



AD / Chief Compliance Officer
35 Medical Center Parkway, Augusta, ME 04330
Phone (207)626-4103 Fax (207)621-1049

Re: Contractor Services at MGMC – Regulatory Requirements

Dear Sir/Madam,

As a licensed hospital, MaineGeneral Medical Center (MGMC) must meet both State and Federal Regulatory requirements for acute care hospitals. Federal regulations require that vendors providing hospitals with clinical services (direct impact on patient care) must also meet the applicable hospital requirements. Therefore, if your company contracts with MGMC to provide clinical services, based on the scope of those services, your company must meet the applicable regulatory requirements. There are requirements related to **personnel** providing direct patient care, vendor **equipment** being used on-site at MGMC to provide patient care, and **patient safety and quality assurance/performance improvement**. These expectations are described in detail on the following pages.

Please provide a copy of this letter to the individual responsible for overseeing the services provided to MaineGeneral and maintain a copy with your contract legal file. MGMC reserves the right to request copies or proof of compliance with any of the expectations listed below. This information must be provided to MGMC within 24 hours of request unless MGMC specifies a different timeframe.

Representatives from MGMC may reach out to you for the following:

- To discuss quality assurance/performance improvement measures;
- To request personnel information for audit/review purposes; and
- To request equipment information/records for audit/review purposes.

If you have questions about the required performance expectations for the services that your company, provides to MGMC, please contact one of the following individuals:

Courtney Lovely
Director of Quality and Patient Safety
Phone: (207) 626-1830
Email: courtney.lovely@mainegeneral.org

Margaret Naas
AD/Chief Compliance Officer
Phone: (207) 626-4103
Email: mnaas@mainegeneral.org

MGMC monitors clinical services that are provided via contracts. At least annually MGMC evaluates the performance of vendors providing clinical services and reports those results to the Board of Directors.

Thank you for your efforts to meet regulatory requirements as you provide services to MGMC and our patients.

Sincerely,

A handwritten signature in black ink that reads "Margaret D. Naas". The signature is written in a cursive style.

Margaret D. Naas, MEd, MT(ASCP), CHC
Administrative Director / Chief Compliance Officer
MaineGeneral Health

Quality of Service / Patient Safety

These apply to ALL clinical contracts/companies.

Hospital licensing and accreditation regulations require that you meet the following performance expectations (as applicable):

- Your company will comply with pertinent Maine, CMS or other licensing or accreditation standards. Proof of compliance may include copies of licenses, letters documenting good standing, etc.
- Your company will inform the MGMC Director of Patient Safety of any patient safety concerns, such as equipment failure, adverse patient events that affect patient care, etc. within 24-hours of the event. Reports must be made to Quality and Risk Reporting: Quality&RiskReporting@mainegeneral.org
- Your company will work with MGMC to respond to patient complaints within two (2) business days of being notified of the complaint.
- If your company receives a complaint involving a MGMC patient, your company will contact MGMC Patient Advocacy Team at (207) 248-5290 or patient.advocacy@mainegeneral.org.
- Your company's contracted personnel will actively participate in root-cause-analyses (RCAs) and other event reviews that involve your personnel or equipment when requested by MGMC.
- **JOINT RESPONSIBILITY:** MaineGeneral and your company will identify quality indicators that are pertinent to the contracted services (e.g. timeliness of service, patient complaints, patient perception of services, patient safety events, etc.) during the contract acquisition phase and as needed for ongoing Quality Assurance/Performance Improvement.

Equipment

These expectations apply to all contracts/companies providing equipment used for patient care at MGMC.

- Your company will maintain an inventory log of all medical equipment.
- Your company will identify equipment that poses a high risk of injury or death to patients or staff members in the event of equipment-failure.
- Prior to patient use, your company will perform safety, operational and functional checks before initial use and after major repairs or upgrades of medical equipment.
- Your company will perform routine inspection, service and maintenance activities in accordance with equipment manufacturer's recommendations and regulatory requirements for all contracted equipment and provide MGMC with a copy of these records as available or as requested.
- Your company will store contracted equipment, devices and supplies per manufacturer's guidelines.
- Your company staff will operate and clean equipment and related supplies per the Manufacturer's Instructions for Use (IFUs).
- Your company will dispose of equipment and disposable supplies per OSHA, EPA, DPA, applicable environmental guidelines, and manufacturer's IFU guidelines.
- Your company will train staff that operate equipment about the purpose, importance and proper operation of the alarm systems. Your company will maintain documentation of training provided to staff.

Personnel

These apply to all contracts/companies providing personnel that perform direct patient care services at MGMC.

- Your company performs **Primary Source Verification** of all licensed and certified contracted personnel at the time of hire and prior to expiration of the credential.
 - **License and Certification Verification:** Credentials of staff providing services via the contract must have their credentials verified using primary source when licensure, certification, **or** registration is required by

law and regulations.

- **Definition of Primary Source Verification:** Verification of an individual's reported qualifications by the original source (ex. Board of Licensure, etc.) should include the expiration date of the license /certification. Acceptable documentation of the verification includes a printed copy that indicates the date of printing. The date of printing must be on or prior to date of hire and/or prior to the expiration date of the license/certification to show that there was no lapse. Certification cards should be copied (front and back).
- If there is a lapse in licensure or certification, for any reason, the individual cannot provide services at MGMC during the lapsed time period. Your company is responsible for notifying MGMC of the lapse prior to or on the day of the expiration of the license and/or certification.
- Your company performs verification and documentation of required education and experience via an original document of a diploma/transcript, background check, or reference check by a third party vendor.
- Your company obtains a documented criminal background check on the contracted personnel providing services.
- Background check components include national & county criminal background, detailed social security address check, GSA/SAM, OIG, State Sex Offender, and National Sex Offender. Background checks should be completed at the time of hire and repeated as required by State of Maine Law. Your company will review and maintain the results of the background checks and notify MGMC Human Resources Department of any concerning findings as outlined by the Maine Background Check Center Rules and Statute. Contracted personnel with adverse background checks will not be permitted to provide services at MGMC.
- Your company will maintain validated proof of immunizations of Measles, Mumps, Rubella, Hepatitis B, Varicella, Tuberculin testing, and the current year's seasonal influenza vaccination or declination form for all contracted staff. Your company will review and maintain the immunization data. Your company will notify MGMC of any contracted personnel without proper immunization status so applicable MGMC Employee Health and Infection Control policies can be followed.
- MGMC will provide initial general orientation / annual education about MGMC. Your employees must complete this orientation prior to providing care, treatment, and services to MGMC patients. Completion of the orientation and training must be documented. Documentation of staff orientation and education will be provided within 24 hours of request by MGMC.
- Your company will provide your staff with ongoing education and training related to the provision of the contracted services. Your company will maintain records of this education and training.
- Your company will assess your staff for competency to perform their responsibilities. MGMC may assess contracted employees for any high risk/low frequency skills they determine to be appropriate. Competency assessments will be performed only by individuals with the educational background, experience, or knowledge related to the skills/tasks being reviewed. Ongoing competencies will be assessed **at least every three years**.
- The vendor's contracted personnel providing services at MGMC will comply with MGH Policies and Procedures. This includes Infection Control Policies such as IC-23 "*Guidelines for the Management of Health Care Providers During Influenza Season*" which requires MGMC staff, including contracted personnel, to wear a procedural/surgical mask during the flu season if they are unable to receive or refuse the annual flu vaccination.
- Your company will provide a list of their employees that provide contracted services at MGMC. This list will be provided at the agreed upon frequency. Your company will notify MGMC of changes in employment status (termination/separation) of their employees providing contracted services at MGMC. If applicable, your company will ensure that MGMC badges are deactivated by MGMC Security and when possible returned.