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Contact C&A for more information: Phone (704) 573-4535 or [www.courtemanche-assocs.com](http://www.courtemanche-assocs.com).

**Senior  
Consultant,  
Charles Milano,  
M.D., J.D.**

For your Medical Staff consulting needs, contact C&A for more information about an onsite consultation with Senior Consultant, Dr. Charles Milano.

**What's New with MS.01.01.01?**

**By: Charles Milano, MD, JD  
Judy Courtemanche, MS, RN  
Sharon Dills, MSN**

**The Background**

The requirements related to medical staff bylaws, MS.01.01.01, formerly MS.1.20, under review by The Joint Commission's (TJC) task force since 2007, have been the topic of much discussion and controversy for healthcare associations and hospitals alike. Although TJC has had medical staff bylaws requirements for many decades, the new release garnered additional attention related to the degree of detail on administrative procedures needed in the bylaws. Concerns arose about the cost and time burden associated with changing bylaws; the potential for disrupting relationships between the medical staff and governing body; and the role of the medical executive committee. The TJC task force heard the concerns and made changes to the requirements, requested several additional field reviews and recently published the final version approved by TJC Board of Commissioners. The changes to the standard are effective on March 31, 2011.

The medical staff, comprised of doctors of medicine and osteopathy and which may include doctors of dental medicine and surgery, podiatry, optometry and chiropractic medicine, is organized as a self-governing body that assures the oversight of its membership in maintaining the quality of patient care. The medical staff bylaws serve as the legal framework for the organization of the medical staff, defining its authority, responsibility and purpose.

The medical staff bylaws also define the governance structure of the medical staff, its committees and decision power, as well as the roles and responsibilities of the officers of the medical staff, the medical executive committee members, and other required medical staff committees. Key in the decision structure is the medical executive committee. This committee plays an essential role in the relationship between the medical staff and the governing body. The medical executive committee approves policies and procedures for patient care, sets standards for physician performance, reviews and recommends applicants to the medical staff, and recommends practitioners for membership and privileges in the organization.

The medical staff's oversight responsibility includes assuring the ongoing performance of its members by reviewing and verifying credentials and performance for requested privileges. Upon their recommendation, prospective providers are presented to the governing body for final approval.

[Click here](#) to read Dr. Milano's bio on the C&A web site.

## Thanks for Your Feedback!

You spoke up and C&A listened

Thank you to everyone who participated in our recent survey regarding C&A's 2011 TJC & CMS Webinar series. We are analyzing your feedback and are planning our upcoming webinar series to better meet your needs. Join us in 2011 to see how your suggestions impacted our webinar offerings for the coming year.

Stay tuned to the C&A newsletter for more information. Specific topics and registration will be available soon.

### New Expectations for 2011

The revised MS.01.01.01 includes new expectations that allow more flexibility for governing bodies and medical staffs to determine what will be placed in the medical staff bylaws and what will be placed in other documents. The changes that are effective March 31, 2011 are as follows:

- Details for the required elements may be documented in the medical staff bylaws, rules and regulations, or policies.
  - The organized medical staff adopts what constitutes the associated details, where they reside, and whether their adoption can be delegated.
  - This means that, except where specifically required, the medical staff determines if it should be addressed in bylaws, rules, regulations or a policy.
    - An example of a requirement that must be addressed in the bylaws is history and physical (H&P) requirements. It is no longer acceptable to have the H&P defined in policy and/or rules and regulations.
- The organized medical staff (OMS) has the ability to adopt medical staff bylaws, rules and regulations, policies, and amendments thereto, and to propose them directly to the governing body.
  - This is different because the standard now states the OMS can directly propose medical staff documents to the governing board if they follow procedure.
- If the voting members of the OMS propose to adopt a rule, regulation, or policy, or an amendment thereto, they first communicate the proposal to the medical executive committee.
  - If the medical executive committee proposes to adopt a rule or regulation, or an amendment thereto, it first communicates the proposal to the medical staff. When it adopts a policy or an amendment thereto, it communicates this to the medical staff.
  - This is new in that the standard now spells out the procedure for the above proposal of medical staff documents: OMS must first communicate with medical executive committee.
- The organized medical staff has a process which is implemented to manage conflict between the medical staff and the medical executive committee on issues including, but not limited to, proposals to adopt a rule, regulation, or policy or an amendment thereto.
  - Now the bylaws must state specifically the conflict resolution process required for conflict between the OMS and the medical executive committee.
- In cases of a documented need for an urgent amendment to the rules and regulations necessary to comply with law or regulation, there is a process by which the medical executive committee, if delegated to do so by the voting members of the OMS, may provisionally adopt and the governing body may provisionally approve an urgent amendment without prior notification of the medical staff.

- This facilitates quick action when needed for an urgent amendment process to medical staff rules and regulations required, exempting prior medical staff notification.
- There must be a description of the medical staff members who are eligible to vote
  - This description must be clearly defined in the bylaws, to clarify which medical staff members are eligible to vote. For example, honorary or emeritus members often cannot vote, but this must be explicit in the bylaws.
- There must be a list of all officer positions for the medical staff
  - The list of officers must now be listed and defined in the bylaws.
- There must be a process for adopting and amending bylaws and rules and regulations
  - As of March 31st, 2011, the process for the adoption or amendment of the medical staff bylaws and rules and regulations must be written in the bylaws

Although these changes do not go into effect until March 31, 2011, it is advised that organizations immediately begin working on these changes. It is also important to ensure that the medical staff, medical executive committee and governing board receive education to assure understanding and time to assure compliance.

This is not meant as legal advice. As always, an organization should consult the TJC web site for specific verbiage and consult with legal counsel before making changes. For more detailed information related to MS.01.01.01 please contact us at [Info@courtemanche-assocs.com](mailto:Info@courtemanche-assocs.com) or call us at 704-573-4535.

## Confused About Clinical Contract Requirements?

### End the confusion - Read on!

**By: Jill Ryan and Sharon Dills, RN, MSN**

Healthcare organizations are responsible for all care and services provided to patients in their care. This holds true even if the service is provided through a contractual arrangement. Historically, organizations have struggled with how to manage contracts for clinical services, what is required for those arrangements and how to monitor and evaluate those services.

Let's take the mystery out of clinical contracts! Leadership is responsible for the care, treatment and services provided in the healthcare organization and, therefore, must oversee the contracting process. Here's what is required for *clinical* contracts under The Joint Commission *Leadership* standards:

- Clinical contracts must be defined in writing and describe the nature and scope of the services to be provided. The contract should outline what services will be included and if there are any specific parameters or limitations to the services provided.

- Clinical and medical staff leaders must have input into contracts for clinical services. This can happen through the medical staff department and committee structure.
- Leadership must approve contracts. Approval should occur in accordance with governing body requirements and organizational policy.
- Performance expectations are defined in writing. This can either be within the contract or as an addendum to the contract. Performance expectations should be specific to the type of service being provided. For example, performance expectations for the provider of acute dialysis services might include:
  - Providing data on water testing quarterly to the Infection Control Committee
  - Supplying a minimum of two RNs per shift with appropriate credentials & certifications
  - Following all TJC and CMS regulatory standards as well as abiding by Association for the Advancement of Medical Instrumentation (AAMI) standards
- Leaders monitor and evaluate contracted clinical services against the identified performance expectations. This evaluation should include appropriate clinical and medical staff involvement and should be done on an ongoing basis, but at least annually.
- Action must be taken to improve services that do not meet expectations. For example, if a clinical outcome target is not being met for patients cared for under the contract, education for practitioners might be required and increased monitoring of performance might be warranted. Such activities might be evidenced in meeting minutes, written communications to the contractor, etc.
- The organization must assure the continuation of clinical services during contract negotiation and transition periods. If the negotiation period will extend beyond the expiration of the current contract, arrangements must be made for the provision of those services so as not to negatively affect patient care. This should be evidenced in communications between the healthcare organization and the contractor or interim contractor.
- Hospitals using TJC accreditation for CMS deemed status must credential any licensed independent practitioners providing services either onsite or via telemedicine.
- Contracted laboratory services must meet federal regulations and provide the organization with evidence of such licensure and/or certification. The lab plays a very important role in every organization and in providing patient care. In addition to assuring that someone is assigned responsibility for reviewing the lab contracts, including that for the Blood Bank, for all elements listed above.

The type of clinical contracts we most frequently see are for hospital-based physician services such as emergency medicine, radiology, anesthesiology and pathology, and specialized services such as dialysis, lithotripsy and chemotherapy, to name a few.

To be sure your process for maintaining, monitoring and evaluating care provided to patients through contracted services is evident to accrediting and regulatory agencies, be sure the following documentation is available:

- Current contracts for clinical services approved by the appropriate leaders
- Defined performance expectations, communicated to the contractor in writing, specific to the services provided
- Evidence that reference and contracted laboratories meet federal requirements

While those are the identified documentation requirements, organizations should also be able to evidence, via minutes, memoranda and other communication, the involvement of clinical and medical staff

in the contracting and evaluation of clinical services.

The assurance of quality, safe patient care is the ultimate responsibility of the governing body. Understanding the requirements and having consistent processes in place to guide the contracting process will assure that care.

To access tools to assist in meeting the expectations defined here, please visit <http://courtemanche-assocs.com/freeLibrary.aspx> to sign up for a free account to access this library of tools.



## Were You Aware?

1. During survey activity, organizations are held to the highest of the following – Joint Commission standards, CMS requirements, State Department of Health regulations OR organizational policy and procedure. Be thoughtful when creating policies that are more restrictive or stringent than accreditation standards or regulatory requirements.

2. The World Health Organization (WHO) has declared that the H1N1 influenza has transitioned into the post-pandemic period. In its briefing note, WHO notes that the virus will continue as a seasonal virus for years to come, but that the intense period of concern is diminished. Visit [www.who.int](http://www.who.int) for more information.

3. COLA (formerly the Commission on Office of Laboratory Accreditation) has voluntarily withdrawn from accrediting organizations in the specialty of Pathology. This withdrawal is limited to Pathology and COLA may continue to accredit laboratories for other specialties (and associated subspecialties) including microbiology, diagnostic immunology, chemistry, hematology and immunochemistry. Organizations currently accredited by COLA for pathology services have 60 days from August 11, 2010, the date this notice was posted in the Federal Register, to

seek CLIA (Clinical Laboratory Improvement Amendments program) from their state agency or another CMS-approved accrediting organization. See the Federal Register, Vol.75, No. 154, August 11, 2010, page 48698, for more information.

4. CMS has adopted revisions to clarify who can prescribe orders for rehabilitation (Section 482.56) and respiratory (Section 482.57) services. The revisions, outlined in Federal Register, Vol. 75, No. 85, May 4, 2010, page 24050 and approved in Federal Register, Vol. 75, No. 157, August 16, 2010, page 50041, require that:

- Orders for REHABILITATION SERVICES are to be limited to qualified, licensed practitioners who are responsible for the care of the patient, are acting within their state scope of practice, are authorized to do so by the medical staff, and the hospital's policies and procedures.
- Orders for RESPIRATORY SERVICES may be provided by licensed practitioners, including nurse practitioners and physician assistants, provided that such privileges to order respiratory services are authorized by the medical staff and are in accordance with hospital policy, state laws and scope of practice requirements.  
It is anticipated that further clarification and survey guidance will be provided by CMS in the coming months.