsiderations shall be carried out in a timely fashion, and patients shall be granted full access to any medical records maintained by the agent pertaining to their care to the extent permitted under Health-General Article, § 4-302, Annotated Code of Maryland.

*10.07.01.17*

**.17 Exemptions from Hospital Utilization Review.**

A. A hospital shall be exempt from carrying out utilization review procedures for a given patient if the:

(1) Person, corporate entity, or insurance plan paying for the patient's hospitalization has a utilization review program that is determined by the Insurance Commissioner and the Secretary to substantially meet the minimum standards described in these regulations, including the reporting requirements detailed in Regulation .19 of this chapter, those programs and amendments to them having been submitted to the Commissioner for approval;

(2) Patient is a subscriber or a member of a health maintenance organization as defined in Health-General Article, §19-701, Annotated Code of Maryland; or

(3) Patient is a Medicare or Maryland Medical Assistance Program beneficiary, and the services rendered at the hospital are within the scope of coverage provided by the relevant program.

B. The Secretary will issue yearly lists of third-party payers known to have utilization review plans that qualify for the exemption described in this regulation.

*10.07.01.18*

**.18 Record Maintenance by Utilization Review Agents.**

A. The plan shall describe how, in addition to maintaining documents which describe its utilization review procedures, the agent shall maintain the following records for each individual patient for whom any aspect of the utilization review procedure has been applied:

(1) The patient's name, hospital history number, source of payment, and other demographic information capable of identifying the patient.

(2) The principal diagnosis or diagnoses (with corresponding codes listed in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) as defined in COMAR 10.09.06.01P), and the particular category of patient chosen for review in accordance with the hospital's utilization review plan.

(3) The date or dates on which review activities were requested and the date or dates on which opinions were rendered.

(4) The type of review carried out, the nature of the criteria applied, and the results of the review. In the case of disallowed services, the reasons for disallowance shall be stated, as well as the name of the physician member of the agent's staff making the final disallowance determination.

(5) In the case of objective second opinions, documentation shall include the name of the physician rendering the second opinion, the physician's specialty, and the nature of the opinion.

B. Each agent shall maintain a listing of all reviewed cases suitable for the selection of a sample of all cases reviewed within each 2-year certification period.

*10.07.01.19*

**.19 Reports to the Secretary.**

A. Each hospital shall report annually to the Secretary the following summary statistics on the activity of its utilization review program:

(1) The number of discharges and total patient days reviewed under the program;

(2) For each of the procedures requiring pre-authorization for inpatient treatment, the number of patients:

(a) Reviewed; and

(b) Approved for inpatient treatment;

(3) For each of the procedures requiring an objective second opinion, the number of patients:

(a) Undergoing the procedure at the hospital;

(b) Admitted non-electively for the procedure;

(c) Admitted electively after the patient had obtained a second opinion; and

(d) Admitted electively but for whom the requirement of a second opinion was waived, including a tabulation of the reasons for waivers;

(4) For admissions reviewed concurrently or retrospectively, the number of all reviewed admissions disapproved, and reasons for disapproval;

(5) The number of all reviewed days of hospitalization disapproved, by reason for disapproval;

(6) A summary of the findings of re-admission review, including the frequency and proportion of these cases, the diagnoses or treatments involved, and the reasons found;

(7) A listing and description of quality care problems found by the agent in the course of reviewing patient records in furtherance of its duties under the utilization review plan.

B. The Secretary shall be allowed access to hospital patient records and to the records of the hospital's utilization review agent pertaining to review activities under the plan for the purpose of enforcing these regulations.

*10.07.01.20*

**.20 Penalties.**

If a hospital fails to submit a utilization review plan or fails, after adequate discussion with the Department, to develop an approvable plan, or fails to operate a plan which has been approved, then the Secretary may impose upon the hospital the following penalties:

A. Delicensure of the hospital; or

B. A fine of $500 for each day that the hospital is in violation of these regulations.

*10.07.01.21*

**.21 Procedures for Which Preauthorization is Required.**

A. The following are procedures for which preauthorization is required.

B. The procedures are:

(1) Myringotomy with or without tubes — incision into middle ear with or without insertion of tubes for drainage of chronic ear infections;

(2) Antral puncture — opens clogged sinus through nasal cavity;

(3) Inferior turbinate fracture — horizontal fracture of nasal bone;

(4) Nose, closed reduction — treating fractured nose without incision;

(5) Breast biopsy (if a two-stage procedure is planned for a possible malignancy) — removing tissue specimen for testing for cancer;

(6) Cervical node biopsy — excision of lymph node of neck;

(7) Lipoma excision — excision of non-cancerous fatty tumor;

(8) Muscle biopsy — excision of muscle specimen;

(9) Rectal Polypectomy — excision of tissue mass from rectum;

(10) Excision of sebaceous cyst — removing sac and contents from under the skin;

(11) Excision of skin lesion with primary closure — removing skin growth, suturing areas;

(12) Marsupialization of Bartholin cyst — removing cyst from female genital area by incision, suturing area;

(13) Treatment of condylomata acuminata — removing wart-like growths from anus, vulva, or penis;

(14) Cryotherapy — alone — removing lesions with extreme cold;

(15) Cryotherapy with biopsy or dilation and curettage, or both, removing tissue specimen from female genital area, using extreme cold, and scraping uterine cavity;

(16) Dilation and curettage — stretching cervix and scraping uterine cavity;

(17) Examination under anesthesia — examination of body area while patient is under anesthesia;

(18) Hymenotomy — surgical incision to enlarge vaginal membrane;

(19) Hysterosalpingogram — an X-ray study of uterus and Fallopian tubes;

(20) Therapeutic abortion (first trimester) — elective termination of pregnancy during first 3 months;

(21) Tubal ligation by laparoscopy — female sterilization by laparoscope through small abdominal incision;

(22) Removal of intrauterine device (IUD) — surgical removal of birth control device;

(23) Hysteroscopy — examination of the uterus and cervix with a magnifying, lighted instrument;

(24) Excision of neuroma — removing tumor derived from nerve tissue;

(25) Avulsion or removal of nail, partial or complete — tearing away a part or a total fingernail or toenail;

(26) Fracture, simple, with or without closed reduction, with or without X-ray — setting or manipulation of a broken bone;

(27) Excision of ganglion — removing cyst-like swelling resembling a tumor;

(28) Manipulation of joints — skillful use of hands to correct a frozen joint;

(29) Phalangectomy — removing a bone between two joints of a finger or toe;

(30) Tenotomy, hand — cutting a tendon for corrective measures;

(31) Incision and drainage of infected or non-infected sebaceous cyst, furuncle — cutting and draining a sac under the skin such as a boil, abscess, or hair follicle;

(32) Drainage of onychia or paronychia, with or without nail removal — draining inflammation from toenail or fingernail bed or from surrounding tissue;

(33) Incision and drainage of carbuncle and other cutaneous or subcutaneous abscesses, simple — incision and drainage of skin and tissue infections;

(34) Incision and removal of foreign body, subcutaneous tissues, simple — removing splinters of wood, glass, metal, etc. from under the skin;

(35) Drainage of hematoma, simple — removing localized mass of blood, usually clotted, from under the skin but outside of blood vessel;

(36) Puncture aspiration of abscess or hematoma — puncturing and removing the contents of an abscess or hematoma with needle and syringe;

(37) Biopsy: excision of skin, subcutaneous tissue for biopsy — removing a skin specimen for laboratory analysis;

(38) Excision of benign lesion — removing non-cancerous skin growth;

(39) Excision or destruction of nail bed — removing nail bed to prevent re-growth of nail;

(40) Electrosurgical destruction of lesion, simple — removing skin growth with electric needle;

(41) Dislocation, simple, closed reduction — replacing bone into its socket by manipulation;

(42) Excision of verruca, local anesthesia — removing wart or warts;

(43) Chemical cauterization of verruca — destroying wart or warts with chemicals;

(44) Tenotomy, tenectomy, tendoplasty-tenotomy — cutting a tendon for corrective measures; tenectomy — removing a part of a tendon; tendoplasty — surgical repair of a tendon;

(45) Drainage of infected bursae — removing infection from the closed sac which surrounds joints;

(46) Excision of chondroma, osteochondroma, condylectomy, or exostosis: open (excluding metatarsal) and closed procedures — removing bony-like, non-cancerous tumors from bones;

(47) Hammertoe operation — surgical correction of deformed toe;

(48) Phalangeal set — surgical correction of a curved toe joint;

(49) Excision of supernumerary ossicle — removing excess bones;

(50) Mammoplasty (augmentation, revision) — inserting breast implant;

(51) Otoplasty — surgery on the external portion of the ear (unilateral, bilateral);

(52) Small skin graft — replacing skin defect with skin from another part of body;

(53) Circumcision (pediatric) — removing foreskin of male child;

(54) Dorsal slit — making opening in foreskin of penis;

(55) Meatotomy — incision for enlarging opening of urethra;

(56) Urethral dilation — increasing size of urethra;

(57) Vasectomy — male sterilization;

(58) Observation bronchoscopy, flexible, in patients under 40 years old — inspection of the bronchial tubes leading into the lungs with a magnifying, lighted instrument;

(59) Triple upper endoscopy — examination of gastrointestinal tract;

(60) Culdoscopy — viewing with instrument of female pelvic organs through the vaginal wall;

(61) Observation cystoscopy — observing bladder functions through an instrument;

(62) Gynecological laparoscopy — observation by instrument of the female genital organs through small incision below the navel;

(63) Otoscopy — examination of internal structures of ear with lighted instrument;

(64) Proctosigmoidoscopy — examination of lower end of large intestine with lighted instrument;

(65) Fiberoptic sigmoidoscopy and fiberoptic colonoscopy, only as diagnostic procedure — examination of rectum and large intestine with lighted, flexible instrument.

*10.07.01.22*

**.22 Practitioner Performance Evaluation.**

A. Consistent with the standards of the Joint Commission for focused and ongoing professional performance evaluations, the hospital shall establish a practitioner performance evaluation process that objectively evaluates the performance of each member of the medical staff.

B. The hospital’s practitioner performance evaluation process shall include a review of care which shall:

(1) Be undertaken for cases:

(a) Chosen at random; and

(b) With unexpected adverse outcomes;

(2) Be based on objective review standards;

(3) Include a review of the appropriateness of the plan of care for the patient, particularly any medical procedures performed on the patient, in relation to the patient’s condition; and

(4) Be conducted by members of the medical staff, or at the discretion of the hospital, by external reviewers, who:

(a) Are of the same specialty as the member of the medical staff under review;

(b) Have been trained to perform practitioner performance evaluation; and

(c) Are not otherwise associated with the case under review.

C. A hospital shall take into account the results of the practitioner performance evaluation process for a member of the medical staff in the reappointment process.

*10.07.01.23*

**.23 Guidelines Governing the Transfer of Patients Between Hospitals.**

A. If a hospital is able to provide adequate care to a patient, the hospital may not transfer the patient to another hospital unless:

(1) One or more of the following circumstances is present:

(a) The patient does not have a physician with privileges at the hospital and the patient refuses treatment by any physician with privileges at the hospital;

(b) The patient or a legally authorized representative of the patient requests the transfer;

(c) The transfer is in compliance with relevant sections of Health-General Article, Title 10, Subtitle 8, Annotated Code of Maryland;

(d) The transfer is in compliance with the Interstate Compact on Mental Health as adopted in Health-General Article, Title 11, Annotated Code of Maryland; or

(e) The transfer is in compliance with any agreement entered into between the Mental Hygiene Administration and a hospital for the provision of acute inpatient psychiatric care in State hospital conversion beds;

(2) These circumstances are documented in the patient's medical record; and

(3) The provisions of this regulation are met.

B. A hospital may not use the inability of a patient to pay or the source of payment for a patient as a reason to transfer the patient to another hospital.

C. Before moving a patient, the transferring hospital shall:

(1) Determine that the patient can be transferred without causing harm to the patient;

(2) Notify the receiving hospital of the transfer; and

(3) Unless otherwise provided for in an agreement with the Mental Hygiene Administration for State hospital conversion beds, obtain from the receiving hospital confirmation that:

(a) The receiving hospital consents to accept the patient; and

(b) The patient meets any criteria that the receiving hospital has established for admission regarding:

(i) The patient's required level of care;

(ii) Physician services available; and

(iii) Other services necessary to treat the patient.

D. Explanation of transfer.

(1) Except as otherwise provided in §C(2),, of this regulation, before moving a patient, the transferring hospital shall provide explanation of the reasons for the transfer and any alternative to the transfer to the patient or to a legally authorized representative of the patient.

(2) If the transferring hospital can document that the necessity to move the patient to the receiving hospital is immediate to protect the health, safety, or welfare of the patient, the transferring hospital may give the explanation required in §C(1), of this regulation, concurrently with the transfer.

E. In effecting a transfer, the transferring hospital shall provide that:

(1) Medically appropriate life-support measures that a reasonable and prudent physician exercising ordinary care would use are used to stabilize the patient before transfer and sustain the patient during transfer;

(2) Appropriate personnel and equipment that a reasonable and prudent physician exercising ordinary care would use are provided and used in the transfer; and

(3) All records necessary for continuing the patient's care are transferred with the patient.

F. The Department shall inspect hospitals for compliance with this regulation as provided in Regulations .07 and .08 of this chapter.

G. Penalties.

(1) The Secretary may impose a penalty not exceeding $1,000 per violation on any hospital that violates this regulation.

(2) In determining the amount of the penalty, the Secretary shall consider:

(a) The hospital's history of previous violations;

(b) The seriousness of the violation;

(c) Whether the hospital demonstrated good faith in attempting to comply with this regulation; and

(d) Whether the violation threatened the health or safety of:

(i) A patient; or

(ii) The public.

*10.07.01.24*

**.24 Physician Credentialing Process.**

A. General. In accordance with this regulation, a hospital shall have in effect a credentialing process.

B. Scope of Credentialing Process. The credentialing process shall apply to any physician who shall admit or treat patients in the hospital.

C. Specific Standard — Appointment and Employment Process.

(1) In accordance with this section, a hospital shall establish a formal written process for the appointment or employment of a physician by the hospital.

(2) The term of an appointment shall be 2 years or less.

(3) The formal written appointment or employment process shall provide for a probationary period that shall be successfully completed before the finalization of the appointment or employment of the physician.

(4) As part of the formal written appointment and employment process, the hospital shall collect, verify, review, and document the following information about the physician:

(a) The physician's education;

(b) The clinical expertise of the physician;

(c) The professional experience of the physician including:

(i) Any board certification or specialty training of the physician;

(ii) The internship of the physician; and

(iii) The residencies of the physician;

(d) Any license or registration to practice a health occupation ever held by the physician, including:

(i) A license to practice medicine; and

(ii) DEA registration;

(e) Whether any license or registration to practice a health occupation ever held by the physician has been:

(i) Suspended;

(ii) Revoked;

(iii) Voluntarily surrendered or not renewed;

(f) Concerning any hospital where the physician was appointed or employed:

(i) The name of the hospital;

(ii) The term of appointment or employment;

(iii) Privileges held and any disciplinary action taken on the privileges, including suspension, revocation, limitation, or voluntary surrender;

(g) Concerning the physician's professional liability insurance:

(i) The physician's present carrier;

(ii) The physician's current limits of coverage;

(iii) The physician's current types of coverage;

(iv) Restrictions on the physician's coverage; and

(v) Whether or not the physician has maintained continuous malpractice coverage since first obtaining professional insurance;

(h) Any claim that has been made against the physician in the practice of any health occupation and the status of the claim;

(i) The physician's medical history including the physician's current mental and physical health status;

(j) A complaint or report filed with:

(i) The Board of Physicians or any other state medical discipline agency;

(ii) A state medical society;

(iii) A state disciplinary body; or

(iv) A professional or specialty association.

(5) The formal written process shall provide for the documentation of any action taken by the hospital regarding the appointment or employment of the physician.

(6) Uniform Standard Credentialing Form.

(a) A hospital shall use the uniform standard credentialing form approved by the Department for the initial credentialing of a physician seeking appointment or employment.

(b) Use of the uniform standard credentialing form does not preclude a hospital from requiring additional information, attestations, or supplemental documentation as required by that hospital's credentialing process.

(c) A physician seeking hospital privileges shall submit an updated and complete uniform standard credentialing form at the time of application to each hospital.

D. Specific Standard—Granting of Delineated Clinical Privileges.

(1) In accordance with this section, a hospital shall establish a formal written process for the granting of delineated clinical privileges.

(2) The formal written process shall include:

(a) Criteria for determining whether a physician shall be granted privileges by the hospital to provide specific services;

(b) Criteria for ongoing evaluation of the performance of the services for which privileges have been granted;

(c) Procedures for altering, suspending, or revoking the delineated privileges.

(3) The formal written process shall provide for documentation of any actions taken regarding delineated privileges.

E. Specific Standard—Reappointment.

(1) In accordance with this section, a hospital shall establish a formal written process for the reappointment of a physician who has been appointed to the hospital.

(2) The term of reappointment shall be 2 years or less.

(3) As part of the formal written appointment process, a hospital shall collect, verify, review, and document the following information about the physician:

(a) An update of the information regarding appointment under §C of this regulation;

(b) Concerning the physician's pattern of performance based on an analysis of the following:

(i) Claims filed against the physician;

(ii) Utilization, quality and risk data;

(iii) A review of clinical skills;

(iv) Adherence to hospital bylaws, policies, and procedures;

(v) Compliance with continuing medical education requirements;

(vi) An assessment of current mental and physical health status;

(vii) Attitudes, cooperation, and the ability to work with others; and

(viii) The results of the Practitioner Performance Evaluation process as described in Health-General Article, §§19-3B-01—19-3B-09, Annotated Code of Maryland.

F. Specific Standard—Record Maintenance.

(1) In accordance with this section, a hospital shall maintain a separate credentialing file for each physician.

(2) The credentialing file for each physician shall contain documentation relating to the credentialing process required under this regulation.

G. Disaster Privileges.

(1) During an emergency or disaster in which the hospital's disaster or emergency management plan has been activated, when the Governor has declared that a state of emergency exists, or when the Secretary has issued an order pursuant to Health-General Article, §18-905, Annotated Code of Maryland, the chief executive officer, medical staff president, or designee may grant temporary disaster privileges to licensed physicians who have not been appointed to the hospital's medical staff.

(2) The hospital shall develop a medical staff plan for the granting of disaster privileges that identifies:

(a) The individual responsible for granting disaster privileges;

(b) The responsibilities of that individual;

(c) A system to manage, assign, and supervise the physicians who have been granted disaster privileges; and

(d) The process by which credentials and privileges are verified as soon as the situation allows, ensuring that the process complies with §C of this regulation.

(3) Physicians granted disaster privileges by a hospital shall:

(a) Be registered and trained by the Department as part of the Department's Maryland Physician Volunteer Corps and possess the Department issued photo identification; or

(b) Comply with the hospital's medical staff plan for granting privileges in a disaster, which shall require at least one of the following:

(i) Presentation of a current Maryland license to practice medicine and a valid identification picture (ID) issued by a state, federal, or regulatory agency;

(ii) Presentation of a license to practice medicine from another state if a state of emergency has been declared by the Governor and the assistance of the physician has been requested by Maryland pursuant to the Emergency Management Assistance Compact, Public Safety Article, §14-702, Annotated Code of Maryland;

(iii) Presentation of a current photo identification card from another Maryland hospital where the physician is a member of the medical staff; or

(iv) Verification by a current member of the hospital's medical staff who has personal knowledge regarding the practitioner's identity and current Maryland medical licensure.

(4) Disaster privileges shall be discontinued when the hospital's chief executive officer, medical staff president, or designee determines that the emergency condition no longer exists and that the hospital has adequate resources to meet the patient's needs.

(5) The hospital shall maintain records that include:

(a) The number of hours worked by each physician;

(b) The type of service provided by each physician;

(c) The location where these services were provided; and

(d) Any additional information required by the Department for federal and State reimbursement.

H. Telemedicine.Notwithstanding any other provision of COMAR 10.07.01.24, in its credentialing and privileging process for a physician who provides medical services to the patients at the hospital only through telemedicine from a distant-site hospital or distant-site telemedicine entity, a hospital may rely on the credentialing and privileging decisions made for the physician by the distant-site hospital or distant-site telemedicine entity as authorized under 42 C.F.R. Part 482, if:

(1) The physician who provides medical services through telemedicine holds a license to practice medicine in the State under Health Occupations Article, Title 14, Annotated Code of Maryland; and

(2) The credentialing and privileging decisions with respect to the physician who provides medical services through telemedicine are:

(a) Approved by the medical staff of the hospital; and

(b) Recommended by the medical staff of the hospital to the hospital’s governing body.

I. Request for Documentation by Department. On request from the Department, a hospital shall provide documentation that before:

(1) Appointment or employment of a physician or granting delineated privileges, the hospital has complied with the requirements of this regulation; and

(2) Reappointment or renewing of employment or specific privileges, the hospital has complied with the requirements of this regulation.

J. Penalties. If a hospital fails to have in effect a credentialing process in accordance with these regulations, the Secretary may impose upon the hospital the following penalties:

(1) Delicensure of the hospital; or

(2) A fine of $500 for each day that the hospital is in violation of these regulations.

*10.07.01.25*

**.25 Medical Professional Liability Closed Claim Form.**

A. A hospital shall complete and submit to the Department the approved Medical Professional Liability Closed Claim form, DHMH form #4668, for each medical liability claim filed regarding the care or services received by a patient under the care of that hospital.

B. Regardless of the result of a closed claim, the hospital shall submit the Medical Professional Liability Closed Claim form to the Department within 90 days after the end of the quarter during which the final judgment, settlement, or final disposition of the claim was made.

*10.07.01.26*

**.26 Anatomical Donations.**

A. This regulation does not:

(1) Limit the right of an individual to make a gift under the Anatomical Gift Act, Estates and Trusts Article, Title 4, Subtitle 5, Annotated Code of Maryland; or

(2) Interfere with the duties of the office of the Chief Medical Examiner.

B. A hospital shall develop and follow a protocol in accordance with this regulation for the procurement of organs and tissues.

C. Requests for Donation on Death of Patient.

(1) In accordance with this regulation, whenever a patient of a hospital meets the following criteria, the administrator of the hospital shall designate a person to request that the representative of the patient consent to the donation of the organs and tissues of the patient:

(a) The patient may be pronounced dead in accordance with Health-General Article, §5-202, Annotated Code of Maryland;

(b) The patient has not given actual notice of an objection to the donation of his or her organs and tissues; and

(c) The patient has not made a gift of all or part of his or her body under the Anatomical Gift Act, Estates and Trusts Article, Title 4, Subtitle 5, Annotated Code of Maryland.

(2) A hospital may not make a request for consent to a donation if the use of all of the organs or tissues of the patient is medically contraindicated.

(3) In making a request required in §C(1), of this regulation, the hospital designee shall:

(a) Make a reasonable effort to locate and contact the appropriate person set forth in §D, of this regulation, as the representative of the deceased patient; and

(b) Request that the representative consent to a donation of any organ or tissue of the patient which is suitable for donation.

D. Determination of Patient Representative for Consent to Donation.

(1) The representative of a deceased patient shall be:

(a) The spouse of the patient, but, if the spouse is not competent; then

(b) Any adult son or daughter of the patient, but, if no adult child of the patient is competent; then

(c) Either parent of the patient, but, if neither is competent; then

(d) Any adult brother or sister of the patient, but, if no adult sibling of the patient is competent; then

(e) Any guardian of the person of the patient, but, if the patient has no guardian of his or her person; then

(f) Any other person authorized or obligated by law to dispose of the body of the patient.

(2) If the death of a patient occurs suddenly and the patient was in apparent good health or unattended by a physician, the hospital shall notify and cooperate with the office of the Chief Medical Examiner before the removal of any organ or tissue.

E. Discretion and Sensitivity in Making Requests. In making a request for donation, the hospital designee shall show reasonable discretion and sensitivity to the:

(1) Circumstances of the family of the patient;

(2) Religious beliefs of the patient; and

(3) Suitability of the organs or tissues for donation.

F. Documentation. The designee shall document in the medical record of the patient:

(1) Any request made for donation of organs or tissues;

(2) Any consent to donate organs or tissues;

(3) Whether a donation is made and accepted;

(4) Any objection to the donation made by:

(a) The patient, or

(b) An appropriate representative of a patient as set forth in §D of this regulation; and

(5) The reason for electing not to make a request for organ or tissue donation.

*10.07.01.27*

**.27 Discharge Planning Requirements.**

A. Discharge Options. A hospital may discharge a patient:

(1) Entirely;

(2) To another level of care, treatment, or services;

(3) To different health care professionals; or

(4) To settings for continued services.

B. A hospital's process for transfer or discharge shall be based on a patient's assessed needs at the time of discharge.

C. To facilitate discharge or transfer, the hospital shall:

(1) Assess the patient's needs beginning at an early stage of the patient's hospitalization and as the patient's needs change throughout the hospitalization;

(2) Develop plans for the patient's discharge or transfer with input, if appropriate, from the patient, the family, or other interested party;

(3) Identify appropriately qualified staff, such as registered nurses or licensed social workers, who have the knowledge and experience necessary to determine what services or type of providers can best meet the patient's discharge needs;

(4) Arrange or help to arrange for services needed to meet the patient's needs after discharge; and

(5) Provide the patient, or the provider who is responsible for providing continuing care to the patient, with written discharge instructions and other necessary medical information in a form the patient or provider can understand.

*10.07.01.28*

**.28 Emergency and Disaster Plan.**

A. A licensed acute general hospital or special hospital shall comply with the Emergency Management standards outlined in the Hospital Accreditation Standards (2009 Edition), pages 47—68 with the exception of standard EM.02.02.13, pages 61—65.

B. A licensee shall prepare an executive summary of the hospital's evacuation procedures to provide to a patient, family member, or legal representative upon request. The summary shall:

(1) Describe the hospital's Emergency Operation Plan (EOP), which is discussed throughout the Emergency Management standards cited in §A(1) of this regulation; and

(2) Describe the role and responsibilities of a patient, family member, or legal representative in the event of an emergency situation.

C. A licensee shall have a tracking system to assist the hospital, family members, government representatives, and other authorized stakeholders, to locate and identify patients in the event of displacement due to an emergency or disaster.

*10.07.01.29*

**.29 Notice to Patients of Outpatient on Observation Status.**

A. A hospital shall provide both an oral and written notice to a patient of:

(1) The patient’s outpatient on observation status;

(2) The billing implications of the outpatient on observation status; and

(3) The impact of the outpatient on observation status on the patient’s eligibility for Medicare rehabilitation services if:

(a) The patient received on-site services from the hospital for more than 23 consecutive hours;

(b) The on-site services received by the patient include a hospital bed and meals that have been provided in an area of the hospital other than the Emergency Department; and

(c) The patient is classified as an outpatient at the hospital for observation rather than as an admitted inpatient.

B. The written notice shall include:

(1) That the patient is considered to be on observation as an outpatient and is not admitted as an inpatient;

(2) The reason or rationale that the patient has not been admitted for inpatient services;

(3) That the patient, if needed upon discharge, may not qualify for Medicare Part A reimbursement for rehabilitation services, including such services provided under Medicare Part A in a skilled nursing facility;

(4) That there may be billing implications based on their outpatient status that may increase the patient’s out-of-pocket costs for their stay;

(5) The name and title of the staff who provided the oral notice stating the date and time of the oral notice; and

(6) The signature of the patient to verify an understanding and receipt of the written notice.

C. Once the patient has received onsite services for more than 23 hours, the hospital shall provide written and oral notice to the patient that the physician has ordered services be provided as outpatient on observation status.

D. The oral and written notice shall be provided in a manner that is understood by the patient.

E. If the patient lacks capacity to understand the medical or financial implications of his or her outpatient on observation status, the oral and written notice shall be provided to a person authorized to make medical or financial decisions for the patient, including:

(1) A guardian of the person under Estates and Trusts Article, §13-705, Annotated Code of Maryland;

(2) A guardian of the property under Estates and Trusts Article, §13-201, Annotated Code of Maryland;

(3) An agent appointed under an advance directive that meets the requirements of Health-General Article, §5-602, Annotated Code of Maryland;

(4) A surrogate decision maker with authority under Health-General Article, §5-605, Annotated Code of Maryland;

(5) An agent appointed under a power of attorney that meets the requirements of Estates and Trusts Article, Title 17, Annotated Code of Maryland;

(6) A representative payee or other similar fiduciary; or

(7) Any other person, if that person was designated by the patient who was competent at the time of designation, and the patient or representative has provided the hospital with documentation of the designation.

*10.07.01.30*

**.30 Physical Environment.**

A. The facility shall be in compliance with:

(1) Guidelines for the Design and Construction of Hospitals and Outpatient Facilities (2014); and

(2) All applicable State and local governing laws, regulations, standards, ordinances, and codes for fire safety, building, and zoning requirements.

B. Any waiver or other modification of these requirements shall be addressed by the appropriate State or local authority having jurisdiction in accordance with established procedures.

*10.07.01.32*

**.32 Penalties — General.**

A. The Secretary shall deny a license to a person who has been convicted of a felony that relates to Medicaid or to a nursing home.

B. The Secretary shall revoke the license of any licensee convicted of a felony that relates to Medicaid or to a nursing home.

C. The Secretary may deny or revoke a license if the hospital does not meet the requirements of:

(1) Health-General Article, Title 19, Subtitle 3, Annotated Code of Maryland;

(2) Any regulation adopted under Health-General Article, Title 19, Subtitle 3, Annotated Code of Maryland, including this chapter.

D. A hospital subject to a fine or a penalty, or to delicensure, denial, or revocation of license under these regulations, may request a hearing as set forth under State Government Article, §10-201 et seq., Annotated Code of Maryland, and COMAR 10.01.03.

*10.07.01.32-1*

**.32-1 Civil Money Penalties — Imposition.**

A. The Department may impose a civil money penalty not to exceed $10,000 for each failure of a hospital to comply with the requirements of Regulation .27 of this chapter.

B. In determining whether to impose a civil money penalty, the Department may consider the following factors:

(1) The number of failures to comply;

(2) The nature and seriousness of the failure to comply;

(3) The degree of risk to the health, life, or safety of the patient being discharged that is caused by the failure to comply;

(4) A hospital's prior history to comply with discharge requirements; and

(5) Such other factors as justice may require.

*10.07.01.32-2*

**.32-2 Civil Money Penalties — Payment of Penalty.**

A. If a hospital owes a civil money penalty to the Department, the hospital shall adhere to the procedures of this regulation.

B. A civil money penalty payment is due to the Department 15 calendar days after:

(1) The time period for requesting a hearing has expired if a request for hearing is not received; or

(2) Receipt of a written request from the hospital to waive its right to a hearing and reduce the amount of the civil penalty by 40 percent, if the written request is received by the Department within 30 calendar days of the Department's order imposing the civil money penalty.

*10.07.01.33*

**.33 Uniform Emergency Codes.**

A. Each hospital shall adopt and implement the following set of uniform codes for the identified emergency situations as part of its emergency or disaster plans:

(1) Fire — Code Red;

(2) Infant or Child Abduction — Code Pink;

(3) Cardiac Respiratory Arrest — Code Blue — Adult;

(4) Cardiac Respiratory Arrest — Code Blue — Child;

(5) Cardiac Respiratory Arrest — Code Blue — Infant;

(6) Combative Person — Code Green;

(7) Bomb Threat — Code Gold;

(8) Hazardous Material Spill or Release — Code Orange;

(9) Elopement — Code Gray;

(10) Security Only Response — Code Purple;

(11) Emergency or Disaster — Code Yellow; and

(12) Armed Assailant — Code Silver.

B. A hospital may adapt the uniform codes referenced in §A of this regulation to meet the specific needs of the hospital by adding a suffix or additional words after that code.

C. For emergency situations not addressed by the codes in §A of this regulation, a hospital may establish its own identifying code.

D. A hospital shall adopt only those uniform color codes that are consistent with the services or needs of the hospital.

E. As part of its emergency or disaster plan, the hospital shall establish its own protocol for each of the uniform codes.

F. A hospital shall provide orientation and training to all staff regarding the uniform emergency codes and the hospital's emergency or disaster plan.

G. A hospital seeking exceptions to the requirements of this regulation shall submit its plan for emergency codes to the Department for review and approval:

(1) Within 90 days after the effective date of this regulation; or

(2) Before implementation of changes in its emergency code that would not comply with §§A—F of this regulation.

*10.07.01.34*

**.34 Infection Prevention and Control Program.**

A. The hospital shall have an active hospital-wide program for the prevention, control, and investigation of communicable diseases and infections.

B. Staffing.

(1) The hospital shall designate qualified staff with training in infection prevention and control to be responsible for the implementation of the infection prevention and control program.

(2) Additional clinical and support staff shall be provided for the infection prevention and control program based on the size and complexity of the hospital's services.

C. Infection Prevention and Control Program.

(1) The infection prevention and control program shall be based on nationally recognized, evidence-based standards.

(2) The infection prevention and control program shall be developed using an interdisciplinary approach with input from:

(a) Administrative staff;

(b) Medical staff;

(c) Pharmacy staff;

(d) Laboratory personnel;

(e) Nursing staff;

(f) Physical plant personnel;

(g) Employee health personnel;

(h) Patient safety officer; and

(i) Staff from other departments whose knowledge and experience would contribute to improved infection prevention and control.

(3) Written policies and procedures for the infection prevention and control program shall be established, implemented, maintained, and updated periodically.

D. Surveillance.

(1) The hospital shall:

(a) Have a process for the identification and surveillance of healthcare- associated infections;

(b) Analyze and utilize surveillance data to monitor and improve infection control and healthcare outcomes; and

(c) Maintain a log of the identified infections.

(2) The infection prevention and control program shall include:

(a) Processes for the monitoring and control of patients who have a communicable disease or infection to prevent its spread to other patients and staff;

(b) A process to identify and investigate the occurrence of outbreaks of communicable diseases or clusters of infections; and

(c) Reporting of infections, communicable diseases, and outbreaks to the local or State health department, as required by COMAR 10.06.01.

(3) When an outbreak occurs, the infection control staff shall have adequate resources and authority to ensure comprehensive and timely investigation and to implement control measures.

E. Education.

(1) The hospital shall provide education to all staff and, if appropriate, to the patient and visitors regarding the prevention and control of communicable diseases and infections. Educational activities shall address problems identified by the infection prevention and control program.

(2) Nonclinical staff shall be included in infection prevention and control training consistent with their assigned responsibilities.

(3) Attendance or participation in an educational program shall be recorded. Educational programs shall be evaluated not less than annually for effectiveness.

(4) Education related to infection prevention and control shall be included in the hospital's orientation program for all new employees, including appropriate contractual personnel.

(5) Physicians who are employed or who have privileges and who do not receive training through the hospital's new employee training program shall receive alternative orientation education on infection prevention and control practices and the hospital's infection prevention and control program.

(6) Outside agency staff shall receive sufficient training in the hospital's infection prevention and control policies and procedures to provide safe care to the patients.

F. Prevention.

(1) The hospital shall establish processes and programs to prevent the spread of communicable diseases and infections.

(2) A hospital's processes and programs to prevent the spread of communicable diseases and infections shall include at least the items listed in §F(3) of this regulation.

(3) Required Processes and Programs.

(a) Hand Hygiene.

(i) The infection prevention and control program shall include activities to educate staff on the need for hand hygiene prior to and after any patient contact and as directed by accepted professional practice.

(ii) Hand hygiene compliance by staff shall be monitored through the infection prevention and control program.

(iii) The infection prevention and control program shall maintain documentation of audits for compliance with this requirement.

(iv) Facilities and supplies to facilitate hand hygiene shall be provided and be accessible in all locations of the hospital where patient care is provided.

(b) Sanitation.

(i) The hospital shall maintain a sanitary environment to prevent the spread of communicable diseases and infections.

(ii) The hospital shall have systems to maintain the environment in a clean and sanitary condition.

(iii) Systems shall be provided to ensure that housekeeping, linen handling, waste disposal including medical waste, food handling, ventilation systems, water systems, and pest control meet acceptable federal and State standards and guidelines.

(c) Aseptic Technique. The hospital shall use aseptic techniques to prevent infections, including surgical site infections and device-associated infections.

(d) Immunocompromised Patients. The hospital shall use professionally accepted procedures to protect immunocompromised patients from infection.

(e) Standard Precautions. The hospital staff shall use standard precautions and other categories of isolation or precautions consistent with current Center for Disease Control (CDC) recommendations.

(f) Equipment and Supplies.

(i) The hospital shall have personal protective equipment, such as gloves, gowns, respirators, and masks or other facial protection for staff readily available.

(ii) Supplies and equipment needed to prevent the spread of communicable diseases and infections shall be available in all patient care areas.

(4) Employee Health Program. The infection prevention and control program shall work in conjunction with the employee health program and include monitoring and identification of employee health concerns such as immunity to measles, mumps, rubella, and varicella (chicken pox).

(5) Immunizations for influenza shall be offered to staff and licensed independent practitioners. Reasons for refusal of the influenza vaccine by an employee shall be documented by the infection control or employee health program.

G. Performance Improvement.

(1) The infection prevention and control program shall include performance improvement and quality assurance measures to address the problems identified through the surveillance, control, and investigation of infections.

(2) The hospital shall develop and implement interventions to address identified problems and monitor the effectiveness of interventions to control and prevent infections.

(3) The infection prevention and control program shall be incorporated into the hospital's performance improvement program.

H. Patient Safety. The infection prevention and control program shall share data regarding healthcare-associated infections with the hospital's designated patient safety officer. Health care associated infections that meet the definition of a Level 1 adverse event shall be reported to the Department, and a root cause analysis submitted as required by COMAR 10.07.06.

I. Reports to the Governing Body.

(1) Infection control data including reports on the numbers and types of healthcare-associated infections shall be reported to the hospital's medical staff and governing body on an ongoing basis.

(2) The hospital leadership shall support infection prevention and control activities, including the provision of adequate resources for the program.

J. Department Oversight.

(1) The hospital shall comply with all data reporting requirements of the Maryland Health Care Commission related to the prevention and acquisition of infections in accordance with Health-General Article, §19-134(e), Annotated Code of Maryland.

(2) The Department shall have access to all data maintained through the hospital's infection prevention and control program to determine the hospital's compliance with State and federal regulations.