

EXHIBIT G

DEPARTMENT OF HEALTH, HEALTH FACILITIES SERVICES

SUBJECT: Critical Access Hospitals in Arkansas

DESCRIPTION: This is a general update to the 2008 critical access hospital rules. Major changes include updating and adding definitions; updating nutrition section; enhancing disaster planning/preparedness and infection control measures; specifying equipment and protocols in emergency departments and elsewhere; clarifying authority and timeliness for orders and authentications; reflecting transferred authority for office-based surgeries to Arkansas State Medical Board; and changing in documentation and authentication of different types of records.

The changes follow:

Section 3, Definitions

1. Remove non-hospital Alcohol/Drug Abuse Inpatient Treatment Centers.
2. Define "basic hospital services.
3. Clarify emergency services facility definition.
4. Change the definition of "institution" due to statutory changes.
5. Delete obsolete terms "maternity and general medical care hospital" and "maternity hospital.
6. Define "off campus emergency department."
7. Correct Outpatient Psychiatric Center hours from 4 to 8 to comply with statute.
8. Correct Outpatient Surgery Center" to comply with statute.
9. Clarify "Rehabilitation Facility" to "Rehab. Hospital or Facility."

Section 4, Licensure and Codes

1. Change to exact statutory language.
2. Add basic services requirement.

Section 6, Medical Staff

1. Change to physician or surgeon.
2. Extend reporting note for loss of privileges to non-physicians.
3. Adopt nationally recognized protocols for ER.
4. Specify components of discharge plan.

Section 7, General Administration

1. Risk-specific disaster planning with considering area, patient volume, transfers, 72 hours supplies, communications, and AWIN training; may be part of community wide drills.

Section 9, Administration Reports

1. Bed availability reporting (disaster).

Section 11, Patient Care Services

1. Simplify and standardize documentation for in-service education requirement throughout.

Section 13, Restraint

1. Permit credentialed non-physicians to order restraint.

Section 14, Health Information Services

1. Specify educational requirement for records directors applies only to hospitals.
2. Authenticate HPE and discharge summary by attending or treating physician.
3. Order authentication and signature in timely manner instead of 96 hours.
4. Authenticate HPE and discharge summary by attending or treating physician.
5. Add physician or surgeon.
6. Refer specific newborn screening requirements to the Newborn Testing Rules.

Section 17, Food and Nutrition Services

1. Authorize food services contracting by hospitals located within hospitals.
2. Provide for patient diet order by dietitians.
3. Correct citation to Retail Food Establishment Rules.
4. Remove restrictions on foods served to non-patients in hospitals.
5. Reduce storage height from 12" to 6".
6. Update terminology and other changes.
7. Revise nutrition monitoring and evaluation requirements.

Section 18, Infection Prevention and Control

1. Update terminology/language throughout rules.
2. Require reporting to CMS.
3. Revise specific HAIs for risk assessment and surveillance.
4. Use national protocols for hand hygiene and respiratory protection.
5. Correct citation to NHSN.
6. Provide Infection Committee oversight of product selection.
7. Use national protocols for employee health.
8. Update TB screening options for healthcare workers.

Section 20, Radiological Services

1. Update dosimetry (exposure badges) requirements to reflect *Rules and Regulations for Control of Sources of Ionizing Radiation, Rh-7055(a)*.

2. Dual image viewing capacity in OR, ER, and Radiology.
3. Maintain capability for viewing films.

Section 25, Pet Therapy Program

1. Add term “zoonotic” for veterinary certification.

Section 30, Labor, Delivery, LDR, LDRP, PP, and Maternal Child Education

1. Add cite for required car seat safety education.
2. Add statutory requirements for shaken baby information distribution by hospital.

Section 34, Central Sterilization and Supply

1. Update terminology “flash” or “immediate use” sterilization.
2. Change allowable shelf life of sterile peel-packs from “indefinite” to “event-related.”
3. Qualify temperature and humidity settings.

Section 35, Respiratory Care

1. De-specify signage.
2. Insert citation for ventilation rates based upon non-smoking facilities.

Section 36, Emergency Services

1. Exempt prison hospitals from dedicated emergency department requirement.
2. Specify ER protocols to be nationally recognized.
3. Specify ER equipment requirements.
4. Specify imaging and lab availability 24/7.
5. Allow treatment and disposition of non-emergent patients by credentialed individuals.
6. Require ACLS or PALS nurse in house.
7. Add provisions for off-campus emergency departments operated by parent hospitals.

Section 39, Ambulatory Surgery Centers

1. Return definition to statutory language and define “general and intravenous” anesthesia to include: deep sedation/analgesia and general anesthesia with definitions of each.
2. Update list of required sections that apply to ASCs.
3. Add option for inpatient transfer by assuring surgeon has admitting privileges at local hospital.

Section 45, Alcohol and Drug Abuse Inpatient Treatment Center

1. Removed non-applicable portions.

Tables

1. Table 10: Remove Table 10 Newborn Screening.
2. Table 3: Update temp and relative humidity requirements.
3. Broaden relative humidity range for OR, Delivery, Endoscopy and Bronchoscopy.
4. Table 5: Add architect/designer approval to final occupancy inspection checklist.

PUBLIC COMMENT: A public hearing was held on this rule on June 2, 2015. The public comment period expired June 2, 2015. The Department received the following public comments:

Harold Simpson, Attorney

COMMENT: Disagree with QMP definition.

RESPONSE: Removed QMP definition from the proposed changes.

David Wroten, Arkansas Medical Society

COMMENT: Disagree with QMP definition.

RESPONSE: Removed QMP definition from the proposed changes.

COMMENT: Need to address opioid use in emergency department.

RESPONSE: Agency is preparing revisions based on comment and Act 1208 of 2015 in next revision.

COMMENT: Changes in documentation and authentication of several types of records (orders, HPE, discharge summary)

RESPONSE: After full discussion and revisions, agency and commenters agreed with proposed language.

COMMENT: Emergency department screening, treatment, and disposition changes.

RESPONSE: After full discussion and revisions, agency and commenters agreed with proposed language.

Elise White, Arkansas Hospital Association

COMMENT: Disagree with QMP definition.

RESPONSE: Removed QMP definition from the proposed changes.

COMMENT: Eliminate requirement for telephone order authentication within 96 hours.

RESPONSE: Agency agrees. Included suggested revisions in proposed rule.

COMMENT: Changes in documentation and authentication of several types of records (orders, HPE, discharge summary)

RESPONSE: After full discussion and revisions, agency and commenters agreed with proposed language.

COMMENT: Emergency department screening, treatment, and disposition changes.

RESPONSE: After full discussion and revisions, agency and commenters agreed with proposed language.

COMMENT: Physical facility standards—should adopt FGI guidelines.

RESPONSE: Agency is favorable. Workgroup is in process.

Rhonda Finnie, Arkansas Nurses Association

COMMENT: Requests adding “collaborative” language to definition of QMP.

RESPONSE: Removed QMP definition from the proposed changes.

COMMENT: Recommends comprehensive additions of “QMP” throughout rules

RESPONSE: Removed QMP definition from the proposed changes.

Sherry Oldner, Dewitt CNO

COMMENT: Requests mechanical ventilator requirement be removed for rural hospitals.

RESPONSE: Revised standard to mirror trauma system Level IV (lowest) hospital requirements.

Rebekah Stark & Michelle Justus, Arkansas Academy of Nutrition and Dietetics

COMMENT: General update of nutrition section language.

RESPONSE: Agency agrees. Included most changes in draft.

Linda Means, Registered Dietician, Baptist Health

COMMENT: General update of nutrition section language.

RESPONSE: Agency agrees. Included most changes in draft.

Rose Hoenig, Registered Dietician, Hot Springs, AR

COMMENT: General update of nutrition section language.

RESPONSE: Agency agrees. Included most changes in draft.

Erin Moore, Arkansas Academy of Nutrition and Dietetics

COMMENT: General update of nutrition section language.

RESPONSE: Agency agrees. Included most changes in draft.

COMMENT: Risk & condition-based assessments instead of 72 hours.

RESPONSE: Agency agrees. Included suggested revisions in proposed rule.

Carol Wright, Arkansas Children's Hospital

COMMENT: Eliminate requirement for telephone order authentication within 96 hours.

RESPONSE: Agency agrees. Included suggested revisions in proposed rule.

Bill Tarpley, Arkansas Dental Association

COMMENT: Add wording . . . physicians or surgeons to allow for dental surgery admissions.

RESPONSE: Agency agrees. Included suggested revisions in proposed rule.

COMMENT: Changes in documentation and authentication of several types of records (orders, HPE, discharge summary)

RESPONSE: After full discussion and revisions, agency and commenters agreed with proposed language.

COMMENT: Emergency department screening, treatment, and disposition changes.

RESPONSE: After full discussion and revisions, agency and commenters agreed with proposed language.

Karen Blankenship, Mercy

COMMENT: Multiple comments & suggestions for additional changes (many accreditation compatible suggestions).

RESPONSE: Agency is satisfied with existing language at present; however, has placed comments in queue for thorough consideration during next revision.

Cheryl Yokey, Sparks

COMMENT: Typographical error in rule identified.

RESPONSE: Changed.

Elizabeth Dove, Arkansas Children's Hospital

COMMENT: Infection control—recommends event-related protocol for re-sterilizing wrapped instruments.

RESPONSE: Agency agrees. Included suggested revisions in proposed rule.

Association for Professionals in Infection Control and Epidemiology

COMMENT: Infection control—multiple updates throughout § 18.

RESPONSE: Agency agrees. Included suggested revisions in proposal.

Bo Ryall, Arkansas Hospital Association

COMMENT: Physical facility standards—should adopt FGI guidelines.

RESPONSE: Agency is favorable. Workgroup is in process.

Brian Cotton

COMMENT: Physical facility standards—should adopt FGI guidelines.

RESPONSE: Agency is favorable. Workgroup is in process.

Association of periOperative Registered Nurses, Colorado

COMMENT: Require an RN circulator in operating room.

RESPONSE: Agency is satisfied with existing language at present; however, has placed comments in queue for thorough consideration during next revision.

Isaac Linam, an attorney with the Bureau of Legislative Research, asked the following questions:

QUESTION #1: In Section 4, your summary of proposed changes states that the language was changed to exact statutory language. However, Section 4.A. does not reflect the corresponding statutory language found in § 20-9-213. Can you explain?

RESPONSE: Our apologies for the summary language stating “exact statutory language”, as that is not accurate. (revised summary attached)

What has been captured in the revision at 4-1 A is a combination of §20--9-213, §20-9-214 (list) and the RULES Section 3 Definitions . The revision was an endeavor to more clearly identify hospital and institution by naming each facility type.

QUESTION #2: In Section 39, I, is there a statutory basis for the inclusion of the “admitting privileges at a local hospital” requirement in lieu of an ASC having a written agreement with a local hospital or was this added under the general rulemaking authority granted the Department under Ark. Code Ann. § 20-9-205?

RESPONSE: This language is added under the general rulemaking authority, and this language mirrors CMS (Medicare) Conditions of Participation for Ambulatory Surgery Centers.

QUESTION #3: Why is Table 10 being removed?

RESPONSE: Rather than have a table , it was determined a better approach is to use the language on page 14-7 H.5, which directs the facility to the proper and current newborn testing information.

The proposed effective date for the final rule is January 1, 2016.

CONTROVERSY: In addition to patients, hospital rules directly impact physicians, nurses, dieticians, technicians, advanced practitioners, assistants, aides, and others. Changes affecting so many patient advocates are often controversial.

FINANCIAL IMPACT: There is no financial impact to the state, county, and municipal government to implement the rule. The cost per facility could be up to \$2,500. The cost per facility depends on present equipment and supplies. Most facilities are already compliant.

LEGAL AUTHORIZATION: Ark. Code Ann. § 20-7-109 authorizes the State Board of Health to promulgate rules for the “protection of the public health and safety”.

Ark. Code Ann. § 20-9-205 requires the Department of Health to promulgate rules to carry out the purposes of the Health Facilities Services subchapter, § 20-9-201 et seq. That subchapter sets minimum standards for hospitals and other facilities, including construction and licensure requirements.

**QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS
WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE**

DEPARTMENT/AGENCY Arkansas Department of Health
DIVISION Health Facility Services
DIVISION DIRECTOR Connie Melton, Section Chief
CONTACT PERSON Reginald Rogers, Deputy General Counsel
ADDRESS 4815 W. Markham St., Slot 31, Little Rock, AR 72205
PHONE NO. 501. 661.2609 FAX NO. 501.661.2357 E-MAIL reginald.rogers@arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING Connie Melton, Section Chief
PRESENTER E-MAIL connie.melton@arkansas.gov

INSTRUCTIONS

- A. Please make copies of this form for future use.
- B. Please answer each question completely using layman terms. You may use additional sheets, if necessary.
- C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
- D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

**Donna K. Davis
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201**

1. What is the short title of this rule? (1) Rules and Regulations for Hospitals and Related Institutions in Arkansas; and (2) Rules and Regulations for Critical Access Hospitals Arkansas;
2. What is the subject of the proposed rule? (1) licensing standards for hospitals and related institutions;
(2) licensing standards for critical access hospitals
3. Is this rule required to comply with a federal statute, rule, or regulation? Yes No
If yes, please provide the federal rule, regulation, and/or statute citation. _____
4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes No
If yes, what is the effective date of the emergency rule? _____

When does the emergency rule expire? _____

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes No

5. Is this a new rule? Yes No
If yes, please provide a brief summary explaining the regulation. _____

Does this repeal an existing rule? Yes No
If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does.

Is this an amendment to an existing rule? Yes No
If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. Ark. Code Ann. § 20-9-201 et seq.

7. What is the purpose of this proposed rule? Why is it necessary? This is a general update to the 2007 Hospital Rules and 2008 Critical Access Hospital Rules. Identical changes are proposed for both sets of rules. Major changes include: updating and adding definitions; enhancing disaster planning/preparedness and infection control measures; specifying equipment and protocols in Emergency Departments and elsewhere; clarifying authority for orders and authentications; reflecting transferred authority for office-based surgeries to Arkansas State Medical Board; and changes in documentation and authentication of different types of records. See attached summary for comprehensive outline of changes.

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b). www.healthy.arkansas.gov "rules and regs" link

9. Will a public hearing be held on this proposed rule? Yes No

If yes, please complete the following:

Date: December 2, 2014

Time: 10:00 am

Place: Room 801, Freeway Medical Tower,
5800 W. 10th St., Little Rock AR

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)

December 2, 2014 at 12:00 noon

11. What is the proposed effective date of this proposed rule? (Must provide a date.)

July 1, 2015

12. Do you expect this rule to be controversial? Yes No

If yes, please explain.

In addition to patients, hospital rules directly impact physicians, nurses, dieticians, technicians, advanced practitioners, assistants, aids, and others. Changes affecting so many patient advocates are often controversial.

13. Please give the names of persons, groups, or organizations that you expect to comment on these rules?
Please provide their position (for or against) if known.

unknown

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health
DIVISION Health Facility Services
PERSON COMPLETING THIS STATEMENT Connie Melton, MBA, FACHE, Section Chief
TELEPHONE NO. 501.661.2201 **FAX NO.** 501.661.2165 **EMAIL:** connie.melton@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE (1) Rules and Regulations for Hospitals and Related Institutions in Arkansas; and (2) Rules and Regulations for Critical Access Hospitals in Arkansas

1. Does this proposed, amended, or repealed rule have a financial impact? Yes No
2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule? Yes No
3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes No

If an agency is proposing a more costly rule, please state the following:

(a) How the additional benefits of the more costly rule justify its additional cost;

(b) The reason for adoption of the more costly rule;

(c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;

(d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

(a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____

Next Fiscal Year

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____

Total _____

Total _____

(b) What is the additional cost of the state rule?

Current Fiscal Year

Next Fiscal Year

General Revenue _____
 Federal Funds _____
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total _____

General Revenue _____
 Federal Funds _____
 Cash Funds _____
 Special Revenue _____
 Other (Identify) _____
 Total _____

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

Current Fiscal Year

Next Fiscal Year

\$ 0 to 2,500

\$ same

Cost per facility depends on present equipment and supplies. Most entities are already compliant.

6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year

Next Fiscal Year

\$ 0

\$ 0

No ascertainable additional cost.

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars (\$100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes No

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

- (1) a statement of the rule's basis and purpose;
- (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;
- (3) a description of the factual evidence that:
 - (a) justifies the agency's need for the proposed rule; and

- (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;
- (4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
 - (5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
 - (6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and
 - (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
 - (a) the rule is achieving the statutory objectives;
 - (b) the benefits of the rule continue to justify its costs; and
 - (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

Summary of Proposed Changes

- (1) Rules and Regulations for Hospitals and Related Institutions in Arkansas; and
- (2) Rules and Regulations for Critical Access Hospitals in Arkansas

| §3 Definitions |
|---|
| §3B Remove non-hospital Alcohol/Drug Abuse Inpatient Treatment Centers |
| §3C Define "Basic Hospital Services" required of all licensed hospitals |
| §3F clarify emergency services facility definition |
| §3(I) result of statutory changes in definition of "Institution" |
| §3(L&M) Delete obsolete terms "Maternity and General Medical Care Hospital" and "Maternity Hospital" |
| §3L Define "Off-campus Emergency Dept." |
| §3M Outpatient Psychiatric Center hours corrected from "4" to "8" – same as statute |
| §3N correct "Outpatient Surgery Center" to statutory definition |
| Clarified "Rehabilitation Facility" to "Rehab. Hospital or Facility" |
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| §4 Licensure and Codes |
| Changed to exact statutory language |
| Add basic services requirement |
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| <u>Physician or surgeon</u> |
| Extend reporting note for loss of privileges to non-physicians |
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| §7 General Administration |
| Risk-specific disaster planning with considering area, patient volume, transfers, 72 hours supplies, communications, and AWIN training. |
| May be part of community wide drills |
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| Simplify and standardize documentation for in-service education requirement throughout |
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| Permit credentialed non-physicians to order restraint |
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| Specify educational requirement for records directors applies only to Hospitals |
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| Refer specific newborn screening requirements to the Newborn Testing Rules. |
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| Update terminology "flash" OR "immediate use" sterilization |
| Change allowable shelf life of sterile peel-packs from "indefinite" to "event-related" |
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| De-specify signage |
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| Removed non-applicable portions |
| |

Tables

Table 10: Remove Table 10 Newborn Screening

Table 3: Updated Temp and relative humidity requirements, Broaden relative humidity range for OR, Delivery, Endoscopy & Bronchoscopy

Table 5: Add architect/designer approval to final occupancy inspection checklist.

