

## Bagby, Tammy (LARA)

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**From:** Cara.Jansma@spectrumhealth.org  
**Sent:** Friday, June 7, 2019 1:21 PM  
**To:** LARA-BCHS-Training  
**Cc:** Carrie.Miedema@spectrumhealth.org  
**Subject:** Comments to Proposed Licensing Rules

To Whom It May Concern,

Please consider the following comments as you finalize your health facility licensing rules.

### 1. Rule 325.45105(a) Governing Body

One area of potential concern for large health systems with many hospitals and chain operations is the definition of “governing body”:

- (a) “Governing body” means any one of the following:
  - (i) The policy making body or director of a health facility or agency that is a governmental entity.
  - (ii) The board of directors or trustees of a health facility or agency that is a not-for-profit corporation.
  - (iii) The board of directors of a health facility or agency that is a business corporation.
  - (iv) The proprietor or owners of a health facility or agency that is a solely owned business or partnership.

This definition assumes that a health facility or agency equals a government entity, nonprofit corp, or business corp. In most cases, a licensed hospital and its certified operations are one business unit within a larger health system that has multiple facilities and agencies. The corporation itself is organized to own and operate hospital and other facilities and agencies. It is not the equivalent of the hospital, it is the business entity that owns the hospital. A *corporation* has a board of trustees, but may have various “governing boards” for its health facilities. They are not necessarily one in the same. This will result in significant disruption to existing governance structures i given the policy oversight requirements of boards contained in these regulations.

Please consider adopting CMS description of “governing body” and allow health facilities discretion on appointment of governing bodies.

Also, the reference to the “governing body’s chief executive officer” is confusing, it should be the health facility or agency’s chief executive officer. (See R 325.45105(d)).

### 2. Rule 325.45171 – Administrator

“Shall designate an individual to serve as an administrator”.. Could you please clarify that this is the same as the Medicare requirement that the governing body must appoint a chief executive officer that is responsible for managing the hospital and distinguish from the nursing home administrator, which may not be the equivalent of the chief executive?

The “delegate in writing” may be overly burdensome for a CEO on the day-to-day aspect, unless it is the intent to have a chief executive and an administrator. If a surveyor comes to a facility and the administrator is not there, are they going to look for written delegation by the administrator to the executive on call? Could having a scheduled “executive on call” be sufficient to meet this requirement when the administrator/CEO is unavailable?

**3. Rule 325.172 - Medical Director**

This doesn't fit well with hospitals who have elected medical staffs who are responsible for oversight of the medical care provided in a hospital. No medical director of a hospital would be authorized to *direct care* because of the medical staff structure and the requirement that it be self-governing. This requirement should be specific to other facilities that are not required to have an organized medical staff.

**4. Rule 325.173 - Director of Nursing**

For rural hospitals, this role should be able to be shared with the administrator/CEO.

**5. Rule 325.199 –Orders**

Subsection (3) Requires licensed health professionals to record an order. Medicare and TJC allow hospitals to specify who is qualified to record a verbal order. For example, in the case of a radiology order, a policy could permit a radiology tech to transcribe a verbal order by a physician.

**6. Rule 325.45201 – Administrative Record**

If there is a requirement for hospitals to maintain incident and accident reports, it needs to specify scope of report. Otherwise, current hospital peer review practices will be subject to disclosure. The confidentiality language is insufficient to assert peer review protection under existing case law and may require significant effort by hospitals to establish duplicate systems for peer review protection and to separately meet these regulatory requirements for incident and accident reports. We need specific confidentiality language to protect these reports as privileged and not subject to subpoena in private litigation. Not sure whether this is within LARA's authority.

Likewise, unlike other licensed providers, there is no "form" for an Incident/Accident report for hospitals.

Any reference to Incident and Accident reports should be limited to Nursing Homes.

**7. Rule 325.45205 – Survey Records**

Are there sufficient protections for personal and sensitive info under FOIA? Should specific language state "and not subject to FOIA" rather than "to the extent permitted by law"?

**8. Rule 325.45213 – Radiological services**

(5) The health facility or agency shall immediately report any adverse testing or machine error or adverse patient reaction to the appropriate licensed health care professional as soon as possible and record this information in the patient's record. Any corrective action must be initiated promptly and recorded in the patient's record.

Standard of care should dictate documentation that goes in the patient record. "Adverse testing, machine error, or adverse patient reaction" all could be inconsequential and this level of response may not be necessary. If it is material, any investigation and corrective action is not appropriate for documentation in the patient's record. Instead, a requirement for facility investigation and corrective action alone should be sufficient. Facilities should be able to demonstrate to surveyors our process for investigation and corrective action.

Thank you for your work on this initiative.

Sincerely,

**Cara L. Jansma**  
Deputy General Counsel  
Spectrum Health  
Legal Department, MC 05

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Grand Rapids, MI 49503  
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## Bagby, Tammy (LARA)

**From:** Andrew Gwinnell <AGwinnell@truvistasurgerycenter.com>  
**Sent:** Friday, June 7, 2019 1:51 PM  
**To:** LARA-BCHS-Training  
**Subject:** Public Comments - regarding Licensing Health Care facilities

This message was sent securely using ZixCorp.

Good afternoon-

Please see our rule set comments on behalf of Michigan Ambulatory Surgical Association (MASA):

-R325.45103 Definitions A to F Rule 103 (1) (I) Business day means a day other than Saturday, Sunday or any legal holiday.

\*Many surgery centers do not operate on a Monday-Friday schedule. Normal operating days can vary greatly depending on the type and location of surgery center. Standards and definitions dependent on a standardized business day definition will be problematic for surgery centers with limited operating days and hours. We would ask that a business day be defined by the operating organization.

-R325.45137 (a) An active surveillance program for infection prevention detection through ongoing data collection and analysis that includes patients, personnel, including onsite contract workers who have access to contact with active patient care areas.

\* We are concerned that gathering information and data could be overly burdensome and problematic on contractors that have very limited access to patient care areas. Many surgery centers will contract or bid with service personnel whom may only visit a site for minutes and often very sporadically. Although they technically have access to patient sites, their risk exposure is extremely limited. What kind of data collection and analysis is expected and will it be overly burdensome to comply?

-R325.45157 (2) "...This requirement may be fulfilled by participating in 1 or more community-based exercises, facility-based, or by activating its emergency plan in response to one or more actual incidents."

\*CMS is reportedly considering dropping the "community-based exercises" for surgery centers because it is often that surgery centers would not be a part of a community disaster plan. Surgery Centers would likely close and not have services available in the event of a community disaster. We want to be sure that 'community-based exercises' are an option not a requirement.

-R325.45183 Employee Records (d) "Results of baseline screening for communicable diseases"

\*Will the state define what communicable diseases will be required for screening and retention? Is this decision left to the individual surgery center?

-R325.45183 Employee Records (e) "For former employees, the date employment ceased"

\*Is that determined by the last day the employee worked or the day the facility last had the employee active in personnel files? With contingent (per-diem) employees the date can vary by a couple months.

-R325.45277 (d) (ii) ...Two scrub positions with gooseneck outlets must be provided near the entrance of each operating room.

\*The dependence on scrub sinks has been reduced since the introduction of alcohol based scrubs. Is it necessary to have 2 scrub sinks for each OR or can that number be reduced?

-R325.45279 (Rule279) A facility that provides surgical services must have patient observation and recovery areas in sufficient numbers to accommodate the patient load with a planned minimum 3-hour recovery and longer when necessary for individual patients.

\*The planned minimum recovery time should be left to a facilities risk assessment based on the type of procedure, the patient and the anesthesia chosen. Surgery centers perform a wide variety of procedures many with local sedation that would not warrant a planned 3- hour stay.

-R325.45295 (Rule 295) (3) “...Individual dressing rooms must be provided for male and female employees...”

\*Some surgery centers are one rom ORs with a one room dressing area. Can that that serve both female and male without the need to build a second dressing room?

-R325.45107 Definitions; M to R MCL333.21703(2) Physician mean an individual licensed to engage in practice of medicine or the practice of osteopathic medicine and surgery under part 170 or 175 of the code,...

\*The CMS definition of physicians includes doctors of dental surgery or dental medicine and doctors of podiatric medicine. With respect to surgery centers we would ask the they be included in the state’s definition to match the CMS definition.

***§416.42 Condition for Coverage: Surgical Services***

***Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.***

**Interpretive Guidelines: §416.42**

**Qualified Physician:** Surgery in an ASC may only be performed by a qualified physician. With respect to ASCs, a physician is defined in accordance with §1861(r) of the Social Security Act to include a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, and a doctor of podiatric medicine. In all cases, the physician must be licensed in the State in which the ASC is located and practicing within the scope of his/her license.

**§416.45(c) Standard: Other Practitioners**

**If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities. Interpretive Guidelines: §416.45(c)**

Patient care responsibilities (which may or may not include formal medical staff privileges, but excluding nursing care services) may be assigned to licensed practitioners not meeting the definition of physician in §1861(r) of the Act. “Physician” is defined in §1861(r) of the Social Security Act as:

- Doctor of medicine or osteopathy;
- Doctor of dental surgery or of dental medicine;
- Doctor of podiatric medicine;

Please feel free to contact me using the information below if needed.

Best,  
Andrew

Andrew Gwinnell, MHSA, CASC  
Executive Director  
Truvista Surgery Center  
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## Bagby, Tammy (LARA)

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**From:** Krzanowski, Karen (LARA)  
**Sent:** Thursday, June 6, 2019 3:06 PM  
**To:** Bagby, Tammy (LARA)  
**Subject:** FW: health facility rules

Tammy, here are the comments that Karen Cafeo, of Angela Hospice, submitted to me today.

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**From:** Karen Cafeo <kcafeo@angelahospice.us>  
**Sent:** Thursday, June 6, 2019 11:51 AM  
**To:** Krzanowski, Karen (LARA) <KrzanowskiK@michigan.gov>  
**Subject:** RE: health facility rules

Thank you!

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**From:** Krzanowski, Karen (LARA) [mailto:KrzanowskiK@michigan.gov]  
**Sent:** Thursday, June 06, 2019 11:41 AM  
**To:** Karen Cafeo  
**Subject:** RE: health facility rules

Karen,  
Thank you for submitting these written comments. We will certainly take them into consideration, along with other comments, before finalizing the rules.

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**From:** Karen Cafeo <kcafeo@angelahospice.us>  
**Sent:** Thursday, June 6, 2019 11:34 AM  
**To:** Krzanowski, Karen (LARA) <KrzanowskiK@michigan.gov>  
**Subject:** health facility rules  
**Importance:** High

Hello Karen

There is a new concern with the rules as written re: Infection control and TB testing. I know it is late, but these were just released. Can this reference be added and the testing by risk categories be removed?

CDC and the National TB Controllers Association released [updated recommendations](#) for TB screening, testing, and treatment of health care personnel on May 17, 2019. These recommendations update the health care personnel screening and testing section of the 2005 CDC [Guidelines for Preventing the Transmission of \*Mycobacterium tuberculosis\* in Health-Care Settings](#). CDC has developed [supporting resources](#) and tools including: [Frequently Asked Questions](#) and a [Baseline Individual TB Risk Assessment Form](#)

Here's the reader's digest version.

1) TB screening with an individual risk assessment and symptom evaluation at baseline (preplacement);

- 2) TB testing with an interferon-gamma release assay (IGRA) or a tuberculin skin test (TST) for persons without documented prior TB disease or latent TB infection (LTBI);
- 3) no routine serial TB testing at any interval after baseline in the absence of a known exposure or ongoing transmission;
- 4) encouragement of treatment for all health care personnel with untreated LTBI, unless treatment is contraindicated;
- 5) annual symptom screening for health care personnel with untreated LTBI; and
- 6) annual TB education of all health care personnel.

We also will need some clarification on the rules re: immunizations in the proposed rules. Not sure if these are recommendations or mandates. (specifically testing all pre hires for Hep B, MMR, chickenpox, etc.)

Thank you Karen,

Karen Cafeo, BSN, RN, CHPN, CPHQ  
Director of Quality



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## Bagby, Tammy (LARA)

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**From:** Salli Pung <spung@meji.org>  
**Sent:** Thursday, June 6, 2019 5:15 PM  
**To:** LARA-BCHS-Training  
**Subject:** Administrative Rules for Health Facilities or Agencies - Comment

Good Afternoon,

Congratulations to the department on the great job you did in updating the administrative rules and combining so many sets into one. I only have one small comment to share. One page 54, under Rule 385 (2) there is a reference to MAHS. Perhaps you already have plans to update this to MOAHR.

Again, congratulations on this huge accomplishment and thank you for allowing the Michigan LTC Ombudsman Program to be part of this process.

Salli

Salli Pung, State Long Term Care Ombudsman  
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