**John Bel Edwards**
GOVERNOR

**Rebekah E. Gee MD, MPH**
SECRETARY

# State of Louisiana

Department of Health
Office of the Secretary

August 7, 2017

**MEMORANDUM**

**TO:** The Honorable John A. Alario, President, Louisiana Senate
The Honorable Taylor F. Barras, Speaker of the House
The Honorable Fred H. Mills, Jr., Chairman, Senate Committee on Health and Welfare
The Honorable Frank A. Hoffmann, Chairman, House Committee on Health and Welfare
The Honorable Eric LaFleur, Chairman, Senate Finance Committee
The Honorable Cameron Henry, Chairman, House Appropriations Committee

**FROM:** Rebekah E. Gee MD, MPH
Secretary

**RE:** Oversight Report on Bureau of Health Services Financing Proposed Rulemaking

In accordance with the Administrative Procedure Act (R.S. 49:950 et seq.) as amended, we are submitting the attached documents for the proposed Rule for Ambulatory Surgical Centers - Licensing Standards.

The Department published a Notice of Intent on this proposed Rule in the February 20, 2017 issue of the *Louisiana Register* (Volume 43, Number 2). A public hearing was held on March 30, 2017 at which Department of Health staff and the individuals listed on the attached attendance roster for this hearing were present. Oral testimony was given and written correspondence was received regarding this proposed Rule.

Based upon comments received and further discussion with stakeholders, the Department determined that revisions to the provisions of the February 20th Notice of Intent were necessary which resulted in non-technical, substantive changes. The Department subsequently published a Public Hearing - Notification of Substantive Changes to Proposed Rule Potpourri containing the non-technical, substantive changes in the June 20, 2017 issue of the *Louisiana Register* (Volume 43, Number 6). A public hearing on the substantive revisions was held on July 27, 2017 at which Department of Health staff and the individuals listed on the attached attendance roster for this hearing were present. No oral testimony was given; however, written correspondence was received.

The Department anticipates adopting a revised Notice of Intent, which incorporates the non-technical, substantive revisions, as a final Rule in the September 20, 2017 issue of the *Louisiana Register*.

The following documents are attached:

1. a copy of the Notice of Intent;
2. the March 30, 2017 public hearing certification;
3. the March 30, 2017 public hearing attendance roster;
4. a copy of the Public Hearing - Notification of Substantive Changes to Proposed Rule Potpourri;
5. the July 27, 2017 substantive changes public hearing certification;
6. the July 27, 2017 substantive changes public hearing attendance roster;
7. summary of oral testimony presented at the March 30, 2017 public hearing;
8. summary of written comments received by the agency;
9. the agency's response to comments from Cindy Bishop; and
10. the agency's response to comments from William Prentice.

REG/WJR/RKA

Attachments (10)

**NOTICE OF INTENT**

**Department of Health**
**Bureau of Health Services Financing**

**Ambulatory Surgical Centers**
**Licensing Standards**
**(LAC 48:I.Chapter 45)**

The Department of Health, Bureau of Health Services Financing proposes to repeal and replace LAC 48:I.Chapter 45 in the Medical Assistance Program as authorized by R.S. 36:254 and R.S. 40:2131-2141. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing amended the licensing standards governing ambulatory surgical centers to exempt facilities operated primarily for the purpose of performing stereotactic radiosurgery procedures from certain requirements (*Louisiana Register*, Volume 28, Number 12).

The Department of Health, Bureau of Health Services Financing now proposes to repeal and replace the licensing standards governing ambulatory surgical centers in order to: 1) clarify the existing provisions; 2) provide for inactivation of the provider license in the event of specific qualifying events or circumstances; 3) establish provisions which allow ambulatory surgical centers to enter into use agreements; and 4) ensure

consistency with other licensing rules, regulations and processes.

**Title 48**

**PUBLIC HEALTH—GENERAL**
**Part I. General Administration**
**Subpart 3. Licensing and Certification**

## Chapter 45. Ambulatory Surgical Center

### Subchapter A. General Provisions

### §4501. Introduction

A. These regulations contain the minimum licensing standards for ambulatory surgical centers, pursuant to R.S. 40:2131-2141. Ambulatory surgical centers are established for the purpose of rendering surgical procedures to its patients on an outpatient basis.

B. The care and services to be provided by an ambulatory surgical center (ASC) shall include:

1. surgical procedures;

2. medications as needed for medical and surgical procedures rendered;

3. services necessary to provide for the physical and emotional well-being of patients;

4. emergency medical services; and

5. organized administrative structure and support services.

C. Licensed ASCs shall have one year from the date of promulgation of the final Rule to comply with all of the provisions herein.

D. For those ASCs that apply for their initial ASC license after the effective date of the promulgation of this Rule, or receive plan review approval for initial construction or major renovations after the effective date of the promulgation of this Rule, or change their geographic address after the effective date of the promulgation of this Rule, such shall be required to comply with all of the provisions herein.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4503. Definitions**

*Administrator*—the person responsible for the on-site, daily implementation and supervision of the overall ASC's operation commensurate with the authority conferred by the governing body.

*Ambulatory Surgical Center (ASC)*—a distinct entity that is wholly separate and clearly distinguishable from any other healthcare facility or office-based physician's practice. An ASC shall be composed of operating room(s) and/or procedure room(s) with an organized medical staff of physicians and permanent facilities that are equipped and operated primarily

for the purpose of performing surgical procedures. An ASC provides continuous physician and professional nursing services to patients whenever a patient is in the ASC, but does not provide services or accommodations for patients to stay overnight.

1. The following services shall be offered by the ASC when a patient is in the center:

a. drug services as needed for medical operations and procedures performed;

b. provisions for the physical and emotional well-being of patients;

c. provision of emergency services;

d. organized administrative structure; and

e. administrative, statistical and medical records.

2. An ASC may also be defined as a treatment center that is organized primarily for the purpose of offering stereotactic radiosurgery by use of a gamma knife or similar neurosurgical tool.

3. An ASC that enters into a use agreement with another entity/individual shall have separate, designated days and hours of operation.

*Certified Registered Nurse Anesthetist (CRNA)*—an advanced practice registered nurse who administers anesthetics or

ancillary services in accordance with the licensing requirements of the State Board of Nursing (LSBN) and under the supervision of a physician or dentist who is licensed under the laws of the state of Louisiana. The CRNA determines and implements the anesthesia care plan for a patient during a procedure and, for the safety of the patient, shall not be involved in other aspects of the procedure.

*Cessation of Business*—when an ASC is non-operational and voluntarily stops rendering services to the community.

*Controlled Dangerous Substance (CDS)*—a drug, substance or immediate precursor in Schedule I through V of R.S. 40:964.

*Department (LDH)*—the Louisiana Department of Health.

*Division of Administrative Law (DAL)*—the agency authorized to conduct fair hearings and take actions on appeals of departmental decisions as provided for in the Administrative Procedure Act, or its successor.

*Endoscopic Retrograde Cholangiopancreatography(ERCP)*—a procedure used to diagnose diseases of the gallbladder, biliary system, pancreas and liver.

*Endoscopic Ultrasound/Fine Needle Aspiration (EUS/FNA)*—a technique using sound waves during an endoscopic procedure to look at, or through, the wall of the gastrointestinal tract.

*Governing Body*—the individual or group of individuals who are legally responsible for the operation of the ASC, including

management, control, conduct and functioning of the ASC, also known as the governing authority.

*Immediately Available*—a person that is not assigned to any uninterruptible tasks.

*Invasive Procedure*—a procedure that:

1. penetrates the protective surfaces of a patient's body;
2. is performed in an aseptic surgical field;
3. generally requires entry into a body cavity; and
4. may involve insertion of an indwelling foreign body.

NOTE: The intent is to differentiate those procedures that carry a high risk of infection, either by exposure of a usually sterile body cavity to the external environment or by implantation of a foreign object(s) into a normally sterile site. Procedures performed through orifices normally colonized with bacteria and percutaneous procedures that do not involve an incision deeper than skin would not be included.

*Length of Patient Stay*—the period of time that begins with the admission of the patient to the ASC and ends with the discharge of the patient from the ASC. The time of admission

shall be calculated in accordance with the ASC's written policy. The length of any patient stay shall be documented.

*Licensing Agency*—the Louisiana Department of Health.

*Medical Staff*—physicians, dentists, podiatrists and other professional licensed medical practitioners who are authorized to practice in the ASC according to these standards and the requirements of the governing authority.

*Minimal Sedation*—as defined by the American Society of Anesthesiology (ASA), a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, ventilatory and cardiovascular functions are unaffected.

*Minor Alterations*—the painting of walls, changing of flooring products or any other cosmetic changes to the ASC which do not involve moving structural walls, doors, windows, electrical or plumbing.

*Miscarried Child*-the fetal remains resulting from a spontaneous fetal death that does not require compulsory registration pursuant to the provisions of R.S. 40:47.

*New Construction*—any of the following structures that will be started after promulgation of these provisions shall be considered new construction:

1. newly constructed buildings;

2. additions to existing buildings;

3. conversions of existing buildings or portions thereof;

4. alterations, other than minor alterations, to an already existing ASC; or

5. any previously licensed ASC that has voluntarily or involuntarily ceased providing ASC services and surrendered its license shall be considered new construction for plan review purposes.

*Non-Operational*—when the ASC is not open for business operation on designated days and hours as stated on the licensing application.

*Operating Room (OR)*—a room in the surgical center that meets the requirements of a restricted area and is designated and equipped for performing surgical or other invasive procedures. An aseptic field is required for all procedures performed in an OR. Any form of anesthesia may be administered in an OR if proper anesthesia gas administration devices are present and exhaust systems are provided.

*Overnight*—the length of admission to an ASC of any patient that exceeds 23 hours, which is calculated as the time of admission to the time of discharge from the ASC.

*Physician*—a licensed medical practitioner who possesses an unrestricted license and is in good standing with the State Board of Medical Examiners. This includes a doctor of:

1. medicine;
2. osteopathy;
3. podiatry;
4. optometry;
5. dental surgery or dental medicine; or
6. chiropracty.

*Procedure Room*—a room designated for the performance of a procedure that is not deemed to be an invasive procedure. The procedure may require the use of sterile instruments or supplies but not the use of special ventilation or scavenging equipment for anesthetic agents.

*Standards*—the rules, regulations and policies duly adopted and promulgated by the Department of Health with the approval of the secretary.

*Unlicensed Assistive Personnel (UAP)*—any unlicensed trained personnel who cannot practice independently or without supervision by a registered nurse. This may include operating and/or procedure room technicians, instrument cleaning and/or sterilization technicians and nursing assistants or orderlies.

*Use Agreement*—a written agreement between a licensed ASC and an individual or entity in which the ASC allows the

individual or entity to use its facility, or a portion thereof, on a part-time basis to provide the services of an ASC. All use agreements shall comply with applicable federal laws and regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4505. Licensing Requirements**

A. The Department of Health, Health Standards Section (HSS), is the only licensing authority for ASCs in the state of Louisiana.

B. Each ASC license shall:

1. be issued only to the person or entity named in the license application;

2. be valid only for the ASC to which it is issued and only for the specific geographic address of that ASC;

3. be valid for one year from the date of issuance, unless revoked, suspended, modified or terminated prior to that date, or unless a provisional license is issued:

a. a provisional license shall be valid for a period of six months if the department determines that there is no immediate and serious threat to the health and safety of patients;

4. expire on the last day of the twelfth month after the date of issuance, unless timely renewed by the ASC;

5. not be subject to sale, assignment, donation or other transfer, whether voluntary or involuntary; and

6. be posted in a conspicuous place on the licensed premises at all times.

C. The ASC shall abide by and adhere to any federal, state, and local laws, rules, policies, procedures, manuals or memorandums applicable to such facilities. ASCs that have entered into a use agreement shall be responsible for compliance with these licensing standards and any applicable state and federal rules and regulations during the period of use of the ASC.

D. A separately licensed ASC shall not use a name which is the same as the name of another such ASC licensed by the department.

E. A licensed ASC shall notify the department prior to any changes or additions of surgical services. If these surgical services are new to the ASC, the ASC shall provide these surgical services in accordance with the provisions of this Chapter and in accordance with accepted standards of practice.

F. All accredited, or deemed ASCs, shall notify the department prior to the expiration date of any changes in accreditation or deemed status.

G. An ASC shall not have any off-site campuses.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4507. Initial Licensure Application Process**

A. An initial application for licensing as an ASC shall be obtained from the department. A completed initial license application packet for an ASC shall be submitted to, and approved by the department, prior to an applicant providing services.

B. The initial licensing application packet shall include:

1. a completed licensure application and the non-refundable licensing fee as established by statute;

2. a copy of the approval letter(s) of the architectural and licensing facility plans from the Office of the State Fire Marshal (OSFM) and any other office/entity designated by the department to review and approve the facility's architectural and licensing plan review;

3. a copy of the on-site inspection report with approval for occupancy by the Office of the State Fire Marshal, if applicable;

4. a copy of the on-site health inspection report with approval for occupancy from the Office of Public Health (OPH);

5. proof of each insurance coverage as follows:

a. general liability insurance of at least $300,000 per occurrence;

b. worker's compensation insurance as required by state law;

c. professional liability insurance of at least $300,000 per occurrence/$300,000 per annual aggregate, or proof of self-insurance of at least $100,000, along with proof of enrollment as a qualified health care provider with the Louisiana Patient's Compensation Fund (PCF);

i. if the ASC is not enrolled in the PCF, professional liability limits shall be $1 million per occurrence/$3 million per annual aggregate; and

d. the LDH Health Standards Section shall specifically be identified as the certificate holder on any policies and any certificates of insurance issued as proof of insurance by the insurer or producer (agent).

6. proof of a line of credit issued from a federally insured, licensed lending institution in the amount of at least $100,000;

7. disclosure of ownership and control information;

8. the usual and customary days and hours of operation;

9. an organizational chart and names, including position titles, of key administrative personnel and governing body;

10. controlled dangerous substance application;

11. fiscal intermediary, if applicable;

12. Secretary of State's *Articles of Incorporation*;

13. Clinical Laboratory Improvement Amendments (CLIA) certificate or CLIA certificate of waiver, if applicable;

14. an 8.5 x 11 inch mapped floor plan; and

15. any other documentation or information required by the department for licensure.

C. If the initial licensing packet is incomplete, the applicant shall be notified of the missing information, and shall have 90 days from receipt of the notification to submit the additional requested information. If the additional requested information is not submitted to the department within 90 days, the application shall be closed. If an initial licensing application is closed, an applicant who is still

interested in becoming an ASC shall be required to submit a new initial licensing application packet with the required fee to start the initial licensing process.

D. Once the initial licensing application packet has been approved by the department, notification of such approval shall be forwarded to the applicant. Within 90 days of receipt of the approval of the application, the applicant shall notify the department that the ASC is ready and is requesting an initial licensing survey. If an applicant fails to notify the department within 90 days, the initial licensing application shall be closed. After an initial licensing application is closed, an applicant who is still interested in becoming a licensed ASC shall be required to submit a new initial licensing packet with the required fee to start the initial licensing process.

E. Applicants shall be in compliance with all appropriate federal, state, departmental or local statutes, laws, ordinances, rules, regulations and fees before the ASC will be issued an initial license to operate.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4509. Initial Licensing Surveys**

A. Prior to the initial license being issued, an initial on-site licensing survey shall be conducted to ensure compliance with the licensing laws and standards.

1. The initial licensing survey of an ASC shall be an announced survey. Follow-up surveys to the initial licensing surveys are unannounced surveys.

B. The ASC shall not provide services to any patient until the initial licensing survey has been performed and the ASC has been determined to be in compliance with the licensing regulations and has received written approval from the Health Standards Section (HSS).

C. In the event that the initial licensing survey finds that the ASC is compliant with all licensing laws, regulations and other required statutes, laws, ordinances, rules, regulations, and fees, the department shall issue a full license to the center. The license shall be valid until the expiration date shown on the license, unless the license is modified, revoked, suspended or terminated.

D. In the event that the initial licensing survey finds that the ASC is noncompliant with any licensing laws or regulations, or any other required rules or regulations that present a potential threat to the health, safety, or welfare of the patients, the department shall deny the initial license.

E. In the event that the initial licensing survey finds that the ASC is noncompliant with any licensing laws or regulations, or any other required rules or regulations, but the department in its sole discretion determines that the noncompliance does not present a threat to the health, safety or welfare of the patients, the department may issue a provisional initial license for a period not to exceed six months. The ASC shall submit a plan of correction to the department for approval, and shall be required to correct all such noncompliance or deficiencies prior to the expiration of the provisional license.

1. If all such noncompliance or deficiencies are corrected on the follow-up survey, a full license may be issued.

2. If all such noncompliance or deficiencies are not corrected on the follow-up survey, or new deficiencies affecting the health, safety or welfare of a patient are cited, the provisional license will expire and the facility shall be required to begin the initial licensing process again by submitting a new initial license application packet and the required licensing fee.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

## §4511. Types of Licenses and Expiration Dates

A. The department shall have the authority to issue the following types of licenses:

1. Full Initial License. The department shall issue a full license to the ASC when the initial licensing survey finds that the ASC is compliant with all licensing laws and regulations, and is compliant with all other required statutes, laws, ordinances, rules, regulations, and fees. The license shall be valid until the expiration date shown on the license, unless the license is modified, revoked, suspended, or terminated.

2. Provisional Initial License. The department may issue a provisional initial license to the ASC when the initial licensing survey finds that the ASC is noncompliant with any licensing laws or regulations or any other required statutes, laws, ordinances, rules, regulations or fees, but the department determines that the noncompliance does not present a threat to the health, safety or welfare of the patients.

3. Full Renewal License. The department may issue a full renewal license to an existing licensed ASC that is in substantial compliance with all applicable federal, state, departmental, and local statutes, laws, ordinances, rules, regulations and fees. The license shall be valid until the

expiration date shown on the license, unless the license is modified, revoked, suspended or terminated.

B. The department, in its sole discretion, may issue a provisional license to an existing licensed ASC for a period not to exceed six months for any of the following reasons.

1. The existing ASC has more than five deficient practices or deficiencies cited during any one survey.

2. The existing ASC has more than three substantiated complaints in a 12 month period.

3. The existing ASC has been issued a deficiency that involved placing a patient at risk for serious harm or death.

4. The existing ASC has failed to correct deficient practices within 60 days of being cited for such deficient practices or at the time of a follow-up survey.

5. The existing ASC is not in substantial compliance with all applicable federal, state, departmental and local statutes, laws, ordinances, rules, regulations and fees at the time of renewal of the license.

C. When the department issues a provisional license to an existing licensed ASC, the ASC shall submit a plan of correction to the department for approval and shall be required to correct all such noncompliance or deficiencies prior to the expiration of the provisional license. The department shall conduct a

follow-up survey, either on-site or by desk review, of the ASC prior to the expiration of the provisional license.

1. If the follow-up survey determines that the ASC has corrected the deficient practices and has maintained compliance during the period of the provisional license, the department may issue a full license for the remainder of the year until the anniversary date of the ASC license.

2. If the follow-up survey determines that all non-compliance or deficiencies have not been corrected, or if new deficiencies that are a threat to the health, safety or welfare of a patient are cited on the follow-up survey, the provisional license shall expire and the facility shall be required to begin the initial licensing process again by submitting a new initial license application packet and fee.

3. The department shall issue written notice to the ASC of the results of the follow-up survey.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4513. Changes in Licensee Information or Personnel**

A. An ASC license shall be valid only for the person or entity named in the license application and only for the specific geographic address listed on the license application.

B. Any permanent change regarding the entity ASC's name, "doing business as" name, mailing address, telephone number, stated days and hours of operation, or any combination thereof, shall be reported in writing to the department within five business days of the change.

1. For any temporary closures of the ASC greater than 24 hours, other than weekends or holidays, the ASC shall notify HSS in advance.

2. At any time that the ASC has an interruption in services or a change in the licensed location due to an emergency situation, the ASC shall notify HSS no later than the next stated business day.

C. Any change regarding the ASC's key administrative personnel shall be reported in writing to the department within 10 days of the change.

1. Key administrative personnel include the:

a. administrator; and

b. director of nursing.

2. The ASC's notice to the department shall include the individual's:

a. name;

b. address;

c. hire date; and

d. qualifications.

D. A change of ownership (CHOW) of the ASC shall be reported in writing to the department within five days of the change. A CHOW may include one of the following.

1. Partnership. In the case of a partnership, the removal, addition, or the substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable state law, constitutes a change of ownership.

2. Unincorporated Sole Proprietorship. Transfer of title and property to another party constitutes a change of ownership.

3. Corporation. The merger of the ASC corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes a change of ownership. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute a change of ownership.

E. The license of an ASC is not transferable or assignable and cannot be sold. The new owner shall submit the legal CHOW document, all documents required for a new license and the applicable licensing fee. Once all application requirements are completed and approved by the department, a new license shall be issued to the new owner.

1. An ASC that is under license revocation, provisional licensure and/or denial of license renewal may not undergo a CHOW.

2. If the CHOW results in a change of geographic address, an on-site survey shall be required prior to issuance of the new license.

F. If the ASC changes its name without a change in ownership, the ASC shall report such change to the department in writing five days prior to the change. The change in the ASC's name requires a change in the license and payment of the required fee for a name change and re-issuance of a license.

G. Any request for a duplicate license shall be accompanied by the applicable required fee.

H. If the ASC changes the physical address of its geographic location without a change in ownership, the ASC shall report such change to the department in writing at least six weeks prior to the change. Because the license of an ASC is valid only for the geographic location of that ASC, and is not transferrable or assignable, the ASC shall submit a new licensing application and all of the required fees, licensing inspection reports, and licensing plan reviews for the new location.

1. An on-site survey shall be required prior to the issuance of the new license.

2. The change in the ASC's physical address results in a new anniversary date and the full licensing fee shall be paid.

I. An ASC that enters into a use agreement shall submit written notification to the department within five days of the effective date of the agreement. This notice shall include:

1. a copy of the signed use agreement;

2. the designated days and hours of operation that each entity/individual will be using the licensed ASC; and

3. the type of surgical procedures, by specialty, that each entity/individual will be performing at the licensed ASC.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4515. Renewal of License**

A. The ASC shall submit a completed license renewal application packet to the department at least 30 days prior to the expiration of the current license. The license renewal application packet shall include:

1. the license renewal application;

2. the non-refundable license renewal fee;

3. the stated days and hours of operation;

4. a current State Fire Marshal report;

5. a current OPH inspection report;

6. proof of each insurance coverage as follows:

a. general liability insurance of at least $300,000 per occurrence;

b. worker's compensation insurance of at least $100,000 as required by state law;

c. professional liability insurance of at least $300,000 per occurrence/$300,000 per annual aggregate, or proof of self-insurance of at least $100,000, along with proof of enrollment as a qualified health care provider with the Louisiana Patient's Compensation Fund (PCF);

i. if the ASC is not enrolled in the PCF, professional liability limits shall be $1 million per occurrence/$3 million per annual aggregate;

d. the LDH Health Standards Section shall specifically be identified as the certificate holder on the any policies and any certificates of insurance issued as proof of insurance by the insurer or producer (agent);

7. proof of a line of credit issued from a federally insured, licensed lending institution in the amount of at least $100,000;

8. statement of attestation of ASC compliance with the provisions of §4581; and

9. any other documentation required by the department or CMS if applicable.

B. The department may perform an on-site survey and inspection upon annual renewal of a license.

C. Failure to submit a completed license renewal application packet prior to the expiration of the current license will result in the voluntary non-renewal of the ASC license. There are no appeal rights for such surrender or non-renewal of the license, as this is a voluntary action on the part of the ASC.

D. If an existing licensed ASC has been issued a notice of license revocation, suspension or termination, and the ASC's license is due for annual renewal, the department shall deny the license renewal application and shall not issue a renewal license.

1. If a timely administrative appeal has been filed by the ASC regarding the license revocation, suspension, or termination, the administrative appeal shall be suspensive, and the ASC shall be allowed to continue to operate and provide services until such time as the administrative tribunal or department issues a decision on the license revocation, suspension, or termination.

2. If the secretary of the department determines that the violations of the ASC pose an imminent or immediate

threat to the health, welfare, or safety of a patient, the imposition of such action may be immediate and may be enforced during the pendency of the administrative appeal. If the secretary of the department makes such a determination, the ASC will be notified in writing.

3. The denial of the license renewal application does not affect in any manner the license revocation, suspension, or termination.

E. The renewal of a license does not in any manner affect any sanction, civil monetary penalty or other action imposed by the department against the ASC.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4517. Survey Activities**

A. The department may conduct periodic licensing surveys and other surveys as deemed necessary to ensure compliance with all laws, rules and regulations governing ASCs and to ensure patient health, safety and welfare. These surveys may be conducted on-site or by administrative review and shall be unannounced.

B. The department may require an acceptable plan of correction from the ASC for any survey where deficiencies have

been cited, regardless of whether the department takes other action against the ASC for the deficiencies cited in the survey. The acceptable plan of correction shall be submitted for approval to the department within the prescribed timeframe.

C. A follow-up survey may be conducted for any survey where deficiencies have been cited to ensure correction of the deficient practices.

D. The department may issue appropriate sanctions for noncompliance, deficiencies and violations of law, rules and regulations. Sanctions may include, but are not limited to:

1. civil fines;

2. directed plans of correction;

3. denial of license renewal; and/or

4. license revocation.

E. LDH surveyors and staff shall be:

1. given access to all areas of the ASC and all relevant files and other documentation as necessary or required to conduct the survey;

a. For any records or other documentation stored on-site, such shall be provided within one to two hours of surveyor request; and

b. For any records or other documentation stored off-site, such shall be provided to the surveyor for

review no later than 24 hours from the time of the surveyor's request.

2. allowed to interview any facility staff, patient or other persons as necessary or required to conduct the survey; and

3. allowed to photocopy any records/files requested by surveyors during the survey process.

F. The department shall conduct complaint surveys in accordance with R.S. 40:2009.13, et seq.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4519. Statement of Deficiencies**

A. Any statement of deficiencies issued by the department to an ASC shall be available for disclosure to the public 30 days after the ASC submits an acceptable plan of correction to the deficiencies or 90 days after the statement of deficiencies is issued to the ASC, whichever occurs first.

B. Unless otherwise provided in statute or in these licensing provisions, the ASC shall have the right to an informal reconsideration of any deficiencies cited as a result of a survey or investigation.

1. Correction of the violation, noncompliance or deficiency shall not be the basis for the reconsideration.

2. The informal reconsideration of the deficiencies shall be requested in writing within 10 calendar days of receipt of the statement of deficiencies, unless otherwise provided in these standards.

3. The request for informal reconsideration of the deficiencies shall be made to HSS and will be considered timely if received by HSS within 10 calendar days of the ASC's receipt of the statement of deficiencies.

4. If a timely request for an informal reconsideration is received, the department shall schedule and conduct the informal reconsideration. The ASC shall be notified in writing of the results of the informal reconsideration.

5. Except as provided for complaint surveys pursuant to R.S. 40:2009.13 et seq., and as provided in these licensing provisions for initial license denials, license revocations and denial of license renewals, the decision of the informal reconsideration team shall be the final administrative decision regarding the deficiencies.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4521. Denial of Initial License, Revocation of License, Denial of License Renewal**

A. The department may deny an application for an initial license or a license renewal, or may revoke a license in accordance with the provisions of the Administrative Procedure Act.

B. Denial of an Initial License

1. The department shall deny an initial license in the event that the initial licensing survey finds that the ASC is noncompliant with any licensing laws or regulations, or any other required statutes or regulations that present a potential threat to the health, safety or welfare of the patients.

2. The department shall deny an initial license for any of the reasons a license may be revoked or denied renewal pursuant to these licensing provisions.

3. If the department denies an initial license, the applicant for an ASC license shall not render services to patients.

C. Voluntary Non-Renewal of a License. If the ASC fails to timely renew its license, the license expires on its face and is considered voluntarily surrendered. There are no appeal rights for such surrender or non-renewal of the license, as this is a voluntary action on the part of the facility.

D. Revocation of License or Denial of License Renewal. An ASC license may be revoked or denied renewal for any of the following reasons, including but not limited to:

1. failure to be in substantial compliance with the ASC licensing laws, rules and regulations;

2. failure to be in substantial compliance with other required statutes, laws, ordinances, rules or regulations;

3. failure to uphold patient rights whereby deficient practices result in harm, injury or death of a patient;

4. failure to protect a patient from a harmful act by an ASC employee or other patient on the premises including, but not limited to:

a. any action which poses a threat to patient or public health and safety;

b. coercion;

d. threat or intimidation;

e. harassment;

f. abuse; or

g. neglect;

5. failure to notify the proper authorities, as required by federal or state law or regulations, of all suspected cases of the acts outlined in §4521.D.4;

6. failure to employ qualified personnel;

7. failure to submit an acceptable plan of correction for deficient practices cited during an on-site survey within the stipulated timeframes;

8. failure to submit the required fees, including but not limited to:

a. fees for address or name changes;

b. any fine assessed by the department; or

c. fee for a CHOW;

9. failure to allow entry into the ASC or access to requested records during a survey;

10. failure to protect patients from unsafe care by an individual employed by the ASC;

11. when the ASC staff or owner knowingly (or with reason to know) makes a false statement of a material fact in any of the following:

a. the application for licensure;

b. data forms;

c. clinical records;

d. matters under investigation by the department;

e. information submitted for reimbursement from any payment source; or

f. advertising.

12. conviction of a felony or entering a plea of guilty or nolo contendere to a felony by an owner, administrator, director of nursing, or medical director as evidenced by a certified copy of the conviction;

13. failure to comply with all of the reporting requirements in a timely manner as requested by the department;

14. failure to comply with the terms and provisions of a settlement agreement with the department or an educational letter;

15. failure to repay an identified overpayment to the department or failure to enter into a payment agreement to repay such overpayment; or

16. failure to timely pay outstanding fees, fines, sanctions or other debts owed to the department.

E. In the event an ASC license is revoked, renewal is denied or the license is surrendered in lieu of an adverse action, any owner, officer, member, manager, director or administrator of such ASC is prohibited from owning, managing, directing or operating another ASC for a period of two years from the date of the final disposition of the revocation, denial action or surrender.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4523. Notice and Appeal of Initial License Denial, License Revocation and Denial of License Renewal**

A. Notice of an initial license denial, license revocation or denial of license renewal shall be given to the ASC in writing.

B. The ASC has a right to an administrative reconsideration of the initial license denial, license revocation or denial of license renewal. There is no right to an informal reconsideration of a voluntary non-renewal or surrender of a license by the ASC.

1. The request for the administrative reconsideration shall be submitted within 15 days of the receipt of the notice of the initial license denial, license revocation or denial of license renewal. The request for administrative reconsideration shall be in writing and shall be forwarded to HSS.

2. The request for administrative reconsideration shall include any documentation that demonstrates that the determination was made in error.

3. If a timely request for an administrative reconsideration is received by HSS, an administrative reconsideration shall be scheduled and the ASC will receive

written notification of the date of the administrative reconsideration.

4. The ASC shall have the right to appear in person at the administrative reconsideration and may be represented by counsel.

5. Correction of a violation or deficiency which is the basis for the initial license denial, revocation or denial of license renewal shall not be a basis for reconsideration.

6. The administrative reconsideration process is not in lieu of the administrative appeals process.

7. The ASC will be notified in writing of the results of the administrative reconsideration.

C. The ASC has a right to an administrative appeal of the initial license denial, license revocation or denial of license renewal. There is no right to an administrative appeal of a voluntary non-renewal or surrender of a license by the ASC.

1. The ASC shall request the administrative appeal within 30 days of the receipt of the results of the administrative reconsideration.

a. The ASC may forego its rights to an administrative reconsideration, and if so, shall request the administrative appeal within 30 days of the receipt of the notice of the initial license denial, license revocation or denial of license renewal.

2. The request for administrative appeal shall be in writing and shall be submitted to the DAL. The request shall include any documentation that demonstrates that the determination was made in error and shall include the basis and specific reasons for the appeal.

3. If a timely request for an administrative appeal is received by the DAL, the administrative appeal of the license revocation or denial of license renewal shall be suspensive, and the ASC shall be allowed to continue to operate and provide services until such time as the department issues a final administrative decision.

a. If the secretary of the department determines that the violations of the ASC pose an imminent or immediate threat to the health, welfare or safety of a patient, the imposition of the license revocation or denial of license renewal may be immediate and may be enforced during the pendency of the administrative appeal. If the secretary of the department makes such a determination, the ASC will be notified in writing.

4. Correction of a violation or a deficiency which is the basis for the denial of initial licensure, revocation or denial of license renewal shall not be a basis for an administrative appeal.

D. If an existing licensed ASC has been issued a notice of license revocation, and the ASC's license is due for annual renewal, the department shall deny the license renewal application. The denial of the license renewal application does not affect, in any manner, the license revocation.

E. If a timely administrative appeal has been filed by the ASC on an initial license denial, denial of license renewal or license revocation, the DAL shall conduct the hearing in accordance with the Administrative Procedure Act.

1. If the final decision is to reverse the initial license denial, denial of license renewal or license revocation, the ASC's license will be re-instated or granted upon the payment of any licensing fees, outstanding sanctions or other fees due to the department.

2. If the final decision is to affirm the denial of license renewal or license revocation, the ASC shall stop rendering services to patients.

a. Within 10 days of the final decision, the ASC shall notify HSS, in writing, of the secure and confidential location where the patient records will be stored.

F. There is no right to an informal reconsideration or an administrative appeal of the issuance of a provisional initial license to a new ASC or the issuance of a provisional license to an existing ASC. An ASC that has been issued a provisional

license is licensed and operational for the term of the provisional license. The issuance of a provisional license is not considered to be a denial of initial licensure, denial of license renewal or revocation.

G. An ASC with a provisional initial license or an existing ASC with a provisional license that expires due to noncompliance or deficiencies cited at the follow-up survey shall have the right to an informal reconsideration and the right to an administrative appeal of the validity of the deficiencies cited at the follow-up survey.

1. The correction of a violation, noncompliance or deficiency after the follow-up survey shall not be the basis for the informal reconsideration or for the administrative appeal.

2. The informal reconsideration and the administrative appeal are limited to whether the deficiencies were properly cited at the follow-up survey.

3. The ASC shall request the informal reconsideration in writing, which shall be received by the Health Standards Section within five calendar days of receipt of the notice of the results of the follow-up survey from the department.

4. The ASC shall request the administrative appeal within 15 days of receipt of the notice of the results of the follow-up survey from the department. The request for

administrative appeal shall be in writing and shall be submitted to the DAL.

5. An ASC with a provisional initial license or an existing ASC with a provisional license that expires under the provisions of this Chapter shall cease providing services to patients unless the DAL issues a stay of the expiration.

a. The stay may be granted by the DAL upon application by the ASC at the time the administrative appeal is filed and only after a contradictory hearing and only upon a showing that there is no potential harm to the patients being served by the ASC.

6. If a timely administrative appeal has been filed by the ASC with a provisional initial license that has expired, or by an existing ASC whose provisional license has expired under the provisions of this Chapter, the DAL shall conduct the hearing in accordance with the Administrative Procedure Act.

a. If the final decision is to remove all deficiencies, the ASC's license will be re-instated upon the payment of any outstanding sanctions and licensing or other fees due to the department.

b. If the final decision is to uphold the deficiencies thereby affirming the expiration of the provisional license, the ASC shall cease rendering services to patients.

i. Within 10 days of the final decision, the ASC shall notify HSS in writing of the secure and confidential location where the patient records will be stored.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4525. Cessation of Business**

A. Except as provided in §4583 and §4585 of these licensing regulations, a license shall be immediately null and void if an ASC ceases to operate.

B. A cessation of business is deemed to be effective the date on which the ASC stopped offering or providing services to the community.

C. Upon the cessation of business, the ASC shall immediately return the original license to the department.

D. Cessation of business is deemed to be a voluntary action on the part of the ASC. The ASC does not have a right to appeal a cessation of business.

E. The ASC shall notify the department in writing 30 days prior to the effective date of the closure or cessation. In addition to the notice, the ASC shall submit a written plan for the disposition of patient medical records for approval by the department. The plan shall include the following:

1. the effective date of the closure;

2. provisions that comply with federal and state laws on storage, maintenance, access and confidentiality of the closed provider's patients medical records; and

3. appointed custodian(s) who shall provide the following:

a. access to records and copies of records to the patient or authorized representative, upon presentation of proper authorization(s); and

b. physical and environmental security that protects the records against fire, water, intrusion, unauthorized access, loss and destruction.

4. Public notice regarding access to records, in the newspaper with the largest circulation in close proximity to the closing provider, at least 15 days prior to the effective date of closure.

F. If an ASC fails to follow these procedures, the owners, managers, officers, directors and administrators may be prohibited from opening, managing, directing, operating or owning an ASC for a period of two years.

G. Once the ASC has ceased doing business, the center shall not provide services until the ASC has obtained a new initial license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

Subchapter B. Administration and Organization

**§4531. Governing Body**

A. An ASC shall have an identifiable governing body with responsibility for, and authority over, the policies and activities of the ASC, which shall include use agreements and all contracts. The governing body is the ultimate governing authority of the ASC and shall adopt bylaws which address its responsibilities. No contract or other arrangements, including use agreements, shall limit or diminish the responsibilities of the governing body.

B. An ASC shall have documents identifying the following information regarding the governing body:

1. names and addresses of all members;

2. terms of membership;

3. officers of the governing body; and

4. terms of office for any officers.

C. The governing body shall be comprised of one or more persons and shall hold formal meetings at least twice a year. There shall be written minutes of all formal meetings, and the

bylaws shall specify the frequency of meetings and quorum requirements.

D. The governing body of an ASC shall:

1. ensure the ASC's continual compliance and conformity with all relevant federal, state, local and municipal laws and regulations;

2. ensure that the ASC is adequately funded and fiscally sound which entails:

a. verification of sufficient assets equal to $100,000 or the cost of three months of operation, whichever is less; or

b. a letter of credit issued from a federally insured, licensed lending institution in the amount of at least $100,000 or the cost of three months of operation, whichever is less;

3. review and approve the ASC's annual budget;

4. designate a person to act as the administrator and delegate sufficient authority to this person to manage the day-to-day operations of the ASC;

5. annually evaluate the administrator's performance;

6. have the authority to dismiss the administrator;

7. formulate and annually review, in consultation with the administrator, written policies and procedures

concerning the ASC's philosophy, goals, current services, personnel practices, job descriptions, fiscal management, contracts and use agreements;

a. the ASC's written policies and procedures shall be maintained within the ASC and made available to all staff at all times;

8. determine, in accordance with state law, which practitioners are eligible candidates for appointment to the medical staff and make the necessary appointments;

9. determine, in conjunction with the medical staff, whether the ASC will provide services beyond the customary hours of operation by allowing a patient to stay up to 23 hours. If permitted the ASC shall provide continuous physician (on call & available to be on-site as needed) and professional nursing services (registered nurse) on-site. In addition, the ASC shall provide for ancillary services to accommodate patient needs during this extended stay including but not limited to medication and nutrition;

10. ensure and maintain quality of care, inclusive of a quality assurance/performance improvement process that measures patient, process, and structural (e.g. system) outcome indicators to enhance patient care;

11. ensure that surgical or invasive procedures shall not be performed in areas other than the operating room or other designated and approved treatment rooms;

12. ensure that surgical or invasive procedures are initiated in accordance with acceptable standards of practice, which includes the use of standard procedures, such as a timeout to ensure proper identification of the patient and surgical site, in order to avoid wrong site, wrong person or wrong procedure errors;

13. meet with designated representatives of the department whenever required to do so;

14. inform the department, or its designee, prior to initiating any substantial changes in the services provided by the ASC; and

15. ensure that pursuant to R.S. 40:1191.2, prior to the final disposition of a miscarried child, but not more than 24 hours after a miscarriage occurs in an ASC, the ASC shall notify the patient, or if the patient is incapacitated, the spouse of the patient, both orally and in writing, of both of the following:

a. the parent's right to arrange for the final disposition of the miscarried child through the use of the notice of parental rights form as provided for in R.S. 40:1191.3; and

b. the availability of a chaplain or other counseling services concerning the death of the miscarried child, if such services are provided by the ASC.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4533. Policy and Procedures**

A. An ASC, through collaboration by the administrator, medical staff, director of nursing, pharmacist, and other professional persons deemed appropriate by the ASC, shall develop, implement and maintain written policies and procedures governing all services rendered at the ASC. The ASC shall comply with all federal and state laws, rules and regulations in the development and implementation of its policies and procedures.

B. All policies and procedures shall be reviewed at least annually and revised as needed.

C. Direct care and medical staff shall have access to information concerning patients that is necessary for effective performance of the employee's assigned tasks.

D. The ASC shall have written policies and procedures for the maintenance and security of records specifying who shall

supervise the maintenance of records, who shall have custody of records and to whom records may be released.

E. The ASC shall allow designated representatives of the department, in the performance of their mandated duties, to:

1. inspect all aspects of an ASC's operations which directly or indirectly impact patients; and

2. interview any physician, staff member or patient.

F. An ASC shall make any required information or records, and any information reasonably related to assessment of compliance with these provisions, available to the department.

G. An ASC shall, upon request by the department, make available the legal ownership documents, use agreements and any other legal contracts or agreements in place.

H. The ASC shall have written policies and procedures approved by the governing body, which shall be implemented and followed, that address, at a minimum, the following:

1. confidentiality and confidentiality agreements;

2. security of files;

3. publicity and marketing, including the prohibition of illegal or coercive inducement, solicitation and kickbacks;

4. personnel;

5. patient rights;

6. grievance procedures;

7. emergency preparedness;

8. abuse and neglect;

9. incidents and accidents, including medical emergencies;

10. universal precautions;

11. documentation, whether electronic or in paper form;

12. admission and discharge procedures;

13. hours outside of stated usual and customary operation, including but not limited to early closures, extended business hours and holidays; and

14. conditions for coverage, if applicable.

I. An ASC shall have written personnel policies, which shall be implemented and followed, that include:

1. written job descriptions for each staff position, including volunteers;

2. policies which provide for staff, upon offer of employment, to have a health assessment as defined by the ASC and in accordance with *LAC Title 51, Public Health Sanitary Code* guidelines;

3. policies which verify that all physicians, clinic employees, including contracted personnel and personnel practicing under a use agreement, prior to, and at the time of employment and annually thereafter, shall be free of

tuberculosis in a communicable state, in accordance with the current *LAC Title 51, Public Health Sanitary Code.*

4. an employee grievance procedure;

5. abuse reporting procedures that require all employees to report any incidents of abuse or mistreatment, whether that abuse or mistreatment is done by another staff member, a family member, a patient or any other person;

6. a written policy to prevent discrimination; and

7. a written policy to address prohibited use of social media. The policy shall ensure that all staff, either contracted or directly employed, receive training relative to the restrictive use of social media and include, at a minimum, ensuring confidentiality of patient information and preservation of patient dignity and respect, including protection of patient privacy and personal and property rights.

J. The ASC shall maintain, in force at all times, the requirements for financial viability under this Chapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**Subchapter C. Admissions, Transfers and Discharges**

**§4539. Admissions and Assessments**

A. Each ASC shall have written admission and assessment policies and criteria.

B. An individual or entity that enters into a use agreement with a licensed ASC shall be required to adhere to all of the provisions of this Section.

C. An ASC shall ensure that each patient has the appropriate pre-surgical and post-surgical assessments completed, inclusive of suitability for less than 23 hour timeframe of patient stay, ability of the ASC to provide services needed in the post-operative period in accordance with prescribed plan of care, and discharge plans to home or another licensed facility setting.

D. Within 30 days prior to the date of the scheduled surgery, each patient shall have a comprehensive medical history and physical assessment completed by a physician or other qualified licensed professional practitioner in accordance with applicable state health and safety laws, ASC policies, and standards of practice.

E. The history and physical assessment prior to surgery shall specify that the patient is medically cleared for surgery in an ambulatory setting and is required on all patients regardless of whether the patient is referred for surgery on the same day that the referral is made and the referring physician

has indicated that it is medically necessary for the patient to have the surgery on the same day.

F. Upon admission, each patient shall have a pre-surgical assessment completed by a physician or other qualified licensed health practitioner. The pre-surgical assessment shall include, at a minimum:

1. an updated medical record entry documenting an examination for any changes in the patient's condition since completion of the most recently documented medical history and physical assessment; and

2. documentation of any known allergies to drugs and/or biological agents.

G. The patient's medical history and physical assessment shall be placed in the patient's medical record prior to the surgical procedure.

H. The patient's post-surgical condition shall be assessed and documented in the medical record by a physician, other licensed medical practitioner, or a registered nurse (RN) with, at a minimum, the required post-operative care experience in accordance with applicable state health and safety laws, ASC policies and standards of practice.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4541. Transfer Agreements and Patient Transfers**

A. The ASC shall secure a written transfer agreement with at least one hospital in the community. A transfer agreement shall serve as evidence of a procedure whereby patients can be transferred to a hospital should an emergency arise which would necessitate hospital admission.

1. If a written transfer agreement is established with a hospital in the community, medical staff at the ASC shall still be required to adhere to the provisions of §4541.B and C.

2. If the ASC is not able to secure a written transfer agreement, the ASC's compliance with §4541.C shall substantiate the ASC's capability to obtain hospital care for a patient if the need arises.

B. Each member of the medical staff of the ASC, including physicians who practice under a use agreement, shall be a member in good standing on the medical staff of at least one hospital in the community and that hospital shall be licensed by the department. Members of the ASC medical staff shall be granted surgical privileges compatible with privileges granted by the hospital for that physician.

C. The admitting physician of the ASC shall be responsible for effecting the safe and immediate transfer of

patients from the ASC to a hospital when, in his/her medical opinion, hospital care is indicated.

D. The ASC is responsible for developing written policies and procedures for the safe transfer of patients and coordination of admission, when necessary, into an inpatient facility. The written policy shall include, but is not limited to:

1. identification of the ASC personnel who shall be responsible for the coordination of admission into an inpatient facility;

2. procedures for securing inpatient services; and

3. procedures for the procurement of pertinent and necessary copies of the patient's medical record that will be sent with the transferring patient so that the information may be included in the patient's inpatient medical record.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4543. Discharges**

A. Each ASC shall have written discharge policies and procedures. The written description of discharge policies shall be provided to the department upon request and made available to the patient or his/her legal representative. The ASC shall

ensure that all elements of the discharge requirements are completed.

B. Any individual or entity that enters into a use agreement with a licensed ASC shall be required to adhere to all of the provisions of this Section.

C. The post-surgical needs of each patient shall be addressed and documented in the discharge notes.

D. Upon discharge, the ASC shall:

1. provide each patient with written discharge instructions;

2. provide each patient with all supplies deemed medically necessary per the discharge orders, excluding medications;

3. make the follow-up appointment with the physician, when appropriate; and

4. ensure that all patients are informed, either in advance of their surgical procedure or prior to leaving the ASC, of the following:

a. necessary prescriptions;

b. post-operative instructions; and

c. physician contact information for follow-up care.

E. The ASC shall ensure that each patient has a discharge order signed by the physician who performed the surgery or procedure.

F. The ASC shall ensure and document that all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician. Such exemptions shall be specific and documented for individual patients. Blanket exemptions are prohibited.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

## Subchapter D. Service Delivery

### §4549. Surgical Services

A. Surgical services shall be well organized and provided in accordance with current acceptable standards of practice adopted from national associations or organizations.

B. Private areas should include pre- and post-operative care areas and should allow for parental presence for pediatric patients.

C. The ASC shall ensure that the scheduled surgeries do not exceed the capabilities of the surgical center, including the post-anesthesia care area, and any length of patient does

not exceed 23 hours from patient admission to discharge from the ASC.

D. At least one RN trained in the use of emergency equipment and certified in advanced cardiac life support (ACLS) and/or pediatric advanced life support (PALS), if a pediatric patient is present, shall be immediately available whenever there is a patient in the ASC.

E. A roster of physicians and other medical practitioners, specifying the surgical privileges of each, shall be kept in the surgical center and available to all professional staff.

F. Medical staff and approved policies shall define which surgical procedures require a qualified first assistant physician, registered nurse or surgical technician.

1. A registered nurse or a surgical technician may be a surgical assistant if the individual:

a. has been approved by the medical director and director of nurses;

b. has documented competency and training to assist in such procedures; and

c. is acting within the scope of practice of his/her respective licensing board(s) and/or certification(s).

G. An operating and procedure room register shall be accurately maintained and kept up-to-date and complete. This

register shall be maintained for a five year period. The register shall include, at a minimum, the:

1. patient's complete name;
2. patient's ASC identification number;
3. physician's name;
4. date of the surgery/procedure; and
5. type of surgery/procedure performed.

H. An RN shall be assigned to, and directly responsible for, the post-anesthesia care area. There shall be a sufficient number of nurses assigned to the post-anesthesia care area to meet the nursing needs of patients in recovery. At a minimum, one licensed RN and one direct care staff shall be onsite and available for the length of any patient stay in the ASC.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4551. Anesthesia Services**

A. Anesthesia services shall be available when surgical services are provided.

B. Anesthesia services shall be provided in a well-organized manner under the direction of an anesthesiologist or the treating physician who is licensed and in good standing with the State Board of Medical Examiners.

C. Anesthesia services and/or conscious sedation shall be administered by licensed practitioners with clinical privileges for which they have been licensed, trained and determined to be competent to administer anesthesia and/or conscious sedation in accordance with their respective state licensing board.

D. Anesthesia and conscious sedation may be administered by the following practitioners who are qualified to administer anesthesia under state law and within the scope of their practice:

1. anesthesiologists;

2. doctors of medicine or osteopathy;

3. dentists or oral surgeons;

4. podiatrists;

5. certified registered nurse anesthetists (CRNAs) licensed by the State Board of Nursing who are under the supervision of a physician or an anesthesiologist who is immediately available if needed, as defined in the medical staff bylaws; and

6. registered nurses who have documented education and demonstrated competency to administer minimal or moderate sedation in accordance with the Nurse Practice Act, and who are under the supervision of the treating physician.

a. The RN (non-CRNA) monitoring the patient shall have no additional responsibility that would require

leaving the patient unattended or would compromise continuous monitoring during the procedure.

E. The practitioner administering the anesthesia and/or conscious sedation shall be present and immediately available during the post-anesthesia recovery period until the patient is assessed as stable in accordance with the ASC's established criteria.

F. The ASC shall develop policies and procedures which are approved by the governing body including, but not limited to:

1. staff privileges of licensed personnel that administer anesthesia;

2. delineation of pre-anesthesia and post-anesthesia responsibilities;

3. the qualifications, responsibilities and supervision required of all licensed personnel who administer any type or level of anesthesia;

4. patient consent for anesthesia, including the American Society of Anesthesiologists (ASA) Physical Status Classification System;

5. infection control measures;

6. safety practices in all anesthetizing areas;

7. protocol for supportive life functions, e.g., cardiac and respiratory emergencies;

8. reporting requirements;

9. documentation requirements;

10. inspection and maintenance reports on all of the supplies and equipment used to administer anesthesia; and

11. monitoring of trace gases and reporting requirements.

G. Anesthesia policies shall ensure that the following are provided for each patient:

1. a pre-anesthesia evaluation performed and recorded immediately prior to surgery to evaluate the risk of anesthesia and of the procedure to be performed by an individual qualified to administer anesthesia;

2. an intra-operative anesthesia record that records monitoring of the patient during any type or level of anesthesia and documentation of at least the following:

a. prior to induction of any type or level of anesthesia, all anesthesia drugs and equipment to be used have been checked and are immediately available and are determined to be functional by the practitioner who is to administer the anesthetic;

b. dosages of each drug used, including the total dosages of all drugs and agents used;

c. type and amount of all fluid(s) administered, including blood and blood products;

d. estimated blood loss;

e. technique(s) used;

f. unusual events during the anesthesia period;

g. the status of the patient at the conclusion of any type or level of anesthesia; and

h. a post-anesthesia report written prior to discharge of the patient by the individual who administers the anesthesia or another fully qualified practitioner within the anesthesia department; and

3. policies developed, approved and implemented that define:

a. minimal, moderate and deep sedation;

b. the method of determining the sedation status of the patient;

c. how the sedation is to be carried out;

d. who is to be present while the patient is under any type or level of anesthesia; and

e. what body systems are to be monitored and equipment to be used with each type of anesthesia administered.

H. Anesthesia policies and procedures shall be developed and approved for all invasive procedures including, but not limited to:

a. percutaneous aspirations and biopsies;

b. cardiac and vascular catheterization; and

c. endoscopies.

I. The ASC shall adopt an individualized patient identification system for all patients who:

1. are administered general, spinal or other types of anesthesia; and

2. undergo surgery or other invasive procedures when receiving general, spinal or other major regional anesthesia and/or intravenous, intramuscular or inhalation sedation/analgesia, including conscious sedation that, in the manner used in the ASC, may result in the loss of the patient's protective reflexes.

J. The ASC shall develop, approve and implement policies and procedures to ensure that the following requirements are met for each patient undergoing:

1. general anesthesia/total intravenous anesthesia:

a. the use of an anesthesia machine that provides the availability and use of safety devices including, but not limited to:

i. an oxygen analyzer;

ii. a pressure and disconnect alarm;

iii. a pin-index safety system;

iv. a gas-scavenging system; and

v. an oxygen pressure interlock system;

b. continuous monitoring of the patient's temperature and vital signs, as well as the continuous use of:

i. an electrocardiogram (EKG/ECG);

ii. a pulse oximetry monitor; and

iii. an end tidal carbon dioxide volume monitor;

2. monitored anesthesia care (MAC):

a. monitored anesthesia care includes the monitoring of the patient by an anesthesiologist and/or a CRNA. Indications for MAC depend on the nature of the procedure, the patient's clinical condition, and/or the potential need to convert to a general or regional anesthetic. Deep sedation/analgesia is included in MAC;

b. equipment sufficient to maintain the patient's airway and ventilatory function shall be immediately available and in the OR/procedure room where the procedure is being performed;

c. continuous monitoring of the patient's vital signs and temperature as well as continuous use of an EKG/ECG and pulse oximetry monitor; and

d. monitoring by the licensed practitioner who administers the anesthetic;

3. conscious sedation;

a. policies and procedures shall be developed, approved, and implemented by the medical staff as to the need for pre-operative cardiac and pulmonary assessments of patients prior to being administered conscious sedation; and

b. there shall be a minimum requirement of a registered nurse to continuously monitor the patient who is receiving conscious sedation.

4. regional anesthesia (major nerve blocks);

a. equipment sufficient to maintain the patient's airway and to convert the case to another form of anesthesia shall be immediately available and in the operating/procedure room where the procedure is being performed;

b. continuous monitoring of the patient's vital signs and temperature, as well as the continuous use of an EKG/ECG and pulse oximetry monitor;

c. monitoring by the licensed practitioner who administers the regional anesthetic;

5. local anesthesia (infiltration or topical);

a. continuous monitoring of the patient's vital signs and temperature as well as the continuous use of an EKG/ECG and pulse oximetry monitor; and

b. local anesthesia, interpreted to mean those anesthetizing agents administered and affecting a very small

localized area that may be administered by the treating physician.

K. The ASC shall develop, approve and implement policies and procedures regarding qualifications and duties of all licensed personnel who administer any type or level of anesthesia.

L. Policies and procedures shall be developed, approved and implemented in accordance with manufacturer's guidelines for the equipment and medications to be used to administer any level or type of anesthesia.

M. Policies and procedures shall be developed, approved, and implemented as stipulated under the current state licensing boards for patients undergoing any level or type of anesthesia sedation. The patient under sedation shall be monitored for blood pressure, respiratory rate, oxygen saturation, cardiac rate and rhythm and level of consciousness. This information shall be recorded at least every five minutes during the therapeutic, diagnostic or surgical procedure and, at a minimum, every 15 minutes during the recovery period or more frequently as deemed appropriate by the authorized prescriber.

N. The ASC shall define in policy and procedures whether the use of reversal agents is to be considered an adverse patient event.

O. The patient shall be kept in the recovery room until assessed by a qualified anesthesia professional as being stable in accordance with the ASCs established criteria.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4553. Radiology Services**

A. All ASCs shall provide radiology services commensurate with the needs of the ASC and to meet the needs of the patients being served.

B. The scope and complexity of radiological services provided within the ASC, either directly or under arrangement, as an integral part of the ASC's services should be specified in writing and approved by the governing body.

C. The ASC is equally responsible for the compliance of radiological services performed in the ASC, regardless of whether the service is provided directly by the ASC or under arrangement.

D. Radiological determinations made by the physician within 72 hours prior to admission shall be acceptable if documented by the physician on the patient's medical record and the determinations conform to the medical staff bylaws and rules and regulations of the center.

E. All radiological determinations shall be in writing and the original shall be a part of the patient's chart.

F. When radiology services are provided by the ASC directly, at a minimum, the following criteria shall be met.

1. The ASC shall comply with periodic inspections of equipment and testing for radiation hazards, and shall promptly correct any identified problems.

2. Radiologic services shall be provided in an area of sufficient size and arrangement to provide for the safety of personnel and patients.

3. Supervision of radiologic services should be appropriate to the types of procedures conducted by the ASC.

4. The ASC governing body is responsible for the oversight and accountability for the quality assessment and performance improvement program, and is responsible for ensuring that all policies and services provide quality healthcare in a safe environment.

5. The governing body is responsible for determining if any procedures, now or in the future, require additional review by a radiologist.

6. The governing body is accountable for the medical staff to ensure that such staff members are legally and professionally qualified for the positions to which they are appointed and for the performance of the privileges granted.

7. The treating physician is expected to demonstrate documented competency in using imaging as an integral part of the surgery or procedure.

8. A licensed practitioner who is qualified by education and experience in accordance with state law, rules and regulations and in accordance with ASC policy shall supervise the provision of radiologic services.

a. For purposes of this Section, a licensed practitioner means a person licensed to practice medicine, dentistry, podiatry, chiropracty or osteopathy in this state, or an advanced practice registered nurse licensed to practice in this state.

9. Radiologic reports shall be signed by the licensed medical practitioner who reads and interprets the reports.

10. The ASC shall adopt written policies and procedures to ensure that radiologic services are rendered in a manner which provides for the safety and health of patients and ASC personnel. At a minimum, the policies and procedures shall cover the following:

a. shielding for patients and personnel;

b. storage, use and disposal of radioactive materials;

c. documented periodic inspection of equipment and handling of identified hazards;

d. documented periodic checks by exposure meters or test badges on all personnel working around radiological equipment which shall also include knowledge of exposure readings at other places of employment;

e. managing medical emergencies in the radiologic department; and

f. methods for identifying pregnant patients.

11. Only personnel who are registered and/or licensed in the appropriate radiologic technology modality or category by the State Radiologic Technology Board of Examiners and designated as qualified by the medical staff may use the radiologic equipment and administer procedures under the direction of a physician

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4555. Laboratory Services**

A. The ASC shall either provide a clinical laboratory directly or make contractual arrangements with a laboratory certified in accordance with the Clinical Laboratory Improvement

Amendments to perform services commensurate with the needs of the ASC.

B. Contractual arrangements for laboratory services shall be deemed as meeting the requirements of this Section when those arrangements contain written policies and procedures defining the scope of services.

C. When laboratory services are provided directly by the ASC, the services shall be performed by a qualified and/or licensed person with documented training and experience to supervise and perform the testing.

1. The ASC shall have sufficient numbers of licensed clinical laboratory and supportive technical staff to perform the required tests.

2. The laboratory shall be of sufficient size and adequately equipped to perform the necessary services of the ASC.

D. Written laboratory policies and procedures shall be developed and implemented for all laboratory services provided directly by the center and/or by contractual arrangement. Policies shall define "stat" labs and the timelines for processing and reporting "stat" labs.

E. Written reports of all ASC performed and contractually performed lab results shall be made a part of the patient's medical record.

F. Documentation shall be maintained for preventive maintenance and quality control programs governing all types of analyses performed in the laboratory.

G. The ASC shall make provisions for the immediate pathological examination of tissue specimens by a pathologist, if applicable. The pathology report shall be made part of the patient's medical record.

H. Handling of Blood and Blood Products

1. Written policies and procedures shall be developed, approved by the governing body and implemented by the ASC, relative to the administration of blood and blood products as well as any medical treatment and notification of the treating physician in the event of an adverse reaction.

2. If the treating physician determines that blood and blood products shall be administered, the ASC shall provide for the procurement, safekeeping and transfusion of the blood and blood products so that it is readily available.

3. The administration of blood shall be monitored by the registered nurse to detect any adverse reaction. Prompt investigation of the cause of an adverse reaction shall be instituted and reported according to ASC policy and procedures.

4. If the ASC regularly uses the services of an outside blood bank, the ASC shall have a written agreement with the blood bank whereby the ASC is promptly notified by the blood

bank of blood or blood products that have been determined at increased risk of transmitting infectious disease.

5. The ASC shall have a system in place which is defined in a "look back" policy and procedure for appropriate action to take when notified that blood or blood products that the ASC has received are at increased risk of transmitting infectious disease. The look back policy shall include, but not be limited to:

a. quarantine of the contaminated products;

b. documented notification to the patient or legal representative and the patient's physician; and

c. the safe and sanitary disposal of blood and blood products not suitable for distribution.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4557. Pharmaceutical Services**

A. The ASC shall provide pharmacy services commensurate with the needs of the patients and in conformity with state and federal laws. Pharmacy services may be provided directly by the ASC or under a contractual agreement as long as all regulatory requirements are met.

1. At a minimum, the ASC shall designate a qualified and licensed healthcare professional to provide direction to the ASC's pharmaceutical service.

B. All ASCs shall have a controlled dangerous substance license issued by the Board of Pharmacy and a Drug Enforcement Agency (DEA) license allowing for the ordering, storage, dispensing and delivery of controlled substances to patients.

C. Drugs and biologicals shall be provided safely and in an effective manner, consistent with accepted professional standards of pharmaceutical practice.

D. When the ASC provides pharmaceutical services, there shall be a current permit issued by the Board of Pharmacy.

E. The designated licensed healthcare professional responsible for pharmaceutical services shall maintain complete, current and accurate records of all drug transactions by the pharmacy.

1. Current and accurate records shall be maintained on the receipt, distribution, dispensing and/or destruction of all scheduled drugs in such a manner as to facilitate complete accounting for the handling of these controlled substances.

F. Dispensing of prescription legend or controlled substance drugs directly to the public or patient by vending machines is prohibited.

G. Medications are to be dispensed only upon written or verbal orders from a licensed medical practitioner. All verbal orders shall be taken by a licensed medical professional.

H. The designated licensed healthcare professional responsible for pharmaceutical services shall assist the center in the development of policies and procedures to:

1. address the distribution, storage and handling of drugs;

2. monitor drug and medication-related activities; and

3. immediately notify the director of nurses to return drugs to the pharmacy or contracted pharmacist for proper disposition in the event of a drug recall.

I. The designated licensed healthcare professional responsible for pharmaceutical services shall assist the ASC with drug administration errors, adverse drug reactions and incompatibilities of medications, and shall report data relative to these issues to the quality assessment performance improvement committee.

J. The designated licensed healthcare professional responsible for pharmaceutical services shall assist the ASC in developing a formulary of medications that will be available for immediate patient use.

K. The designated licensed healthcare professional responsible for pharmaceutical services shall ensure that medication and supplies are on-site at all times and immediately available for the management of malignant hyperthermia, where applicable, based upon the type and level of anesthesia delivered and all other anesthesia-related complications.

L. The consultant pharmacist shall provide consultation to the ASC on an as needed basis and consistent with provisions of the State Board of Pharmacy. The consultations shall be documented in writing showing the date, amount of time spent, subjects reviewed and recommendations made.

M. All drug errors, adverse drug reactions and incompatibilities of medications shall be entered into the patient's medical record and reported according to federal and state laws and per ASC policy and procedure.

N. The ASC shall provide for a drug administration storage area which allows for the proper storage, safeguarding and distribution of drugs. All drug cabinets or drug storage areas at the nursing station(s) are to be constructed and organized to ensure proper handling and safeguard against access and removal by unauthorized personnel. All drug cabinets or drug storage areas are to be kept clean, in good repair and are to be inspected each month by a designated licensed healthcare professional responsible for pharmaceutical services.

Compartments appropriately marked shall be provided for the storage of poisons and external use drugs and biological, separate from internal and injectable medications.

O. All drug storage areas shall have proper controls for ventilation, lighting and temperature. Proper documentation shall be maintained relative to routine monitoring of temperature controls.

P. Drugs and biologicals that require temperature controlled refrigeration shall be refrigerated separately from food, beverages, blood and laboratory specimens.

Q. Locked areas that maintain medications, including controlled substances, shall conform to state and federal laws and the ASC's policies and procedures.

R. Unit dose systems shall include on each unit dose the:

1. name of the drug;
2. strength of the drug;
3. lot and control number or equivalent; and
4. expiration date.

S. Outdated, mislabeled or otherwise unusable drugs and biologicals shall:

1. be separated from useable stock;
2. not be available for patient use or other use;

and

3. be returned to an authorized agency for credit or destroyed according to current state and/or federal laws as applicable.

T. Abuses and losses of controlled substances shall be reported to the individual responsible for pharmaceutical services, the chief executive officer or administrator, the director of nurses, the Board of Pharmacy, and to the Regional DEA office, and according to ASC policy and procedure.

U. Any medications administered to a patient shall be administered only as ordered by a licensed medical practitioner and shall have documentation entered into the patient's medical record of the name of the drug, amount, route, the date and time administered, response and/or any adverse reactions to medications.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4559. Stereotactic Radiosurgery Services**

A. Ambulatory surgical centers operated primarily for the purpose of offering stereotactic radiosurgery by use of a gamma knife or similar neurosurgical tool are exempt from the following requirements:

1. having a minimum of two operating/procedure rooms and one post-anesthesia recovery room within the ASC;

2. caseload shall not exceed the capabilities of the surgical center including the recovery room;

3. the surgical area shall be located within the facility as to be removed from the general lines of traffic of both visitors and other ASC personnel; and

4. the following requirements:

a. scrub station(s) shall be provided directly adjacent to the entrance to each operating or procedure room;

b. a scrub station may serve two operating or procedure rooms if it is located directly adjacent to the entrances to both; and

c. scrub stations shall be arranged to minimize splatter on nearby personnel or supply carts.

B. The aforementioned exemptions do not apply to ASCs performing surgical procedures in conjunction with stereotactic radiosurgery.

C. These facilities shall be responsible for compliance with these licensing standards and any applicable state and federal laws, rules and regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**Subchapter E. Facility Responsibilities**

**§4565. General Provisions**

A. Ambulatory surgical centers shall comply and show proof of compliance with all relevant federal, state, local rules and regulations. It is the ASC's responsibility to secure the necessary approvals from the following entities:

1. Health Standards Section;

2. Office of the State Fire Marshal's plan review;

3. Office of Public Health;

4. Office of the State Fire Marshal's *Life Safety Code* inspection; and

5. the applicable local governing authority (e.g., zoning, building department or permit office).

B. The administrator or person authorized to act on behalf of the administrator shall be accessible to ASC staff or designated representatives of the department any time there is a patient in the ASC.

C. An ASC shall have qualified staff sufficient in number to meet the needs of patients and to ensure provision of services.

D. The ASC shall develop and maintain documentation of an orientation program for all employees of sufficient scope and

duration to inform the individual about his/her responsibilities, how to fulfill them, review of policies and procedures, job descriptions, competency evaluations and performance expectations. An orientation program and documented competency evaluation and/or job expectations of assigned or reassigned duties shall be conducted prior to any assignments or reassignments.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4567. Staffing Requirements**

A. Administrative Staff. The following administrative staff is required for all ASCs:

1. a qualified administrator at each licensed geographic location who shall meet the qualifications as established in these provisions;

2. other administrative staff as necessary to operate the ASC and to properly safeguard the health, safety and welfare of the patients receiving services; and

3. an administrative staff person on-call after routine daytime or office hours for the length of any patient stay in the ASC.

B. Administrator/Director

1. Each ASC shall have a qualified administrator/director who is an on-site employee responsible for the day-to-day management, supervision and operation of the ASC on a full-time basis.

2. Any current administrator employed by a licensed and certified ASC, at the time these licensing provisions are adopted and become effective, shall be deemed to meet the qualifications of the position of administrator as long as the individual holds his/her current position. If the individual leaves his/her current position, he/she shall be required to meet the qualifications stated in these licensing provisions to be re-employed into such a position.

3. The administrator shall meet the following qualifications:

a. possess a college degree from an accredited university; and

b. have one year of previous work experience involving administrative duties in a healthcare facility.

4. An RN shall meet the following qualifications to hold the position of administrator:

a. maintain a current and unrestricted RN license; and

b. have at least one year of management experience in a health care facility;

5. Changes in administrator shall be reported to the department within 10 days.

C. Medical Staff

1. The ASC shall have an organized medical staff, including any licensed medical practitioners who practice under a use agreement with the ASC.

2. All medical staff shall be accountable to the governing body for the quality of all medical and surgical care provided to patients and for the ethical and professional practices of its members.

3. Members of the medical staff shall be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted.

4. The medical staff shall develop, adopt, implement and monitor bylaws and rules for self-governing of the professional activity of its members. The medical staff bylaws shall be maintained within the ASC. The bylaws and rules shall contain provisions for at least the following:

a. developing the structure of the medical staff, including allied health professionals and categories of membership;

b. developing, implementing and monitoring to review credentials, at least every two years, and to delineate and recommend approval for individual privileges;

c. developing, implementing and monitoring to ensure that all medical staff possess current and unrestricted Louisiana licenses and that each member of the medical staff is in good standing with his/her respective licensing board;

d. recommendations to the governing body for membership to the medical staff with initial appointments and reappointments not to exceed two years;

e. developing, implementing and monitoring for suspension and/or termination of membership to the medical staff;

f. developing, implementing and monitoring criteria and frequency for review and evaluation of past performance of its individual members. This process shall include monitoring and evaluation of the quality of patient care provided by each individual;

g. the election of officers for the ensuing year;

h. the appointment of committees as deemed appropriate; and

i. reviewing and making recommendations for revisions to all policy and procedures at least annually;

5. Medical staff shall meet at least semi-annually. One of these meetings shall be designated as the official annual

meeting. A record of attendance and minutes of all medical staff meetings shall be maintained within the ASC.

6. A physician shall remain within the ASC until all patients have reacted and are assessed as stable.

7. The patient's attending physician, or designated on-call physician, shall be available by phone for consultation and evaluation of the patient, and available to be onsite if needed, until the patient is discharged from the ASC.

8. Each patient admitted to the ASC shall be under the professional supervision of a member of the ASC's medical staff who shall assess, supervise and evaluate the care of the patient.

9. Credentialing files for each staff physician shall be kept current and maintained within the ASC at all times.

D. Nursing Staff. A staffing pattern shall be developed for each nursing care unit (preoperative unit, operating/procedure rooms, post anesthesia recovery area). The staffing pattern shall provide for sufficient nursing personnel and for adequate supervision and direction by registered nurses consistent with the size and complexity of the procedure(s) performed and throughout the length of any patient stay in the ASC.

1. Nursing services shall be under the direction of an RN that includes a plan of administrative authority with written delineation of responsibilities and duties for each category of nursing personnel.

2. The ASC shall ensure that the nursing service is directed under the leadership of a qualified RN. The ASC shall have documentation that it has designated an RN to direct nursing services.

3. The director of nursing (DON) shall:

a. have a current, unrestricted Louisiana RN license;

b. be in good standing with the State Board of Nursing; and

c. shall have a minimum of one year administrative experience in a health care setting and the knowledge, skills and experience consistent with the complexity and scope of surgical services provided by the ASC.

4. The RN holding dual administrative/nursing director roles shall meet the qualifications of each role.

5. Changes in the director of nursing position shall be reported in writing to the department within 10 days of the change on the appropriate form designated by the department.

6. Nursing care policies and procedures shall be in writing, formally approved, reviewed annually and revised as

needed, and consistent with accepted nursing standards of practice. Policies and procedures shall be developed, implemented and monitored for all nursing service procedures.

7. There shall be a sufficient number of duly licensed registered nurses on duty at all times to plan, assign, supervise and evaluate nursing care, as well as to give patients the high quality nursing care that requires the judgment and specialized skills of a registered nurse.

a. There shall be sufficient nursing staff with the appropriate qualifications to assure ongoing assessment of patients' needs for nursing care and that these identified needs are addressed. The number and types of nursing staff is determined by the volume and types of surgery the ASC performs.

8. All professional nurses employed, contracted or working under a use agreement with the ASC shall have a current, unrestricted and valid Louisiana nursing license. Nonprofessional or unlicensed personnel employed, contracted, or working under a use agreement and performing nursing services shall be under the supervision of a licensed registered nurse.

9. There shall be, at minimum, one RN with ACLS certification and, at minimum, one RN with PALS certification, if a pediatric population is served, on duty and immediately available at any time there is a patient in the ASC.

10. The RN who supervises the surgical center shall have documented education and competency in the management of surgical services.

11. A formalized program on in-service training shall be developed and implemented for all categories of nursing personnel, employed or contracted, and shall include contracted employees and those working under a use agreement. Training is required on a quarterly basis related to required job skills.

a. Documentation of such in-service training shall be maintained on-site in the ASC's files. Documentation shall include the:

i. training content;

ii. date and time of the training;

iii. names and signatures of personnel in attendance; and

iv. name of the presenter(s).

12. General staffing provisions for the OR/procedure rooms shall be the following:

a. Circulating duties for each surgical procedure and for any pediatric procedure shall be performed by a licensed RN. The RN shall be assigned as the circulating nurse for one patient at a time for the duration of any surgical procedure performed in the center.

b. Appropriately trained licensed practical nurses (LPNs) and operating/procedure room technicians may perform scrub functions under the supervision of a licensed registered nurse.

c. Staffing for any nonsurgical, endoscopic procedure shall be based upon the level of sedation being provided to the adult patient, the complexity of the procedure, and the assessment of the patient. The role and scope of the nurses staffing the procedure rooms shall be in accordance with the Nurse Practice Act and nursing staff shall only perform duties that are in accordance with the applicable requirements for such personnel set forth in the Nurse Practice Act. A physician shall be required to complete a pre-procedural assessment to determine the suitability of the patient for the planned level of sedation. Depending upon the level of sedation deemed appropriate and administered, at a minimum, the following staffing levels shall be utilized for each nonsurgical, endoscopic procedure:

i. Patient is Unsedated. The OR/procedure room shall be staffed with a single assistant who may be an RN, licensed practical nurse (LPN) or unlicensed assistive personnel (UAP).

ii. Patient Receives Moderate/Conscious Sedation. With moderate/conscious sedation, a single RN may

administer the sedation under physician supervision, and such RN may assist only with minor, interruptible technical portions or tasks of the procedure. In accordance with the LSBN, the RN monitoring the patient shall have no additional responsibility that would require leaving the patient unattended or that would compromise continuous monitoring during the procedure.

iii. Complex Endoscopy Procedure (with or without sedation). For any complex endoscopy procedure (e.g. ERCP, EUS/FNA, etc.), there shall be an RN in the operating/procedure room to continuously monitor the patient, and a second RN, LPN or UAP to provide technical assistance to the physician.

NOTE: For purposes of §4567.D(12)c(i)-(iii), a reference to RN may be substituted by a CRNA or advanced practiced registered nurse. Said nursing staff shall have documentation of knowledge, skills, training, ability and competency of assigned tasks.

iv. Deep Sedation. This level requires a CRNA or anesthesiologist to administer the deep sedation and to monitor the patient. There shall be a second staff person (RN, LPN or UAP) dedicated to provide technical assistance for the endoscopy procedure.

NOTE: At any level of staffing for the nonsurgical, endoscopic procedure described above, if an LPN or UAP is the assigned staff providing assistance, in addition to such LPN or UAP assigned staff in the operating/procedure room, an RN shall be immediately

available in the ASC to provide emergency assistance. That RN shall not be assigned to a non-interruptible task during the duration of the procedure.

13. Post-Surgical Care Area. There shall be an RN whose sole responsibility is the post-surgical care of the patient. There shall be at least one other member of the nursing staff in the post-surgical care area(s) onsite and continually available to assist the post-surgical care RN until all patients have been discharged from the ASC.

E. General Personnel Requirements

1. All physicians and ASC employees, including contracted personnel and personnel practicing under a use agreement, shall meet and comply with these personnel requirements.

2. All physicians and ASC employees, including contracted personnel and personnel practicing under a use agreement, prior to and at the time of employment and annually thereafter, shall be verified to be free of tuberculosis in a communicable state in accordance with the ASC's policies and procedures and current Centers for Disease Control (CDC) and OPH recommendations.

3. All unlicensed staff involved in direct patient care and/or services shall be supervised by a qualified professional employee or staff member.

4. A personnel file shall be maintained within the ASC on every employee, including contracted employees and personnel providing services under a use agreement. Policies and procedures shall be developed to determine the contents of each personnel file. At a minimum, all personnel files shall include the following:

a. an application;

b. current verification of professional licensure;

c. health care screenings as defined by the ASC;

d. orientation and competency verification;

e. annual performance evaluations;

f. criminal background checks for UAPs, prior to offer of direct or contract employment after the effective date of this Rule, as applicable and in accordance with state law. The criminal background check shall be conducted by the Louisiana State Police or its authorized agent; and

f. any other screenings required of new applicants by state law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

## §4569. Medical Records

A. Each ASC shall make provisions for securing medical records of all media types, whether stored electronically or in paper form. The identified area or equipment shall be secured to maintain confidentiality of records and shall be restricted to staff movement and remote from treatment and public areas.

B. All records shall be protected from loss or damage.

C. The ASC shall have a designated area located within the ASC which shall provide for the proper storage, protection and security for all medical records and documents.

D. The ASC shall develop a unique medical record for each patient. Records may exist in hard copy, electronic format or a combination thereof.

E. ASCs that enter into a use agreement shall integrate the medical records of patients into the medical records of the ASC and shall comply with all requirements of this Section.

F. The ASC shall ensure the confidentiality of patient records, including information in a computerized medical record system, in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Regulations and any state laws, rules and regulations.

1. If computerized records are used, the ASC shall develop:

a. a back-up system for retrieval of critical medical records ;

b. safeguards/firewalls to prevent unauthorized use and access to information; and

c. safeguards/firewalls to prevent alterations of electronic records.

G. A unique medical record shall be maintained for every patient admitted and/or treated.

H. The medical record cannot become part of any other medical record associated with another entity.

I. The following data shall be documented and included as part of each patient's basic medical record:

1. unique patient identification;

2. admission and discharge date(s) and times;

3. medical and social history;

4. physical examination notes in accordance with medical staff bylaws, policies and procedures;

5. chief complaint or diagnosis;

6. physician's orders;

7. clinical laboratory report(s);

8. pathology report(s), when appropriate;

9. radiological report(s), when appropriate;

10. consultation report(s), when appropriate;

11. medical and surgical treatment regimen;

12. physician progress notes;

13. nurses' records of care provided and medications administered;

14. authorizations, consents or releases;

15. operative report;

16. anesthesia record to include, but not limited to:

a. type of anesthesia used;

b. medication administered;

c. person administering the anesthesia; and post-anesthesia report;

17. name of the treating physician(s), names of surgical assistants, and nursing personnel (scrub and circulator(s));

18. start and end time of the surgery/procedure;

19. a current informed consent for surgery/procedure and anesthesia that includes the following:

a. name of the patient;

b. patient identification number;

c. name of the procedure or operation being performed;

d. reasonable and foreseeable risks and benefits;

e. name of the licensed medical practitioner(s) who will perform the procedure or operation;

f. signature of patient or legal guardian or individual designated as having power of attorney for medical decisions on behalf of the patient;

g. date and time the consent was obtained; and

h. signature and professional discipline of the person witnessing the consent;

20. special procedures report(s);

21. patient education and discharge instructions;

22. a discharge summary, including:

a. physician progress notes and discharge notes; and

23. a copy of the death certificate and autopsy findings, when appropriate.

J. The medical records shall be under the custody of the ASC and maintained in its original, electronic, microfilmed or similarly reproduced form for a minimum period of 10 years from the date a patient is discharged, pursuant to R.S. 40:2144(F)(1). The ASC shall provide a means to view or reproduce the record in whatever format it is stored.

K. Medical records may be removed from the premises for computerized scanning for the purpose of storage. Contracts entered into, for the specific purpose of scanning at a location other than the ASC, shall include provisions addressing how:

1. the medical record shall be secured from loss or theft or destruction by water, fire, etc.; and

2. confidentiality shall be maintained.

L. Medical records may be stored off-site provided:

1. the confidentiality and security of the medical records are maintained; and

2. a 12-month period has lapsed since the patient was last treated in the ASC.

M. Each clinical entry and all orders shall be signed by the physician, and shall include the date and time. Clinical entries and any observations made by nursing personnel shall be signed by the licensed nurse and shall include the date and time.

1. If electronic signatures are used, the ASC shall develop a procedure to assure the confidentiality of each electronic signature, and shall prohibit the improper or unauthorized use of any computer-generated signature.

2. Signature stamps shall not be used.

N. All pertinent observations, treatments and medications given to a patient shall be entered in the nurses' notes as part of the medical record. All other notes relative to specific instructions from the physician shall be recorded.

O. Completion of the medical record shall be the responsibility of the admitting physician within 30 days of patient discharge.

P. All hard copy entries into the medical record shall be legible and accurately written in ink. The recording person shall sign the entry to the record and include the date and time of entry. If a computerized medical records system is used, all entries shall be authenticated, dated and timed, complete, properly filed and retained, accessible and reproducible.

Q. Written orders signed by a member of the medical staff shall be required for all medications and treatments administered to patients, and shall include the date and time ordered. Verbal orders shall include read-back verification. All verbal orders shall be authenticated by the ordering physician within 48 hours to include the signature of the ordering physician, date and time.

R. The use of standing orders shall be approved by the medical staff, and the standing orders shall be individualized for each patient. Standing orders shall be approved for use by the medical staff on a yearly basis. If standing orders are utilized, the standing orders shall become part of the medical record and include the patient's name, date of surgery and shall be authenticated by the ordering physician's signature, date and time. Any changes to the pre-printed orders shall be initialed

by the physician making the entry or change to the pre-printed form. The changes shall be legible, noted in ink (if hard copy), and shall include the date and time.

1. Range orders are prohibited.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4571. Other Records and Reports**

A. The following indexes, records and registers shall be required of the licensed ASC, including any individual or entity that enters into a use agreement:

1. a patient's register;

2. an operating/procedure room register;

3. a death register;

4. a daily census report of admissions and discharges;

5. records of reportable diseases as required by state and/or federal regulations;

6. a laboratory log denoting laboratory specimens that are sent to pathology;

a. the laboratory log shall include, at a minimum, the following information:

i. the patient's name;

ii. the specimen site; and

iii. the date the specimen was sent for pathology interpretation; and

7. an implant log, when appropriate.

B. Other statistical information shall be maintained to expedite data gathering for specialized studies and audits.

C. Nothing in this Chapter is intended to preclude the use of automated or centralized computer systems or any other techniques provided the regulations stated herein are met.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4573. Quality Assurance and Performance Improvement**

A. The governing body shall ensure that there is an implemented, maintained, effective, written, data-driven and ongoing program designed to assess and improve the quality of patient care. This program shall include all contracted services and those services provided under a use agreement.

B. The governing body shall ensure that it allocates sufficient staff, time, information systems and training to implement the Quality Assurance and Performance Improvement (QAPI) Program.

C. The ASC shall ensure there is a written quality assurance plan for assessing and improving quality of care that is focused on high risk, high volume and problem-prone areas, and which specifies the intervals that the ASC shall actively collect data related to the quality indicators. Performance improvement activities shall consider incidence, prevalence and severity of problems and those that can affect health outcomes, patient safety and quality of care. The plan shall describe the system for overseeing and analyzing the effectiveness of monitoring, evaluation and sustained improvement activities. All services related to patient care, including services furnished by a contractor or under a use agreement, shall be evaluated.

D. Nosocomial infections, patient care outcomes, surgical services and other invasive procedures performed in the ASC shall be evaluated as they relate to appropriateness of diagnosis and treatment.

E. The services provided by each licensed practitioner with ASC privileges shall be periodically evaluated to determine whether they are of an acceptable level of quality and appropriateness and in accordance with medical staff bylaws/rules and regulations.

F. Quality assurance and performance improvement shall include monitoring of in-line gases.

G. The QAPI program shall monitor, identify and develop a plan for elimination of medication errors and adverse patient events.

H. Corrective actions to problems identified through the QAPI program with on-going monitoring for sustained corrective action shall be documented. All QAPI data shall be documented and remain within the ASC. Staff education and training related to the correction of problems shall be documented.

I. The number and scope of distinct QAPI improvement projects conducted annually shall reflect the scope and complexity of the ASC's services and operations.

J. The ASC shall document the projects that are being conducted. The documentation, at a minimum, shall include:

1. the reason(s) for implementing the project; and

2. a description of the project's results.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**Subchapter F. Safety, Sanitization and Emergency Preparedness**

**§4575. General Provisions**

A. The ASC shall have policies and procedures, approved and implemented by the medical staff and governing body, that address provisions for:

1. sanitizing, disinfecting and sterilizing supplies, equipment and utensils; and

2. the safe use of cleaning supplies and solutions that are to be used and the directions for use, including:

a. terminal cleaning of the OR/procedure rooms; and

b. cleaning of the OR/procedure rooms between surgical and nonsurgical procedures.

B. Policies and procedures shall be developed, implemented and approved by the ASC's governing body for the types and numbers of sterilizing equipment and autoclaves sufficient to meet the surgical sterilization needs of the ASC.

1. Procedures for the proper use of sterilizing equipment for the processing of various materials and supplies shall be in writing, according to manufacturer's recommendations, and readily available to personnel responsible for the sterilizing process.

2. All sterilization monitoring logs shall be maintained within the ASC for a minimum of 18 months.

C. All steam sterilizing equipment shall have live bacteriological spore monitoring performed at a frequency according to the manufacturer's instructions.

1. If tests are positive, a system shall be in place to recall supplies that have tested substandard in accordance

with the ASC's policies and procedures set forth by the ASC's governing body.

D. All ethylene oxide sterilizing equipment shall have live bacteriological spore monitoring performed with each load and according to manufacturer's recommendation. There shall be ventilation of the room used for this sterilization to the outside atmosphere. There shall be a system in place to monitor trace gases of ethylene oxide with a working alert system which is tested and documented daily.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4577. Infection Control**

A. The ASC shall maintain an infection control program that minimizes infections and communicable diseases through prevention, investigation and reporting of infections. This program shall include all contracted services and those services provided under a use agreement.

B. The ASC shall provide a functional and sanitary environment for the provision of surgical or endoscopy services, if provided, by adopting and adhering to professionally accepted standards of practice. The ASC shall have documentation that the infection control program was considered, selected and

implemented based on nationally recognized infection control guidelines.

C. The infection control program shall be under the direction of a designated and qualified professional. The ASC shall determine that the individual selected to lead the infection control program has had documented training in the principles and methods of infection control. The individual shall maintain his/her qualifications through ongoing education and training, which can be demonstrated by participation in infection control courses or in local and national meetings organized by a nationally recognized professional infection control society.

D. The ASC shall develop, with the approval of the medical director and the governing body, policies and procedures for preventing, identifying, reporting, investigating, controlling and immediately implementing corrective actions relative to infections and communicable diseases of patients and personnel. At a minimum, the policies shall address:

1. hand sanitizers and hand hygiene;
2. use of all types of gloves;
3. surgical scrub procedures;
4. linen cleaning and reuse;
5. waste management;
6. environmental cleaning;

7. reporting, investigating and monitoring of surgical infections;

8. sterilization and cleaning procedures and processes;

9. single use devices;

10. disinfecting procedures and processes;

11. breaches of infection control practices; and

12. utilization of clean and dirty utility areas.

E. The ASC shall have policies and procedures developed and implemented which require immediate reporting, according to the latest criteria established by the Centers for Disease Control, Office of Public Health and the Occupational Safety and Health Administration (OSHA), of the suspected or confirmed diagnosis of a communicable disease.

F. The ASC shall maintain an infection control log of incidents related to infections. The log is to be maintained within the ASC for a minimum of 18 months.

G. Any employee with a personal potentially contagious/ or infectious illness shall report to his/her immediate supervisor and/or director of nursing for possible reassignment or other appropriate action to prevent the disease or illness from spreading to other patients or personnel.

1. Employees with symptoms of illness that have the potential of being potentially contagious or infectious (i.e.

diarrhea, skin lesions, respiratory symptoms, infections, etc.) shall be either evaluated by a physician and/or restricted from working with patients during the infectious stage.

H. Provisions for isolation of patients with a communicable or contagious disease shall be developed and implemented according to ASC policy and procedure.

I. Provisions for transfer of patients from the ASC shall be developed and implemented according to ASC policy and procedure.

J. The ASC shall develop a system by which potential complications/infections that develop after discharge of a patient from the ASC are reported, investigated and monitored by the infection control officer.

K. Procedures for isolation techniques shall be written and implemented when applicable.

L. The ASC shall have a written and implemented waste management program that identifies and controls wastes and hazardous materials to prevent contamination and the spread of infection within the ASC. The program shall comply with all applicable laws and regulations governing wastes and hazardous materials and the safe handling of these materials.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4579. Laundry Handling and Sanitation**

A. The ASC shall be responsible for ensuring the proper handling, cleaning, sanitizing and storage of linen and other washable goods whether provided by the ASC or provided by a contracted vendor. All linen used in the ASC shall be of sufficient quantity to meet the needs of the patients.

B. Laundry services shall be provided either in-house or through a contracted commercial laundry service in accordance with the ASC's policies and procedures as set forth by the governing body.

1. Contracted Laundry Service

a. If laundry service is contracted, the ASC shall assess the cleaning and sanitizing processes that are used by the commercial laundry service.

2. In-House Laundry Service

a. If laundry services are provided in-house, policies and procedures shall be developed which follow manufacturer's recommended guidelines for water temperature, the method for cleaning and sanitizing reusable laundry and the type of cleaning products utilized to prevent the transmission of infection through the ASC's multi-use of these washable goods.

b. The water temperature shall be monitored and documented on a daily use log and maintained for a minimum of 18 months.

C. Procedures shall be developed for the proper handling and distribution of linens to minimize microbial contamination from surface contact or airborne deposition.

D. Cross contamination of clean and dirty linen shall be prevented. Provisions shall be made for the separation of clean and soiled linen. All contaminated laundry shall be handled according to the ASC's written protocols in accordance with current applicable OSHA and CDC guidelines.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4581. Emergency Preparedness and Emergency Procedures**

A. Disaster and emergency plans shall be developed by the governing body, and updated annually, which are based on a risk assessment using an all hazards approach for both internal and external occurrences. Disaster and emergency plans shall include provisions for persons with disabilities.

B. The ASC shall develop and implement policies and procedures based on the emergency plan, risk assessment and communication plan which shall be reviewed and updated at least

annually. Such policies shall include a system to track on duty staff and sheltered patients, if any, during the emergency.

C. The ASC shall develop and maintain an emergency preparedness communication plan that complies with both federal and state laws. Patient care shall be well-coordinated within the ASC, across health care providers and with state and local public health departments and emergency systems.

D. The ASC shall develop and maintain training and testing programs, including initial training in policies and procedures and demonstrate knowledge of emergency procedures. Such training shall be provided at least annually.

E. Additional Requirements:

1. Each ASC shall post exit signs and diagrams conspicuously through the facility.

2. Flash lights or battery operated lamps for emergency use shall be available for ASC personnel and kept in operational condition.

3. The ASC shall ensure that emergency equipment is:

a. immediately available for use during emergency situations;

b. appropriate for the ASC's patient population; and

c. maintained by appropriate personnel.

4. The ASC shall have written policies and procedures that address the availability and relevant use of the following emergency equipment in the ASC's operating/procedure rooms sufficient in number to handle multiple simultaneous emergencies:

a. emergency call system;

b. oxygen;

c. mechanical ventilatory assistance equipment, including:

i. airways;

ii. manual breathing bag; and

iii. ventilator;

d. cardiac defibrillator;

e. cardiac monitoring equipment;

f. tracheostomy set;

g. laryngoscope and endotracheal tubes;

h. suction equipment; and

i. any other emergency medical equipment and supplies specified by the medical staff and approved by the governing body for treatment of all age groups serviced in the ASC.

5. The ASC shall have an operable backup generator of sufficient size to support and maintain necessary life-sustaining medical equipment.

a. A sufficient amount of fuel shall be maintained to ensure the operation of the generator for at least four hours to maintain:

i. temperatures to protect patient health and safety and for the safe and sanitary storage of provisions;

ii. emergency lighting; and

iii. fire detection, extinguishing and alarm systems.

6. The ASC is responsible for:

a. developing and implementing policies and procedures for the safe emergency transfer of patients from the ASC in the event that an emergency impacts the ASC's ability to provide services;

b. developing policies that address what types of emergency procedures, equipment and medications shall be available; and

c. providing trained staff to sustain the life of the patient prior to the transfer.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4583. Inactivation of License due to a Declared Disaster or Emergency**

A. An ASC licensed in a parish which is the subject of an executive order or proclamation of emergency or disaster, issued in accordance with R.S. 29:724 or R.S. 29:766, may seek to inactivate its license for a period not to exceed one year, provided that the following conditions are met:

1. the ASC shall submit written notification to the Health Standards Section within 60 days of the date of the executive order or proclamation of emergency or disaster that:

a. the ASC has experienced an interruption in the provisions of services as a result of events that are the subject of such executive order or proclamation of emergency or disaster issued in accordance with R.S. 29:724 or R.S. 29:766;

b. the ASC intends to resume operation as an ASC in the same service area;

c. includes an attestation that the emergency or disaster is the sole casual factor in the interruption of the provision of services;

2. the ASC resumes operating in the same service area within one year of the issuance of an executive order or proclamation of emergency or disaster in accordance with R.S. 29:724 or R.S. 29:766;

3. the ASC continues to pay all fees and costs due and owed to the department including, but not limited to, annual

licensing fees and outstanding civil monetary penalties, if applicable; and

4. the ASC continues to submit required documentation and information to the department.

B. Upon receiving a completed written request to inactivate an ASC license, the department shall issue a notice of inactivation of license to the ASC.

C. Upon completion of repairs, renovations, rebuilding or replacement, an ASC which has received a notice of inactivation of its license from the department shall be allowed to reinstate its license upon the following conditions being met:

1. The ASC shall submit a written license reinstatement request to HSS 60 days prior to the anticipated date of reopening.

a. The license reinstatement request shall inform the department of the anticipated date of opening, and shall request scheduling of a licensing survey.

b. The license reinstatement request shall include a completed licensing application with appropriate licensing fees.

c. The ASC shall submit the following:

i. a copy of the approval letter of the architectural facility plans from the Office of the State Fire Marshal (OSFM) and any other office/entity designated by the

department to review and approve the facility's architectural plans;

ii. a copy of the on-site inspection report with approval for occupancy by OSFM, if applicable; and

iii. a copy of the on-site health inspection report with approval of occupancy from OPH;

2. The ASC resumes operating in the same service area within one year.

D. Upon receiving a completed written request to reinstate an ASC license, the department shall conduct a licensing survey. If the ASC meets the requirements for licensure and the requirements under this Section, the department may issue a notice of reinstatement of the ASC license.

E. No change of ownership of the ASC shall occur until such ASC has completed repairs, renovations, rebuilding or replacement construction and has resumed operations as an ASC.

F. The provisions of this Section shall not apply to an ASC which has voluntarily surrendered its license and ceased operation.

G. Failure to comply with any of the provisions of this Section shall be deemed a voluntary surrender of the ASC license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4585. Inactivation of License due to a Non-Declared Emergency or Disaster**

A. An ASC in an area or areas which have been affected by a non-declared emergency or disaster may seek to inactivate its license, provided that the following conditions are met:

1. the ASC shall submit written notification to the Health Standards Section within 30 days of the date of the non-declared emergency or disaster stating that:

a. the ASC has experienced an interruption in the provisions of services as a result of events that are due to a non-declared emergency or disaster;

b. the facility intends to resume operation as an ASC in the same service area;

c. the ASC attests that the emergency or disaster is the sole causal factor in the interruption of the provision of services; and

d. the ASC's initial request to inactivate does not exceed one year for the completion of repairs, renovations, rebuilding or replacement of the facility.

NOTE: Pursuant to these provisions, an extension of the 30-day deadline for initiation of request may be granted at the discretion of the department.

2. the ASC continues to pay all fees and costs due and owed to the department including, but not limited to, annual licensing fees and outstanding civil monetary penalties and/or civil fines; and

3. the ASC continues to submit required documentation and information to the department, including but not limited to, cost reports.

B. Upon receiving a completed written request to temporarily inactivate the ASC license, the department shall issue a notice of inactivation of license to the ASC.

C. Upon the ASC's receipt of the department's approval of request to inactivate the license, the ASC shall have 90 days to submit plans for the repairs, renovations, rebuilding or replacement of the ASC to OSFM and OPH as required.

D. The ASC shall resume operating as an ASC in the same service area within one year of the approval of renovation/construction plans by OSFM and OPH as required.

Exception: If the ASC requires an extension of this timeframe due to circumstances beyond the ASC's control, the department will consider an extended time period to complete construction or repairs. Such written request for extension shall show the ASC's active efforts to complete construction or repairs and the

reasons for request for extension of the ASC's inactive license. Any approvals for extension are at the sole discretion of the department.

E. Upon completion of repairs, renovations, rebuilding or replacement of the ASC, an ASC which has received a notice of inactivation of its license from the department shall be allowed to reinstate its license upon the following conditions being met:

1. the ASC shall submit a written license reinstatement request to the licensing agency of the department;

2. the license reinstatement request shall inform the department of the anticipated date of opening and shall request scheduling of a licensing or physical environment survey; and

3. the license reinstatement request shall include a completed licensing application with appropriate licensing fees.

F. Upon receiving a completed written request to reinstate an ASC license, the department may conduct a licensing or physical environment survey. The department may issue a notice of reinstatement if the ASC has met the requirements for licensure including the requirements of this Subsection.

G. No change of ownership of the ASC shall occur until such ASC has completed repairs, renovations, rebuilding or replacement construction and has resumed operations as an ASC.

H. The provisions of this Section shall not apply to an ASC which has voluntarily surrendered its license and ceased operation.

I. Failure to comply with any of the provisions of this Section shall be deemed a voluntary surrender of the ASC license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**Subchapter G. Physical Environment**

**§4587. General Requirements**

A. The standards in this Subchapter shall apply to any ASC constructed after the effective date of this rule, or an ASC that makes alterations, additions or substantial rehabilitation to an existing ASC or adaptation of an existing building to create an ASC. Cosmetic changes to the ASC such as painting, flooring replacement or minor repairs shall not be considered an alteration or substantial rehabilitation.

Exception: For those applicants for ASC licensure who received plan review approval from the OSFM before the effective date of the promulgation of this Rule, or who have begun construction or renovation of an existing building before the effective date of the promulgation of this Rule, the physical environment requirements of §4587 shall not apply.

B. An applicant for an ASC license shall furnish one complete set of architectural plans and specifications to the entity/office designated by the department to review and approve the facility's architectural plans and the Office of State Fire Marshal.

1. The office designated by the department to review and approve architectural drawings and specifications and the Office of State Fire Marshal shall review and approve the *Life Safety Code* plans before construction is allowed to begin.

2. When the plans and specifications have been reviewed and all inspections and investigations have been made, the applicant will be notified whether the plans for the proposed ASC have been approved.

C. No alterations, other than minor alternations, shall be made to existing facilities without the prior written approval of, and in accordance with, architectural plans and specifications approved in advance by the department, or its designee, and the Office of State Fire Marshal.

D. All new construction, additions and renovations, other than minor alterations, shall be in accordance with the specific requirements of the Office of State Fire Marshal and the department, or its designee, who shall be responsible for the review and approval of architectural plans. Plans and specifications submitted to these offices shall be prepared by

or under the direction of a licensed architect and/or a qualified licensed engineer and shall include scaled architectural plans stamped by an architect.

E. All designs and construction shall be in accordance with the provisions of *LAC Title 51 Public Health Sanitary Code*.

F. Facility Within A Facility

1. If more than one health care provider occupies the same building, premises or physical location, all treatment facilities and administrative offices for each health care facility shall be clearly separated from the other by a clearly defined and recognizable boundary.

2. There shall be clearly identifiable and distinguishable signs posted inside the building as well as signs posted on the outside of the building for public identity of the ASC. Compliance with the provisions of R.S. 40:2007 shall be required.

3. An ASC that is located within a building that is also occupied by one or more other businesses and/or other healthcare facilities shall have all licensed spaces and rooms of the ASC contiguous to each other and defined by cognizable boundaries.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4589. General Appearance and Space Requirements**

A. The ASC shall be constructed, arranged and maintained to ensure the safety and well-being of the patients and the general public it serves.

B. The ASC shall have a minimum of two operating and/or procedure rooms and a minimum of one post-anesthesia recovery room to meet the needs of the patients being served. In addition to the operating and/or procedure rooms and post-anesthesia recovery rooms, the ASC may also have one or more treatment rooms.

C. The location of the operating and procedure rooms within the ASC, and the access to it, shall conform to professionally-accepted standards of practice, particularly for infection control, with respect to the movement of people, equipment and supplies in and out of the operating or procedure rooms.

1. The operating and procedure rooms' temperature and humidity shall be monitored and maintained in accordance with accepted standards of practice and documented on a daily use log that is maintained for a minimum of 18 months.

D. The ASC shall have a separate waiting area sufficient in size to provide adequate seating space for family members and/or guests of the patient.

E. The ASC shall meet the following requirements including, but not limited to:

1. A sign shall be posted on the exterior of the ASC that can be viewed by the public which shall contain, at a minimum, the "doing business as" name that is on the ASC's license issued by the department.

2. Signs or notices shall be prominently posted in the ASC stipulating that smoking is prohibited in all areas of the ASC.

3. Policies and procedures shall be developed for maintaining a clean and sanitary environment at all times.

4. There shall be sufficient storage space for all supplies and equipment. Storage space shall be located away from foot traffic, provide for the safe separation of items, and prevent overhead and floor contamination.

5. All patient care equipment shall be clean and in working order. Appropriate inspections of patient care equipment shall be maintained according to manufacturer's recommendations and ASC policies and procedures.

6. Designated staff areas shall be provided for surgical and other personnel to include, but not be limited to:

a. dressing rooms;

b. toilet and lavatory facilities including soap and towels; and

c. closets or lockers to secure the personal belongings of the staff.

7. Adequate toilet facilities shall be provided for patients and/or family which maintain proper ventilation, properly functioning toilet(s) in each toilet facility, hot and cold water in all lavatories, soap and towels.

8. A private area shall be provided for patients to change from street clothing into hospital gowns and to prepare for surgery.

9. Provisions shall be made for securing patients' personal effects.

10. All doors to the outside shall open outward and be provided with self-closing devices.

11. All stairways, ramps and elevators shall be provided with non-skid floor surfaces and all stairways shall have handrails on both sides.

12. An effective and on-going pest control program shall be maintained to ensure the ASC is free of insects and rodents.

13. Proper ventilation, lighting and temperature controls shall be maintained in all areas of the ASC.

14. Waste products shall be stored in covered containers of a capacity and type approved by the Office of Public Health, and disposal of such wastes shall be in a manner approved by the Office of Public Health.

15. Each ASC shall provide for a covered entrance, well-marked, and illuminated for drop off and/or pick up of patients before and after surgery. The covered entrance shall extend to provide full overhead coverage of the entire transporting automobile and/or ambulance to permit protected transfer of patients. Vehicles in the loading area should not block or restrict movement of other vehicles in the drive or parking areas immediately adjacent to the ASC.

16. The ASC shall provide a separate room for meetings to ensure privacy between medical staff and family members.

17. Patient and family parking spaces shall be provided adjacent to the ASC that are in proportion to the number of pre- and post-operative stations.

18. Adequate staff and physician parking spaces shall be available.

F. Surgical Area

1. The surgical area shall be comprised of a minimum of two operating rooms. In new construction and renovation, each operating room shall have a minimum clear floor area of 250

square feet with a minimum clear area of 15 feet between fixed cabinets and built-in shelves.

2. The surgical/ procedure room area shall be located in a segregated and restricted section of the ASC and be removed from general lines of traffic of both visitors and other ASC personnel, and from other departments so as to prevent traffic through them.

3. The surgical/procedure room area shall be defined by the following unrestricted, semi-restricted and restricted areas.

a. Unrestricted Area. This area shall include a central control point established to monitor the entrance of patients, personnel and materials into the restricted areas. Street clothes are permitted in this area, and traffic is not limited.

b. Semi-Restricted Area. This area shall include the peripheral support areas of the surgical center which includes storage areas for clean and sterile supplies, work areas for storage and processing of instruments and corridors leading to the restricted areas of the surgical center. Staff attire appropriate for the semi-restricted area shall be defined in policy. Traffic in this area is limited to authorized personnel and patients.

c. Restricted area. This area shall include operating and procedure rooms, the clean core and scrub sink areas. Surgical attire, including hair coverings and masks, shall be required in accordance with professionally accepted standards.

4. The operating/procedure room(s) shall be appropriately equipped to safely provide for the needs of the patient and in accordance with accepted clinical practices. The operating/procedure room(s) shall consist of a clear and unobstructed floor area to accommodate the equipment and personnel required, allowing for aseptic technique. Only one surgical case or procedure can be performed in an operating/procedure room at a time.

5. There shall be scrub-up facilities in the surgical center which provide hot and cold running water and that are equipped with knee, foot or elbow faucet controls.

6. Space for supply and storage of medical gases, including space for reserve cylinders shall be provided. Provisions shall be made for the secure storage of all medical gas cylinders to prevent tipping and falling. Policies and procedures shall be developed for testing of medical gases.

7. Equipment storage room(s) shall be provided for equipment and supplies used in the operating/procedure room(s).

Equipment storage room(s) shall be located within the semi-restricted area.

a. Stretchers shall be stored in an area that is convenient for use, out of the direct line of traffic and shall not create an obstacle for egress.

8. There shall be emergency resuscitation equipment and supplies including a defibrillator and tracheostomy set available to both surgery and post-anesthesia recovery areas.

a. The numbers of crash carts (emergency medical supply carts) in the ASC should be based on current professionally accepted standards of practice adopted from a national association or organization and defined in policies and procedures, and shall be immediately available to both surgery and post-anesthesia recovery areas.

G. Post-Anesthesia Recovery Area

1. Rooms for post-anesthesia recovery in an ASC shall be provided in accordance with the functional program and sufficient in size and equipment to efficiently and safely provide for the needs of the staff and patients. There shall be at least one separate post-anesthesia recovery area within the ASC.

2. Provisions to ensure patient privacy such as cubicle curtains shall be made.

3. The post-anesthesia recovery area shall be accessible directly from the semi-restricted area and adjacent to the operating/procedure rooms.

4. A nurse's station(s) shall be located within the post-anesthesia recovery area and shall be centrally located with complete visualization of all patients in the post-anesthesia recovery area.

a. Each nurse's station or nursing care area shall be equipped to perform nursing functions to include:

i. desk space;

ii. chart racks and/or electronic medical record equipment;

iii. telephone(s) or other communication equipment; and

iv. lockable cupboard, closet or room designed for the storage and preparation of patient medications;

b. A double locked storage shall be provided for controlled substances. Separate areas shall be provided for the separation of internal and external drugs and medications. This area shall be well lighted with temperature controls and accessible only to authorized personnel. A separate refrigerator for pharmaceuticals shall be provided and monitored regularly for documented compliance with temperature controls.

A sink with running hot and cold water and sufficient work area shall also be provided in the area of drug preparation.

5. Hand washing station(s) shall be available in the post-anesthesia recovery area.

6. The post-anesthesia recovery area shall have a minimum of 80 square feet provided for each patient in a lounge chair/stretcher.

H. There shall be sufficient space between and around lounge chairs/stretchers and between fixed surfaces and lounge chairs/stretchers to allow for nursing and physician access to each patient.

I. General and individual office(s) for business transactions, records and administrative and professional staff shall be provided within the ASC. Space for private patient interviews relating to admission shall be provided within the ASC.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have positive impact on family functioning,

stability or autonomy as described in R.S. 49:972 by ensuring the safe operation of facilities that provide ambulatory surgical services.

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973.

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service and no direct or indirect cost to the provider to provide the same level of service. These provisions will have no impact the provider's ability to provide the same level of service as described in HCR 170.

Interested persons may submit written comments to Cecile Castello, Health Standards Section, P.O. Box 3767, Baton Rouge, LA 70821 or by email to MedicaidPolicy@la.gov. Ms. Castello is responsible for responding to inquiries regarding this proposed Rule. A public hearing on this proposed Rule is scheduled for Thursday, March 30, 2017 at 9:30 a.m. in Room 118, Bienville

Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Rebekah E. Gee MD, MPH

Secretary

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

# State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

**PUBLIC HEARING CERTIFICATION**
**March 30, 2017**
**9:30 a.m.**

RE: Ambulatory Surgical Centers
Licensing Standards
Docket # 03302017-01
Department of Health
State of Louisiana

CERTIFICATION

In accordance with LA R.S. 49:950 et seq., the attached public hearing agenda, together with one digital recording of the public hearing conducted on March 30, 2017 in Baton Rouge, Louisiana constitute the official record of the above-referenced public hearing.

Robert K. Andrepont
Medicaid Policy and Compliance
Section

03/30/17
Date

# LDH/BHSF PUBLIC HEARING

**Topic** – Ambulatory Surgical Centers – Licensing Standards

**Date** – March 30, 2017

PERSONS IN ATTENDANCE

| Name | Address | Telephone Number | AGENCY or GROUP you represent |
|---|---|---|---|
| 1. Carol Rumfola | 628 N 4th BR 70802 | 225 342 6943 | LDH |
| 2. Jennfer Haines | 628 N. 4th BR, LA 70802 | 225-342-9348 | LDH |
| 3. Brenda Blanchard | " | (225) 342-2471 | " NSS |
| 4. Cindy B[illegible] | PO Box 80053 BR 70898 | 225 933 5435 | Checkmate Strat |
| 5. Michael Willis | P.O. Box 80053 BR 70898 | 225-454 2209 | Checkmate Strategies |
| 6. | | | |

**POTPOURRI**

**Department of Health**
**Bureau of Health Services Financing**

**Public Hearing—Substantive Changes to Proposed Rule**
**Ambulatory Surgical Centers**
**Licensing Standards**
**(LAC 48:I.4503, 4567, 4569 and 4573)**

In accordance with the provisions of the Administrative Procedures Act, R.S. 49:950 et seq., the Department of Health, Bureau of Health Services Financing published a Notice of Intent in the February 20, 2017 edition of the *Louisiana Register* (LR 43:429-455) to repeal and replace LAC 48:I.Chapter 45 in the Medical Assistance Program as authorized by R.S. 36:254 and R.S. 40:2131-2141. This Notice of Intent proposed to repeal and replace the licensing standards governing ambulatory surgical centers in order to: 1) clarify the existing provisions; 2) provide for inactivation of the provider license in the event of specific qualifying events or circumstances; 3) establish provisions which allow ambulatory surgical centers to enter into use agreements; and 4) ensure consistency with other licensing rules, regulations and processes.

The department conducted a public hearing on this Notice of Intent on March 30, 2017 to solicit comments and testimony on the proposed Rule. As a result of the comments received, the department now proposes to amend the provisions in §4503 and

§§4567, 4569 and 4573 of the proposed Rule to further clarify these provisions.

Taken together, all of these revisions will closely align the proposed Rule with the department's original intent and the concerns brought forth during the comment period for the Notice of Intent as originally published. No fiscal or economic impact will result from the amendments proposed in this notice.

**Title 48**

**PUBLIC HEALTH—GENERAL**
**Part I. General Administration**
**Subpart 3. Licensing and Certification**

**Chapter 45. Ambulatory Surgical Center**

**Subchapter A. General Provisions**

**§4503. Definitions**

***

*Ambulatory Surgical Center (ASC)*—a distinct entity that is wholly separate and clearly distinguishable from any other healthcare facility or office-based physician's practice. An ASC shall be composed of operating room(s) and/or procedure room(s) with an organized medical staff of physicians and permanent facilities that are equipped and operated primarily for the purpose of performing surgical procedures. An ASC provides continuous physician and professional nursing services to patients whenever a patient is in the ASC, but does not

provide services or accommodations for patients to stay overnight.

1. - 2. ...

3. An ASC that enters into a use agreement with another entity/individual shall have separate, designated hours of operation.

***

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**Subchapter E. Facility Responsibilities**

**§4567. Staffing Requirements**

A. - A.3. ...

B. Administrator/Director

1. Each ASC shall have a qualified administrator/director who is an on-site employee responsible for the day-to-day management, supervision and operation of the ASC.

2. - E.3. ...

4. A personnel file shall be maintained within the ASC on every employee, including contracted employees and personnel providing services under a use agreement. Policies and procedures shall be developed to determine the contents of

each personnel file. At a minimum, all personnel files shall include the following:

a. - e. ...

f. criminal background checks for UAPs, prior to offer of direct or contract employment after the effective date of this Rule, as applicable and in accordance with state law. The criminal background check shall be conducted by the Louisiana State Police or its authorized agent; and

g. any other screenings required of new applicants by state law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4569. Medical Records**

A. - H. ...

I. The following data shall be documented and included as part of each patient's basic medical record:

1. - 15. ...

16. anesthesia record to include, but not limited to:

a. - b. ...

c. person administering the anesthesia; and

d. post-anesthesia report;

I.17. - R.1. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**§4573. Quality Assurance and Performance Improvement**

A. The governing body shall ensure that there is an implemented, maintained, effective, written, data-driven and ongoing program designed to assess and improve the quality of patient care. This program shall include all services, provided directly or through contract, and those services provided under a use agreement, where applicable.

B. - J.2. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2141.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

Interested persons may submit written comments to Cecile Castello, Health Standards Section, P.O. Box 3767, Baton Rouge, LA 70821 or by email to MedicaidPolicy@la.gov. Ms. Castello is responsible for responding to inquiries regarding these substantive amendments to the proposed Rule. A public hearing on these substantive changes to the proposed Rule is scheduled for Thursday, July 27, 2017 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that

time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Rebekah E. Gee MD, MPH

Secretary

**John Bel Edwards**
GOVERNOR

**Rebekah E. Gee MD, MPH**
SECRETARY

# State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

**PUBLIC HEARING CERTIFICATION**
**July 27, 2017**
**9:30 a.m.**

RE: Public Hearing
Substantive Changes to Proposed Rule
Ambulatory Surgical Centers
Licensing Standards
Docket # 07272017-05
Department of Health
State of Louisiana

CERTIFICATION

In accordance with LA R.S. 49:950 et seq., the attached public hearing agenda, together with one digital recording of the public hearing conducted on July 27, 2017 in Baton Rouge, Louisiana constitute the official record of the above-referenced public hearing.

Medicaid Policy and Compliance
Section

07/27/17
Date

# DHH/BHSF PUBLIC HEARING

**Topic – Public Hearing Substantive changes to Proposed Rule Ambulatory Surgical Centers Licensing Standards**

**Date** – July 27, 2017

PERSONS IN ATTENDANCE

| Name | Address | Telephone Number | AGENCY or GROUP you represent |
|---|---|---|---|
| 1. Keydra Singleton | 628 N. 4th St. Baton Rouge LA 70805 | 225-342-3086 | LDH |
| 2. Brenda Blanchard | LDH - HSS | (225)342-2471 | HSS |
| 3. Jennifer Haines | LDH-HSS | 225-342-9348 | HSS |
| 4. Cindy Bishop | LASCA | 225 933 5435 | LASCA |
| 5. Amanda Trapp | | 225-342-2102 | Senate Health & Welfare. |
| 6. | | | |

# SUMMARY OF PUBLIC HEARING TESTIMONY

**Proposed Rule:** Ambulatory Surgical Centers – Licensing Standards Notice of Intent
**Public Hearing Date:** March 30, 2017
**Docket No. :** 03302017-01
**Conducted By:** Louisiana Department of Health, Bureau of Health Services Financing Staff

| Oral Testimony Given By | Organization Represented | Summary of Comments |
|---|---|---|
| Michael Willis | Louisiana Ambulatory Surgery Centers Association | §4513. Changes in Licensee Information or Personnel - Felt that reporting requirements for temporary closure were over burdensome and requested that it be changed to five or more days before a center is required to report a temporary closure.<br>§4539. Admissions and Assessments – Felt that these requirements were more stringent than the federal requirements for Ambulatory Surgical Centers (ASCs) and should match the federal ones.<br>§4567. Staffing Requirements – Felt that the requirements for the center administrator/director to be full time administrator would burden smaller ASCs. |
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# SUMMARY OF WRITTEN COMMENTS

**Proposed Rule:** Ambulatory Surgical Centers - Licensing Standards
**Public Hearing Date:** March 30, 2017
July 30, 2017 (Substantive Changes Public Hearing)
**Docket No. :** 03302017-01 (March 2017)
07272017-05 (July 2017)
**Conducted By:** Department of Health, Bureau of Health Services Financing Staff

| Written Comments Received From | Mode of Receipt | Summary of Comments (April 20, 2015 Notice of Intent) |
|---|---|---|
| William Prentice, Ambulatory Surgery Center Association | Medicaid Policy Email Account | • §4503. Definitions. Concerned that language is more restrictive than CMS guidance.<br>• §4505. Licensing Requirements. Feels that failure to notify the department of any changes seems burdensome and that "off-site campuses" is unclear.<br>• §4509. Initial Licensing Surveys. Concerned that there are some aspects of the regulations that an ASC cannot show compliance with until it has seen patients (i.e., medical records).<br>• §4513. Changes in Licensee Information or Personnel. Feels that reporting requirements for temporary closure are over burdensome.<br>• §4517. Survey Activities. Requests that language be changed from 24 hours to three days for providing records for review.<br>• §4533. Policies and Procedures. Believes language concerning hours of operation is confusing.<br>• §4539. Admissions and Assessments. Concerned that language for physician referrals is more restrictive than CMS requirements.<br>• §4553. Radiology Services. Feels that two provisions in NOI do not belong with radiology services and that the definition of licensed practitioner is more restrictive than CMS guidelines.<br>• §4567. Staffing Requirements. Recommend the following language, "Each ASC shall have a qualified administrator/director who is an on-site employee responsible for the day-to-day |

| | | |
|---|---|---|
| | | management, supervision and operation of the ASC on a fulltime basis."<br><br>• §4569. Medical Records. Felt that subsections D and G were duplicative and combined and that provisions where a medical record cannot become part of any other medical record associated with another entity are inconsistent with the current direction of health care and should be removed.<br><br>• §4581. Emergency Preparedness and Emergency Procedures. Believes coordination with state and local public health departments and emergency systems is not applicable to ASCs because patients would be stabilized and sent home or to a higher level of care such as a hospital. Also believes that having written policies and procedures that address the availability and relevant use of the following emergency equipment in the ASC's operating/procedure rooms sufficient in number to handle multiple simultaneous emergencies is a potential burden on ASCs. |
| **Written Comments Received From** | **Mode of Receipt** | **Summary of Comments<br>( June 20, 2015 Substantive Changes Potpourri)** |
| Cindy Bishop, Checkmate Strategies | Email to Health Standards Section | • Concerned about the time needed to get background checks through the Louisiana State Police. |

**John Bel Edwards**
GOVERNOR

**Rebekah E. Gee MD, MPH**
SECRETARY

# State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

August 7, 2017

Cindy Bishop, President
Checkmate Strategies, LLC
P.O. Box 80053
Baton Rouge, LA 70898

Dear Ms. Bishop:

**RE: Public Hearing – Substantive Changes to Proposed Rule
Ambulatory Surgical Centers – Licensing Standards**

This correspondence is in response to the written comments you submitted relative to the Public Hearing – Substantive Changes to Proposed Rule – Ambulatory Surgical Centers – Licensing Standards Potpourri which was published in the June 20, 2017 edition of the *Louisiana Register*.

The Department would like to thank you for taking the time to provide comments regarding the non-technical, substantive revisions to the Notice of Intent for Ambulatory Surgical Centers – Licensing Standards which was published in the February 20, 2017 edition of the *Louisiana Register*. This Notice of Intent proposes to repeal and replace LAC 48:I.Chapter 45 governing the licensing standards for ambulatory surgical centers (ASCs) in order to: 1) clarify the existing provisions; 2) provide for inactivation of the provider license in the event of specific qualifying events or circumstances; 3) establish provisions which allow ambulatory surgical centers to enter into use agreements; and 4) ensure consistency with other licensing rules, regulations and processes.

The Department's Health Standards Section's licensing staff has reviewed and given consideration to your comments and has determined that, although no additional revisions are required to the provisions of the proposed Rule, the following clarification is necessary in order to address each of your concerns.

***"...Reference is made to Criminal Background Checks for Unlicensed Personnel who work in an ASC. The Potpourri Rule makes reference to Criminal Background Checks (CBCS) by State Police OR authorized agents.***

***We hope (And Pray) that it is not the intent of the Department of Health to require licensed surgery centers to obtain their CBCs through the Louisiana State Police..."***

The Department is unable to change the proposed Rule's provisions relative to criminal background checks as these requirements are set forth in R.S. 40:1203.1 et seq., which stipulates that these checks be conducted by the Louisiana State Police or its authorized agent. Therefore, it is the Department's intent that the ACS provider will make the choice as to which entity to utilize in compliance with this statute.

The Health Standards Section maintains on the HSS webpage a list of entities currently designated as authorized agencies of the Louisiana State Police which is updated as changes occur. The current list is attached to this correspondence for your convenience and the link to the HSS webpage is as follows:
http://www.ldh.la.gov/index.cfm/directory/detail/12468

***"The area regarding the need for personnel files in the ASC for all contracted services seems very vague – need more clarification regarding exactly what the department is trying to address here."***

The ASC establishes policy regarding the contents of the personnel file, inclusive of minimally required documentation, which is the same for a contract or a staff employee.

I would like to thank you for your continued interest in the administrative rulemaking process and hope that you will continue to work with us as we strive to improve health care outcomes for Louisiana citizens.

Should you have any questions or comments regarding Medicaid administrative rulemaking activity or rulemaking activity relative to the health care licensing standards, you may contact Veronica Dent, Medicaid Program Manager, at 225-342-3238 or by email to Veronica.Dent@la.gov.

Sincerely,

Cecile Castello, BSN, RN
Health Standards Section Director

Attachments (2)

CC/KHB/VYD

c: Darlene A. Budgewater
Kimberly Humbles

**Criminal History Checks on Nonlicensed Persons and Licensed Ambulance Personnel**

**August 4th, 2017**

The Louisiana Office of State Police, Bureau of Criminal Identification and Information (Bureau), is the State's designated repository for criminal history information pursuant to the laws cited in La. R.S. 15:575 et seq. Any criminal event that is documented by the submission of fingerprints to the State is stored in the Louisiana Computerized Criminal History (LACCH) database. The Bureau may only release criminal history information stored in LACCH for noncriminal justice purposes when authorized by law. The Bureau is authorized to release criminal history information stored in LACCH to those employers and Authorized Agencies defined in La. R.S. 40:1203.1 as required by La. R.S. 40:1203.2

Employers may request criminal history information stored in LACCH in one of three ways: (1) use of the Bureau's Internet Background Check (IBC) website (https://ibc.dps.louisiana.gov/), (2) via Authorized Agents, and (3) submission of applicants' fingerprints.

Employers and Authorized Agencies may establish an account with the Bureau to use the IBC, which is a web-based application that allows for name-based, criminal background checks. If the Bureau cannot match any of the applicant's descriptors, such as name, DOB, SSN, etc., a letter stating no disqualifying information was found is issued. Additionally, if the applicant may have criminal history, fingerprints will be required for positive identification before the history is released.

Authorized Agents may also run name-based background checks on applicants defined in La. R.S. 1203.1 through a local law enforcement agency. Local law enforcement agencies are only authorized to query LACCH. They are not authorized to request criminal history information through the FBI's federal, criminal history database or records stored in the National Crime Information Center (NCIC) database.

Pursuant to La. R.S. 40:1203.7, Authorized Agencies must be domiciled in the state of Louisiana and must be certified by the La. Secretary of State's office. Authorized Agents must also be certified by the Bureau. Companies that perform background check services that are not domiciled in Louisiana nor certified through the Secretary of State's office and the Bureau are not authorized to request or receive criminal history information stored in LACCH. Additionally, Authorized Agents are not authorized to request criminal history information on behalf of national background check companies. La. R.S. 15:579 mandates the Bureau to issue rules and regulations consistent with the U.S. Dept. of Justice governing the privacy and security of criminal history records. To meet this requirement, the Bureau has adopted rules and regulations including those described in 28 Code of Federal Regulations (CFR) 20.21 which limits the release of criminal history information to only those agencies authorized by statute. Employers may contact LDH or the Bureau for a current list of Authorized Agencies.

Employers may also require applicants to submit fingerprints to the Bureau. Employers may contact the Bureau for more information regarding this service.

For more information, contact the LSP Bureau at (225) 925-6095 (Applicant Processing Section), or by mail at P.O. Box 66614, #A-6, Baton Rouge, LA 70896-6614.

**LOUISIANA STATE POLICE**
**CERTIFIED AUTHORIZED AGENCIES (rev 06/23/17)**

**ACCUSCREEN SYSTEMS** — **LARRY B. CHILDERS**, **DARIN N. MORGAN**
1038 Main St.
Baton Rouge, LA 70802
(225) 343-8378

**BACKGROUND RESEARCH SOLUTION** — **HAROLD HEBERT JR**
1020 Tricia Dr
Slidell, LA 70461
(985) 503-7911

**B4 HEALTH SCREENING INC** — **MARIE KNIGHT**
3900 North Causeway Blvd Ste 1200
Metairie, LA 70002
(866) 279-7574

**BROWN INVESTIGATION, LLC** — **RUBIANTE BROWN**
8288 Tom Dr
Baton Rouge, LA 70815
(504) 606-0042

**CARDINAL INFO SERVICES** — **WARREN W. HOAG JR.**, **JAMES BEALER**
P.O. Box 852
Jennings, LA 70546
(337) 207-5218

**CASTILLO INVESTIGATIONS** — **ALLEN N. CASTILLO**
110 Welch St
Mansfield, LA 71052
(318) 872-3052

**COMPREHENSIVE SCREENING SOLUTIONS (Trak 1)** — **SHAWN W BURCH**
4705 Palmetto Rd # 4
Benton, LA 71006
(318) 965-5756

**CONFIDENTIAL RESEARCH SERVICES LLC.** — **MARY K. DAVIS**
2668 Vulcan St.
Harvey, LA 70058
(504) 363-3306

**E. F. RESEARCH LLC** — **ERNEST FREEMAN III**
11732 Market Place Ave Suite B
Baton Rouge, LA 70816
(225) 291-1498

**ERMS SPECIAL INVESTIGATIONS & RECOVERY** — **LYMAN B. PHILLIPS JR.**
P.O. Box 11944
Alexandria, LA 71315
(318) 484-6110

**GLOBAL DATA FUSION LLC dba Ed Roy, Ltd** — **EDWIN C. ROY**
P.O. Box 53889
Lafayette, LA 70505
(337) 233-3816

**HYATT INVESTIGATIONS** — **MATTHEW E. HYATT**
397 Old Hwy. 171
Lake Charles, LA 70611

**INFINITY BACKGROUNDCHEX PLUS** — **CHRISTINE RICHARD**
407 West Magnolia Dr
Ville Platte, LA 70586
(337) 363-0346

**INVESTIGATIVE RESEARCH SPECIALTIES** — **DAVID THOMAS**
927 Cascio Rd
Lake Charles, LA 70611
800-883-0672

**JMAC INVESTIGATIONS & SOLUTIONS** — **JAMILA MCKEE**
P.O. Box 84102
Baton Rouge, LA 70884
(225) 407-9111

**NATION INVEST. & PROTECTION AGENCY** — **PETER L. DALE**
P. O. Box 23871
New Orleans, LA 70183-0871
(504) 405-4247

**NATIONAL ENFORCEMENT INVESTIGATIONS** — **GARRY WILLIAMS**
4480 General Degaulle Blvd
Suite #108
New Orleans, LA 70131
(800) 636-6040
(504) 265-9934

**OUACHITA INVESTIGATIVE SERVICES** — **JOEY CRUSE**
P.O. Box 873
West Monroe, LA 71294
(318) 884-0092

**P & M INVESTIGATIONS LLC** — **JOHN GABRIEL**
P.O. Box 90741
Lafayette, La 70509
(337) 593-8246

**POWELL'S BACKTRACKING** — **DOYLE POWELL**, **DORIS POWELL**
112 Lake Lynn Dr
Harvey, LA 70058
(504) 342-2052

**QUALITY EMPLOYEE VERIFICATION SYSTEM, LLC** — **MATTHEW J ROVIRA**
103 Woodsboro Dr
Lafayette, LA 70508
(337) 254-8174

**RADLEYS INVESTIGATIONS LLC** — **LANCE RADLEY**
32447 Mangum Chapel Rd
Walker, LA
(225)686-3890

**SOUTHERN RESEARCH** — **ROY R. SCHULTZ**, **THOMAS OSTENDORFF**
P.O. Box 1590
Shreveport, LA 71165-1590
(318) 227-9700

**SOUTHERN RESEARCH** — **SHERYL B. OSTENDORFF**
P.O. Box 1590
Shreveport, LA 71165-1590
(318) 227-9700

**TENSTAR CORPORATION** — **CHARLES C. THIBODEAUX**, **DEBRA D. THIBODEAUX**
326 Mineral Road
Lafayette, LA 70598
(337) 839-1833 Ext. 201

**TRACEPOINT, LLC** — **KRISTI BARRANCO**
641 N. Alexander St
New Orleans, LA 70119
504-284-2285

**WALKER INVESTIGATIONS, LLC.** — **PATRICE WALKER**
5422 Galeria Dr
Baton Rouge, LA 70816
(222) 663-2382

**WALLACE INVESTIGATIONS, LLC.** — **LANCE S. WALLACE**
4934 Westridge Park East
Lake Charles, LA 70605
(337) 802-9569

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

# State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

June 16, 2017

William Prentice, CEO
Ambulatory Surgery Center Association
1012 Cameron Street
Alexandria, VA 22314

Dear Mr. Prentice:

**RE: Notice of Intent for Ambulatory Surgical Centers – Licensing Standards**

This letter is in response to your correspondence regarding the Notice of Intent for Ambulatory Surgical Centers – Licensing Standards which was published in the February 20, 2017 edition of the *Louisiana Register*.

The Notice of Intent proposes to repeal and replace LAC 48:I.Chapter 45 governing the licensing standards for ambulatory surgical centers (ASCs) in order to: 1) clarify the existing provisions; 2) provide for inactivation of the provider license in the event of specific qualifying events or circumstances; 3) establish provisions which allow ambulatory surgical centers to enter into use agreements; and 4) ensure consistency with other licensing rules, regulations and processes. A public hearing on this proposed Rule was held on Thursday, March 30, 2017 at 9:30 a.m. in Room 118 of the Bienville Building, 628 North Fourth Street, Baton Rouge, LA.

As a result of your concerns and the comments received, the Department has determined that changes are needed to the proposed Rule in order to further clarify these provisions. These substantive, non-technical revisions will be published in a Public Hearing-Substantive Changes to Proposed Rule Potpourri in the June 20, 2017 edition of the *Louisiana Register.*

In addition, the Department's Health Standards Section's licensing staff has given consideration to the comments received and has determined that clarification is necessary regarding the following sections of the Notice of Intent by way of explanation, but not necessitating a revision to the language of the proposed Rule.

**§4505. Licensing Requirements**

**G. An ASC shall not have any off-site campuses.**

An off-site campus is one that is a parent facility's alternate program that provides services on a routine basis in a geographic location that:

1. is detached from the parent provider;
2. is owned by, leased by or donated or loaned to the parent provider for the purpose of providing services; and
3. has a sub-license issued under the parent facility's license.

An ASC is separately licensed and shall have no off-site campuses. Offices, such as for billing, are not addressed in licensing standards.

**§4569. Medical Records**

**H. The medical record cannot become part of any other medical record associated with another entity.**

This language does not preclude a medical record from being shared between entities that are in need of the patient's information in accordance with all applicable federal and state privacy laws. This regulation means that a practitioner shall not take his/her records from the ASC to include in his/her office records in place of keeping those records in the ASC. The ASC shall maintain a unique medical record for every patient admitted and/or treated.

I would like to thank you for taking the time to provide comments and hope that you will continue to work with us as we strive to improve health care outcomes for Louisiana citizens.

Should you have any questions or comments regarding Medicaid administrative rulemaking activity or rulemaking activity relative to the health care licensing standards, you may contact Veronica Dent, Medicaid Program Manager, at 225-342-3238 or by email to Veronica.Dent@la.gov.

Sincerely,

Cecile Castello
Health Standards Section Director

CC/DAB/VYD

c: Kimberly Humbles
Lou Ann Owen

**John Bel Edwards**
GOVERNOR

**Rebekah E. Gee MD, MPH**
SECRETARY

# State of Louisiana

Louisiana Department of Health
Office of the Secretary

August 7, 2017

**MEMORANDUM**

**TO:** The Honorable John A. Alario, President, Louisiana Senate
The Honorable Taylor F. Barras, Speaker of the House
The Honorable Fred H. Mills, Jr., Chairman, Senate Committee on Health and Welfare
The Honorable Frank A. Hoffmann, Chairman, House Committee on Health and Welfare
The Honorable Eric LaFleur, Chairman, Senate Finance Committee
The Honorable Cameron Henry, Chairman, House Appropriations Committee

**FROM:** Rebekah E. Gee MD, MPH
Secretary

**RE:** Oversight Report on Bureau of Health Services Financing Proposed Rulemaking

In accordance with the Administrative Procedure Act (R.S. 49:950 et seq.) as amended, we are submitting the attached documents for the proposed Rule for Pharmacy Benefits Management Program - Managed Care Supplemental Rebates.

The Department published a Notice of Intent on this proposed Rule in the June 20, 2017 issue of the *Louisiana Register* (Volume 43, Number 6). A public hearing was held on July 27, 2017 at which the Louisiana Department of Health staff and several interested parties from various organizations were present. No oral testimony was given. However, written comments were received regarding this proposed Rule.

The Department anticipates adopting the Notice of Intent as a final Rule in the September 20, 2017 issue of the *Louisiana Register*.

The following documents are attached:

1. a copy of the Notice of Intent;
2. the public hearing certification;
3. the public hearing attendance roster;
4. summary of all comments received by the agency;
5. the agency's response to comments from Randal Johnson; and
6. the agency's response to comments from Peter Martinez.

REG/WJR/CEC
Attachments (6)

**NOTICE OF INTENT**

**Department of Health**
**Bureau of Health Services Financing**

**Pharmacy Benefits Management Program**
**Managed Care Supplemental Rebates**
**(LAC 50:XXIX.1103)**

The Department of Health, Bureau of Health Services Financing proposes to adopt LAC 50:XXIX.1103 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

The Department of Health, Bureau of Health Services Financing promulgated a Rule which amended the provisions governing the Pharmacy Benefits Management Program in order to establish provisions for the Medicaid Program's participation in The Optimal PDL $olution (TOP$) State Supplemental Rebate Agreement Program and assure compliance with the technical requirements of R.S. 49:953 (*Louisiana Register*, Volume 43, Number 5).

The department has now determined that it is necessary to amend the provisions governing the TOP$ State Supplemental Rebate Agreement Program in order to include pharmacy utilization of managed care organizations (MCOs) that participate in the Healthy Louisiana (formerly Bayou Health) Program and implement a single state managed preferred drug list

for selected therapeutic classes to maximize supplemental rebates on MCO utilization.

**Title 50**

**PUBLIC HEALTH-MEDICAL ASSISTANCE**
**Part XXIX. Pharmacy**

**Chapter 11. State Supplemental Rebate Agreement Program**

**§1103. Managed Care Organization Utilization**

A. Effective for dates on or after October 1, 2017, the TOP$ State Supplemental Rebate Agreement Program shall include pharmacy utilization of managed care organizations (MCOs) that participate in the Healthy Louisiana Program for state supplemental drug rebates on selected therapeutic classes.

1. The Healthy Louisiana Program's contracts with the participating MCOs shall:

a. allow inclusion of the pharmacy utilization data for supplemental rebate purposes; and

b. mandate that each participating MCO shall align their respective formulary(ies) and/or preferred drug list (PDL) on selected therapeutic classes, as applicable, to the fee-for-service (FFS) preferred drug list and adopt FFS prior authorization criteria for the non-preferred agents.

B. The Department of Health shall implement a single state managed PDL for selected therapeutic classes for all participating MCOs in order to maximize the supplemental and federal rebates on MCO utilization.

C. Supplemental rebates on MCO utilization shall be excluded from best price or average manufacturer price (AMP) calculations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have no impact on family functioning, stability and autonomy as described in R.S. 49:972.

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973.

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the

provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, no direct or indirect cost to the provider to provide the same level of service, and will have no impact on the provider's ability to provide the same level of service as described in HCR 170.

Interested persons may submit written comments to Jen Steele, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821—9030 or by email to MedicaidPolicy@la.gov. Ms. Steele is responsible for responding to inquiries regarding this proposed Rule. A public hearing on this proposed Rule is scheduled for Thursday, July 27, 2017 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Rebekah E Gee MD, MPH

Secretary

**John Bel Edwards**
GOVERNOR

**Rebekah E. Gee MD, MPH**
SECRETARY

# State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

**PUBLIC HEARING CERTIFICATION**
**July 27, 2017**
**9:30 a.m.**

RE: Pharmacy Benefits Management Program
Managed Care Supplemental Rebates
Docket # 07272017-02
Department of Health
State of Louisiana

CERTIFICATION

In accordance with LA R.S. 49:950 et seq., the attached public hearing agenda, together with one digital recording of the public hearing conducted on July 27, 2017 in Baton Rouge, Louisiana constitute the official record of the above-referenced public hearing.

Medicaid Policy and Compliance Section

07/27/17
Date

# DHH/BHSF PUBLIC HEARING

**Topic – Pharmacy Benefits Management Program Managed Care Supplemental Rebates**

**Date** – July 27, 2017

PERSONS IN ATTENDANCE

| Name | Address | Telephone Number | AGENCY or GROUP you represent |
|---|---|---|---|
| 1. Keyora Singleton | 628 N 4th Street Baton Rouge LA 70805 | 225-342-3086 | LDH |
| 2. Dan Barbera | 1404 Carissa Ct Covington, LA 70433 | 985-630-2575 | Lilly |
| 3. ALICIA PREVOST | 628 N. 4th St. BR LA 70802 | 342-3892 | LDH |
| 4. Wayne Camp | 14421 [illegible] Rd [illegible], La 70810 | 710-9561 | |
| 5. John Harris | 7008 Greenshores Austin Tx 78730 | 2108422142 | |
| 6. Doug Weld | 405 Fawnwood Dr Brandon, MS 39042 | 601-668-0698 | Merck |

# DHH/BHSF PUBLIC HEARING

**Topic – Pharmacy Benefits Management Program Managed Care Supplemental Rebates**

**Date** – July 27, 2017

| Name | Address | Telephone Number | AGENCY or GROUP you represent |
|---|---|---|---|
| 7. John Schlib | MN | 612-716-9833 | Lundbeck |
| 8. Tim Hambacher | 1 Lakewood Estates Drive NOLA 70131 | 504 654 9283 | Otsuka |
| 9. Mary Beth Wilkerson | 16333 Columns Way | 256-366-4517 | LSMS |
| 10. Sue Fontenot | LDH | 225-342-1367 | LDH |
| 11. Madi Rajulapalli | | 504-417-0387 | Aetna. |
| 12. David Large | 1591 Red Oak Lane Brentwood, TN 37027 | 615-691-0101 | Supernus |

# DHH/BHSF PUBLIC HEARING

**Topic – Pharmacy Benefits Management Program Managed Care Supplemental Rebates**

**Date** – July 27, 2017

| Name | Address | Telephone Number | AGENCY or GROUP you represent |
|---|---|---|---|
| 13. Rick Born | 2400 Veteran's Memorial Blvd Kenner LA 70062 | 504 667 4580 | AETNA |
| 14. John Ford | 450 Laurel St, Ste 1850 BR, LA 70801 | 225 378 3206 | LAHP |
| 15. Rob Lancon | 450 Laurel, Ste 1900 BR, LA 70801 | 337 577 7064 | Adams and Reese, LLP |
| 16. Derrell Cohoon | 714 N. 5th St. Baton Rouge, LA | 225.921.9233 | Capitol Partners |
| 17. Christine Peck | | 225-342-2114 | Senate Health + Welfare |
| 18. Jeanine Plante | 10000 Perkins Rowe ste 400 BR LA 70810 | 225-300-9179 | AmeriHealth Caritas Louisiana |

# DHH/BHSF PUBLIC HEARING

**Topic – Pharmacy Benefits Management Program Managed Care Supplemental Rebates**

**Date** – July 27, 2017

| Name | Address | Telephone Number | AGENCY or GROUP you represent |
|---|---|---|---|
| 19. Ginny Martinez | 521 Laurel St, BR | 344-0381 | |
| 20. | | | |
| 21. | | | |
| 22. | | | |
| 23. | | | |
| 24. | | | |

# SUMMARY OF WRITTEN COMMENTS

**Proposed Rule:** Pharmacy Program - Managed Care Supplemental Rebates Notice of Intent
**Public Hearing Date:** July 27, 2017
**Docket No. :** 07272017-02
**Conducted By:** Louisiana Department of Health, Bureau of Health Services Financing Staff

| Written Comments Received From | Mode of Receipt | Summary of Comments |
|---|---|---|
| Pete Martinez, Deputy Vice President, State Advocacy, PhRMA | Medicaid Policy email account | 1. The Notice of Intent does not prohibit MCOs from separately collecting their own commercially-negotiated rebates on the same utilization and manufactures could be subjected to a double-dip wherein both supplemental and commercial rebates are requested. |
| Randal Johnson, President and CEO, Louisiana Independent Pharmacies Association (LIPA) | Medical Policy email account. | LIPA submitted several comments in the form of questions and are as follows:<br>• What are the savings associated with the Single PDL?<br>• What is the number of brand to generic prescriptions and the associated rebate amounts for generic and brand drugs by each MCO and the Medicaid legacy program?<br>• What is the estimated impact of any change to the brand to generic ratio with the implementation of the single PDL?<br>• What analysis has Magellan conducted in regard to the single PDL, the state contractor that performs negotiation for the state supplemental rebates?<br>• What are the savings associated with the Single PDL?<br>• What is the number of brand to generic prescriptions and the associated rebate amounts for generic and brand drugs by each MCO and the Medicaid legacy program?<br>• What is the estimated impact of any change to the brand to generic ratio with the implementation of the single PDL?<br>• What analysis has Magellan conducted in regard to the single PDL, the state contractor that performs negotiation for the state supplemental rebates?<br>• What is the contract amount for Magellan?<br>• Has the Medicaid P&T committee reviewed their analysis? When will the single PDL be implemented?<br>• What is the rebate offset amount?<br>• What are the amounts of rebates received by the MCOs for these 10 therapeutic classes?<br>• What is the comparison including rebates, state supplemental rebates and projected savings with the single PDL compared to the current MCO PMPM rates?<br>• What happens to the generic percentage of drugs paid?<br>• Are the MCO plans cost going to increase or decrease over time with the use of the single PDL? |

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| | | • Does the current state plan allow for a single PDL and/or has the state plan/state supplemental rebate agreement been submitted to CMS for review and approval?<br>• How will members be notified on the single PDL?<br>• Will there be a transition policy for members who will be impacted by the therapeutic classes in the single PDL?<br>• How many members will be impacted by their copayments, i.e., higher copays for brand name drugs?<br>• Has the Department notified the various associations of prescribing providers regarding the single PDL and requested information regarding the impact to their practice?<br>• Will prescribers have to reconfigure their electronic prescribing systems to comply with the single PDL? Are there any costs involved in the reconfiguration?<br>• As pharmacy providers have their current stock of drug inventory in which may or may not include drugs on the PDL, what measures has the Department taken for them to utilize their current inventory?<br>• What is the current utilization for each therapeutic class in the single PDL to the projected utilization and savings?<br>• What is the projected reduction/increase in generic utilization for each class?<br>• What time period was analyzed to determine any savings/costs with the impacted therapeutic classes?<br>• How will the MCOs and Medicaid ensure that the supplemental rebates and cost shift savings ensure that the savings to the state are greater than any increase in the MCO per member per month cost?<br>• How will the state ensure that the lower cost generic drug is dispensed rather than the higher cost drug with a supplemental rebate?<br>• How will the state ensure that that the supplemental rebates are a savings to the state rather than the MCOs/PBMs negotiating their drug prices discounts with their network?<br>• What are the lists of assumptions made in the savings analysis listed in the Notice of Intent?<br>• While the state cannot disclose rebate amounts per drug, the state should disclose the estimates of the range of anticipated savings using the impact of generic/brand utilization and the average rebate percentages before and after the single PDL along with the cost impact of per member per month.<br>• How has the analysis of savings been determined that it is in the best interest of the Medicaid MCOs to not manage the prescription drug benefit with or without the single PDL?<br>• Will the Medicaid Pharmaceutical and Therapeutics Committee review the single PDL recommendations prior to its implementation?<br>• How many therapeutic classes of drugs are projected to be in the single PDL?<br>• What will be the frequency of changing drugs from preferred to non-preferred and vice-versa?<br>• Will emergency filling of drugs be allowed? |

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|---|---|---|
| | | • What will be the policy when there is a drug shortage?<br>• When patients are hospitalized and generics are prescribed and they are discharged from the hospital with a generic drug prescription which requires PA, will the prescription deny and PA is required?<br>• What are the projected total pharmacy expenditures without the single PDL and with the single PDL? What are the projected expenditures for the initial ten therapeutic classes and for additional therapeutic classes, by brand and generic (innovator and non-innovator) drug, without the single PDL and with the single PDL for fiscal year 2018 and 2019?<br>• Is the Department considering reimbursing the pharmacist a higher dispensing fee when dispensing the lower cost drug?<br>• As patents expire and lower cost generics become available, along with newer drug products on the market, how will these drugs, both brand and generic, be placed on the PDL and/or PA?<br>• What assurance does the Department have that the drug manufacturer will continue to participate in the supplemental rebate agreement if their market share does not shift?<br>• If a rebate nets the cost of a brand name product, what is the economic impact to the budget if a less costly generic is cheaper than the brand name drug net of rebate?<br>• Under Notes, it states Mercer estimated non-PDL class federal rebates to be 46% based on guidance provided by Magellan. What does the 46% represent? |
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John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

# State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

August 9, 2017

Randal Johnson
Louisiana Independent Pharmacies Association
543 Spanish Town Road
Baton Rouge, LA 70802

Dear Mr. Johnson:

**RE: Notice of Intent**
**Pharmacy Benefits Management Program - Managed Care Supplemental Rebates**

This letter is in response to your correspondence regarding the Notice of Intent for Pharmacy Benefits Management Program – Managed Care Supplemental Rebates which was published in the June 20, 2017 edition of the *Louisiana Register*.

The Notice of Intent proposes to amend the provisions governing the TOP$ State Supplemental Rebate Agreement Program in order to include pharmacy utilization of managed care organizations (MCOs) that participate in the Healthy Louisiana (formerly Bayou Health) Program and implement a single state managed preferred drug list (PDL) for selected therapeutic classes to maximize supplemental rebates on MCO utilization. A public hearing on this proposed Rule was held on Thursday, July 27, 2017 at 9:30 a.m. in the Bienville Building, Room 118, 628 North Fourth Street, Baton Rouge, LA.

I would like to thank you for taking the time to provide comments regarding the Department's intent to implement a Single Preferred Drug List for selected therapeutic classes for purposes of reducing administrative complexity for providers and allowing the State to invoice manufacturers for supplemental rebates on impacted managed care pharmacy claims.

Our responses to your specific questions are as follows.

***1-"What are the savings associated with the Single PDL?"***
In response to LIPA's public records request, on Wednesday, July 26, 2017 at 9:29 a.m., Kimberly Sullivan, LDH Deputy General Counsel, sent to Randal Johnson the rulemaking fiscal impact, including the following summary table:

| | Total | SGF (Net Premium Tax Impact) | Federal |
|---|---|---|---|
| **SFY18** | (18,556,470) | (4,997,340) | (13,559,130) |
| **SFY 19** | (71,329,350) | (21,158,895) | (50,170,455) |
| **SFY 20** | (73,469,230) | (21,793,662) | (51,675,569) |

***2-"What is the number of brand to generic prescriptions and the associated rebate amounts for generic and brand drugs by each MCO and the Medicaid legacy program?"***
Our analysis focused on the impact of changes to a drug's preferred or non-preferred status. It did not enumerate prescriptions or rebates on the basis of brand or generic status, as both brand and generic drugs can be preferred or non-preferred.

***3-"What is the estimated impact of any change to the brand to generic ratio with the implementation of the single PDL? Percent change, average cost per prescription"***
As stated above, our analysis focused on the impact of changes to a drug's preferred or non-preferred status. It did not address brand to generic ratios, as both brand and generic drugs can be preferred or non-preferred.

***4-"What analysis has Magellan conducted in regard to the single PDL, the state contractor that performs negotiation for the state supplemental rebates? The draft states Mercer estimated the reduction is rebate receivables based on guidance from Magellan."***
The single PDL by therapeutic class, as proposed, is a joint work product of Magellan and Mercer. Our work toward a comprehensive single PDL in early 2016 taught us the importance of teamwork by our actuaries and supplemental rebate vendors from the start. This work product, unlike the 2016 effort which included the entire FFS PDL, began with the explicit intent to include only those therapeutic classes and drugs with the greatest net savings potential. Specifically, Magellan's review of Medicaid FFS and MCO claims data and related rebate estimates serve as the foundation for the resulting single PDL by therapeutic class drug list and related Mercer rate setting.

***5-"What are the savings associated with the Single PDL?"***
See response to question 1.

***6-"What is the number of brand to generic prescriptions and the associated rebate amounts for generic and brand drugs by each MCO and the Medicaid legacy program?"***
See response to question 2.

***7-"What is the estimated impact of any change to the brand to generic ratio with the implementation of the single PDL? Percent change, average cost per prescription"***
See response to question 3.

***8-"What analysis has Magellan conducted in regard to the single PDL, the state contractor that performs negotiation for the state supplemental rebates? The draft states Mercer estimated the reduction is rebate receivables based on guidance from Magellan."***
See response to question 4.

***9-"What is the contract amount for Magellan?"***
The Magellan contract is $612,000 for State Fiscal Year 2017-18.

***10-"Has the Medicaid P&T committee reviewed their analysis?"***
Reviewing the analysis for feasibility of the Single PDL for selected therapeutic classes is not within the scope of the P&T committee. The P&T committee considers clinical and financial factors in determining which drug products should be preferred/non-preferred. Therefore, the P&T committee has already determined the status of the drugs on the Single PDL for selected therapeutic classes.

***11-"When will the single PDL be implemented?"***
The Single PDL for selected therapeutic classes will be implemented on October 1, 2017.

***12-"What is the rebate offset amount?"***
See fiscal impact sheets labeled "Exhibit (non-exp)" and "Exhibit (expansion)", $0.10 per member month.

***13-"What are the amounts of rebates received by the MCOs for these 10 therapeutic classes?"***
The rebate amount received by the MCO for these 10 therapeutic classes was estimated by taking one-third of the total rebate amount reported by the MCO on the Financial Reporting Requirements (FRR).

***14-"Based on the January 15, 2017 Louisiana Medicaid Preferred Drug List and Program Overview and Results, Table 3: projected Savings by Quarter for Fiscal Year 2017, indicates estimated supplemental rebates of $1.6 million and estimated switch savings of $721,665 totaling $2.3 million in savings. What is the comparison including rebates, state supplemental rebates and projected savings with the single PDL compared to the current MCO PMPM rates? What happens to the generic percentage of drugs paid?"***
The Magellan PDL report does not include analysis for the Single PDL for selected therapeutic classes as this project was not established by the report release date. In the fiscal analysis provided, Mercer took into consideration the MCO rebate changes, the prescription administrative costs, the underwriting gain, premium taxes, potential rebates

(federal and supplemental) for the Department, return of premium taxes and impact of PMPM. See fiscal impact sheets labeled "Exhibit (non-exp)" and "Exhibit (expansion)". The generic percentage of drugs paid was not considered in our analysis.

***15-"Are the MCO plans cost going to increase or decrease over time with the use of the single PDL?"***
Mercer has calculated an increase in PMPM due to increased expenditures and the MCO rebate decrease. See fiscal impact sheets labeled "Exhibit (non-exp)" and "Exhibit (expansion)".

***16-"Does the current state plan allow for a single PDL and/or has the state plan/state supplemental rebate agreement been submitted to CMS for review and approval?"***
Not yet. The proposed rule begins the process of amending the state plan by meeting federal public notice requirements. We will submit a State Plan Amendment and supplemental rebate agreement by the end of August.

***Members***
***17-"How will members be notified on the single PDL?"***
Public notice has been given through the administrative rulemaking process with promulgation of the Notice of Intent in the June 20, 2017 edition of the *Louisiana Register*. When drugs change from preferred to non-preferred, the MCOs are required to send notice to recipients 30 days in advance.

***18-"Will there be a transition policy for members who will be impacted by the therapeutic classes in the single PDL?"***
The MCOs will follow the continuity of care (COC) policy in the MCO contract which is 60 days for non-behavioral health agents and 90 days for behavioral health drugs. During this continuity of care period, the prescriber should submit a prior authorization request if he/she deems the non-preferred agent use is justified. After the COC period, if the drug is non-preferred, the prescriber would need to submit a prior authorization request for the recipient to be considered to remain on the drug.

***19-"How many members will be impacted by their copayments, i.e., higher copays for brand name drugs?"***
On average, 58 percent of recipients are exempt from copayments. The maximum copayment is $3.00 per prescription. As the cost of generic drugs has increased, most prescriptions with copayment requirements will hit the maximum copayment whether the drug is preferred or non-preferred. Currently, one of the MCOs exempts all prescriptions from copayment requirements.

***Prescribing providers***
***20-"Has the Department notified the various associations of prescribing providers regarding the single PDL and requested information regarding the impact to their practice?"***

A primary objective of the Department in implementing a single PDL is to reduce administrative complexity for providers. The single PDL itself is only the first step. Equally important is the standardization of prior authorization criteria and forms for use by all five MCOs. We are actively detailing the operational aspects of these administrative simplifications now and plan to engage prescribing providers for input on implementation in the coming weeks.

***21-"Will prescribers have to reconfigure their electronic prescribing systems to comply with the single PDL? Are there any costs involved in the reconfiguration?"***
The Single PDL for selected therapeutic classes will align with the current fee-for-service (FFS) PDL. Changes in these classes will be twice a year in January and July. This will not require prescribers to change their electronic prescribing systems.

***Pharmacy providers***
***22-"As pharmacy providers have their current stock of drug inventory in which may or may not include drugs on the PDL, what measures has the Department taken for them to utilize their current inventory?"***
The pharmacy providers who service FFS recipients should already have the preferred FFS agents in stock. The addition of lives subject to the FFS PDL should promote more rapid turn-over of preferred agents

***State Government***
***23-"What is the current utilization for each therapeutic class in the single PDL to the projected utilization and savings?"***
Current utilization for the 10 therapeutic classes in units is 2,603,192. Projected utilization for the 10 therapeutic classes in units is 37,497,816. See response to question 1 for savings.

***24-"What is the projected reduction/increase in generic utilization for each class?"***
Our analysis focused on the impact of changes to a drug's preferred or non-preferred status. It did not address brand to generic ratios, as both brand and generic drugs can be preferred or non-preferred. Many drugs on the FFS PDL are generic agents.

***25-"What time period was analyzed to determine any savings/costs with the impacted therapeutic classes?"***
Calendar year 2015 data was used for the analysis. This was trended forward for relevance.

***26-"How will the MCOs and Medicaid ensure that the supplemental rebates and cost shift savings ensure that the savings to the state are greater than any increase in the MCO per member per month cost?"***
The Department will continue to monitor pharmacy utilization (FFS claims and MCO encounter data), supplemental rebate revenues and MCO financial performance against rate setting targets.

***27-"How will the state ensure that the lower cost generic drug is dispensed rather than the higher cost drug with a supplemental rebate?"***
Our focus remains on ensuring that the lower cost drug is dispensed, which is not always generic when considering federal and state supplemental rebates. The Department will continue its P&T committee process for determining the lower cost drug to be preferred in dispensing to its Medicaid members.

***28-"How will the state ensure that that the supplemental rebates are a savings to the state rather than the MCOs/PBMs negotiating their drug prices discounts with their network?"***
We will amend the MCO contract and Medicaid State Plan to prohibit MCOs/PBMs from negotiating drug price discounts with manufacturers (rebates) in addition to supplemental rebates paid to the State for these 10 therapeutic classes.

***29-"What are the lists of assumptions made in the savings analysis listed in the Notice of Intent?"***
Mercer provided Magellan with utilization information for the ten selected classes' respective base data used in the analysis, and Magellan estimated the projected increase in federal and state supplemental rebates. Utilization was estimated by therapeutic class category, and included expected changes due to implementation of the Single PDL based upon historical program experience. Mercer estimated the increase in capitation rate per member per month (PMPM) amounts by evaluating the estimated increase to unit costs per script, the estimated decrease in rebates received by the managed care organizations, and the net change in administrative costs. Switch savings were not calculated on some of the therapeutic classes such as antipsychotics and progestational agents.

***30-"While the state cannot disclose rebate amounts per drug, the state should disclose the estimates of the range of anticipated savings using the impact of generic/brand utilization and the average rebate percentages before and after the single PDL along with the cost impact of per member per month."***
As stated above, generic and brand status was not included in the analysis. The Department's rebate contractor will monitor overall rebate collected before and after the Single PDL for selected therapeutic classes. The final PMPM adjustment rate will determine the cost impact of the PMPM increase.

***31-"How has the analysis of savings been determined that it is in the best interest of the Medicaid MCOs to not manage the prescription drug benefit with or without the single PDL?"***
Our analysis sought to determine the best interest to the state, in terms of both net cost to taxpayers and administrative simplicity for prescribing providers. Related rate setting sought to fairly compensate MCOs for any increase in their drug costs or loss of manufacturer discounts, while ensuring the lowest net (inclusive of rebates) cost to the State.

***32-"Will the Medicaid Pharmaceutical and Therapeutics Committee review the single PDL recommendations prior to its implementation?"***
The P&T committee has already reviewed the current FFS PDL. The ten classes are a subset of the total FFS PDL.

***33-"How many therapeutic classes of drugs are projected to be in the single PDL?"***
There will be 10 therapeutic classes on the Single PDL for selected therapeutic classes.

***34-"What will be the frequency of changing drugs from preferred to non-preferred and vice-versa?"***
The selection of drugs will be reviewed twice a year by the FFS P&T committee. Any recommended changes would be effective January and July.

***35-"Will emergency filling of drugs be allowed?"***
Emergency filling will be allowed and audits of these claims are likely.

***36-"What will be the policy when there is a drug shortage?"***
The pharmacist needs to use professional judgment to address drug shortages.

***37-"When patients are hospitalized and generics are prescribed and they are discharged from the hospital with a generic drug prescription which requires PA, will the prescription deny and PA is required?"***
When the brand is preferred, the brand name drug can be dispensed by the pharmacist if the prescription is written for the generic product without prescriber consultation.

***Program Questions:***
***38-"What are the projected total pharmacy expenditures without the single PDL and with the single PDL? What are the projected expenditures for the initial ten therapeutic classes and for additional therapeutic classes, by brand and generic (innovator and non-innovator) drug, without the single PDL and with the single PDL for fiscal year 2018 and 2019? "***
The projected pharmacy pre-rebate expenditures for the 10 therapeutic classes before the Single PDL for selected therapeutic classes are $219,716,953 and $233,429,973 after. However, the projected net expenditures for the 10 classes decrease from approximately $114,843,764 to $96,497,984 after implementation. The analysis accounted for shifts from non-preferred to preferred status, but did not address brand and generic products. In some instances, based on clinical efficacy and stability of patients on established drug therapy no shift was anticipated.

***39-"While the goal of LDH is to have cost controls to increase the use of generic drugs which typically cost less than the brand drug and normally a lower copayment, many plans provide for a higher dispensing fee for the dispensing of a generic drug or pay incentives for achieving certain levels of performance in dispensing of generic drugs.***

***Is the Department considering reimbursing the pharmacist a higher dispensing fee when dispensing the lower cost drug?"***
Our current Medicaid State Plan allows a maximum dispensing fee of $10.41. New legislation (Act 301 of the 2017 Regular Session of the Louisiana Legislature) requires the MCO plans to align reimbursement with FFS for local pharmacies.

***40-"As patents expire and lower cost generics become available, along with newer drug products on the market, how will these drugs, both brand and generic, be placed on the PDL and/or PA?"***
Medicaid prescription utilization, clinical guidelines and expenditures will be evaluated by LDH's supplemental rebate contractor. New drugs, including new generics, are always a consideration in this process. Recommendations will be sent to LDH for consideration, and if deemed appropriate, be presented to P&T committee members.

***41-"What assurance does the Department have that the drug manufacturer will continue to participate in the supplemental rebate agreement if their market share does not shift?***
The potential for a manufacturer to continue to participate in the supplemental rebate agreement is enhanced with the advent of the Single PDL for selected therapeutic classes since the number of lives will increase.

***42-"While rebates are intended to reduce net pharmacy program costs and their impact can be significant, maximizing rebates should coincide with minimizing pharmacy expenditures in order to attain cost control. If a rebate nets the cost of a brand name product, what is the economic impact to the budget if a less costly generic is cheaper than the brand name drug net of rebate?"***
Medicaid prescription utilization drug expenditures and clinical guidelines will be considered prior to a recommendation being made. In many instances, the generic drug is the preferred agent.

***<u>Additional:</u>***
***43-"Magellan/Mercer has prepared information on Exhibit (Non-Exp) on a PMPM basis on Healthy LA 2-1-17 and Healthy LA with Single PDL which reflects $2.64 increase due to the loss of MCO Rebates and increase to Premium tax with the implementation of a single PDL for 10 therapeutic classes. Additionally, Exhibit (Non-Exp) reflects an increase of $1.65 for Federal Rebates and $4.91 for state supplemental rebates and rebate offset of $0.10 resulting in a total of $6.46? What does the $4.91 supplemental rebate represent? Also, was any consideration given that perhaps the MCO rebates may have increased?"***
In order to calculate the savings to the Department, the analysis compared the PMPM increase to the rebate increase. The $6.46 represents the projected total (federal plus supplemental) rebate increase per member month. The $4.91 represents just the supplemental rebate increase per member month. Even if the MCO rebates increase, at a

minimum the federal rebate in Medicaid is equal to or greater than the best price. Supplemental rebates are negotiated above and beyond federal rebates.

***44-"Under Notes, it states Mercer estimated non-PDL class federal rebates to be 46% based on guidance provided by Magellan. What does the 46% represent?"***
The 46 percent represents the federal rebate for FFS pharmacy claim expenditures.

***45-"The rebate impact sheet states the $6.46 rebate increase has been applied to all members per month. Would the state have received the federal rebate whether or not the single PDL was implemented for the 10 therapeutic classes? Why is the federal rebate included in the savings calculation?***
The Department is currently receiving federal rebates on all pharmacy claims (MCO and FFS). The federal rebate is included since the percentage changes based on the drug.

Your continued cooperation and support of the Louisiana Medicaid Program efforts to coordinate care and improve health are greatly appreciated.

Should you have any questions or comments regarding Medicaid administrative rulemaking activity, you may contact Veronica Dent, Medicaid Program Manager, at (225) 342-3238 or by email to Veronica.Dent@la.gov.

Sincerely,

for Jen Steele
Medicaid Director

JS/KHB/VYD

c: Darlene A. Budgewater
Sue Fontenot
Melwyn Wendt

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

# State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

August 9, 2017

Peter Martinez
Pharmaceutical Research and Manufacturers of America (PhRMA)
830 North Street, Suite B
Baton Rouge, LA 70802

Dear Mr. Martinez:

**RE: Notice of Intent**
**Pharmacy Benefits Management Program - Managed Care Supplemental Rebates**

This letter is in response to your correspondence regarding the Notice of Intent for Pharmacy Benefits Management Program – Managed Care Supplemental Rebates which was published in the June 20, 2017 edition of the *Louisiana Register.*

The Notice of Intent proposes to amend the provisions governing the TOP$ State Supplemental Rebate Agreement Program in order to include pharmacy utilization of managed care organizations (MCOs) that participate in the Healthy Louisiana (formerly Bayou Health) Program, and implement a single state managed preferred drug list (PDL) for selected therapeutic classes to maximize supplemental rebates on MCO utilization. A public hearing on this proposed Rule was held on Thursday, July 27, 2017 at 9:30 a.m. in the Bienville Building, Room 118, 628 North Fourth Street, Baton Rouge, LA.

I would like to thank you for taking the time to provide comments regarding the proposed Rule. The Department has reviewed your comments and determined that further explanation should be provided.

The request to prohibit duplicate rebates is reasonable and we appreciate the suggestion. Therefore, the Department intends to amend its Managed Care Organization (MCO) contracts to prohibit the MCOs from acquiring discounts or additional rebates from manufacturers for drugs in the Single Preferred Drug List selected therapeutic classes, effective October 1, 2017.

We, likewise, intend to incorporate the same prohibition into a future amendment of the administrative Rule governing the Pharmacy Benefits Management Program in Title 50

of the *Louisiana Administrative Code*. These provisions will be promulgated in a forthcoming edition of the *Louisiana Register*.

Your continued cooperation and support of the Louisiana Medicaid Program efforts to coordinate care and improve health are greatly appreciated.

Should you have any questions or comments regarding Medicaid administrative rulemaking activity, you may contact Veronica Dent, Medicaid Program Manager, at (225) 342-3238 or by email to Veronica.Dent@la.gov.

Sincerely,

for Jen Steele
Medicaid Director

JS/KHB/VYD

c: Darlene A. Budgewater
Sue Fontenot
Melwyn Wendt

**John Bel Edwards**
GOVERNOR

**Rebekah E. Gee MD, MPH**
SECRETARY

# State of Louisiana

Louisiana Department of Health
Office of the Secretary

August 7, 2017

**MEMORANDUM**

**TO:** The Honorable John A. Alario, President, Louisiana Senate
The Honorable Taylor F. Barras, Speaker of the House
The Honorable Fred H. Mills, Jr., Chairman, Senate Committee on Health and Welfare
The Honorable Frank A. Hoffmann, Chairman, House Committee on Health and Welfare
The Honorable Eric LaFleur, Chairman, Senate Finance Committee
The Honorable Cameron Henry, Chairman, House Appropriations Committee

**FROM:** Rebekah E. Gee MD, MPH
Secretary

**RE:** Oversight Report on Bureau of Health Services Financing Proposed Rulemaking

In accordance with the Administrative Procedure Act (R.S. 49:950 et seq.) as amended, we are submitting the attached documents for the proposed Rule for Professional Services Program – Enhanced Federal Medical Assistance Percentage Rate for Preventive Services.

The Department published a Notice of Intent on this proposed Rule in the June 20, 2017 issue of the *Louisiana Register* (Volume 43, Number 6). A public hearing was held on July 27, 2017 at which only Louisiana Department of Health staff were present. No oral testimony was given or written comments received regarding this proposed Rule.

The Department anticipates adopting the Notice of Intent as a final Rule in the September 20, 2017 issue of the *Louisiana Register*.

The following documents are attached:

1. a copy of the Notice of Intent;
2. the public hearing certification; and
3. the public hearing attendance roster.

REG/WJR/RKA

Attachments (3)

Bienville Building · 628 N. Fourth St. · P.O. Box 629 · Baton Rouge, Louisiana 70821-0629
Phone: (225) 342-9500 · Fax: (225) 342-5568 · www.dhh.la.gov
*An Equal Opportunity Employer*

**NOTICE OF INTENT**

**Department of Health**
**Bureau of Health Services Financing**

**Professional Services Program**
**Enhanced Federal Medical Assistance Percentage Rate for Preventive Services**
**(LAC 50:IX.15101)**

The Department of Health, Bureau of Health Services Financing proposes to adopt LAC 50:IX.15101 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Section 4106(b) of the Patient Protection and Affordable Care Act (P.L. No. 111-148), hereafter referred to as the Affordable Care Act (ACA), established a one percentage point increase in the Federal Medical Assistance Percentage (FMAP) rate applied to Medicaid covered expenditures for specified adult vaccines and clinical preventive services provided on a fee-for-service or managed care basis to states that provide coverage without cost sharing. In compliance with the requirements of the ACA, the Department of Health, Bureau of Health Services Financing promulgated an Emergency Rule which amended the provisions governing reimbursement for professional services in the Medical Assistance Program in order to establish provisions governing the enhanced FMAP for the coverage of those specified preventive services (*Louisiana Register,* Volume 43, Number 5). This proposed Rule is being

promulgated in order to continue the provisions of the May 15, 2017 Emergency Rule.

**Title 50**
**PUBLIC HEALTH—MEDICAL ASSISTANCE**
**Part IX. Professional Services Program**
**Subpart 15. Reimbursement**

## Chapter 151. Reimbursement Methodology

### Subchapter A. General Provisions

#### §15101. Enhanced Federal Medical Assistance Percentage Rate for Preventive Services

A. Effective for dates of service on or after May 15, 2017, the Federal Medical Assistance Percentage (FMAP) rate received by the department for specified adult vaccines and clinical preventive services shall increase one percentage point of the rate on file as of May 14, 2017.

1. Services covered by this increase are those assigned a grade of A or B by the United States Preventive Services Task Force (USPSTF) and approved vaccines and their administration as recommended by the Advisory Committee on Immunization Practices (ACIP).

2. The increased FMAP rate applies to these qualifying services whether the services are provided on a fee-for-service (FFS) or managed care basis.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have no impact on family functioning, stability and autonomy as described in R.S. 49:972.

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on child, individual, or family poverty in relation to individual or community asset development as described in R.S. 49:973.

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, no direct or indirect cost to the provider to provide the same level of service, and will have no impact on the provider's

ability to provide the same level of service as described in HCR 170.

Interested persons may submit written comments to Jen Steele, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030 or by email to MedicaidPolicy@la.gov. Ms. Steele is responsible for responding to inquiries regarding this proposed Rule. A public hearing on this proposed Rule is scheduled for Thursday, July 27, 2017 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Rebekah E. Gee MD, MPH

Secretary

**John Bel Edwards**
GOVERNOR

**Rebekah E. Gee MD, MPH**
SECRETARY

# State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

**PUBLIC HEARING CERTIFICATION**
**July 27, 2017**
**9:30 a.m.**

RE: Professional Services Program
Enhanced Federal Medical Assistance Percentage Rate for
Preventive Services
Docket # 07272017-03
Department of Health
State of Louisiana

CERTIFICATION

In accordance with LA R.S. 49:950 et seq., the attached public hearing agenda, together with one digital recording of the public hearing conducted on July 27, 2017 in Baton Rouge, Louisiana constitute the official record of the above-referenced public hearing.

Medicaid Policy and Compliance
Section

07/27/17
Date

# DHH/BHSF PUBLIC HEARING

**Topic – Professional Services Program Enhanced Federal Medical Assistance Percentage Rate for Preventive Services**

**Date** – July 27, 2017

PERSONS IN ATTENDANCE

| Name | Address | Telephone Number | AGENCY or GROUP you represent |
|---|---|---|---|
| 1. Carol Rumfola | 628 N 4th St BR LA 70802 | 342 6943 | LDH |
| 2. ALICA PREVOST | 628 N. 4th St BR LA 70802 | 342-3892 | LDH |
| 3. Karen H Barnes | LDH - Policy | 342-1325 | LDH |
| 4. Addie Imseis | 628 N. 4th St BR LA 70802 | 342-3892 | LDH |
| 5. | | | |
| 6. | | | |

**John Bel Edwards**
GOVERNOR

**Rebekah E. Gee MD, MPH**
SECRETARY

# State of Louisiana

Louisiana Department of Health
Office of the Secretary

August 7, 2017

**MEMORANDUM**

**TO:** The Honorable John A. Alario, President, Louisiana Senate
The Honorable Taylor F. Barras, Speaker of the House
The Honorable Fred H. Mills, Jr., Chairman, Senate Committee on Health and Welfare
The Honorable Frank A. Hoffmann, Chairman, House Committee on Health and Welfare
The Honorable Eric LaFleur, Chairman, Senate Finance Committee
The Honorable Cameron Henry, Chairman, House Appropriations Committee

**FROM:** Rebekah E. Gee MD, MPH
Secretary

**RE:** Oversight Report on Bureau of Health Services Financing Proposed Rulemaking

In accordance with the Administrative Procedure Act (R.S. 49:950 et seq.) as amended, we are submitting the attached documents for the proposed Rule for Professional Services Program – Reimbursement Methodology – State-Owned or Operated Professional Services Practices.

The Department published a Notice of Intent on this proposed Rule in the June 20, 2017 issue of the *Louisiana Register* (Volume 43, Number 6). A public hearing was held on July 27, 2017 at which only Louisiana Department of Health staff were present. No oral testimony was given or written comments received regarding this proposed Rule.

The Department anticipates adopting the Notice of Intent as a final Rule in the September 20, 2017 issue of the *Louisiana Register*.

The following documents are attached:

1. a copy of the Notice of Intent;
2. the public hearing certification; and
3. the public hearing attendance roster.

REG/WJR/YE

Attachments (3)

NOTICE OF INTENT

**Department of Health**
**Bureau of Health Services Financing**

**Professional Services Program**
**Reimbursement Methodology**
**State-Owned or Operated Professional Services Practices**
**(LAC 50:IX.15110 and 15113)**

The Department of Health, Bureau of Health Services Financing proposes to adopt LAC 50:IX.15110 and amend §15113 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

The Department of Health, Bureau of Health Services Financing provides reimbursement under the Medicaid State Plan to physicians and other professional services practitioners for services rendered to Medicaid covered recipients.

The department promulgated an Emergency Rule which amended the provisions governing the Professional Services Program in order to revise the reimbursement methodology for services rendered by physicians and other professional services practitioners employed by, or under contract to provide services in affiliation with a state-owned or operated entity (*Louisiana Register,* Volume 43, Number 5). This proposed Rule is being promulgated to continue the provisions of the May 1, 2017 Emergency Rule.

**Title 50**

**PUBLIC HEALTH—MEDICAL ASSISTANCE**
**Part IX. Professional Services Program**
**Subpart 15. Reimbursement**

## Chapter 151. Reimbursement Methodology

### Subchapter A. General Provisions

#### §15110. State-Owned or Operated Professional Services Practices

A. Qualifying Criteria. Effective for dates of service on or after May 1, 2017, in order to qualify to receive payments for services rendered to Medicaid recipients under these provisions, physicians and other eligible professional service practitioners must be:

1. licensed by the state of Louisiana;

2. enrolled as a Louisiana Medicaid provider; and

3. employed by, or under contract to provide services in affiliation with, a state-owned or operated entity, such as a state-operated hospital or other state entity, including a state academic health system, which:

a. has been designated by the department as an essential provider. Essential providers include:

i. LSU School of Medicine - New Orleans;

ii. LSU School of Medicine - Shreveport; and

iii. LSU state-operated hospitals (Lallie Kemp Regional Medical Center and Villa Feliciana Geriatric Hospital.

B. Payment Methodology. Effective for dates of service on or after May, 1, 2017, payments shall be made in the amount of the billed charges for services rendered by physicians and other

eligible professional service practitioners who qualify under the provisions of §15110.A.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 43:

**Subchapter B. Physician Services**

**§15113. Reimbursement Methodology**

A. - M. ...

N. Effective for dates of service on or after May 1, 2017, physicians, who qualify under the provisions of §15110 for services rendered in affiliation with a state-owned or operated entity that has been designated as an essential provider, shall receive payment in the amount of the billed charges for qualifying services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1252 (June 2010), amended LR 36:2282 (October 2010), LR 37:904 (March 2011), LR 39:3300, 3301 (December 2013), LR 41:541 (March 2015), LR 41:1119 (June 2015), LR 41:1291 (July 2015), amended by the Department of Health, Bureau of Health Services Financing, LR 43:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and

Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have a positive impact on family functioning, stability and autonomy as described in R.S. 49:972 as it will ensure continued access to by Medicaid recipients to services rendered by physicians and other professional services practitioners affiliated with state-owned or operated professional services practices.

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the poverty impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have a positive impact on child, individual or family poverty in relation to individual or community asset development as described in R.S. 49:973 as it reduces the financial burden for families of Medicaid recipients who are in need of access to services rendered by physicians and other professional services practitioners affiliated with state-owned or operated professional services practices.

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is

anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, and may reduce the total direct and indirect cost to the provider to provide the same level of service and enhance the provider's ability to provide the same level of service since this proposed Rule increases the payment to providers for the same services they already render.

Interested persons may submit written comments to Jen Steele, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. Ms. Steele is responsible for responding to inquiries regarding this proposed Rule. A public hearing on this proposed Rule is scheduled for Thursday, July 27, 2017 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Rebekah E. Gee MD, MPH

Secretary

John Bel Edwards
GOVERNOR

Rebekah E. Gee MD, MPH
SECRETARY

# State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

**PUBLIC HEARING CERTIFICATION**
**July 27, 2017**
**9:30 a.m.**

RE: Professional Services Program
Reimbursement Methodology
State-Owned or Operated Professional Services Practices
Docket # 07272017-04
Department of Health
State of Louisiana

CERTIFICATION

In accordance with LA R.S. 49:950 et seq., the attached public hearing agenda, together with one digital recording of the public hearing conducted on July 27, 2017 in Baton Rouge, Louisiana constitute the official record of the above-referenced public hearing.

Medicaid Policy and Compliance
Section

07/27/17
Date

# DHH/BHSF PUBLIC HEARING

**Topic – Professional Services Program Reimbursement Methodology State-Owned or Operated Professional Services Practices**

**Date** – July 27, 2017

PERSONS IN ATTENDANCE

| Name | Address | Telephone Number | AGENCY or GROUP you represent |
|---|---|---|---|
| 1. Keydra Singleton | 628 N 4th Street Baton Rouge LA 70805 | 225-342-3086 | LDH |
| 2. | | | |
| 3. | | | |
| 4. | | | |
| 5. | | | |
| 6. | | | |