

RULES FOR THE LICENSING OF HOSPITALS

10-144 C.M.R. Ch. 112
Effective January 1, 2009



**MAINE DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF LICENSING AND REGULATORY SERVICES**

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Table of Contents

Statement of Purpose.....	1-1
Section 1. Definitions.....	1-1
Section 2. Licensing and Enforcement.....	2-1
Section 3. Standards.....	3-1
Section 4. Complaint Investigation and Incident Reports.....	4-1
Statutory Authority.....	A

Section 1. DEFINITIONS. As used in this rule, unless the context indicates otherwise, the following terms have the following meanings:

- 1.1 Applicant.** An applicant is any person, firm, partnership, association, corporation, or other entity requesting a license pursuant to these rules.
- 1.2 CMS.** “CMS” means the United States Department of Health and Human Services Centers for Medicare and Medicaid Services.
- 1.3 Critical Access Hospital.** “Critical Access Hospital”, as established pursuant to 22 M.R.S.A. §7932(10), means a rural hospital which provides not more than 25 beds for acute hospital-level inpatient care. A swing-bed facility may have up to 25 inpatient beds that can be used interchangeably for acute or skilled nursing care. In addition to the 25-bed limit for acute inpatient care, a Critical Access Hospital may have distinct parts with 10 or fewer psychiatric inpatient beds, or 10 or fewer inpatient rehabilitation beds, or both. In order to be a Critical Access Hospital, inpatient care may not exceed on an annual average basis, 96 hours per patient.
- 1.4 Department.** Unless otherwise indicated, the “Department” means the Maine Department of Health and Human Services.
- 1.5 General Hospital.** “General Hospital” means an acute health care facility with permanent inpatient beds planned, organized, operated, and maintained to offer for a continuing period of time, facilities and services for the diagnosis and treatment of illness, injury, and deformity; with a governing board, and an organized medical staff, offering continuous twenty-four hour professional nursing care; with a plan to provide, emergency treatment twenty-four hours a day. Any institution not meeting this definition of a general hospital is a specialty hospital. General hospitals do not include federal or state government controlled institutions, community health centers, independent outpatient diagnostic or treatment centers, doctors’ offices, college infirmaries or industrial dispensaries. General hospitals include the provision of, either directly or indirectly, the following services or organizational units:
- 1.5.1** Governing Board
 - 1.5.2** Administration
 - 1.5.3** Medical Staff
 - 1.5.4** Nursing Services
 - 1.5.5** Emergency Services
 - 1.5.6** Food and Dietetic Services
 - 1.5.7** Medical Records
 - 1.5.8** Imaging Services
 - 1.5.9** Pathology or Laboratory Services, and
 - 1.5.10** Pharmacy Services.

- 1.6 Incident.** The term “incident” means the following occurrences that must be reported to the department on department-approved forms within the indicated number of hours of discovery or occurrence:
- 1.6.1** a suspected violation of the Emergency and Medical Treatment and Labor Act shall be reported within 72 hours, 42 C.F.R. §§ 489.20 and 489.24.
http://a257.g.akamaitech.net/7/257/2422/09nov20051500/edocket.access.gpo.gov/cfr_2005/octqtr/pdf/42cfr489.20.pdf
http://www.cms.hhs.gov/EMTALA/01_overview.asp;
- 1.6.2** fires shall be reported within 24 hours as follows:
- 1.6.2.1** fires requiring patient movement;
- 1.6.2.2** fires requiring patient evacuation; or
- 1.6.2.3** fires causing injury to a patient;
- 1.6.3** an emergency evacuation of patients from all or portions of a facility shall be reported within 24 hours; and
- 1.6.4** suspected abuse, neglect or exploitation shall be reported within 24 hours; 22 M.R.S.A. §§ 3472 (1) and 4002 (1).
<http://janus.state.me.us/legis/statutes/22/title22sec3472.html>
<http://janus.state.me.us/legis/statutes/22/title22sec4002.html>
- 1.7 Licensee.** Licensee means any person, firm, partnership, association, corporation, or other entity, other than a receiver appointed under 22 M.R.S.A. §7933, who is licensed or required to be licensed to operate a facility.
- 1.8 Psychiatric hospital.** “Psychiatric hospital” means a state or non-state hospital that, in addition to meeting the requirements of a General Hospital, is organized, directed, and staffed, in whole or in part, to meet the needs of psychiatric patients.
- 1.9 Specialty hospitals.** “Specialty hospitals” means critical access hospitals, psychiatric hospitals/units, and hospitals that specialize in specific services, including but not limited to transplant services, rehabilitation services, long term acute care services, cardiac services, orthopedic services or surgical procedures.
- 1.10 Standard-level deficiency.** A deficiency is at the standard level when there is noncompliance with any single requirement or several requirements within a particular standard that are not of such character as to substantially limit a facility’s capacity to furnish adequate care, or which would not jeopardize or adversely affect the health or safety of patients if the deficient practice recurred. This definition is incorporated herein by reference to the State Operations

Manual, Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, (Rev. 1, 05-21-04), adopted by the United States Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS).

- 1.11 Substantial compliance.** “Substantial compliance” for the purpose of these rules means that the hospital had either [A] no deficiencies; or [B] Standard-level deficiencies as defined in Section 1.11 above.
- 1.12 Swing beds.** “Swing beds” means licensed acute care beds that are approved to be used interchangeably as skilled nursing beds.

Section 2. LICENSING AND ENFORCEMENT

- 2.1 Responsibility for compliance.** The applicant and licensee must comply with these rules.
- 2.2 Unlicensed facilities.** No person, firm, partnership, association, corporation, or other entity, nor any state, county or local governmental units shall establish, operate, conduct and maintain in the State any hospital for the hospitalization and nursing care of human beings without a license issued by the department. Unless otherwise specified, the term hospital includes any type of hospital, including but not limited to general, critical access, psychiatric or other specialty hospital.
- 2.3 License not transferable.** No license may be assigned or transferred.
- 2.4 License posted.** The license must be conspicuously posted in the facility where it may be seen by the public.
- 2.5 Application for initial license and renewal.**
- 2.5.1 Application.** Either prior to the commencement of operation as a hospital, or thirty (30) days prior to the expiration of the existing license, the applicant or licensee must file an application for a license on forms provided by the department. An application on behalf of a corporation or association must be made by any two officers or by its managing agent. Applicants and licensees must demonstrate satisfactory evidence of compliance with all laws and rules of the State of Maine.
- 2.5.2 Building lease.** The lease for any building or buildings not owned by the applicant or licensee that are used in connection with the provision of patient services on an inpatient or outpatient basis must show clearly in its context which party to the agreement is responsible for the maintenance and upkeep of the property. The department shall be notified at least 72 hours in advance of any changes in the lease that may impact responsibilities for maintenance and upkeep, and compliance with these rules.
- 2.5.3 Building plans.** A set of plans and specifications for each building used in the provision of patient care services, drawn to scale, must be provided to the department. These plans must identify the source of utilities and method of waste disposal. Plans and specifications drawn to scale for proposed changes in the facility, its physical environment or its utilities that materially affect patient care must be approved by the department prior to implementation of proposed changes.

Submission of plans and specifications are not required for routine maintenance and repair of the facility.

- 2.5.4 Beds.** The applicant or licensee must identify the number of beds defined for each of the services rendered.
- 2.5.5 Fire safety inspection.** Prior to the issuance of a license, and annually thereafter, the department must receive a written statement, signed by the Commissioner of Public Safety or the proper municipal official designated to make fire safety inspections, that the premises comply with fire safety provisions pursuant to 22 M.R.S.A. §1816.
- 2.5.6 New services.** In order for a license to extend to a new service or other applicable project subject to the Certificate of Need process outlined in 22 M.R.S.A. Chapter 103-A, and any applicable rules promulgated thereunder, the applicant or licensee must request a ruling from the Certificate of Need Unit, Division of Licensing and Regulatory Services.
- 2.5.7 Plumbing, water supply and sewage disposal.** The applicant or licensee must provide evidence that the facility complies with all applicable State laws and rules relating to plumbing, water supply and sewage disposal.
- 2.5.8 Fee.** Licensing fees are nonrefundable.
- 2.5.8.1** The fee for an initial license is \$40 for each bed.
- 2.5.8.2** The fee for a 2-year renewal license is \$80 for each bed.
- 2.5.8.3** The fee for a temporary license is \$15.00.
- 2.5.8.4** The department may assess a fee for plan review at an hourly rate not to exceed \$50 an hour.
- 2.5.9 Local laws and codes.** The applicant or licensee must provide evidence from the appropriate municipal official indicating compliance with all local laws or codes relative to the type of facility for which the license is requested. This requirement is necessary upon initial licensure and whenever a change occurs.
- 2.5.10 Accreditation reports.** A copy of the latest survey by an accrediting body must be on file with the department, if the hospital is accredited.

- 2.6 Term of license.** Pursuant to 22 M.R.S.A. Chapter 405, the term of the license is as follows:
- 2.6.1 Initial license.** An initial license may be issued for up to 12 months.
 - 2.6.2 Renewed license.** A license may be renewed for up to 24 months.
 - 2.6.3 Temporary license.** A temporary license may be issued for a specified period not to exceed 90 days, during which time corrections specified by the department must be made by the applicant or licensee for compliance with these rules, if in the judgment of the commissioner the best interest of the public will be served.
 - 2.6.4 Conditional license.** A conditional license may be issued for a specified period not to exceed 12 months, setting forth conditions that must be met by the applicant or licensee to the satisfaction of the department if in the judgment of the commissioner the best interest of the public will be served.
- 2.7 Waivers.** A waiver may be granted under the following terms and conditions:
- 2.7.1** The department may waive or modify a provision of these rules as long as the provision is not mandated by state or federal law and does not violate patient rights.
 - 2.7.2** A written request for a waiver must be made at the time of initial or renewal application and submitted to the department.
 - 2.7.3** A request for a waiver must be accompanied by documentation that demonstrates that the terms of the waiver will comply with the intent of the rule. At the request of the department, expert opinion shall be provided.
 - 2.7.4** A waiver shall be granted for a specific period not to exceed the term of the license.
 - 2.7.5** To renew a waiver, the hospital must submit a renewal request to the department ninety (90) days prior to the expiration of the term of the existing license.
 - 2.7.6** A violation of a waiver is enforceable as rule and subject to actions described in Section 2.12 regarding enforcement procedures.

- 2.8 Issuance of a license.** The license issued by the department extends to the premises identified in the application.
- 2.9 Specifications of a license.** The license must specify the following:
- 2.9.1** the name of the facility,
 - 2.9.2** the name of the Chief Executive Officer or Administrator,
 - 2.9.3** the location of the building(s),
 - 2.9.4** the maximum allowable number of licensed beds,
 - 2.9.5** any state licensing waivers that have been granted,
 - 2.9.6** the effective date and term of the license,
 - 2.9.7** the identification of each level of care, and
 - 2.9.8** the identification of outpatient services.
- 2.10 Distinct parts.** When two or more distinct parts exist within one structure, the license must identify each level of care or outpatient service provided within the structure. When the applicant or licensee has separate facilities located in physically separated structures on the same grounds, one license shall be issued. Facilities operated by the same applicant or licensee on different grounds shall have one license.
- 2.11 Changes in licensing information.** No change in licensed capacity may be implemented, and no new construction, additions or alterations shall commence without the applicant having plans approved by the department. This does not apply to minor alterations which do not effect the primary functional operation or the number of beds, or to routine maintenance and repairs. Changes in Chief Executive Officer or Administrator must be reported to the department within ten (10) working days. A new license shall be issued following notification to the department.
- 2.12 Enforcement procedures**
- 2.12.1 Voiding a temporary or conditional license.** Failure to meet any of the department's conditions immediately voids the temporary or conditional license upon personal service of written notice to the licensee, or, if the licensee cannot be reached for personal service, by personal service to the person in charge.
 - 2.12.1.1 New application.** A new application for a regular license may be considered by the department after the conditions set forth by the department at the time of the issuance of the temporary or conditional license have been met and satisfactory evidence of this fact has been furnished to the department.

- 2.12.2 Refusal to issue a license.** The department may refuse to issue a license to the applicant if it finds misrepresentation, materially incorrect or insufficient information on the application, or if the premises do not meet the requirements for issuing a license.
- 2.12.3 Amending, modifying, or refusing to renew a license.** The department may amend, modify or refuse to renew a license in conformity with the Maine Administrative Procedure Act.
- 2.12.4 Grounds for suspension or revocation.** The department may file a complaint with the District Court requesting suspension or revocation of any license based on any of the following grounds:
- 2.12.4.1** violation of these rules and applicable laws;
 - 2.12.4.2** permitting, aiding or abetting the commission of any illegal act in the facility; or,
 - 2.12.4.3** conduct or practices detrimental to the welfare of a patient.
- 2.12.5 Suspension or revocation of license.** The department may file a complaint with the District Court requesting suspension or revocation of a license pursuant 22 M.R.S.A. §1817.
- 2.12.5.1 Private psychiatric hospital license suspension or revocation.** Pursuant to 22 M.R.S.A. §1783, if the department believes a license for a private psychiatric hospital should be suspended or revoked, the department shall file a statement or complaint with the District Court Judge, designated in the Maine Revised Statutes, Title 5, chapter 375.
- 2.12.6 Emergency suspension or revocation of license.** Whenever, on inspection by the department, conditions are found to exist that, in the opinion of the commissioner, immediately endanger the health or safety of patients in the facility, or create an emergency, the department by its duly authorized agents may, under the emergency provisions of 4 M.R.S.A. §184(6), request that the District Court suspend or revoke the license.
- 2.13 Appeals.** Any person who is aggrieved by a decision of the department to refuse to issue a license or to renew a license, or to issue a conditional license

may request an administrative hearing in writing within ten (10) working days of receipt of the decision in accordance with the Administrative Procedures Act, 5 M.R.S.A. §9051 *et seq.* A request for an administrative hearing must specify the reasons of the appeal. Administrative hearings will be held in conformity with the department's Administrative Hearing Regulations.

2.14 Appeal of refusal to issue a license to a private psychiatric hospital. A person aggrieved by the refusal of the department to issue a license to a private psychiatric hospital may file a statement or complaint with the District Court Judge.

2.15 Inspections.

2.15.1 Exemption from state inspection. A hospital is exempt from state licensure inspection if the following conditions apply:

2.15.1.1 The hospital is certified by the Centers for Medicare and Medicaid Services (CMS) for participation in the federal Medicare program, and

2.15.1.2 The hospital holds full accreditation status by a health care facility accrediting organization recognized by the Centers for Medicare and Medicaid Services.

2.15.2 State inspection required. A hospital that is certified by the Centers for Medicare and Medicaid Services for participation in the federal Medicare program but is not accredited by a health care facility accrediting organization recognized by the Centers for Medicare and Medicaid Services, shall be inspected for state licensure purposes by the department every three (3) years for compliance with these rules.

2.15.2.1 The hospital will receive a ten (10) working day notice of the inspection.

2.15.2.2 Federal certification survey findings will be used as evidence of compliance with these rules to avoid duplication of effort and satisfy the requirements of Section 3.1.

2.15.3 Complaints. Regardless of its accreditation status, a hospital may be inspected, without notice, by the department in response to a complaint or suspected violation of these rules, or inspected by another state agency or municipality for violation of building codes, fire codes, life

safety codes or for other purposes unrelated to health care facility licensing or accreditation.

- 2.16 Change in accreditation.** The hospital must notify the department of any change in accreditation status within ten (10) days of its occurrence.
- 2.17 Statement of deficiencies.** A statement of deficiencies shall be issued by the department as a result of a determination that a violation of these rules has occurred.
- 2.17.1 Violations of federal conditions of participation.** When a violation under Section 3.1 has occurred, and a federal statement of deficiencies is issued to the applicant or licensee, the plan of correction accepted by the Centers for Medicare and Medicaid Services shall be accepted by the department.
- 2.17.2 Other violations.** The department shall notify the applicant or licensee of any violation of these rules not covered by Section 3.1, and a statement of deficiencies may be issued when the department determines that a plan of correction is necessary.
- 2.17.3 Corrective action.** In the event a facility does not implement its approved plan of correction, the department may direct the facility to implement its plan of correction, or take additional corrective action as specified in these rules.
- 2.18 Informal conference.** Within ten (10) days of receipt of the statement of deficiency, the licensee may request an informal conference to provide evidence to dispute the findings, if a licensee disagrees with the finding of a deficiency by the department. In the event a deficiency relates to one or more standards or conditions of participation, as outlined in Section 4, if the deficiency is upheld by CMS, it is upheld as a state licensing deficiency.
- 2.19 Receivership.** Pursuant to 22 M.R.S.A. Chapter 1666-A, Appointment of Receivers, the department may petition the Superior Court to appoint a receiver to operate the hospital.
- 2.20 Right of entry.** The department and any duly designated representative shall have the right to enter upon and into the premises of any facility licensed pursuant to these rules at any time without threat of injury, verbal abuse or harassment and in the spirit of mutual cooperation in order to determine the status of compliance with the provisions of these rules.

- 2.20.1** Such right of entry shall extend to any premises which the department has reason to believe is being operated or maintained as a hospital without a license, but no such entry or inspection shall occur without the permission of the owner or person in charge, unless a warrant is first obtained from a court having jurisdiction.
- 2.20.2** An application for a license pursuant to these rules constitutes permission for complete acquiescence to any entry or inspection for which the license is sought in order to facilitate verification of the information submitted on, or in connection with, such application.
- 2.20.3** Right of entry shall afford department authorized personnel full access to all records, documents and reports in accordance with the federal Health Insurance Portability and Accountability Act, 42 U.S.C. §201 *et seq.* (42 U.S.C. §1320d-2)(1996), or other applicable law. Right of entry gives the department authorization to copy records, documents and reports either manually or by photocopy unless otherwise protected by law, at no expense to the department.

2.21 Construction and renovations. All construction of new buildings for occupancy as a hospital and additions, renovations, alterations or repairs of existing buildings with a total project cost of fifty-thousand (\$50k) or more must comply with state and local codes, zoning and building ordinances, and the building and design standards of the American Institute of Architects' *2006 Guidelines for Design and Construction of Health Care Facilities* (AIA guidelines). Additions, renovations, alterations or repairs with a total project cost of less than fifty-thousand may require local and municipal permits, and copies must be on file at the facility.

- 2.21.1 Architectural plans.** When architectural plans are required by law or rule, the hospital must file a copy of the plans with the department.
- 2.21.2 Architect's certification.** When architectural plans are required, the hospital must submit to the department, prior to construction, an architect's certification that the drawings and specifications were prepared according to state and local codes, zoning and building ordinances, and the AIA guidelines. When state or local codes take precedence over the AIA guidelines, the architect must so note.
- 2.21.3 Documentation.** Upon completion of the project and prior to occupancy, the following information must be received by the department before a license is issued:

- 2.21.3.1** Architect's letter of certification, as applicable, that construction conformed to the certified drawings and specifications that were prepared according to code requirements and the AIA guidelines;
 - 2.21.3.2** State Fire Marshal approval; and
 - 2.21.3.3** Documentation of department approval of facility policies and procedures, contractual agreements, staffing plans or materials necessary to determine compliance with these rules, if applicable.
- 2.21.4** A physical walkthrough may be conducted by the department to determine compliance with these rules.

Section 3. STANDARDS

- 3.1 Federal standards and certification requirements.** All applicants and licensees must comply with the federal standards and certification requirements for hospitals, adopted by the United States Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS) as set forth in 42 C.F.R. §482.1 through §482.104 and §485.601 through §485.647, revised as of October 1, 2007, which is incorporated herein by reference.
- 3.1.1** Copies of the federal standards and certification requirements can be found at 42 C.F.R. §482.1 through §482.104 and §485.601 through §485.647, revised as of October 1, 2007, or may be obtained from the Maine Department of Health and Human Services, Division of Licensing and Regulatory Services, 11 State House Station, Augusta, Maine 04333, or the Maine Office of the Secretary of State, 101 State House Station, Augusta, Maine 04333.
- 3.1.2** A violation of any of the federal standards and certification requirements constitutes a violation of the state of Maine Rules for the Licensing of Hospitals, 10-144 C.M.R. Ch. 112.
- 3.2 Patient Rights in Critical Access Hospitals.** A critical access hospital must protect patient rights and comply with the conditions for patient rights contained in 42 C.F.R. §482.13, revised as of October 1, 2007, which is incorporated herein by reference as described in Section 3.1.
- 3.3 Federal Standards for Distinct Part Hospital Units.**
- 3.3.1 Psychiatric Unit.** All applicants and licensees must also comply with the federal standards and certification requirements for psychiatric units, adopted by the United States Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS) as set forth in 42 C.F.R. §412.25 and §412.27, revised as of October 1, 2007, which is incorporated herein by reference.
- 3.3.2 Rehabilitation Unit.** All applicants and licensees must comply with the federal standards and certification requirements for rehabilitation units, adopted by the United States Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS) as set forth in 42 C.F.R. §412.25, §412.29, and §412.30, revised as of October 1, 2007, which is incorporated herein by reference.
- 3.3.3 Copies.** Copies of the federal standards and certification requirements for distinct part hospital units can be found at 42 C.F.R. §412.25, §412.27, §412.29, and §412.30, revised as of October 1, 2007, or may

be obtained from the Maine Department of Health and Human Services, Division of Licensing and Regulatory Services, 11 State House Station, Augusta, Maine 04333, or the Maine Office of the Secretary of State, 101 State House Station, Augusta, Maine 04333.

3.3.4 Violations. A violation of any of the federal standards and certification requirements for distinct part hospital units constitutes a violation of the state of Maine Rules for the Licensing of Hospitals, 10-144 C.M.R. Ch. 112.

3.4 Requirements for Medicare patients apply to all patients. Wherever the federal standards and certification requirements refer to requirements, standards or conditions applying to Medicare patients, for purpose of state licensing they must apply to all patients, regardless of payment source.

3.5 Maine laws and rules. In addition to compliance with the federal standards and certification requirements in Section 3.1, the following state laws and rules apply:

3.5.1 Grievance procedure for recipients of mental health services. Pursuant to 22 M.R.S.A. §1719, private psychiatric hospitals, including any part of a general or specialty hospital that operates a distinct part for the provision of psychiatric services under these rules, and state psychiatric facilities, as defined in 34-B M.R.S.A. §3801(6), are subject to the grievance procedures set forth in 14-193 C.M.R. Chapter 1 (Rights of Recipients of Mental Health Services) and 14-472 C.M.R. Chapter 1 (Rights of Recipients of Mental Health Services who are Children in Need of Treatment).

3.5.1.1 A violation of the Rights of Recipients of Mental Health Services or the Rights of Recipients of Mental Health Services who are Children in Need of Treatment constitutes a violation of the state of Maine Rules for the Licensing of Hospitals.

3.5.1.2 Copies of the Rights of Recipients of Mental Health Services or the Rights of Recipients of Mental Health Services who are Children in Need of Treatment may be obtained from the Maine Department of Health and Human Services, Division of Licensing and Regulatory Services, 11 State House Station, Augusta, Maine 04333, or the Maine Office of the Secretary of State, 101 State House Station, Augusta, Maine 04333.

3.5.1.3 Appeals to department. The commissioner shall be responsible for issuing final decisions for any grievance appealed to the department level in accordance with the procedures set forth in 14-193 C.M.R. Chapter 1 (Rights of Recipients of Mental Health Services) and 14-472 C.M.R. Chapter 1 (Rights of Recipients of Mental Health Services who are Children in Need of Treatment).

3.5.2 Patient visitors. Pursuant to 22 M.R.S.A. §1711-D, a patient may designate persons to be considered as immediate family members for the purpose of granting visitation rights. The following provisions apply to the designation of visitors under this rule.

3.5.2.1 The patient must be 18 years of age or older or a minor who is authorized by law to consent to health care.

3.5.2.2 The patient must be a patient in a critical care unit that restricts visitors to immediate family members, or emergency room that restricts visitors to immediate family members.

3.5.2.3 The patient may designate visitors under this rule by communicating the designation to a healthcare provider at the hospital orally or in writing. The patient may designate visitors, change the designation or revoke the designation at any time.

3.5.2.4 A hospital must provide patients with a process to designate visitors under this rule and must note in the patient's medical record the names of designated visitors, the date of the designation and any changes in the designation.

3.5.2.5 Except as provided in Section 3.5.2.6, a hospital may not deny visitation to the patient by a designated visitor during hospital visiting hours.

3.5.2.6 A hospital may deny visitation with a patient to any visitor designated under Section 3.5.2, if:

3.5.2.6.1 The hospital denies all visitors;

3.5.2.6.2 The hospital determines that the presence of the visitor might endanger the health or

safety of the patient or interfere with the primary operations of the hospital; or

3.5.2.6.3 The patient has communicated orally or in writing the choice not to visit with the visitor.

- 3.5.3 Patient access to patient records.** A patient may submit a written request for copies of the patient's medical and treatment records after discharge from a hospital, pursuant to 22 M.R.S.A. §§ 1711 and 1711-B. A copy of 22 M.R.S.A. §§ 1711 and 1711-B may be obtained from the Maine Department of Health and Human Services, Division of Licensing and Regulatory Services, 11 State House Station, Augusta, Maine 04333, or the Maine Office of the Secretary of State, 101 State House Station, Augusta, Maine 04333.
- 3.5.4 Fees charged for records.** Fees charged to patients for copies of requested copies of a patient's medical and treatment records shall be in accordance with 22 M.R.S.A. §1711-A. A copy of this statute may be obtained from the Maine Department of Health and Human Services, Division of Licensing and Regulatory Services, 11 State House Station, Augusta, Maine 04333, or the Maine Office of the Secretary of State, 101 State House Station, Augusta, Maine 04333.
- 3.5.5 Record Retention.** Records must be retained for a period of seven (7) years. If the patient is a minor, the record must be retained for at least six (6) years after the minor's age of majority. In addition, all licensees must comply with applicable federal and state laws and rules governing record retention.
- 3.5.6 Confidentiality of health care information.** Confidentiality of health care information must be maintained in accordance with 22 M.R.S.A. §1711-C and the federal Health Insurance Portability and Accountability Act, 42 U.S.C. §201 *et seq.* (42 U.S.C. §1320d-2) (1996), or other applicable law. A copy of these laws may be obtained from the Department of Health and Human Services, Division of Licensing and Regulatory Services, #11 State House Station, Augusta, Maine 04333, or the Maine Office of the Secretary of State, 101 State House Station, Augusta, Maine 04333.
- 3.5.7 Itemized bill.** Pursuant to 22 M.R.S.A. §1712, each hospital must give written notice to all patients, or their legal guardians, at the time of the patient's discharge that, upon request by the patient, the hospital will provide the patient with an itemized bill.

- 3.5.7.1** A request for an itemized bill may be made by the patient or his legal guardian at discharge or at any time within 7 years after discharge.
- 3.5.7.2** The hospital must provide an itemized bill to the person making the request within 30 days of request.
- 3.5.7.3** In addition to giving the notice required by 22 M.R.S.A. §1712 in Section 3.5.7 above, a hospital bill must be given to each patient that itemizes the cost of nursing services provided to the patient.
- 3.5.8 Price list.** Each hospital must maintain a price list of the most common inpatient services and outpatient procedures provided by the licensee, in accordance with 22 M.R.S.A. §1718.
- 3.5.9 Notice of intent to destroy images.** Pursuant to Resolves 2005, ch. 164, general and specialty hospitals that record images of a patient using x-rays, magnetic resonance imaging or computerized tomography must provide notice of intent to destroy or purge those images. This notice may be provided through publication in a newspaper that has broad general circulation in the region served by the hospital or directly to the patient prior to or after taking the image.
- 3.5.10 Notice to medical utilization review entities.** Hospitals must comply with 22 M.R.S.A. §1829, requiring notification to medical utilization review entities when the hospital provides emergency treatment to a person who is insured or otherwise covered under a policy or contract that requires review of a hospitalization by the medical utilization review entity.
- 3.5.11 Provider lists.** Hospitals must comply with 22 M.R.S.A. §1831, which requires hospitals to provide for informed patient decisions by providing lists of licensed providers of care and services for all patients prior to discharge for whom home health care or nursing care is needed.
- 3.5.11.1** For all patients requiring home health care, the list must include all licensed home health care providers that request to be listed and any branch offices, including addresses and phone numbers, which serve the area in which the patient resides.

3.5.11.2 For all patients requiring nursing facility care, the list must include all nursing facilities that request to be listed that serve the area in which the patient resides or wishes to reside.

3.5.11.3 The hospital must disclose to the patient any direct or indirect financial interest the hospital has in the nursing facility or home health care provider.

3.6 Administrative Segregation. Notwithstanding the limitations on restraint and seclusion in Section 3.1, a state-operated psychiatric hospital may have an Administrative Segregation program for a person arriving from a correctional facility, in beds that are not CMS-certified, to ensure patient safety and the safety of others, to maintain security, and to protect the rights of patients placed in Administrative Segregation.

3.6.1 Administrative Segregation is the temporary separation of a patient from other patients and the normal living environment for the purpose of maintaining safety and security, while a transitional plan, including a safety assessment, is completed.

3.6.2 Administrative Segregation must not exceed 120 hours.

3.6.3 Administrative Segregation must take place in a secure suite that includes a bedroom, an open room and a bathroom.

3.6.4 A chair, table, television and appropriate recreational supplies must be supplied unless the attending physician documents that these items pose a safety risk. Such determination must be made and documented consistent with the Rights of Recipients of Mental Health Services, pursuant to 14-193 C.M.R. Chapter 1.

3.6.5 The area must be observed by a camera and recorded to assist in assessing the effects of the segregation and patient tolerance. Constant visual monitoring must be maintained.

3.6.6 Administrative Segregation is only permitted when the following two criteria are met:

3.6.6.1 Administrative Segregation is necessary for patient safety or for the safety of others; and

3.6.6.2 The patient is on forensic status.

- 3.7 Laboratories.** In addition to the requirements in Section 3.1, all laboratory services provided must be in compliance with all applicable provisions of the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. §263a, as amended.
- 3.8 Annual notice of Whistleblowers' Protection Act.** Pursuant to Resolves 2007, ch. 88, once each year, the hospital must give an individual notice to each registered nurse in its employ regarding information about the Maine Whistleblowers' Protection Act, including a copy of the text of statutory provisions in 26 M.R.S.A. Chapter 7, Subchapter 5-B.

Section 4. COMPLAINT INVESTIGATION AND INCIDENT REPORTS

- 4.1 Complainant resolution.** Complainants shall be encouraged to resolve complaints directly with the hospital before initiating a department complaint investigation.
- 4.1.1 Consumer education.** Each hospital must publish a toll-free telephone number for complainants to contact the hospital. Each hospital must educate the public about hospital complaint resolution procedures. At a minimum, each hospital must post information in a public part of the hospital explaining the complaint resolution procedures and listing the toll-free complaint telephone number.
- 4.2 Department complaint investigation.** The department may investigate complaints, incidents, and suspected non-compliance in order to protect patients from abuse, neglect, exploitation, and inadequate care or supervision, and to determine compliance with these rules. Department investigations may also involve suspected violation of state and/or federal law and/or rules. On-site investigations may be either announced or unannounced.
- 4.3 First Priority (Immediate Jeopardy).** First priority will be given to suspected noncompliance that may pose the greatest potential for harm to patients. Immediate jeopardy means a situation that may have caused or is likely to cause, serious injury, physical or psychological harm, impairment or death to a patient.
- 4.4 Second priority (High Priority).** Second priority will be given to suspected non-compliance that does not allege a threat of serious harm, but could have a negative impact on the health care services provided. These investigations are designed to identify and correct less serious situations that have potential to escalate into threats to the health, safety and welfare of patients.
- 4.5 Medium, low or administrative complaint investigations.**
- 4.5.1 By Department.** The department may investigate medium, low or administrative complaints.
- 4.5.2 By Hospital.** The department may authorize the hospital to investigate the medium, low or administrative complaint, if the complainant gives written or verbal permission.
- 4.6 Criteria for investigation by hospital.** The department may authorize a hospital to investigate a complaint when the hospital complies with the following requirements:

- 4.6.1** The hospital agrees to investigate the complaint. When the hospital agrees to investigate the complaint, the hospital may not withdraw its agreement before the investigation is completed. The hospital investigation of the complaint is complete when the department accepts the hospital's report. See Section 4.7.
- 4.6.2** The hospital provides the department with the name of a specific staff person, and an alternate, who will coordinate and conduct the investigation and communicate with the complainant and the department.
- 4.6.3** The hospital agrees to complete the investigation and submit its report to the department within forty-five (45) days. The department will then determine whether the report meets the criteria contained in Section 4.7.
- 4.6.4** The hospital agrees to submit a report that meets the requirements of Section 4.7.

4.7 Hospital report of investigation. The written report to the department must be made on forms approved by the department and must include the following:

- 4.7.1** A summary of the hospital's investigation;
- 4.7.2** A summary of the hospital's investigation methods;
- 4.7.3** A list of the dates the investigation was conducted;
- 4.7.4** A statement indicating whether the hospital found the allegation to be substantiated (supported by the evidence) or unsubstantiated (not supported by the evidence);
- 4.7.5** Identification of the hospital's areas for improvement, if applicable;
- 4.7.6** Identification of the hospital's plan for improvement, if applicable; and
- 4.7.7** A copy of the hospital's response to the complainant.

Statutory Authority: Public Law 2007, Chapters 314 and 324; 22 M.R.S.A. Chapter 405; 22 M.R.S.A. §42; and 22-A M.R.S.A. §205.

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