HCCA
Tulare Regional Medical Center

Tulare Local Health Care District
Board of Directors
Regular Meeting Agenda

Wednesday, September 28, 2016
Board Convenes at 4:00 p.m.

Evolution Fitness & Wellness Center
Conference Room
1425 E. Prosperity Ave.
Tulare, CA 93274

I. CALL TO ORDER
-Chair of the Board

II. CITIZEN REQUESTS/PUBLIC COMMENTS

III. APPROVAL OF MINUTES

- Regular Board Meeting Minutes of August 24, 2016 and Special Board Meeting Minutes for September 1, 2016.

Proposed Action: Approval of Minutes for August 24, 2016 Regular Board Meeting and for September 1, 2016 Special Board Meeting Minutes.

IV. OPEN SESSION AGENDA

A. Consent Agenda

1. Request to approve the following Tulare Local Health Care District (TLHCD) Medical Executive Committee Policies:

12-1045	Pain Assessment and Management
12-3099	Central Service- Traffic Control
12-3100	Central Service- Environmental Cleaning of Central Service
12-3101	Central Service- Infection Control
12-3102	Central Service- Department Cleaning
12-3103	Central Service Storage of Sterile Supplies
20-8011	Reportable Diseases and Conditions
20-8012	Pregnant Healthcare Worker
20-8018	Work Restrictions and Management of Personnel Illnesses and Exposures to Communicable Diseases
ISO50-1000	Quality Manual System

2. **Request to approve the following Tulare Local Health Care District (TLHCD) Hospital Policies:**

10-1002.2	Corporate Compliance Plan
13-12001	Educational Services Plan
13-12002	AHA Training Center

Proposed Action: Approval of Consent Agenda Items

B. **Board of Director Update/Action Items** - *Board Chair*

1. **Board Member Reports**

D. **Medical Staff Report** – *Ronald Ostrom, D.O., Chief of Medical Staff (or MEC representative)*

1. **MEC Recommendations to the Board and Report of Actions**

Proposed Action: Acceptance of MEC Recommendations

V. SUSPEND OPEN SESSION - ADJOURN TO CLOSED SESSION

VI. CLOSED SESSION

A. **Medical Executive Committee Report of Hospital Medical Audit or Quality Assurance Activities**
-Ronald Ostrom, D.O., Chief of Medical Staff (or MEC representative)
MEC Reports relating to Peer Review, Credentialing, and Quality Assurance, pursuant to Health and Safety Code section 32155

B. **Conference with Legal Counsel**
Existing Litigation pursuant to subdivision (d)(1) of Government Code section 54956.9:
Discussion regarding *Aghapy Group, Inc. dba Aghapy Construction v. Tulare Local Healthcare District*
Tulare County Superior Court Case No.: 264380

C. **Conference With Legal Counsel**
Significant exposure to litigation pursuant to Subdivision (d)(4) of government Code section 54956.9:
Discussion regarding two (2) potential actions

D. **Conference With Legal Counsel**
Existing Litigation pursuant to Subdivision (d)(1) of Government Code section 54956.9
Discussion regarding *Tulare Regional Medical Center Medical Staff v. Tulare Local Healthcare District*
Tulare County Superior Court Case No.: 264227

E. **Conference With Legal Counsel**
Existing Litigation pursuant to subdivision (d)(1) of Government Code section 54956.9:
Discussion regarding *Parmod Kumar, M.D., et al. v. Abraham Betre, D.O. et al.*
Tulare County Superior Court Case No.: VCU265230

F. **Conference With Legal Counsel**
Existing Litigation pursuant to subdivision (d)(1) of Government Code section 54956.9:
Discussion regarding *Opper v. Tulare Regional Medical Center, et al.*
Tulare County Superior Court Case No.: 263554

G. **Conference With Legal Counsel**
Existing Litigation pursuant to subdivision (d)(1) of Government Code section 54956.9:

Discussion regarding *Carlos Chavez, Kevin Lopez and Christian Lopez v. Ronald Allen Smith, M.D., David Smith, M.D. and Tulare Regional Medical Center*
Tulare County Superior Court Case No.: 261060

H. **Conference With Legal Counsel**
Existing Litigation pursuant to subdivision (d)(1) of Government Code section 54956.9:
Discussion regarding *Deanne Martin-Soares and Emily Yenigues v. Tulare Local Health Care District, et, al.*
Tulare County Superior Court Case No.: 266902

I. **Conference With Legal Counsel**
Existing Litigation pursuant to subdivision (d)(1) of Government Code section 54956.9:
Discussion regarding *Firstsource Solutions USA, LLC v. Tulare Regional Medical Center*
Eastern District of California Case No.: 1:15-01136-KJM-EPG

VII. ADJOURN CLOSED SESSION/RECONVENE OPEN SESSION

-Public report of action taken in closed session, pursuant to Government Code section 54957.1

VIII. ADJOURNMENT

NOTICE TO THE PUBLIC

Tulare Regional Medical Center does not discriminate against any person on the basis of gender, religion, race, color, national origin, disability, or age in admission, treatment, or participation in its programs, services and activities, or in employment. For further information about this policy, contact: Bruce Greene of Baker & Hostetler LLP at telephone number (310) 442-8834 or by e-mail at bgreene@bakerlaw.com.

PUBLIC COMMENT PERIOD FOR REGULAR MEETINGS

At this time, members of the public may comment on any item of interest to the public that is within the subject matter jurisdiction of the Board (Gov't Code, § 54954.3(a)). Provided, however, the Board shall not take action on any item not appearing on the agenda unless the action is otherwise authorized by law. Any person addressing the Board will be limited to a maximum of three (3) minutes so that all interested parties have an opportunity to speak.

OPEN SESSION AGENDA ITEMS

All writings, materials and information provided to the Board for their consideration relating to any Open Session Agenda item of the meeting are available for public inspection during regular business hours at the Administration Office of the District located at 869 Cherry Street, Tulare, California.

CLOSED SESSION AGENDA ITEMS

As provided in the Ralph M. Brown Act, Government Code §54950 et seq., the Board may meet in closed session with members of its staff, employees and its attorneys. These sessions are not open to the public and may not be attended by members of the public. The matters the Board will meet on in closed session are identified in the Regular Meeting agenda. Any public reports of action taken in the closed session will be made in accordance with Government Code § 54957.1.

COMPLIANCE WITH ADA

This agenda shall be made available upon request in alternative formats to persons with a disability, as required by the Americans with Disabilities Act of 1990 (42 U.S.C. § 12132) and the Ralph M. Brown Act (Cal. Gov't Cod. § 54954.2). Persons requesting a disability related modification or accommodation in order to participate in the meeting, should contact the Executive Office at (559) 685-3462, during regular business hours.

HCCA
Tulare Regional Medical Center

Tulare Local Health Care District
Board of Directors
Regular Meeting Minutes

Wednesday, August 24, 2016
Board Convenes at 4:00 p.m.

Evolution Fitness & Wellness Center
Conference Room
1425 E. Prosperity Ave.
Tulare, CA 93274

PRESENT
Sherrie Bell, Chair
Richard Torrez, Treasurer
Linda Wilbourn, Secretary
Laura Gadke, Board Member

ABSENT
Parmod Kumar, MD, Vice Chair

OTHERS PRESENT
Benny Benzeevi, M.D., Chair HCCA
Claudia Razo, Executive Assistant
Community Members
Legal Counsel (Baker & Hostetler LLP)

I. CALL TO ORDER

Chair Sherrie Bell called the meeting to order at 4:00 p.m.

II. CITIZEN REQUESTS/PUBLIC COMMENTS

The following individuals provided public comments:

- Ms. Susana Aguilera-Marrero
- Mr. Tim Moore
- Ms. Sally Boucher
- Dr. Edward Henry, DVM
- Mr. Shawn Burgess
- Mr. Dou McNearney
- Ms. Michelle Moore
- Mr. Steven Harold

Mr. Tim Ward presented the hospital with a trophy and a certificate for its services in connection with the March of Dimes campaign.

III. APPROVAL OF MINUTES

- Regular Board Meeting Minutes of July 27, 2016.

Action: Laura Gadke made a motion to approve the minutes for the Regular Board Meeting of July 27, 2016 with the minutes amended to correct two typos. Linda Wilbourn seconded the motion. The motion passed unanimously.

IV. OPEN SESSION AGENDA

A. Consent Agenda

1. Request to approve the following Tulare Local Health Care District (TLHCD) Medical Executive Committee Policies:

13-5008	Hospital Drug Formulary
13-9028	Approved Abbreviations-Symbols and Prohibited Abbreviations, Acronyms and Symbols (Do not use) List

2. Request to approve the following Tulare Local Health Care District (TLHCD) Hospital Policies:

10-1113	General HIPAA Overview for Education Purpose (HIPAA) --DELETE
22-1009	Safety (Environment of Care) Committee
22-1012	Eyewash Management
22-1015	Lockout Tagout Plan
22-1016	Hazardous Communication Program
22-1017	Hazardous Waste Management Program
22-1019	Medical Waste Management Plan
22-1020	Incarcerated Patient Policy

3. Request to approve the following Tulare Local Health Care District (TLHCD) Physician Orders:

None

4. Request to approve the following Physician/Other Agreements:

a. **Physician Orders**
645 Hypertension Preeclampsia--NEW

b. **Second Amendment**
Medsphere Systems Corporation

c. **Lease Agreement- Renewal**
Indulgence Salon & Spa

Action: Laura Gadke made the motion to approve the Consent Agenda Items. Richard Torrez seconded the motion. The motion passed unanimously.

B. Report by Administration - *HCCA Management*

1. Finance

a. Monthly Financial Update – Alan Germany presented the financial summary highlighting the results for the month of July. He also provided an overview of the volume trends of the various operating components within the healthcare District. He noted that the District's operating margin continues to be solidly positive. Average daily census was 43, deliveries have slightly increased from prior month with a volume of 52 for July. Primary

care visits had a growth of 9.2% from July 2015 to July 2016. The cash position continues to be solid, but is weighed down by Tower construction costs.

Action: Laura Gadke made the motion to approve of the July 2016 Financial Statements. Richard Torrez seconded the motion. The motion passed unanimously.

2. Compliance and Quality

a. Compliance Presentation Update – Alan Germany

C. Board of Director Update/Action Items - *Board Chair*

1. Board Member Reports
The next regularly scheduled board meeting will take place on September 28, 2016 at 4:00 p.m.

D. Medical Staff Report

1. MEC Recommendations to the Board and Report of Actions

Action: Laura Gadke made the motion to approve the of MEC Recommendations (which were presented in written form). Richard Torrez seconded the motion. The motion passed unanimously.

V. SUSPEND OPEN SESSION - ADJOURN TO CLOSED SESSION

Chair Sherrie Bell adjourned to closed session at approximately 4:53 p.m.

VI. CLOSED SESSION

Chair Sherrie Bell opened closed session at approximately 5:20 p.m.

A. **Medical Executive Committee Report of Hospital Medical Audit or Quality Assurance Activities**
MEC Reports (which were presented in written form) relating to Peer Review, Credentialing, and Quality Assurance, pursuant to Health and Safety Code section 32155

B. **Conference With Legal Counsel**
Significant exposure to litigation pursuant to Subdivision (d)(2) of Government Code section 54956.9:
- One (1) potential action

C. **Conference With Legal Counsel**
Existing Litigation pursuant to subdivision (d)(1) of Government Code section 54956.9:
Discussion regarding *Opper v. Tulare Regional Medical Center, et al.*
Tulare County Superior Court Case No.: 263554

D. **Conference With Legal Counsel**
Existing Litigation pursuant to subdivision (d)(1) of Government Code section 54956.9:
Discussion regarding *Ibarra v. Tulare Regional Med Center, David Smith, Douglas Middleton, Family Health Care Network, David Larios, and DOES 1 to 10*
United States District Court, Eastern District of California Case No.: 1:16-cv-0039-LJO-BAM

E. **Conference With Legal Counsel**
Significant exposure to litigation pursuant to Subdivision (d)(4) of government Code section 54956.9:
Discussion regarding two (2) potential actions

F. **Conference With Legal Counsel**
Existing Litigation pursuant to Subdivision (d)(1) of Government Code section 54956.9
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G. **Conference With Legal Counsel**
Existing Litigation pursuant to subdivision (d)(1) of Government Code section 54956.9:
Discussion regarding *Parmod Kumar, M.D., et al. v. Abraham Betre, D.O. et al.*
Tulare County Superior Court Case No.: VCU265230

VII. ADJOURN CLOSED SESSION/RECONVENE OPEN SESSION

Chair Sherrie Bell adjourned closed session and reconvened to open session at approximately 5:40 p.m.

Pursuant to Government Code section 54957.1, the following reportable actions were taken by the Board in Closed Session:

Item A – The Board took action to accept the closed session MEC Reports relating to Peer Review, Credentialing and Quality Assurance. The motion was made by Laura Gadke to accept the MEC Reports. Chair Sherrie Bell seconded the motion. The motion passed unanimously.

Item B – The Board voted unanimously to approve the rejection of a government claim as untimely. Notice of Rejection of the Claim was signed by Chair Sherrie Bell and will be sent via certified mail to the claimant shortly after the meeting, which will make the action final. The motion was made by Richard Torrez and seconded by Laura Gadke.

No further action was taken.

VIII. ADJOURNMENT

There being no further business, Chair Sherrie Bell adjourned the meeting at approximately 6:00 p.m.

Respectfully submitted,

_____
Linda Wilbourn, Secretary

NOTICE TO THE PUBLIC

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PUBLIC COMMENT PERIOD FOR REGULAR MEETINGS

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OPEN SESSION AGENDA ITEMS

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CLOSED SESSION AGENDA ITEMS

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COMPLIANCE WITH ADA

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HCCA
Tulare Regional Medical Center

Tulare Local Health Care District
Board of Directors
Special Meeting Minutes

Thursday, September 1, 2016
Board Convened at 5:00 p.m.

Evolution's Fitness & Wellness Center
Conference Room
1425 E. Prosperity Ave.
Tulare, CA 93274

PRESENT
Sherrie Bell, Chair
Parmod Kumar, MD, Vice Chair
Linda Wilbourn, Secretary
Richard Torrez, Treasurer

ABSENT
Laura Gadke, Board Member

OTHERS PRESENT
Benny Benzeevi, M.D., Chair HCCA
Claudia Razo, Executive Assistant
Community Members
Legal Counsel (Baker & Hostetler LLP) *(Closed session only / Telephonically)*

I. CALL TO ORDER

Chair Sherrie Bell called the meeting to order at 5:07 p.m.

II. CITIZEN REQUESTS/PUBLIC COMMENTS

The following individual provided public comments:

- Mr. Kevin Northcraft

III. OPEN SESSION AGENDA

A. **Board of Directors Update / Action Items**

1. **Loan from Bank of Sierra – *Board Chair***
   Approval of loan from Bank of Sierra in the amount of $800,000 and the related resolutions as set forth in Exhibit A and incorporated herein by this reference.

   Action: Dr. Kumar made a motion to approve the resolutions set forth in the attached Exhibit A and authorize Chair Sherrie Bell to sign such resolutions. Linda Wilbourn seconded the motion. The motion passed unanimously.

2. **Percutaneous Coronary Intervention (PCI) program – *Alan Germany***

Alan Germany, Chief Financial Officer and Chief Operating Officer, presented to the Board the new PCI program to perform cardiac interventions. No action was taken.

IV. SUSPEND OPEN SESSION - ADJOURN TO CLOSED SESSION

Chair Sherrie Bell adjourned to closed session at approximately 5:19 p.m.

V. CLOSED SESSION

Chair Sherrie Bell opened closed session at approximately 5:25 p.m.

A. **Conference With Legal Counsel**
Significant exposure to litigation pursuant to Subdivision (d)(2) of Government Code section 54956.9:
- One (1) potential action

VI. ADJOURN CLOSED SESSION/RECONVENE OPEN SESSION

Chair Sherrie Bell adjourned closed session and reconvened to open session at approximately 5:35 p.m.

Pursuant to Government Code section 54957.1, the following reportable actions were taken by the Board in closed session:

Item A – The Board voted unanimously to approve entering into a final settlement agreement with respect to Item A on the closed session agenda. Dr. Kumar made the motion and Richard Torrez seconded the motion. Immediately after the motion was carried, Sherrie Bell signed the settlement agreement, making it fully executed and final. By way of the settlement agreement, in return for a payment to Novia Solutions, Inc., a California corporation, Novia has released the Tulare Regional Medical Center from all claims and liabilities arising out of a dispute between Novia and TRMC over payments for services rendered. The details of the settlement are subject to confidentiality provisions set forth in the settlement agreement, which can be released only by a public records act request.

VII. ADJOURNMENT

There being no further business, Chair Sherrie Bell adjourned the meeting at approximately 5:40 p.m.

Respectfully submitted,

_____
Linda Wilbourn, Secretary

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TULARE LOCAL HEALTH CARE DISTRICT
dba TULARE REGIONAL MEDICAL CENTER

POLICY / GUIDELINE

TO: All Departments

FROM: Administration

SUBJECT: Pain Assessment and Management

I. Introduction:

Patients requiring pain management at Tulare Regional Medical Center can expect staff to respect and support the patient's right to optimal pain assessment and management. Pain is assessed in all patients. The organization will address the appropriateness and effectiveness of pain management.

II. Process:

A. A multi-disciplinary team approach will be used to provide care. This team will consist of physicians, independent licensed practitioners, nursing staff, Respiratory Care staff, Medical Imaging, Laboratory staff, Pharmacists, Social Services, Physical Therapist and Case Management. Benefits of this approach include:

1. Improved coordination of care and education

2. Multiple reinforcement of pain management objectives

3. Consistent approach to assessment and treatment

III. Policy:

A. Effective pain assessment and management can remove the adverse psychological and physiological effects of unrelieved pain. Optimal management of the patient experiencing pain enhances healing and promotes both physical and psychological wellness. Patients need to be involved in all aspects of their care including pain management.

IV. Assessment:

A. It is the responsibility of all clinical staff to assess and periodically reassess the patient for pain and relief from pain including the intensity and quality (i.e., character, frequency, location and duration of pain), and responses to treatment.

Effective Date: (12) Clinical Services
General:
APPROVED: Pain Assessment and Management
12-1045

Medical Executive Comm.: 09/14/16

Board Of Directors:

1. At time of admission to the facility, the patient will be questioned regarding pain during the initial nursing assessment.

2. All other clinical department staff will also question the patient regarding pain during the initial patient assessment performed by that department's care provider.

3. Questions related to pain may include, but are not limited to:

   a. Nature of pain

   b. Duration

   c. Type

   d. Intensity

   e. Any pain relief methods that have proven effective

   f. Patient's desires for pain management, i.e., pain control, complete pain relief.

B. Intensity of pain may be assessed by one of the methods below as appropriate to the patient's ability to respond:

   1. Wong-Baker (adjusted to 0-10 scale)

   2. NIPS (neonate/Infant scale)

   3. Analog (Linear) (0-10 scale)

   4. FLACC (0-10 scale)

C. Intensity ratings will be categorized as mild 1-3; moderate 4-7; severe 8-10. Any rating of 5 or greater requires an intervention.

D. All patients will undergo reassessment of pain every shift with vital signs, after every pain control mechanism employed by patient care providers, and prn. Each department scope of practice may vary; (see Department Specific Scope of Practice).

E. Any patient care provider, from any department, that has implemented a pain control mechanism will reassess the patient in approximately 30 minutes for injectable pain medications and 60 minutes for oral pain medications from time of administration to determine amount of pain control or relief achieved and respond

to the patient's needs accordingly.

F. Management of the patient's pain is an interdisciplinary process and is to be included in the interdisciplinary plan of patient care. Inclusion of this component of the patient's care process will alert and educate all members of the healthcare team regarding the patient's pain experience. Pain management issues will be included in topics of discussions during interdisciplinary care planning conferences.

G. Pain Management is a patient's right. If barriers prevent TRMC staff from providing pain management, refer to Chain of Command policy #12-3078.

V. Patient and Family Education Topics:

A. Patients will be taught that pain management is part of their treatment.

B. The patient and his/her family/significant other (s) will receive education provided by the staff regarding management of the patient's pain. Education included, but is not limited to:

1. Types of pain the patient actually or potentially experience.

2. Pain control mechanisms available and/or that have been employed.

3 Potential limitation of pain management and treatment.

4. Potential and/or actual side effects of pain management and treatment.

5. Determination of the patient's acceptable level of pain; e.g., the terminally ill patient may wish complete relief from pain, knowing this may render him/her in a semi-somnolent state; or this patient may request relief from pain to the degree where pain may still be experienced, however his/her ability to remain mentally alert and relate to family/significant others remains intact.

6. Discharge planning process with emphasis on symptom management (e.g. pain, nausea or dyspnea).

C. All patient care providers will provide information to the patient and the patient's family/significant others that optimal management of pain is a primary goal of patient care and is consistent with the organization's mission and value statement.

VI. Documentation:

A. Refer to department specific documentation if there are any deviations from below:

POLICY / GUIDELINE

1. Initial assessment of patient pain will be documented in the Electronic Health Record (EHR) and electronic Medication Administration system as follows:
   a. Care Plan Management (CPM)
   b. Pain Assessment Flowsheet.
   c. Electronic Medication Administration.
   d. Unit specific nursing care record.

2. Vital Signs will be charted.

3. Electronic documentation of pain medication administered with pain related comment and reassessment.
   a. The clinician must indicate numeric pain score.
   b. The clinician must indicate which Pain Scale was used for pain assessment.
   c. The clinician must reassess pain level.

Questions concerning any aspect of this policy/guideline should be referred to Administration.

This policy/guideline replaces and supersedes all previous policies/guidelines concerning this matter and is effective immediately.

ATTACHMENT A

WONG BAKER PAIN SCALE

Wong-Baker FACES Pain Rating Scale

Brief word instructions: Point to each face using the words to describe the pain intensity. Ask the child to choose face that best describes own pain and record the appropriate number.

Original instructions: Explain to the person that each face is for a person who feels happy because he has no pain (hurt) or sad because he has some or a lot of pain.

- **Face 0** is very happy because he doesn't hurt at all.
- **Face 1** hurts just a little bit.
- **Face 2** hurts a little more.
- **Face 3** hurts even more.
- **Face 4** hurts a whole lot.
- **Face 5** hurts as much as you can imagine, although you don't have to be crying to feel this bad. Ask the person to choose the face that best describes how he is feeling.

Rating scale is recommended for age 3 years and older.

POLICY / GUIDELINE

ATTACHMENT B

(NIPS) NEONATAL/INFANT PAIN SCALE

(Recommended for children less than 1 year old) A score greater than 3 indicates pain.

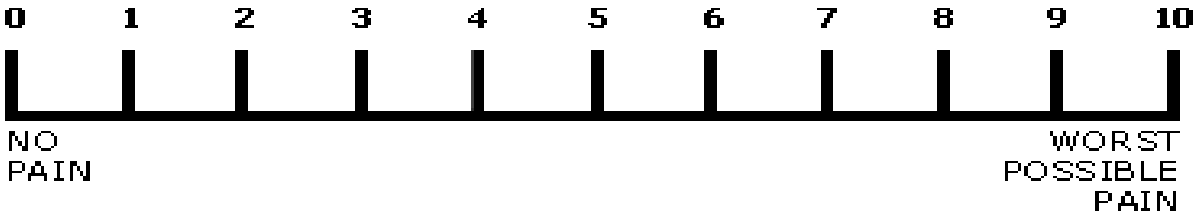
Pain Assessment		Score
Facial Expression		
0 - Relaxed Muscles	Restful face, neutral expression	
1 - Grimace	Tight facial muscles; furrowed brow, chin, jaw (negative facial expression – nose, mouth brow)	
Cry		
0 - No cry	Quiet, not crying	
1 - Whimper	Mild moaning, intermittent	
2 - Vigorous cry	Loud scream; rising, shrill, continuous (Note: Silent cry may be scored if baby is intubated as evidenced by obvious mouth and facial movement	
Breathing Pattern		
0 - Relaxed	Usual pattern for this infant	
1- Change in breathing	Indrawing, irregular, faster than usual; gagging, breath holding	
Arms		
0 - Relaxed/Restrained	No Muscular rigidity; occasional random movements of arms	
1 - Flexed/Extended	Tense, straight arms; rigid and/or rapid extension, flexion	
Legs		
0 - Relaxed/Restrained	No Muscular rigidity; occasional random movements of legs	
1 - Flexed/Extended	Tense, straight legs; rigid and/or rapid extension, flexion	
State of Arousal		
0 - Sleeping/Awake	Quiet, peaceful, sleeping or alert, random leg movements	
1 - Fussy	Alert, restless and thrashing	

At the American Family Children's Hospital (AFCH) the NIPS is used in children less than one year of age. Children at this age are not able to tell us if they are in pain. This scale uses body language to help us to understand if a child is in pain. A child is evaluated and either scored a 0 or 1 in each category based on their behavior. A total score is calculated. Most of the time a score greater than 3 tells us a child is likely to be experiencing pain or discomfort. If you notice this, you could try some of the comfort methods listed below.

- Repositioning
- Singing or soft music
- Gentle stroking
- Rocking with the child in a rocking chair
- Swaddling

ATTACHMENT C

ANALOG (LINEAR) PAIN SCALE



ATTACHMENT D

FLACC Scale

Category	Scoring		
	1	2	3
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid or jerking
Cry	No cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging or being talked to, distractible	Difficult to console or comfort

Each of the five categories (F) Face; (L) Legs; (A) Activity; (C) Cry; (C) Consolability is scored from 0-2, which results in a total score between zero and ten.

Descriptive Name: Pain Assessment and Management

Descriptive Type: Revised Policy

Document Number: 12-1045

Attachments: Yes

Author: Carol Bradford

Typist: Melissa Arend

Creation Date: 08/27/09

Revision Date: 12/09/15

Previous Dist. Date: 04/26/12

Committee Review and Approval:	Approval Date:	Comments:
P & T Committee	04/14/16	
Family Medicine Service	08/25/16	
MEC	09/14/16	
Board of Directors		

Effective Date:

Forward To: Policy Binders – (PBX and Administration) and Post to Intranet Site

Disposition: Copy and Distribution - Administration

Comments:

TULARE LOCAL HEALTH CARE DISTRICT
dba TULARE REGIONAL MEDICAL CENTER

POLICY / GUIDELINE

TO: Medical Staff, Clinical Services

FROM: Administration

SUBJECT: Central Service- Traffic Control

I. PURPOSE:

II. POLICY:

- Traffic control is strictly enforced in Central Service Department:
  - All doors opening into the main corridor are to remain closed at all times.
  - Decontamination door is the only door used to enter Central Service.
    - Personnel who are not members of Central Service but find it necessary to enter the department (engineers, servicemen, physicians and administrative personnel, etc.) must don shoe covers, head and cover-up clothing before being allowed to enter the department.
  - The flow of traffic in and out of the department will be kept to a minimum.

Effective Date:

APPROVED:

Medical Executive Comm.: 09/14/16

Board Of Directors:

(12) Clinical Services
Inpatient Care Units:
Central Service-Traffic Control
#12-3099

Descriptive Name: Central Service-Traffic Control

Descriptive Type: New Policy

Document Number: 12-3099

Attachments: None

Author: Paul Stratman

Typist: Maritza Sevillano/Melissa Arend

Creation Date: 9/16/15

Revision Date: N/A

Prev. Dist. Date: N/A

Committee Review and Approval:	Approval Date:	Comments:
Infection Prevention Committee	03/21/16	
Surgery Committee	08/17/16	
MEC	09/14/16	
Board of Directors		

Effective Date:

Forward To: Policy Binders (PBX and Administration) and Post to Intranet

Disposition: Copy and Distribution - Administration

Comments:

TULARE LOCAL HEALTH CARE DISTRICT
dba TULARE REGIONAL MEDICAL CENTER

POLICY / GUIDELINE

TO: Medical Staff, Clinical Services

FROM: Administration

SUBJECT: Central Service-Environmental Cleaning of Central Service

I. PURPOSE:

To maintain a standard of environmental cleanliness.

II. POLICY:

III. PROCEDURE:

- All shelves shall be wiped with an approved antibacterial solution weekly.
- Wire racks and carts shall be cleaned on a weekly basis with a hospital approved germicide.
- Table tops, counters, sinks and cupboard doors require daily cleaning.
- Environmental Services shall clean all walls weekly, and floors on a daily basis.
- Air conditioning vent surfaces are to be cleaned on a weekly basis by Environmental Services.
- Air conditioning filters will be changed by the Engineering Department on a routine basis.
- All cleaning procedures shall be documented on the appropriate cleaning checklist by the person performing the cleaning. The checklist shall be dated and initialed.

Effective Date:

APPROVED:

Medical Executive Comm.: 09/14/16

Board Of Directors:

(12) Clinical Services
Inpatient Care Units:
Central Service-Environmental Cleaning of Central Service
#12-3100

IV. RESPONSIBILITY:

- Central Service personnel are responsible for completion and documentation of assigned environmental cleaning.
- Environmental Services and Engineering Departments are responsible for completion and documentation of their designated environmental cleaning.

Questions concerning any aspect of this policy/guideline should be referred to Administration.

This policy/guideline replaces and supersedes all previous policies/guidelines and is effective immediately.

Descriptive Name: Central Service-Environmental Cleaning of Central Service

Descriptive Type: New Policy

Document Number: 12-3100

Attachments: None

Author: Paul Stratman

Typist: Maritza Sevillano/Melissa Arend

Creation Date: 9/16/15

Revision Date: N/A

Prev. Dist. Date: N/A

Committee Review and Approval:	Approval Date:	Comments:
Infection Prevention Committee	03/21/16	
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MEC	09/14/16	
Board of Directors		

Effective Date:

Forward To: Policy Binders (PBX and Administration) and Post to Intranet

Disposition: Copy and Distribution - Administration

Comments:

TULARE LOCAL HEALTH CARE DISTRICT
dba TULARE REGIONAL MEDICAL CENTER

POLICY / GUIDELINE

TO: Medical Staff, Clinical Services

FROM: Administration

SUBJECT: Central Service-Infection Control

I. PURPOSE:
To provide infection control guidelines for Central Service; including standardized policies and procedures for receiving, processing, storing and issuing various kinds of materials which are purchased pre-sterilized, sterilized in the hospital and certain equipment requiring cleaning and processing in an area designated, equipped and staffed for this purpose.

II. POLICY:

III. RESPONSIBILITIES:

- Central Service Manager:
  - Formulates, in writing, Infection Control policies and procedures for Central Service.
  - Provides written procedures for the following:
    - Handling of disposable and non-disposable items
    - Checking and returning of outdated items to Central Service
    - Storage and rotation of sterile supplies
    - Dating of sterile processed supplies
    - Separation of clean supplies from those to be processed
    - Handling of contaminated supplies; decontamination
    - Proper methods for sterilization

Effective Date: (12) Clinical Services
Inpatient Care Units:
APPROVED: Central Service-Infection Control
#12-3101

Medical Executive Comm.: 09/14/16

Board Of Directors:

- Cleaning and disinfection of equipment which cannot be sterilized

- Establishes proper flow patterns for handling supplies and traffic and maintains separate dirty/clean work areas.
- Maintains all requirements of cleaning, wrapping, packaging and storing of sterile items processed or stored within the hospital.
- Provides and documents continuing education in infection control and safety for Central Service personnel.
- Maintains personnel health standards and required dress attire policies.
- Reports potential infection hazards to the Infection Control Practitioner.
- Is a member (or assigns a representative of the department) of the Infection Control Committee.

- Central Service Technician:
  - Shall be qualified by training and experience, and operates under the supervision of the Central Service Manager.
  - Shall observe all policies and procedures of the Central Service Department.

- Infection Control Practitioner:
  - Reviews all infection control practices and processes in Central Service.
  - Orders environmental cultures as indicated.
  - Assists in the preparation and presentation of educational infection control programs.
  - Acts as a resource person.
  - Makes periodic prevalence rounds to determine adherence to guidelines.

- Infection Control Committee:
  - Reviews and approves all policies and practices relevant to infection control.
  - Serves as consultant to all of the above.

INFECTION CONTROL PRACTICES:

- Employee Health:
  - Employees shall comply with the Employee Health Program.
  - Personnel shall not work if they have skin, respiratory or gastrointestinal infections.
  - Eating, drinking or smoking shall not be permitted in Central Service.
  - Personnel off duty for three (3) or more days because of an illness shall be cleared by a physician before returning to work.
  - Personnel with a communicable disease shall be referred to the Infection Control Practitioner for follow-up.
- Personal Hygiene:
  - Cleanliness and good personal hygiene habits are mandatory.
  - Frequent and thorough hand-washing is mandatory.
  - Gloves shall be used when handling and sorting soiled bio-hazardous articles.
- Dress Code:
  - Keep nails short; use nail sticks to clean under the nails.
  - Remove excessive or hanging jewelry and other ornaments before reporting to duty. These items often have bacteria which can be transmitted to clean or sterile materials.

- Hair shall be completely covered with disposable head cover while assembling trays and discarded at end of shift. Shoe covers will be worn as required.

- Personnel shall wear designated scrub uniforms - one day use only. Scrubs will be changed if exposed to spills.

- Personnel shall wear impermeable cover gowns, gloves, goggles/face shields and shoe covers when cleaning soiled bio-hazardous instruments, utensils, etc., and change appropriately when leaving dirty areas.

- Visitor Control:

  - With the approval of the Central Service Manager or designee, visitors may be allowed to enter the Central Service area with the proper apparel:

    - Head cover

    - Cover gown/jump suit

    - Shoe covers

- Education:

  - Programs in infection control measures begin in orientation and continue with on-the-job training and in-service education. Personnel will attend annual update yearly.

  - Basic training in aseptic techniques, personal hygiene, sterility, storage and safe handling practices shall be a requirement at the time of hire.

  - Continuing education specific to Central Service is strongly encouraged.

- Indications for Sterilization/Disinfection:

  - Patient care equipment that enters normally sterile tissue or the vascular system, or through which blood flows, shall be sterile.

  - Laparoscopes and other scopes that enter the peritoneal cavity shall be subjected to a sterilization procedure before each use.

- Endoscopes and respiratory therapy equipment that go though mucous membranes shall be subjected to a sterilizing procedure before each use.

- Method of Processing:
  - Patient care equipment contaminated with blood shall be sterilized; if this is not feasible, it shall receive high-level disinfection.
  - Most environmental surfaces contaminated with blood shall be cleaned with a solution of hospital-approved germicide.
  - Other patient care and environmental objects that are potentially contaminated with virulent microorganisms shall be processed accordingly with the hospital-approved germicide solution.

- Equipment and Packaging:
  - The most reliable type of sterilization available for each type material will be used.
  - Non-sterile items:
    - Areas in Central Service are designated for receiving, servicing, cleaning, storing and issuing of non-sterile equipment.
  - Sterile reusable equipment and material:
    - Must be processed in two (2) physically separate areas by separate staffs. If this is not possible, careful hand-washing and uniform change shall be required before the move from "dirty" to "clean" areas.
    - Written procedures are established for washing, wrapping and arranging packages, and the various types and sizes of materials or containers used.
    - Equipment and supplies shall be purchased on the basis of their reaction to steam or plasma i.e. Sterrad. Use chemicals only when absolutely necessary.
  - Sterile supplies:
    - Proper storage and handling of sterile supplies shall be maintained to prevent contamination.

- Stock shall be rotated to reduce the need for re-sterilization.
- Procedures are written and maintained in the department for establishing shelf life of sterile items and/or for checking outdated supplies or package integrity in event-related shelf-life sterility.
- Any sterile reusable materials that leave Central Service and are then returned are considered contaminated and shall be cleaned, re-sterilized and/or reprocessed.

- Disposable items:
  - Written procedure for staff handling disposable items shall include inspection of packaging, expiration date or package integrity, stock rotation, inventory control and disposal.

- Traffic and Supply Control:
  - Good flow patterns shall be established for handling supplies and traffic.
  - Transportation system shall be used as "one-way" systems for either clean or dirty supplies.

- Environmental Services:
  - All work surfaces, shelves and fixtures shall be cleaned daily with approved germicidal cleaner.

- Engineering:
  - Preventive maintenance records are kept on equipment in the Bio Med/Engineering Department. Please refer to equipment lists.
  - Equipment shall be carefully tested and inspected before it is cleaned and dispensed for patient use by Central Service personnel. Rental equipment must be inspected and approved by the Engineering Department prior to use on any patient.
  - Manufacturers' recommendations shall be followed regarding care, use and/or repair of equipment.

- Decontamination/Cleaning:

- Objects to be disinfected or sterilized shall be thoroughly cleaned to remove all blood, tissue, food and other debris, before reprocessing. The using department shall return objects to Central Service in plastic bags to confine and contain contamination.

CONTROLS OF THE SYSTEM:

- Administrative:
  - Autoclave indicating tape:
    - Indicating type autoclave tape, indicating labels or indicating printed legends shall by affixed to or printed on all hospital assembled packages intended for sterilization. Tape, label or legend shall be examined after sterilization and also before use to make sure that it indicates adequate exposure to the appropriate sterilizing process.
  - Sterilizer logs, chart chemical/biological tests and spore tests shall be maintained as required.
  - Expiration dates:
    - See event-related shelf-life sterilization.
  - Lot control:
    - Lot control numbers shall be placed on each package for later retrieval if needed.
- Process Control:
  - Recording charts and gauges:
    - Shall be examined by the sterilizer operator at the beginning and end of each cycle (temperature and pressure). There is a written procedure for this activity. Records shall be maintained per hospital/regulatory requirements.
  - Chemical indicators:

- A temperature accurate chemical indicator is used at the center of each package of hospital-assembled material and among materials which are heat-sterilized without packaging.

- Biological Indicators:
  - There is a written biological indicator procedure for steam or plasma.
- Rotation of Supplies:
  - There is a written procedure covering the rotation of supplies, including shelf life of various packaging and event-related shelf life.
- Autoclaves and Sterilizers:
  - Autoclaves and sterilizers will be maintained in operating condition at all times.
  - Instructions for operating autoclaves and sterilizers are posted in the area where the autoclaves and sterilizers are located.
  - Written procedures are developed, maintained and available to personnel responsible for sterilization of supplies and equipment that include, but are not limited to, the following:
    - Time, temperature and pressure for sterilizing the various bundles, packs, dressings, instruments, solutions, etc.
    - Cleaning, packaging, storing and issuing of supplies and equipment
    - Dating of materials sterilized
    - Loading of the sterilizer
    - Daily checking of log sheets recording and indicating thermometers and filing for seven (7) years of recording thermometer charts
    - Weekly (on steam; biweekly on gas) bacteriological test, the bacterial organism used and filing for seven (7) years of the test results

- Length of aeration time for materials gas-sterilized is eight (8) to 30 hours. See manufacturer's recommendations.

- Recall:
  - There is a written system for recall of all sterilized goods.

Questions concerning any aspect of this policy/guideline should be referred to Administration.

This policy/guideline replaces and supersedes all previous policies/guidelines and is effective immediately.

Descriptive Name: Central Service-Infection Control

Descriptive Type: New Policy

Document Number: 12-3101

Attachments: None

Author: Paul Stratman

Typist: Maritza Sevillano/Melissa Arend

Creation Date: 9/16/15

Revision Date: N/A

Prev. Dist. Date: N/A

Committee Review and Approval:	Approval Date:	Comments:
Infection Prevention Committee	04/18/16	
Surgery Committee	08/17/16	
MEC	09/14/16	
Board of Directors		

Effective Date:

Forward To: Policy Binders (PBX and Administration) and Post to Intranet

Disposition: Copy and Distribution - Administration

Comments:

TULARE LOCAL HEALTH CARE DISTRICT
dba TULARE REGIONAL MEDICAL CENTER

POLICY / GUIDELINE

TO: All Departments

FROM: Administration

SUBJECT: Central Service Department Cleaning

I. POLICY:

- Central Service is a housing area for sterile and clean supplies intended for patient usage. Bacteria shall be controlled as much as mechanically and humanly possible by all employees who work in this area.

- Establishing a clean work and storage environment is a constant aim that shall be achieved in Central Service in order to maintain an asepsis state. Cleaning procedures shall be considered one of the most important tasks. and each technician or other staff member is responsible for cleaning the area he/she has been assigned to. In addition, those areas that are not used exclusively to store or handle direct patient contact items, but are a part of the department, are to be kept clean and in order. This is the responsibility of all Central Service personnel.

- The Environmental Service Department is responsible for cleaning the floors, walls, overhead vent surfaces and hoppers

- Central Service is responsible for all other cleaning tasks.

    - For all cleaning assignments, obtain clean cloths, clean basins, water, hospital-approved soluble detergent and a germicide solution. Be sure to follow mixing instructions for all cleaning solutions and germicide solutions. This applies to all of the following work assignments:

        - Surface Area Cleaning:
            - Surface cleaning, shelves, closets, woodwork, tables, etc. Purpose: To provide for cleanliness and orderliness on a continuing basis for supplies and equipment.

Effective Date:

APPROVED:

Medical Executive Comm.: 09/14/16

Board Of Directors:

(12) Clinical Services
Inpatient Care Units
Central Service Department Cleaning
12-3102

- Closed and Open Shelving - Sterile Area:

Once a week or more often as needed, wash shelves with disinfectant solution starting from the top down. allow to air dry

- Work Tables and Counters:
  - . The continuous cleaning of these surface areas isare necessary throughout the day. A dampened cloth (germicide solution) is used for continued cleaning.
- Work Areas:
  - All work areas must be kept neat and clean at all times. Allow 10 minutes before going off duty to make certain the work area is in proper order.
- :
  - .
- Closed Sterile Supply Carts:
    - closed carts used for sterile instruments and supplies movement.
    - All carts used for transport of sterile instruments and supplies shall upon their return to CPD be wiped down with a germicidal solution and allowed to air dry according to the Mfr's. IFU.
- Cart Wheels:
  - Shall be checked daily to remove any debris or lint which may adhere to wheels. Use soap and water solution for cleaning. Rinse well.
- Central Service's Storage Room:
  - . Storage racks and shelves must be cleaned and stock neatly arranged. . Supplies must be 18 inches from the ceiling as sprinkler system (fire) must be kept clear. Do not store case goods on the floor.

- Satellite Areas:
  - Cleaning procedures are identical to departmental cleaning and sterile storage areas, as this area is your clean and sterile supply distribution point.
  - All storage areas used for the purpose of sterile supplies must be kept neat and clean at all times. All areas are on a rotating schedule for terminal cleaning. Should be done Bimonthly. Questions concerning any aspect of this policy/guideline should be referred to Administration.

This policy/guideline replaces and supersedes all previous policies/guidelines and is effective immediately.

Descriptive Name: Central Service Department Cleaning

Descriptive Type: New Policy

Document Number: 12-3102

Attachments: No

Author: Paul Stratman

Typist: Maritza Sevillano/Melissa Arend

Creation Date: 09/16/15

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Infection Prevention Committee	03/21/16	
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MEC	09/14/16	
Board of Directors		

Effective Date:

Forward To: Policy Binders (PBX and Administration) and Post to Intranet

Disposition: Copy and Distribution - Administration

Comments:

TULARE LOCAL HEALTH CARE DISTRICT
dba TULARE REGIONAL MEDICAL CENTER

POLICY / GUIDELINE

TO: All Departments

FROM: Administration

SUBJECT: Central Service-Storage of Sterile Supplies

I. PURPOSE:

To outline proper storage of sterile supplies.

II. POLICY:

- All sterile supplies shall be stored in a secure location which maintains the integrity of the sterile item.
  - All storage areas shall be clean, dry, protected from moisture, vermin or insect excreta.
  - Before storage, all sterile items shall be checked for the following:
    - Make certain items are completely dry
    - Integrity of the outer wrap
    - Coloring of sterile indicator tape, date prepared, initialed
    - Sterilization
    - Sterile expiration date (if item is not included in event-related sterility program)
    - Lot number labels

- All sterile cloth and paper wrap items are stored in the Central Service sterile area in closed shelf section or in drawers as designated. These items shall be double-wrapped.

Effective Date: (12) Clinical Services
Inpatient Care Units:
APPROVED: Central Service Storage of Sterile Supplies
Medical Executive Comm.: 09/14/16 12-3103

Board Of Directors:

- Stock shall be rotated so that items do not outdate. Stock is checked monthly in order to verify that no item in the sterile storage area is outdated. Stock shall be rotated so that older stock is in front and newer stock is placed in back or older stock is on the right and newer stock is on the left. Paper wrappers also may become brittle with age and this compromises sterility.

- The closures of sterile items shall be tamper proof and impossible to reseal. If there is a suspicion of incomplete closure, the item shall not be used.

- Cases and cartons shall not be placed directly on the floor when stored. They shall be stocked on lower shelves or platforms.

- A cloth or paper-wrapped tray or items which are seldom used shall be protected by protective plastic wrap immediately after a thorough cooling period. Heat seal or tape opening.

- All storage areas shall be clearly labeled. Any item sterilized by the hospital shall be identified on outside of the wrap with the following information:

    - Name of item

    - Month, day and year

    - Sterile expiration date (if item is not included in event-related sterility program)

    - Lot and load number label or stamp

    - Initials of the Central Service employee who processed and wrapped the item

- Sterile supplies shall be separated from clean supplies:

    - A clean non-sterile storage area is designated for this purpose.

    - Ideally, items shall not be stacked or piled on top of each other in storage. If space determines this must occur, then items shall be of the same size and shape, neatly stacked, with item identification plainly visible.

- Do not store any item in the sterile or clean area in the original carton. Articles are to be removed from the shipping boxes and placed on small transfer cart which can be wheeled into the area.
- All sterile supplies are to be stored at least eight (8) to 10 inches above floor level to allow for cleaning and wet mopping and to lessen the possibility of contamination. To allow for air circulation, supplies are to be stored 18 inches from the ceiling, and to reduce the possibility of bacteria invasion and for air circulation purposes, a minimum distance of two to three (2-3) inches from the wall is maintained.

- Storage of sterile supplies shall be done under conditions which tend to preserve, not threaten the integrity of the packaging.

  - Traffic in storage areas shall be kept to minimum.

  - Rubber bands, paper clips, etc., shall not be placed around "paper or plastic" packages.

  - Supplies shall be handled as little as possible, to reduce risk of damage.

  - When stored in drawers, packages shall not be "packed in", due to risk of tearing or sliding when drawer is opened.

  - No sterile packages of any type shall be placed next to or below any sink. Water contaminates sterile packages automatically and necessitates their reprocessing (or disposal) before use.

I. RESPONSIBILITY:

All personnel in Central Service, Materials Management and other areas with sterile supplies are responsible for proper storage of these supplies.

Questions concerning any aspect of this policy/guideline should be referred to Administration.

This policy/guideline replaces and supersedes all previous policies/guidelines and is effective immediately.

Descriptive Name: Central Service Storage of Sterile Supplies

Descriptive Type: New Policy

Document Number: 12-3103

Attachments: No

Author: Paul Stratman

Typist: Maritza Sevillano/Melissa Arend

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MEC	09/14/16	
Board of Directors		

Effective Date:

Forward To: Policy Binders (PBX and Administration) and Post to Intranet

Disposition: Copy and Distribution - Administration

Comments:

TULARE LOCAL HEALTH CARE DISTRICT
dba TULARE REGIONAL MEDICAL CENTER

POLICY / GUIDELINE

TO: All Departments

FROM: Administration

SUBJECT: Reportable Diseases and Conditions

I. POLICY:

A. All reportable diseases and conditions are, by State law, required to be promptly reported as designated by the attached Title 17, California Code of Regulations (CCR) §2500 "Reportable Disease and Conditions Report " form (See Attachment A).

B. Outpatient Procedure: Lab will fax lab report to Tulare County. Tulare County will follow up with Confidential Morbidity Report from physicians.

C. Inpatient Procedure - ED and Inpatients: Lab will send identifying lab report to the Infection Prevention and Control department as soon as disease or condition is identified. The Infection Prevention Department will facilitate completion of the CMR into California Reportable Disease Information Exchange website (CalREDIE) https://calredie.cdph.ca.gov/webcmr/pages/login/login.aspx . If CalREDIE is unavailable a paper CMR will be generated and faxed to Tulare County Department of Public Health at 559-685-4835. In the event a case will need to be reported immediately, on the weekend or a holiday, call 559-471-7092.

D. In the event the lab report is not available and the disease is identified, a report can be filed by those health care providers who have ready access to the clinical information. The provider will complete a CMR and fax to the health department at 559-685-4835. A copy ***must*** be sent to the Infection Prevention and Control department. The copy can be faxed to 3888. Any questions should be referred to the Infection Prevention and Control department at extension 3487.

E. The Confidential Morbidity Report may be accessed by clicking on the following links: To report reportable diseases: http://www.cdph.ca.gov/pubsforms/forms/CtrldForms/cdph110a.pdf

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Effective Date:

Approved:

Medical Executive Comm.: 09/14/16

Board Of Directors:

(20) Clinical Guidelines: Infection Control Reportable Diseases and Conditions 20-8011

To report TB:
http://www.cdph.ca.gov/pubsforms/forms/CtrldForms/cdph110b.pdf

Reports to the DMV
http://www.cdph.ca.gov/pubsforms/forms/CtrldForms/cdph110c.pdf

II. ALL REPORTABLE DISEASES EXCLUDING TUBERCULOSIS AND CONDITIONS REPORTABLE TO DMV

- Use Confidential Morbidity Report (CMR) PM 110 A (see Attachment B)
- Responsibility of Infection Prevention and Control and TRMC Laboratory

- Complete all the applicable fields on the form related to:
  - Patient demographic data
  - Date of disease onset
  - Add any treatment provided for reported STDs
  - Attach laboratory data supporting the diagnosis of the reportable disease
  - Add your contact information

III. REPORTING TUBERCULOSIS

- Use Confidential Morbidity Report (CMR) PM 110 B (see Attachment C)
-
- Responsibility of Infection Prevention and Control and Case Management
- Complete all the applicable fields on the form related to:
  - Patient demographic data
  - Date of disease onset
  - Date first specimen collected
  - Date of diagnosis
  - Complete fields related to tuberculosis treatment if this information is available
  - Fax the CMR to 559-685-4786 Attention: TB Program
  - Add your contact information
- Note: Refer to Policy 20-8013 Tuberculosis Prevention Plan “TB Inpatient Notification/Discharge Planning” for additional reporting requirements unique to Tuberculosis

IV. NON-COMMUNICABLE DISEASES & CONDITIONS

- Alzheimer's Disease and Related Conditions
- Disorders Characterized by Lapses of Consciousness
- Use Confidential Morbidity Report (CMR) PM 110 C (see Attachment D)
- Responsibility of Emergency Department Physicians
- Complete all the applicable fields on the form related to:
  - Patient demographic data

- Add your contact information

V. PESTICIDE-RELATED ILLNESS OR INJURY (KNOWN OR SUSPECTED CASES)

- Contact Tulare County Department of Public Health - Health Officer at (559)-685-5730. In the event a case will need to be reported immediately, on the weekend or a holiday, call (559) 471-7092.
- Responsibility of Emergency Department Physicians
  - Be prepared to share information regarding:
    - The type of pesticide involved in the exposure
    - How many people exposed
    - Duration of exposure
    - How exposure occurred
- Note: The Health Officer will contact the County Agricultural Commissioner who will in turn determine whether the State Office of Environmental Health and Hazard Assessment must be notified.

Questions concerning any aspect of this policy/guideline should be referred to Administration.

This policy/guideline replaces and supersedes all previous policies/guidelines and is effective immediately.

ATTACHMENT A

Title 17, California Code of Regulations (CCR) §2500, §2593, §2641.5-2643.20, and §2800-2812 Reportable Diseases and Conditions*

§ 2500. REPORTING TO THE LOCAL HEALTH AUTHORITY.

- **§ 2500(b)** It shall be the duty of every health care provider, knowing of or in attendance on a case or suspected case of any of the diseases or condition listed below, to report to the local health officer for the jurisdiction where the patient resides. Where no health care provider is in attendance, any individual having knowledge of a person who is suspected to be suffering from one of the diseases or conditions listed below may make such a report to the local health officer for the jurisdiction where the patient resides.
- **§ 2500(c)** The administrator of each health facility, clinic, or other setting where more than one health care provider may know of a case, a suspected case or an outbreak of disease within the facility shall establish and be responsible for administrative procedures to assure that reports are made to the local officer.
- **§ 2500(a)(14)** "Health care provider" means a physician and surgeon, a veterinarian, a podiatrist, a nurse practitioner, a physician assistant, a registered nurse, a nurse midwife, a school nurse, an infection control practitioner, a medical examiner, a coroner, or a dentist.

URGENCY REPORTING REQUIREMENTS [17 CCR §2500(h)(i)]

✆! = Report immediately by telephone (designated by a ♦ in regulations).
† = Report immediately by telephone when two or more cases or suspected cases of foodborne disease from separate households are suspected to have the same source of illness (designated by a ♦ in regulations.)
✆ = Report by telephone within one working day of identification (designated by a + in regulations).
FAX ✆ ✉ = Report by electronic transmission (including FAX), telephone, or mail within one working day of identification (designated by a + in regulations).
+ All other diseases/conditions should be reported by electronic transmission (including FAX), telephone, or mail within seven calendar days of identification.

REPORTABLE COMMUNICABLE DISEASES §2500(j)(1)

FAX ✆ ✉ Amebiasis
Anaplasmosis
✆ ! Anthrax, human or animal
FAX ✆ ✉ Babesiosis
✆ ! Botulism (Infant, Foodborne, Wound, Other)
Brucellosis, animal (except infections due to *Brucella canis*)
✆ ! Brucellosis, human
FAX ✆ ✉ Campylobacteriosis
Chancroid
FAX ✆ ✉ Chickenpox (Varicella) (outbreaks, hospitalizations and deaths)
Chlamydia trachomatis infections, including lymphogranuloma venereum (LGV)
FAX ✆ ✉ Chikungunya Virus Infection
✆ ! Cholera
✆ ! Ciguatera Fish Poisoning
Coccidioidomycosis
Creutzfeldt-Jakob Disease (CJD) and other Transmissible Spongiform Encephalopathies (TSE)
FAX ✆ ✉ Cryptosporidiosis
Cyclosporiasis
Cysticercosis or taeniasis
✆ ! Dengue Virus Infection
✆ ! Diphtheria
✆ ! Domoic Acid Poisoning (Amnesic Shellfish Poisoning)
Ehrlichiosis
FAX ✆ ✉ Encephalitis, Specify Etiology: Viral, Bacterial, Fungal, Parasitic
✆ ! *Escherichia coli*: shiga toxin producing (STEC) including *E. coli* O157
✆ ! Flavivirus infection of undetermined species
† FAX ✆ ✉ Foodborne Disease
Giardiasis
Gonococcal Infections
FAX ✆ ✉ *Haemophilus influenzae*, invasive disease, all serotypes (report an incident of less than five years of age)
FAX ✆ ✉ Hantavirus Infections
✆ ! Hemolytic Uremic Syndrome
FAX ✆ ✉ Hepatitis A, acute infection
Hepatitis B (specify acute case or chronic)
Hepatitis C (specify acute case or chronic)
Hepatitis D (Delta) (specify acute case or chronic)
Hepatitis E, acute infection
Human Immunodeficiency Virus (HIV) infection, stage 3 (AIDS)
✆ Human Immunodeficiency Virus (HIV), acute infection
Influenza, deaths in laboratory-confirmed cases for age 0-64 years
✆ ! Influenza, novel strains (human)
Legionellosis
Leprosy (Hansen Disease)
Leptospirosis
FAX ✆ ✉ Listeriosis
Lyme Disease
FAX ✆ ✉ Malaria
✆ ! Measles (Rubeola)
FAX ✆ ✉ Meningitis, Specify Etiology: Viral, Bacterial, Fungal, Parasitic
✆ ! Meningococcal Infections
Mumps
✆ ! Novel Virus Infection with Pandemic Potential
✆ ! Paralytic Shellfish Poisoning
FAX ✆ ✉ Pertussis (Whooping Cough)
✆ ! Plague, human or animal
FAX ✆ ✉ Poliovirus Infection
FAX ✆ ✉ Psittacosis
FAX ✆ ✉ Q Fever
✆ ! Rabies, human or animal
FAX ✆ ✉ Relapsing Fever
Respiratory Syncytial Virus (only report a death in a patient less than less than five years of age)
Rickettsial Diseases (non-Rocky Mountain Spotted Fever), including Typhus and Typhus-like Illnesses
Rocky Mountain Spotted Fever
Rubella (German Measles)
Rubella Syndrome, Congenital
FAX ✆ ✉ Salmonellosis (Other than Typhoid Fever)
✆ ! Scombroid Fish Poisoning
✆ ! Shiga toxin (detected in feces)
FAX ✆ ✉ Shigellosis
✆ ! Smallpox (Variola)
FAX ✆ ✉ Streptococcal Infections (Outbreaks of Any Type and Individual Cases in Food Handlers and Dairy Workers Only)
FAX ✆ ✉ Syphilis
Tetanus
FAX ✆ ✉ Trichinosis
FAX ✆ ✉ Tuberculosis
Tularemia, animal
✆ ! Tularemia, human
FAX ✆ ✉ Typhoid Fever, Cases and Carriers
FAX ✆ ✉ Vibrio Infections
✆ ! Viral Hemorrhagic Fevers, human or animal (e.g., Crimean-Congo, Ebola, Lassa, and Marburg viruses)
FAX ✆ ✉ West Nile Virus (WNV) Infection
✆ ! Yellow Fever
FAX ✆ ✉ Yersiniosis
✆ ! Zika Virus Infection
✆ ! OCCURRENCE of ANY UNUSUAL DISEASE
✆ ! OUTBREAKS of ANY DISEASE (Including diseases not listed in **§ 2500**). Specify if institutional and/or open community.

HIV REPORTING BY HEALTH CARE PROVIDERS §2641.30-2643.20
Human Immunodeficiency Virus (HIV) infection at all stages is reportable by traceable mail, person-to-person transfer, or electronically within seven calendar days. For complete HIV-specific reporting requirements, see Title 17, CCR, §2641.30-2643.20 and http://www.cdph.ca.gov/programs/aids/Pages/tOAHIVRptgSP.aspx

REPORTABLE NONCOMMUNICABLE DISEASES AND CONDITIONS §2800–2812 and §2593(b)
Disorders Characterized by Lapses of Consciousness (§2800-2812)
Pesticide-related illness or injury (known or suspected cases)**
Cancer, including benign and borderline brain tumors (except (1) basal and squamous skin cancer unless occurring on genitalia, and (2) carcinoma in-situ and CIN III of the Cervix) (§2593)***

LOCALLY REPORTABLE DISEASES (If Applicable):

* This form is designed for health care providers to report those diseases mandated by Title 17, California Code of Regulations (CCR). Failure to report is a misdemeanor (Health & Safety Code §120295) and is a citable offense under the Medical Board of California Citation and Fine Program (Title 16, CCR, §1364.10 and 1364.11).
** Failure to report is a citable offense and subject to civil penalty ($250) (Health and Safety Code §105200).
*** The Confidential Physician Cancer Reporting Form may also be used. See Physician Reporting Requirements for Cancer Reporting in CA at: www.ccrcal.org

CDPH 110a (06/2016)

ATTACHMENT B

State of California—Health and Human Services Agency — California Department of Public Health

CONFIDENTIAL MORBIDITY REPORT

PLEASE NOTE: Use this form for reporting all conditions except Tuberculosis and conditions reportable to DMV.

DISEASE BEING REPORTED ➡

Patient Name - Last Name | *First Name* | *MI*

Home Address: Number, Street | *Apt./Unit No.*

City | *State* | *ZIP Code*

Home Telephone Number | *Cell Telephone Number* | *Work Telephone Number*

Email Address | *Primary Language* ☐ English ☐ Spanish ☐ Other: _____

Birth Date (mm/dd/yyyy) | *Age* ☐ Years ☐ Months ☐ Days | *Gender* ☐ Male ☐ Female ☐ M to F Transgender ☐ F to M Transgender ☐ Other: _____

Pregnant? ☐ Yes ☐ No ☐ Unknown | *Est. Delivery Date (mm/dd/yyyy)* | *Country of Birth*

Ethnicity (check one)
☐ Hispanic/Latino ☐ Non-Hispanic/Non-Latino ☐ Unknown

Race (check all that apply)
☐ African-American/Black
☐ American Indian/Alaska Native
☐ Asian *(check all that apply)*
☐ Asian Indian ☐ Hmong ☐ Thai
☐ Cambodian ☐ Japanese ☐ Vietnamese
☐ Chinese ☐ Korean ☐ Other *(specify)*: _____
☐ Filipino ☐ Laotian
☐ Pacific Islander *(check all that apply)*
☐ Native Hawaiian ☐ Samoan
☐ Guamanian ☐ Other *(specify)*: _____
☐ White
☐ Other *(specify)*: _____
☐ Unknown

Occupation or Job Title

Occupational or Exposure Setting (check all that apply): ☐ Food Service ☐ Day Care ☐ Health Care ☐ Correctional Facility ☐ School ☐ Other *(specify)*: _____

Date of Onset (mm/dd/yyyy) | *Date of First Specimen Collection (mm/dd/yyyy)* | *Date of Diagnosis (mm/dd/yyyy)* | *Date of Death (mm/dd/yyyy)*

Reporting Health Care Provider | *Reporting Health Care Facility*

Address: Number, Street | *Suite/Unit No.*

City | *State* | *ZIP Code*

Telephone Number | *Fax Number*

Submitted by | *Date Submitted (mm/dd/yyyy)*

Laboratory Name | *City* | *State* | *ZIP Code*

REPORT TO:

Jeremy Kempf, RN,PHN
Communicable Disease Coordinator
1150 South K Street
Tulare, CA. 93274
Phone: 559-687-6965
Fax: 559-685-4835
After hours: 559-471-7092

(Obtain additional forms from your local health department.)

SEXUALLY TRANSMITTED DISEASES (STDs)

Gender of Sex Partners (check all that apply)
☐ Male ☐ M to F Transgender
☐ Female ☐ F to M Transgender
☐ Unknown ☐ Other: _____

STD TREATMENT ☐ Treated in office ☐ Given prescription
Drug(s), Dosage, Route | *Treatment Began (mm/dd/yyyy)*
☐ *Untreated*
☐ Will treat
☐ Unable to contact patient
☐ Patient refused treatment
☐ Referred to: _____

If reporting Syphilis, Stage:
☐ Primary (lesion present)
☐ Secondary
☐ Early latent < 1 year
☐ Latent (unknown duration)
☐ Late latent > 1 year
☐ Late (tertiary)
☐ Congenital
Neurosyphilis? ☐ Yes ☐ No ☐ Unknown

Syphilis Test Results | *Titer*
☐ RPR ☐ Pos ☐ Neg _____
☐ VDRL ☐ Pos ☐ Neg _____
☐ FTA-ABS ☐ Pos ☐ Neg
☐ TP-PA ☐ Pos ☐ Neg
☐ EIA/CLIA ☐ Pos ☐ Neg
☐ CSF-VDRL ☐ Pos ☐ Neg _____
☐ Other: _____

If reporting Chlamydia and/or Gonorrhea:
Specimen Source(s) (check all that apply)
☐ Cervical
☐ Pharyngeal
☐ Rectal
☐ Urethral
☐ Urine
☐ Vaginal
☐ Other: _____

Symptoms?
☐ Yes
☐ No
☐ Unknown

If reporting Pelvic Inflammatory Disease: (check all that apply)
☐ Gonococcal PID
☐ Chlamydial PID
☐ Other/Unknown Etiology PID

Partner(s) Treated?
☐ Yes, treated in this clinic
☐ Yes, Meds/Prescription given to patient for their partner(s)
☐ Yes, other: _____
☐ No, instructed patient to refer partner(s) for treatment
☐ No, referred partner(s) to: _____
☐ Unknown

VIRAL HEPATITIS

Diagnosis (check all that apply)
☐ Hepatitis A
☐ Hepatitis B (acute)
☐ Hepatitis B (chronic)
☐ Hepatitis B (perinatal)
☐ Hepatitis C (acute)
☐ Hepatitis C (chronic)
☐ Hepatitis D
☐ Hepatitis E

Is patient symptomatic? ☐ Yes ☐ No ☐ Unknown

Suspected Exposure Type(s)
☐ Blood transfusion, dental or medical procedure
☐ IV drug use
☐ Other needle exposure
☐ Sexual contact
☐ Household contact
☐ Perinatal
☐ Child care
☐ Other: _____

ALT (SGPT) Result: _____ Upper Limit: _____
AST (SGOT) Result: _____ Upper Limit: _____
Bilirubin result: _____

		Pos	Neg
Hep A	anti-HAV IgM	☐	☐
Hep B	HBsAg	☐	☐
	anti-HBc total	☐	☐
	anti-HBc IgM	☐	☐
	anti-HBs	☐	☐
	HBeAg	☐	☐
	anti-HBe	☐	☐
	HBV DNA: _____		

		Pos	Neg
Hep C	anti-HCV	☐	☐
	RIBA	☐	☐
	HCV RNA (e.g., PCR)	☐	☐
Hep D	anti-HDV	☐	☐
Hep E	anti-HEV	☐	☐

Remarks:

CDPH 110a (1/11) (for reporting all conditions except Tuberculosis and conditions reportable to DMV) — Page 1 of 2

ATTACHMENT C (PAGE 1)

Tulare County
Health & Human Services Agency
Health Services Department
Public Health / Tuberculosis Program

CONFIDENTIAL TUBERCULOSIS SUSPECT CASE REPORT

☐ In Patient ☐ Out Patient

**Within 24 Hours of Diagnosis/Suspicion of TB…Complete this form in entirety and FAX to Tulare County TB Control Program: 559-685-4786

Contact Name	Facility	Phone Number	Fax Number	Today's Date

PART I: PATIENT/INSTITUTION INFORMATION

Name: LAST	FIRST	MI	ALIAS: LAST	FIRST	MI

STREET (Address Prior to Admission)	CITY	ZIP CODE	COUNTY

Sex ☐ Male ☐ Female	Age	Date of Birth	Phone Number	Social Security Number	Occupation

Name of Workplace	Workplace Address	Workplace Phone Number x

Race/Ethnicity	Primary Language	Translator
☐ WHITE-NON HISPANIC ☐ NATIVE AMERICAN/ALASKAN NATIVE ☐ BLACK-NON HISPANIC ☐ ASIAN /PACIFIC ISLANDER (Specify _____) ☐ HISPANIC ☐ OTHER (Specify_____)		☐ Yes ☐ No
	Country of Birth	Date Arrived in US

Emergency Contact	Phone Number	Legal Guardian (If applicable)	Phone Number
Physician Name	Admission Date	Correctional Facility	Phone Number
Physician Phone Number	Physician Pager/Fax Number	Parole Officer (If applicable)	Phone Number

Insurance Company	Medical Record Number	PFN/CDC Number	Other

PART II: CLINICAL FINDINGS

HIV: ☐ Positive ☐ Negative	Cocci: ☐ Positive ☐ Negative	Other Medical Conditions:

Site: ☐ PULMONARY ☐ LARYNGEAL ☐ EXTRAPULMONARY ☐ OTHER:	Diagnosis Date:	Status: ☐ Suspect ☐ Definite	Symptom Onset Date	Prior TB Treatment ☐ Yes ☐ No

TST Done? ☐ Yes ☐ No ☐ Unknown Date: MM Reading:	Productive Cough? ☐ Yes ☐ No	SYMPTOMS: ☐ Cough ☐ WGT Loss ☐ Night Sweats ☐ Fatigue ☐ Fever ☐ Hemoptysis ☐ Chest Pain ☐ Other:
Household Contacts: Yes☐ #_____ No☐ Unk☐ # of children <5 Immuno Comp In Household: Yes☐ #_____ No☐		

CXR: Submit All Reports

Initial Date: _____ ☐ Not Done ☐ Normal ☐ Abnormal If Abnormal: ☐ Cavitary ☐ Non-cavitary	Describe:
Follow Up Date: : _____ ☐ Not Done ☐ Normal ☐ Stable ☐ Improving ☐ Worse	Describe:

Risk Factors (Check all that apply)

Converter (within 2 yrs)	☐ Yes	☐ No	☐ UNK
Alcohol Abuse:	☐ Yes	☐ No	☐ UNK
Non-Injection Drug Use:	☐ Yes	☐ No	☐ UNK
Injection Drug Use:	☐ Yes	☐ No	☐ UNK
Institutionalized:	☐ Yes	☐ No	☐ UNK
Homeless/transient:	☐ Yes	☐ No	☐ UNK
Immunocompromised:	☐ Yes	☐ No	☐ UNK
HIV Status:	☐ Yes	☐ No	☐ UNK
Other:			

Current Bacteriology: Submit All Reports

DATE (month/day/year)	SOURCE	SMEAR +/-	CULTURE +/-

Current Medication **Weight:**

MEDICATION	DAILY DOSAGE IN MGMS	START DATE
ISONIAZID		
RIFAMPIN		
PYRAZINAMIDE		
ETHAMUTOL		
B6		
OTHER		
OTHER		

DOT Recommended? ☐ YES ☐ NO Start Date: _____
Legal Order Required? ☐ YES ☐ NO

TB Appendix 24 (HSD 46-18A) (04/2008; **Rev Feb 2012**) Page 1 of 2

ATTACHMENT C (Page 2)

Tulare County
Health & Human Services Agency
Health Services Department
Public Health / Tuberculosis Program

CONFIDENTIAL TUBERCULOSIS SUSPECT CASE REPORT

Reporting of all patients with confirmed or suspect Tuberculosis (TB) is mandated by State Health and Safety Codes Div. 4, Chapter 5, and Admin. Codes, Title 17, Chapter 4, Section 2500, and must be done **WITHIN ONE DAY OF SUSPICION OR CONFIRMATION OF A CASE OF TUBERCULOSIS.**

Why Do You Report?

BECAUSE IT'S THE LAW! The Health Department performs many vital functions to ensure public health safety including contact investigation, home visit and education, assessment of compliance with treatment and directly observed therapy (DOT), when indicated. The TB Control staff will also assist in facilitating timely and appropriate discharge planning. LAW MANDATES ALL TB PATIENTS HAVE A HEALTH DEPARTMENT APPROVED DISCHARGE PLAN PRIOR TO TRANSFER TO ANOTHER FACILITY OR COMMUNITY RESIDENCE.

Who Must Report?

All health care providers in attendance of a patient suspected to have or confirmed with active TB.

Tulare County Guidelines for Reporting Tuberculosis

DIAGNOSTIC CRITERIA	WHO TO REPORT	TIME FRAME IN WHICH TO REPORT
PPD>5mm Normal CXR Asymptomatic	• Household/Close contacts to known TB Suspect/case*	1 week
PPD>5mm CXR Suggestive of TB and/or Symptomatic	• Household/Close contacts known TB Suspect/case* • Known to be HIV+ Or at risk of being HIV+	1 working day 1 working day
PPD>10mm Normal CXR Asymptomatic	• 5 years of age or under • Clusters of individual recent converters (prior negative TBST less than 2 years ago) in a school/daycare/congregate living/ institutional/occupational/hospital setting	1 week 1 working day
TB Case/Suspect (Class3/5) PPD>10mm CXR suggestive of TB and/or Patient on more than one anti-TB medication and/or Sputum/bronchial/fluid or any other specimen positive for AFB	All Individuals	1 working day

Tuberculin Skin Test Conversion is Defined as an increase of at least 10-mm of induration from <10mm to >10mm with 24 months from a documented negative to a positive tuberculin skin test.

***Call TB Program to verify known/suspect TB in index case (559) 685-5715.**

All reports should be submitted to the local health jurisdiction in which the patient resides.

How Do I Report?

For Tulare County residents: fill out the Tulare County Public Health Department Confidential Tuberculosis Suspect Case Report in its entirety and fax it to the TB Control Program. Staff will review this form and may contact the provider as needed.

TB Program numbers

Phone: (559) 685-5715
Fax: (559) 685-4786
Cell: (559) 280-9418

For additional copies of this form call: (559) 685-5700

TB Appendix 24 (HSD 46-18A) (04/2008; **Rev Feb 2012**) Page 2 of 2

ATTACHMENT D

State of California—Health and Human Services Agency — California Department of Public Health

CONFIDENTIAL MORBIDITY REPORT

PLEASE NOTE: Use this form for reporting lapses of consciousness or control, Alzheimer's disease or other conditions which may impair the ability to operate a motor vehicle safely (persuant to H&S 103900).

CONDITION BEING REPORTED ➡

Patient Name - Last Name	*First Name*	*MI*	*Ethnicity (check one)* ☐ Hispanic/Latino ☐ Non-Hispanic/Non-Latino ☐ Unknown
Home Address: Number, Street		*Apt./Unit No.*	*Race (check all that apply)* ☐ African-American/Black ☐ American Indian/Alaska Native ☐ Asian *(check all that apply)* ☐ Asian Indian ☐ Hmong ☐ Thai ☐ Cambodian ☐ Japanese ☐ Vietnamese ☐ Chinese ☐ Korean ☐ Other *(specify)*: ☐ Filipino ☐ Laotian ☐ Pacific Islander *(check all that apply)* ☐ Native Hawaiian ☐ Samoan ☐ Guamanian ☐ Other *(specify)*: ☐ White ☐ Other *(specify)*: ☐ Unknown
City	*State*	*ZIP Code*	
Home Telephone Number	*Cell Telephone Number*	*Work Telephone Number*	
Email Address	*Primary Language* ☐ English ☐ Spanish ☐ Other:		
Birth Date (mm/dd/yyyy)	*Age* ☐ Years ☐ Months ☐ Days	*Gender* ☐ Male ☐ Female ☐ M to F Transgender ☐ F to M Transgender ☐ Other:	
Pregnant? ☐ Yes ☐ No ☐ Unknown	*Est. Delivery Date (mm/dd/yyyy)*	*Country of Birth*	
Occupation or Job Title	*Occupational or Exposure Setting (check all that apply):* ☐ Food Service ☐ Day Care ☐ Health Care ☐ Correctional Facility ☐ School ☐ Other *(specify)*:		
Date of Onset (mm/dd/yyyy)	*Date of First Specimen Collection (mm/dd/yyyy)*	*Date of Diagnosis (mm/dd/yyyy)*	
Reporting Health Care Provider	*Reporting Health Care Facility*		**REPORT TO:** Jeremy Kempf, RN,PHN Communicable Disease Coordinator 1150 South K Street Tulare, CA. 93274 Phone: 559-687-6965 Fax: 559-685-4835 After hours: 559-471-7092
Address: Number, Street		*Suite/Unit No.*	
City	*State*	*ZIP Code*	
Telephone Number	*Fax Number*		
Submitted by	*Date Submitted (mm/dd/yyyy)*		(Obtain additional forms from your local health department.)

DEPARTMENT OF MOTOR VEHICLES (DMV)

California Driver License or Identification Card Number (eight characters): ☐☐☐☐☐☐☐☐

1. If this report is based upon episodic lapses of consciousness, when was the most recent episode?: _____ *(mm/dd/yyyy)*
2. If there have been multiple episodes of loss of consciousness or control within the past three years, please indicate the dates if they are known to you.
   (a): _____ *(mm/dd/yyyy)* (b): _____ *(mm/dd/yyyy)* (c): _____ *(mm/dd/yyyy)* (d): _____ *(mm/dd/yyyy)* (e): _____ *(mm/dd/yyyy)* (f): _____ *(mm/dd/yyyy)*
3. Within the past 12 months, has there been an episode of loss of consciousness or control while driving? ☐ Yes ☐ No ☐ Uncertain
4. Are additional lapses of consciousness likely to occur? ☐ Yes ☐ No ☐ Uncertain
5. If the patient has had episodes of nocturnal seizures, is there likelihood of lapses of consciousness occurring while he/she is awake? ☐ Yes ☐ No ☐ Uncertain
6. Has this patient been diagnosed with dementia or Alzheimer's disease? ☐ Yes ☐ No ☐ Uncertain
7. Would you currently advise this patient not to drive because of his/her medical condition? ☐ Yes ☐ No ☐ Uncertain
8. Does this patient's condition represent a permanent driving disability? ☐ Yes ☐ No ☐ Uncertain
9. Would you recommend a driving evaluation by DMV? ☐ Yes ☐ No ☐ Uncertain

Remarks:

CDPH 110c (1/11) **(for reporting conditions reportable to DMV)** — Page 1 of 2

Descriptive Name: Reportable Diseases and Conditions

Descriptive Type: Revised Policy

Document Number: 20-8011

Attachments: Yes

Author: Joetta Denney

Typist: Melissa Arend

Creation Date: 08/25/11

Revision Date: 07/29/16

Prev. Dist. Date: 06/27/13

Committee Review and Approval:	Approval Date:	Comments:
Infection Prevention Committee	08/15/16	
MEC	09/14/16	
Board of Directors		

Effective Date:

Forward To: Policy Binders (PBX and Administration) and Post to Intranet

Disposition: Copy and Distribution - Administration

Comments:

TULARE LOCAL HEALTH CARE DISTRICT
dba TULARE REGIONAL MEDICAL CENTER

POLICY / GUIDELINE

TO: All Departments

FROM: Administration

SUBJECT: Infectious Diseases of Concern to the Pregnant Employee

PURPOSE: To provide information to staff who may have concerns regarding pregnancy and infectious diseases possibly encountered while in the workplace and especially for health care workers in the clinical environment. – See latest APIC Text

The following precautions are outlined per infectious disease:

INFECTIOUS DISEASE	In-hospital Source(s)	PRECAUTIONS
HIV	Blood, body fluids, vaginal secretions, semen	**Standard Precautions** No reassignment of pregnant worker is necessary.
CYTOMEGALOVIRUS (CMV)	Urine, blood, semen, vaginal secretions, semen, the immunosuppressed (transplant), dialysis,	**Standard Precautions** Good hand washing. No reassignment of pregnant worker is necessary.
Fifth's Disease (Parvovirus B19) Erythema infectiosum	Respiratory secretions, blood, immunocompromised patients	**Droplet Precautions** Defer care of immunocompromised patients with chronic anemia when possible.
HEPATITIS A	Feces, blood (rare)	**Contact Precautions** Good hand washing. Gowns if soiling likely. Gloves if touching infective material. No reassignment of pregnant worker necessary.
HEPATITIS B	Blood, body fluids, vaginal secretions, semen	**Standard Precautions** No reassignment of pregnant worker necessary. Hepatitis B vaccine strongly recommended for employees who have contact with blood or blood-containing body fluids. Vaccine safe during pregnancy.
INFECTIOUS DISEASE	**In-hospital Source(s)**	**PRECAUTIONS**

HEPATITIS C	Blood, sexual transmission	**Standard Precautions** No reassignment of pregnant worker is necessary.
HERPES SIMPLEX (Virus)	Vesicular fluid, oropharyngeal and vaginal secretions	**Standard precautions** Add ***Contact Precautions*** when lesions present. Reassignment of the pregnant worker is not necessary.
HERPES ZOSTER (SHINGLES)	Vesicular fluid	**Airborne & Contact Precautions** Administer VZIG within 96 hours of exposure. Restrict assignment of all susceptible health care workers.
RUBELLA (GERMAN MEASLES)	Respiratory secretions	**Droplet Precautions for Acute Infection**. ***Contact Precautions*** for Congenital < 12 mos. in age. Pregnant women who are not immune should not care for these patients.
RUBEOLA (THE "HARD" MEASLES)	Respiratory secretions, cough	**Airborne Precautions** Vaccine can be done within 6 days of exposure. Pregnant women who are not immune should not care for these patients.
SYPHILIS	Blood, lesion, fluid, amniotic fluid	**Standard Precautions** Gloves until 24 hours of effective therapy completed for infants with congenital syphilis and all patient with skin and mucous membrane lesions.
TOXOPLASMOSIS	Rare through blood transfusion, contact with raw meats,	No human-to-human spread.
TUBERCULOSIS	Sputum, skin contact (rare)	**Airborne Isolation** The pregnant employee may not be able to tolerate wearing the respirator, as it is somewhat airflow restrictive. Reassignment may be necessary. May take TB Meds.
VARICELLA (CHICKENPOX)	Vesicular secretions, Respiratory secretions, Cough	**Airborne & Contact Isolation** The non-immune health care worker, pregnant or not, should not have patient care contact with varicella patients. The immune worker can safely care for varicella patient.

Reference:

Association for Professionals in Infections Control and Epidemiology*. (APIC TEXT)* 4th Edition

CDC 2007 Guideline for Isolation precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

Questions concerning any aspect of this policy/guideline should be referred to Administration.

This policy/guideline replaces and supersedes all previous policies/guidelines concerning this matter and is effective immediately.

Descriptive Name: Infectious Diseases of Concern to the Pregnant Employee

Descriptive Type: Revised

Document Number: 20-8012

Attachments: None

Author: Joetta Denney

Typist: Melissa Arend

Creation Date: 05/27/10

Revision Date: 07/29/16

Prev. Dist. Date: 06/27/13

Committee Review and Approval:	Approval Date:	Comments:
Infection Prevention Committee	08/15/16	
MEC	09/14/16	
Board of Directors		

Effective Date:

Forward To: Policy Binders (PBX and Administration) and Post to Intranet

Disposition: Copy and Distribution - Administration

Comments:

TULARE LOCAL HEALTH CARE DISTRICT
dba TULARE REGIONAL MEDICAL CENTER

POLICY / GUIDELINE

TO: All Departments

FROM: Administration

SUBJECT: Work Restrictions and Management of Personnel Illnesses and Exposures to Communicable Diseases

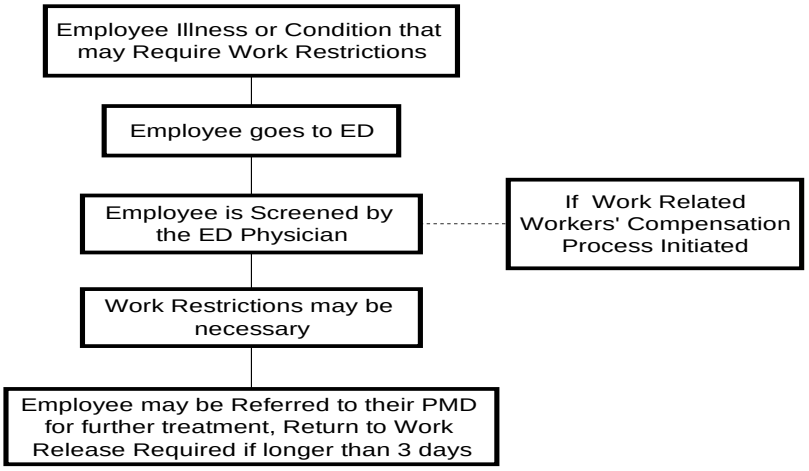
PURPOSE:

To Prevent the Transmission of Infection to Patients and Other Personnel

A. **Employees who report to work ill or have a health condition that may restrict work.**

Employees who report to work ill or become ill while at work and employees who may have a condition that may limit their ability to work may be sent home at the discretion of their supervisors. If there are questions of infectiousness or work restrictions, the supervisor may refer the employee to the Emergency Department physician for screening of the illness or condition. If the ED physician imposes work restrictions, they must be followed by employee.

The Emergency Department physician will screen the patient for the necessity of work restrictions related to the current condition with possible referral to the employees primary medical physician for further follow up and, if necessary, for return to work release.



Effective Date:

APPROVED:

Medical Executive Comm.: 09/14/16

Board of Directors:

(20) Clinical Services Guidelines
Infection Control:
Work Restrictions and Management of Personnel Medical Illnesses and Exposures
20-8018

Management of Personnel Exposed to Various Diseases:

Exposure occurs when an employee comes in contact with an infectious or potentially infectious agent in a manner that may lead to acquisition of the disease.

1. Employees who believe they have been exposed to a communicable disease outside of work, shall notify the RN Infection Preventionist or if the RN Infection Preventionist is not available, the House Supervisor, prior to reporting to work. The RN IP or Supervisor will determine if it is safe for the employee to report for work. In the event it is determined the employee has been exposed to an infectious agent and must remain off work, the employee will be referred to their PMD for treatment and for a Return to Work Release.

2. If the exposure occurred at work, an employee will notify their supervisor and report to the Emergency Department for follow through. The Emergency Department practitioner may determine that prophylactic treatment is indicated as per current CDC recommendations, APIC Text 4th edition, , Red Book 2015 30 thEd.). **The Infection Prevention & Control Department should be notified at this time.**

RECOMMENDATIONS FOR PROPHYLAXIS AFTER EXPOSURE TO VARIOUS DISEASES	
DISEASE	**RECOMMENDATIONS**
General	When prophylactic treatment with drugs, vaccines, or immune globulins is necessary, personnel should be informed of alternative means of prophylaxis, the risk (if known) of infection if treatment is not accepted, the degree of protection provided by the therapy, and the potential side effects. A positive C&S (if Applicable) should be available to support the diagnosis.
Hepatitis A	Administration of IG to hospital personnel caring for patients with hepatitis A is not indicated routinely, unless an outbreak among patients between patients and staff is documented. See The Red Book 2015 (30th Ed.) for recommendations for Post exposure Immunoprophylaxis of Hepatitis A .
Hepatitis B	For prophylaxis against hepatitis B after percutaneous (needle-stick) or mucous membrane exposure to blood that might be infective, the recommendations in Clinical Guideline #20-8007 Blood and Body Fluid Exposure Control and Guidelines, should be followed.
Hepatitis C	For prophylaxis against hepatitis C after percutaneous (needle-stick) or mucous membrane exposure to blood that might be infective, the recommendations in Clinical Guideline #20-8007 Blood and Body Fluid Exposure Control and Guidelines, should be followed.

HIV	Prophylaxis treatment must begin as soon as possible post exposure. See Clinical Guideline #20-8007 Blood and Body Fluid Exposure Control and Guidelines. HIV prophylaxis kit available in pharmacy
Measles	The measles vaccine should be administered to susceptible hospital personnel, who have had contact with a measles patient, within 72 hours. Personnel who are not immune must be excluded from work 5 days after first exposure to 21 days after last exposure per APIC Text 4th edition.
Meningococcal disease Neisseria Meningitidis	Routine prophylaxis is not recommended for healthcare professionals unless they have had intimate exposure such as occurs with unprotected mouth to mouth resuscitation, intubation or suctioning. Prophylactic therapy should be administered immediately after the unprotected exposure. Should Chemoprophylaxis be necessary, Ciprofloxacin 500mg orally as a single dose or Rifampin 600mg orally every 12 hours for 2 days or Ceftriaxone 250 mg IM x 1 injection (recommended for pregnant healthcare professionals). (The Redbook 2015 30th edition.
Mumps	Two doses of MMR vaccine should be administered to personnel who do not have immunity following exposure. Exclusion from work is recommended the 9th day after the first exposure to the 26th day after the last exposure. APIC Text 4th edition
Pertussis	Prophylaxis treatment recommended for susceptible personnel is a 14 day course of Erythromycin 500mg PO four times daily, Azithromycin 500mg PO x 1 dose on Day 1 then 250mg PO daily on days 2-5, a 7 day course of clarithromycin 500mg PO twice daily, or a 14 day course of Trimethoprim-Sulfamethaxozole 800mg-160mg PO twice daily.
Rubella	Exposed personnel who do not have immunity should be excluded from duty from the 7th day after the first exposure through the 21st day after the last exposure. APIC Text 4th edition.
Varicella	Susceptible personnel should be excluded from duty from the 10th day after exposure through the 21st day after exposure
Viral, Aseptic and non-meningococcal/ H.influenzae meningitis	Do *not* routinely provide prophylaxis.

Reference: APIC Text –4th edition, CDC Guideline for Infection Control in Health Care Personnel, Current CDC recommendations, Red Book 2015 (30th Edition) ,

Questions concerning any aspect of this policy/guideline should be referred to Administration.

This policy/guideline replaces and supersedes all previous policies/guidelines and is effective immediately.

TULARE LOCAL HEALTH CARE DISTRICT
dba TULARE REGIONAL MEDICAL CENTER

POLICY / GUIDELINE

Summary of suggested work restrictions for health care personnel exposed to or infected with infectious diseases of importance in health care settings, in the absence of state and local regulations (modified from ACIP recommendations) and the CDC HICPAC Guideline for the Prevention and Control of Norovirus Gastroenteris Outbreaks in Healthcare Settings.

Disease/Problem	***Work Restriction***	***Duration***
Conjunctivitis	Restrict from patient contact and contact with the patient's environment	Until discharge ceases
Cytomegalovirus infections	No restriction	
Diarrheal diseases		
Acute stage (diarrhea with other symptoms)	Restricts from patient contact, contact with the patient's environment, or food handling	Until symptoms resolve
Convalescent stage, Salmonella spp.	Restrict from care of high-risk patients	Unit symptoms resolve, consult with local and state health authorities regarding need for negative stock cultures
Diphtheria	Exclude from duty	Until antimicrobial therapy completed and 2 cultures obtained ≥24 hours apart are negative
Enteroviral infections	Restrict from care of infants, neonates, and immunocompromised patients and their environments	Until symptoms resolve
Hepatitis A	Restrict from patient contact, contact with patient's environment, and food handling	Until 7 days after onset of jaundice
Norovirus	Exclude from duty	A minimum of 48 hours after resolution of symptoms
Hepatitis B		
Personnel with acute or chronic hepatitis B surface antigens who do not perform exposure-prone procedures	No restriction*; refer to state regulations; standard precautions should always be observed	
Personnel with acute or chronic hepatitis B e antigen who perform exposure-prone procedures	Do not perform exposure-prone invasive procedures until counsel from an expert review panel has been sought; panel should review and recommend procedures the worker can perform, taking into account specific procedure as well as skill and technique of worker; refer to state regulations	Until hepatitis B e antigen is negative
Hepatitis C	No recommendation	
Herpes Simplex		
Genital	No restriction	
Hands (herpetic whitlow)	Restrict from patient contact and contact with the patient's environment	Until lesions heal
Orofacial	Evaluate for need to restrict from care of high-risk patients	
Human immunodeficiency virus	Do not perform-prone invasive procedures until counsel from an expert review panel has been sought; panel should review and recommend procedures the worker can perform, taking into account specific procedure as well as skill and technique of the worker; standard precautions should always be observed; refer to state regulations	
Measles		
Active	Exclude from duty	Until 7 days after the rash appears
Disease/Problem	***Work Restriction***	***Duration***

Postexposure (susceptible personnel)	Exclude from duty	From 5th day after 1st exposure through 21st day after last exposure and/or 4 days after rash appears
Meningococcal infections	Exclude from duty	Until 24 hours after start of effective therapy
Mumps		
Active	Exclude from duty	Until 9 days after onset of parotitis
Postexposure (susceptible personnel)	Exclude from duty	From 12th day after 1st exposure through 26th day after last exposure or until 9 days after onset of parotitis
Pediculosis	Restrict from patient contact	Until treated and observed to be free of adult and immature lice
Pertussis		
Active	Exclude from duty	From beginning of catarrhal stage through 3rd week after onset of paroxysms or until 5 days after start of effective antimicrobial therapy
Postexposure (asymptomatic personnel)	No restriction, prophylaxis recommended	
Postexposure (symptomatic personnel)	Exclude from duty	Until 5 days after start of effective antimicrobial therapy
Scabies	Restrict from patient contact	Until cleared by medical evaluation
Staphylococcus aureus infection		
Active, draining skin lesions	Restrict from contact with patients and patient's environment or food handling	Until lesions have resolved
Carrier state	No restriction, unless personnel are epidemically linked to transmission of the organism	
Streptococcal Infection, group A	Restrict from patient care, contact with patient's environment, or food handling	Until 24 hours after adequate treatment started
Tuberculosis		
Active disease	Exclude from duty	Until proved noninfectious
PPD converter	No restriction	
Varicella		
Active	Exclude from duty	Until all lesions dry and crust
Postexposure *susceptible personnel)	Exclude from duty	From 10th day after 1st exposure through 21st day (28th day if VZIG given) after last exposure
Zoster		
Localized, in healthy person	Cover lesions; restrict from care of high-risk patients (neonate, immunocompromised people)	Until all lesion dry and crust
Generalized or localized in immunocompromised person	Restrict from patient contact	Until all lesions dry and crust
Postexposure (Susceptible personnel)	Restrict from patient contact	From 10th day after 1st exposure through 21st day (28th day if VZIG given) after last exposure or, if varicella occurs, until lesions dry and crust
Viral respiratory infections, acute febrile	Consider excluding from the care of high-risk patients (for complications of influenza) or contact with their environment during community outbreak of RSV and influenza	Until acute symptoms resolve

Descriptive Name: Work Restrictions and Management of Personnel Illnesses and Exposures

Descriptive Type: Revised Policy

Document Number: 20-8018

Attachments: None

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Board of Directors		

Effective Date:

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Disposition: Copy and Distribution - Administration

Comments:

HCCA
Tulare Regional Medical Center

Quality Management System

ISO 9001:2008

Tulare Regional Medical Center
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INTRODUCTION

Tulare Regional Medical Center (TRMC) developed and implemented a Quality Management System (QMS) to demonstrate its ability to provide consistent services that meet customer and applicable statutory, regulatory and legal requirements, and to address customer satisfaction through the effective application of the system, including continual improvement and the prevention of nonconformity.

The QMS complies with the International Organization for Standardization (ISO), ISO 9001 and to statutory, regulatory and legal requirements.

HOSPITAL PROFILE

Tulare Local Healthcare District, dba Tulare Regional Medical Center, is a rural general acute care hospital licensed for 112 Medical / Surgical, Labor and Delivery and ICU (Intensive Care Unit) patient care beds. The hospital district, located in Tulare County, geographically identified as California's the Central Valley Region was established in 1946 and comprised both incorporated and unincorporated communities. Agriculture and Dairy are the predominate industries in the District. According to 2010 US Census Data, 79,130 individuals live in the Tulare Local Healthcare District. The ethnic makeup of the District is 60.3% Hispanic, 33.1% Non-Hispanic White, 3.1% Non- Hispanic Black, 1% Native American and 2.1% Asian Pacific Islander.

Tulare Regional Medical Center (TRMC) provides clinical and non-clinical, diagnostic, treatment and support services, for newborn, pediatric, adult and geriatric populations in our District. Prevention, early detection and recovery strategies are encouraged through the four Rural Health Clinics operated by TRMC and our Fitness and Wellness Center.

The services available at TRMC and its clinics can be found in Exhibit 1. The interrelationship of these service components can be found in the process map in Exhibit 2. The performance improvement model, Plan, Do, Study, Act (PDSA), can be found in Exhibit 3.

Exhibit 1

Clinical Services:

• Obstetrics and Gynecology	• Pediatric
• General Surgery	• Ambulatory Surgery
• Internal and Family Medicine	• Emergency Room
• Intensive Care	• Gastroenterology
• Cardiac Catheterization Laboratory	• Interventional Radiology

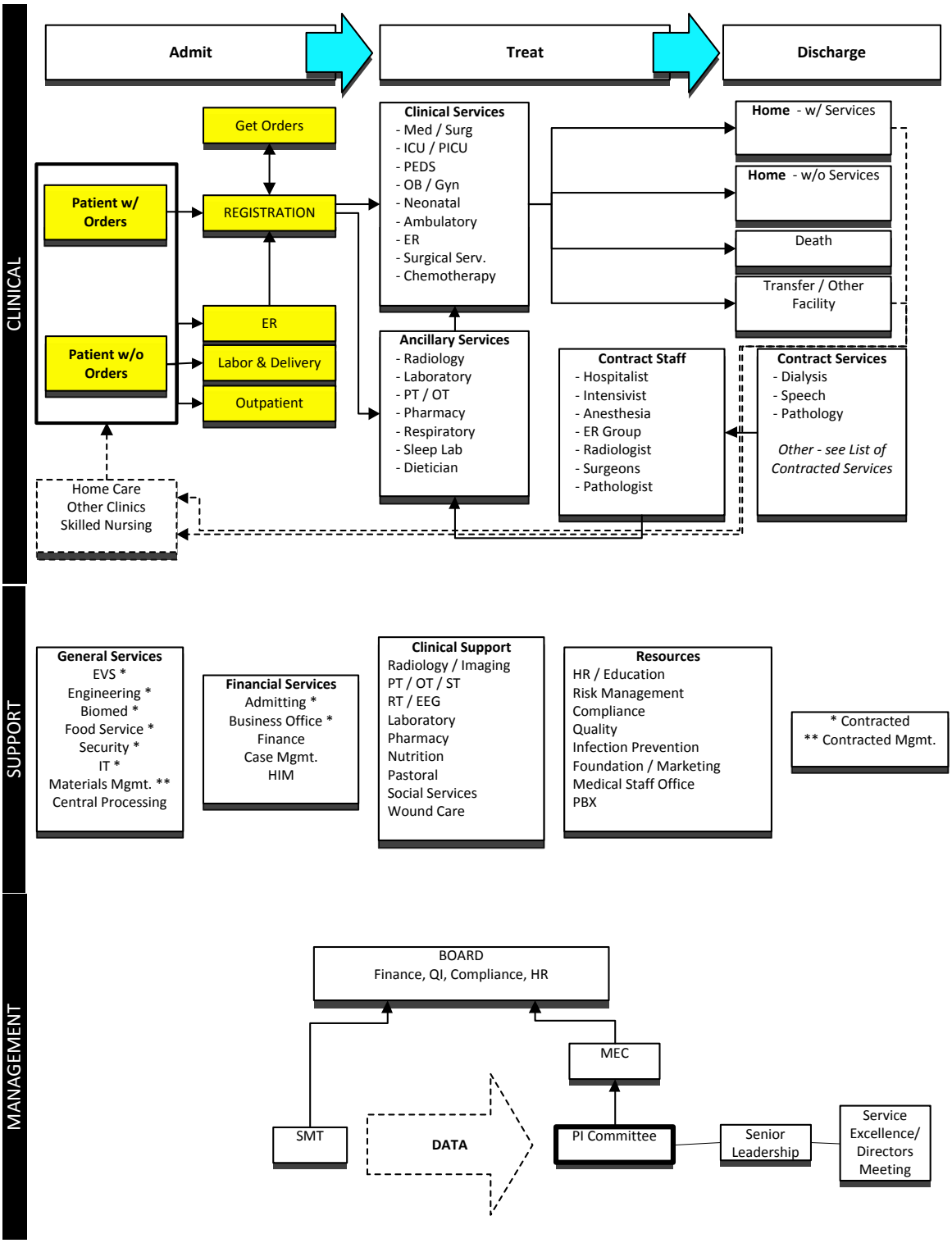
Clinical Support Services:

• Physical Therapy	• Clinical Laboratory
• Inpatient Pharmacy	• Nutritional Services
• Biomedical Engineering	• Social Services
• Case Management	• Home Healthcare Services
• Occupational Therapy	• Speech Therapy
• Sleep Disorder Center	• Respiratory Care Services
• Toxicology Laboratory	• Medical Imaging

Non-Clinical / Ancillary Support Services:

• Housekeeping	• Engineering	• Health Information Management
• Admitting / Business Office	• Materials Management	• Infection Prevention
• Risk Management	• Quality Management	• Admitting / Registration
• Finance Department	• Information Systems	• Human Resources
• Security	• Education / Organizational Development	• Business Development
• Foundation / Marketing	• Evolutions Fitness Wellness Center	• Hospital Administration

Exhibit 2



Process Map → **Patient Flow**

Support Departments → **Resources to support patient flow**

Management → **Resources and decisions to support patient flow**

Exhibit 3

1 SCOPE

1.1 General

TRMC maintains a strong commitment to quality and customer safety. The Quality Management System (QMS) provides the basis for analyzing customer requirements, defining the processes that contribute to the achievement of a service and the provisions for keeping these processes in control. Patient safety is an essential and inseparable component of TRMC policy.

The top level document defining the overall quality management system is the Quality Manual.. It is patient focused and aimed at enhancing patient satisfaction and winning their loyalty. It also meets the regulatory and legal requirements of the service.

Quality Policy:

TRMC's Quality Policy goal is to promote positive patient outcomes by designing processes well, and systematically monitoring, analyzing and improving performance.

The Quality Policy, committed to by Senior Leadership:

a) provides a framework for establishing and reviewing quality initiatives
b) is communicated and understood within the organization

c) is reviewed for continuing suitability

These goals are supported by our Mission below and our Vision, Values and Guiding Principles as stated in Exhibit 4.

Mission Statement: To develop a best-in-class, performance-driven, integrated delivery system focused on wellness and improving the health status of the community.

1.2 Application

Exclusions:

Clause 7.3, Design and Development: TRMC does not perform design and development activities. TRMC provides the services, surgery and treatments, which are accepted worldwide in medical circles as standards of performance/practice.

2 Normative References

The following documents are referenced in this manual and unless otherwise specified, the latest edition of the document applies.

2.1 International Standards/Industry Standards

The standardized documents guiding the organization's approach to quality are:

a) ISO 9000 Quality Management Systems – Fundamentals and Vocabulary
b) ISO 9001:2008 Quality Management Systems – Requirements
c) ISO 9004 Managing for the Sustained Success of an Organization – A Quality Management Approach
d) ISO 19011 Guidelines for Quality and/or Environmental Management Systems Auditing
e) NIAHO Accreditation Requirements

The parent documents guiding the development of the quality manual are:

a) ISO 9001 4.2.3 Document Control Policy
b) ISO 9001 4.2.4 Record Control Policy
c) ISO 9001 8.2.2 Internal Audit Policy
d) ISO 9001 8.3 Nonconforming Policy
e) ISO 9001 8.5.2 Corrective Action Policy
f) ISO 9001 8.5.3 Preventive Action Policy

2.2 Approval:

a) Board of Directors
b) Senior Leadership/Management Review (Informational Input, not for approval)

2.3 Distribution:

a) Senior Leadership/Management Review
b) Board of Directors
c) Organization wide

2.4 Management Systems:

a) Business Management

These are the departments and processes that manage the organization's resources such as finances, people and the facility. While all departments may not have direct contact with the provision of patient care and service, they are indirectly related because of their impact on product, people, environment and financial stability. They support Tulare Regional Medical Center's Vision, Values and Guiding Principles as stated in Exhibit 4 and Mission to develop a best-in-class, performance-driven, integrated delivery system focused on wellness and improving the health status of the community..

b) Regulatory / Compliance

Compliance management is focused on meeting legal and regulatory requirements such as NFPA and EPS regulations, CMS requirements for accreditation and applicable State and Federal laws. The departments involved in meeting legal and regulatory requirements are directly related to the provision of safe patient care..

c) Quality Management

This management process refers to the organization's performance and its ability to develop systems to monitor, prevent and correct deficiencies and variances from the expected outcomes. Quality Management focuses on the patient/customer and utilizes a process approach to understand and organize all levels of service in order to recognize variation, take action and prevent the variation from repeating.

3 TERMS AND DEFINITIONS

Audit A planned, independent and documented assessment to determine whether agreed-upon requirements are being met.

Competence The ability of an individual to perform a specific job or task.

Corrective Action	Action taken to eliminate the causes(s) of existing problems, defects or any other desirable situation in order to prevent recurrence.
Customer	Organization or person that receives a service
DNV	Stiftelsen Det Norske Veritas. Is a classification society organized as a foundation, with the objective of *"Safeguarding life, property, and the environment"*. The organization's history goes back to 1864, when the foundation was established in Norway to inspect and evaluate the technical condition of Norwegian merchant vessels. Today, DNV Healthcare is an accreditor of US hospitals integrating ISO 9001 quality compliance with the Medicare Conditions of Participation.
Document	Any written item of a factual or informative nature.
Document Control	A system to regulate the handling and management (including archiving, storing and destruction) of documents containing information that communicates policies, processes, procedures as well as records and usually pertains to documents that are part of the QMS.
Empowerment	Giving staff the authority and responsibility to make decisions and take action.
Error	A deviation from truth, accuracy or correctness; a mistake.
Form	A paper or electronic document on which information or results are captured. Once completed, a form becomes a record.
Incident	A single distinct occurrence or event.
ISO	International Organization for Standardization. A network of standards institutes from 140 countries working in partnership with international organizations, governments, industry, business and consumer representation. The source of more than 13,000 international standards for business, government and society.
NIAHO	National Integrated Accreditation for Healthcare Organizations. The core of DNV hospital accreditation is the NIAHO® standards platform, created by DNV in 2008 for US hospitals. DNV's belief is that accreditation is not an inspection but rather a catalyst for quality and patient safety. This innovation allowed DNV accreditation to earn acceptance from the US Centers for Medicare and Medicaid Services (CMS). NIAHO® integrates requirements

	based on the US CMS Conditions of Participation (CoPs) with the internationally recognized ISO 9001 Standard, ISO 14001 and ISO 27001 and international standards of medical care for patients. This approach helps healthcare organizations reach maximum effectiveness and efficiency, with improved clinical performance, financial outcomes and operational processes.
Occurrence	Something that generally happens; an event, incident.
Policy	A written statement of overall intentions and directions defined by those in the organization and endorsed by management.
Preventive Action	Action taken to eliminate potential problems, defects, or any other undesirable situation from happening.
Preventive Maintenance	Scheduled periodic work on a piece of equipment that is not the result of malfunction or failure and is intended to avert such failure.
Procedure	A specified way to perform an activity. Written work instructions for each step in a process.
Process	Series of inter-related steps involved in an activity or examination that uses resources and is managed to transform inputs into outputs.
Process Control	Operational techniques and activities that are used to fulfill requirements for quality.
Quality	The totality of characteristics of an entity that bear on its ability to satisfy stated and implied need and expectations.
Quality Assurance	Planned and systematic activities to provide adequate confidence and evidence that requirements for quality will be met.
Quality Management	All activities of the management function that determine quality objectives, responsibilities and implementation including quality planning, process control, quality assurance; and quality improvement.
Management Representative	An individual with delegated responsibility and authority to ensure compliance with the quality management system.
Quality Policy	Overall intentions and direction of an organization with regard to quality (e.g. quality system essentials) as formally expressed in writing by Senior Leadership.
Quality System	A quality system is a program developed to support efficient and effective, high quality and appropriate patient services. It is a

	comprehensive and coordinated effort (policies, processes and procedures) designed to meet quality objectives, to direct and control an organization with regard to quality and encompasses quality (management) system and quality assurance.
Record	A document that furnishes objective evidence of information obtained, activities performed or results achieved.
Service	The result generated by activities at the interface between the provider and the customer and by provider internal activities to meet the customer needs.
Statistical Tools	Methods and techniques used to generate, analyze, interpret and present data.
Value	Degree of worth relative to cost and relative to possible alternatives of a product, service, process, asset, or function.
Vendor	An organization that provides a product or service to the organization.
Verification	The confirmation by examination and provision of objective evidence that specified requirements has been fulfilled.

4 QUALITY MANAGEMENT SYSTEM

TRMC's Vision, Values and Guiding Principles are stated in Exhibit 4.

EXHIBIT 4

HCCA
Healthcare Conglomerate Associates

HealthCare Conglomerate Associates (HCCA) is a performance driven organization dedicated to providing the highest level of service to our patients, our physicians, our teammates, and our community.

Our vision

HCCA's vision is to develop a high quality, affordable integrated delivery system focused on improving the wellness and health of the community. Our goal is to be recognized as the best integrated delivery system in the country by being the:

Best Place to Work
Best Place to Practice
Best Place to Receive Care

Our values

Our values provide the foundation for all that HCCA does. They are:

Honesty and integrity
Innovation and creativity
High-quality, affordable care
Service excellence
Results-oriented
Teamwork and mutual accountability
Forward-thinking
Culturally competent team and organization

Our guiding principles

HCCA's guiding principles are to:

Provide exceptional patient care and member services
Maintain modern and efficiently operated facilities for the convenience of our physicians
Maintain a great work environment for our employees
Seek out the best and brightest to support our mission and vision
Develop systems and processes to measure our success
Develop mutual accountability for expected results

4.1 General QMS Requirements

TRMC has developed and implemented a documented QMS to meet the requirements of ISO 9001:2008 standards for ensuring that the service conforms to customer satisfaction. The QMS is supported by documents and records for individual departments as required.

The associated metrics and goals of the QMS shall be evaluated for continued suitability as part of the QMS Review. Senior Leadership reviews the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from Senior Leadership reviews are maintained see 4.2.4.

Specific authority is given to those responsible for product, process or system quality to:

- Determine the sequence and interaction of the processes needed to maintain the QMS and their application throughout the organization
- Determine criteria and methods needed to ensure that both the operation and control of the processes are effective
- Ensure availability of resources and information necessary to support the operation and monitoring of the processes
- Monitor, measure where applicable and analyze the processes and implement actions necessary to achieve planned results and continual improvement
- Initiate action to prevent nonconformance
- Initiate action to identify, record and correct anomalies
- Initiate, recommend or provide solutions
- Verify implementation of solutions

The sequence and interaction of the process within the QMS is described below:

4.2 Documentation Requirements

4.2.1 General

The QMS documentation is comprised of the following:

a) documented statements of a quality policy and quality objectives
b) a quality manual
c) documented procedures and records required by this International Standard
d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes

NOTE 1: Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 2: The documentation can be in any form or type of medium.

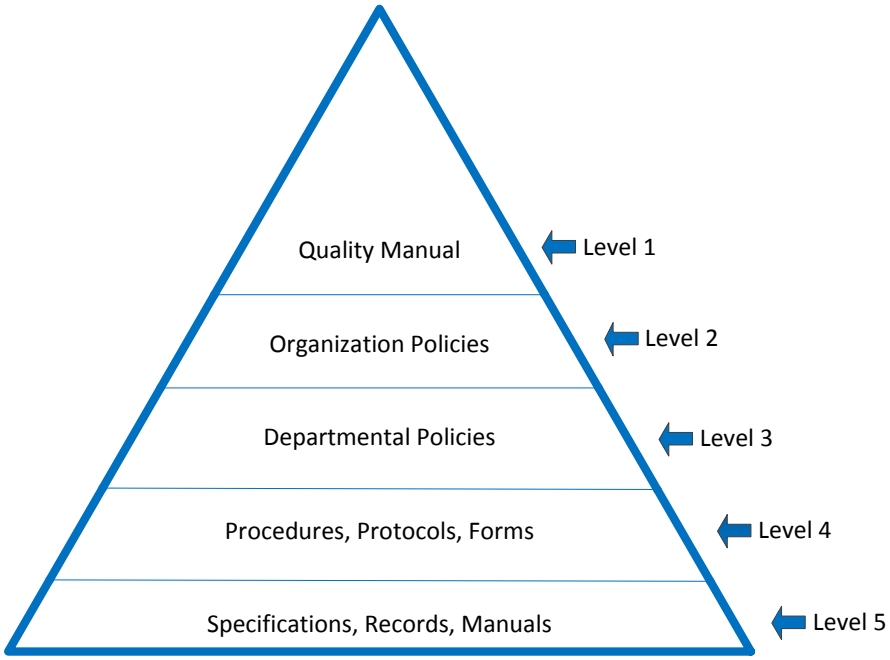
4.2.2 Quality Manual

The organization's established and maintained quality manual (this manual) includes, see Exhibit 5:

a) the scope of the quality management system, including details of and justification for any exclusions, see 1.2
b) the documented procedures established for the quality management system or reference to them
c) a description of the interaction between the processes of the quality management system

EXHIBIT 5

ISO 9001 QMS Document Structure



4.2.3 Control of documents

Documents are required by the QMS for efficient and effective documentation of product, process and outcome performances. Records are a special type of document and controlled according to the requirements given in 4.2.4.

A documented procedure, ISO 9001 4.2.3, is established that defines the controls needed to:

a) approve documents for adequacy prior to issue
b) review and update as necessary and re-approve documents

c) ensure that changes and the current revision status of documents are identified
d) ensure that relevant versions of applicable documents are available at points of use
e) ensure that documents remain legible and readily identifiable
f) ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled
g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose

4.2.4 Control of Records

Records needed to provide evidence of conformity to requirements and of the effective operation of the quality management system are controlled.

The organization established a documented policy to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records, as referenced in ISO 9001 4.2.4, see Appendix A.

Records remain legible, readily identifiable and retrievable.

5 MANAGEMENT RESPONSIBILITY

Senior Leadership has established a quality policy and quality objectives that identify the process for collecting, identifying, analyzing, interpreting and acting upon opportunities or deficiencies and helps the organization improve its ability to provide quality care, treatment, and services. The hospital collects data from many areas, including internal data obtained from staff, medical staff, patients, records and observations. Data is also available from risk management activities and external accrediting and regulatory agencies.

The goal of the quality policy is to promote positive patient outcomes by designing processes well, and systematically monitoring, analyzing and improving performance.

The quality policy and effectiveness of the QMS will be evaluated annually during Senior Leadership Meetings, where quality measurements are analyzed against their established objectives and suggestions for improvement of the system are considered. Further quality planning is also conducted during Senior Leadership Meetings to ensure the continuing availability of the resources necessary to meet the expectations of our customers.

5.1 Management Commitment

Senior Leadership has established a quality policy as a framework for establishing and reviewing quality objectives. The quality objectives are controlled according to the Document and Records Control procedure, see ISO 9001 4.2.3. Senior Leadership ensures that the quality policy is communicated and understood by staff and that the policy is implemented throughout the organization.

In order to maintain the quality standard committed, Senior Leadership and the leadership team of TRMC will monitor and review its quality performance from time to time through the implementation of an effective Performance Improvement Committee and Quality Management System based in accordance with the ISO standards.

Senior Leadership will maintain an environment of continuous improvement and empower its staff to achieve success in both individual performance and teamwork.

5.2 Customer Focus

TRMC ensures to provide compassionate, courteous, respectful and dignified care, maintaining confidentiality and sensitivity to every individual through an independent audit process through a third party vendor. Results and actions are handled through the Service Excellence/Directors Meeting.

5.3 Quality Policy

TRMC will be recognized as the premier provider of high-quality care, based on the best practices and in collaboration with Medical Staff that exceeds patient expectations.

Quality objectives establish measurements to monitor its performance. The scope of measurement will take into consideration, and be consistent with, the care and services provided, the critical functions of the hospital and industry identified areas of concern. Senior Leadership sets the priorities for performance improvement activities and patient health outcomes.

The following criteria are used to determine the prioritization of performance measurement and improvement:

a) Improve the safety of the health care environment.
b) Improve the safety of the care provided to the recipients.
c) Further the Mission and strategic objectives of TRMC.
d) Meet legal, regulatory, licensure and accreditation requirements.

e) Improve the effectiveness, timeliness and stability of processes that are high risk, high-volume or problem prone.
f) Improve desirable outcomes of care for at-risk patient populations.
g) Reprioritize performance improvement activities in response to changes in the internal or external environment.
h) Data shall be collected quarterly, unless otherwise specified and shall be organization-wide.
i) The availability of evidence-based practices applicable to our scope of services.

5.4 Planning

To expand access and availability of healthcare while growing services based on regional need.

5.4.1 Quality Objectives

TRMC has established measurements to monitor its performance. The scope of measurement will take into consideration and be consistent with, the care and services provided, the critical functions of the organization and industry identified areas of concern. Senior Leadership set the priorities for performance improvement activities and patient health outcomes.

The following are the organization's quality objectives for financial year 2015-2016:

Departmental Quality Objectives

1) Reduce the 30-day re admission rate by 5%
2) Achieve customer satisfaction rate of 85%
3) Before implementation of the new EHR, 100% of staff will be trained and compentent
4) Reduce the Left Without Being Seen (LWBS) rate to the national average
5) Maintain necessary regulatory requirements

5.4.2 Quality Management System Planning

The plans of the QMS are in accordance with the requirements of TRMC quality objectives and ISO standards.

Senior Leadership ensures that the integrity of the QMS is maintained by evaluating performances and changing the QMS as necessary.

The approach and deployment to quality planning include as appropriate:

Goals for improving quality and customer satisfaction which can focus on:

1) Service Excellence
2) Clinical Quality
3) Training
4) Procedure capability
5) Potential Failure Mode and Effects Analysis (FMEA)

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Senior Leadership ensures that responsibilities and authorities are defined and communicated within the organization as follows:

a) Job Descriptions for staff
b) Annual Performance Evaluations
c) Centralized Annual Update
d) Monthly Directors Meeting
e) Organizational wide notification system

Staff are authorized to identify and record any service quality anomaly and is responsible for forwarding the anomaly to the appropriate department director for resolution. Staff are also empowered to resolve issues at time of notice.

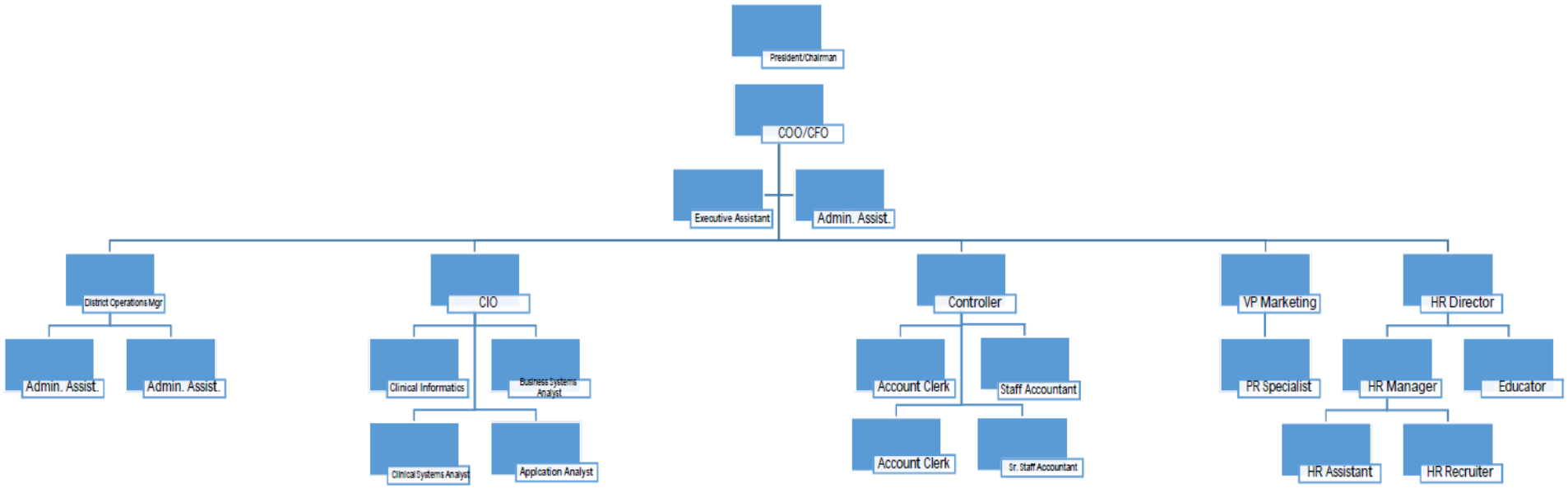
An organizational chart, Exhibit 6, has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions on the organizational chart. Job descriptions and the organizational chart are reviewed and approved by Senior Leadership for adequacy and are available in Administration.

Exhibit 6

Organizational Chart

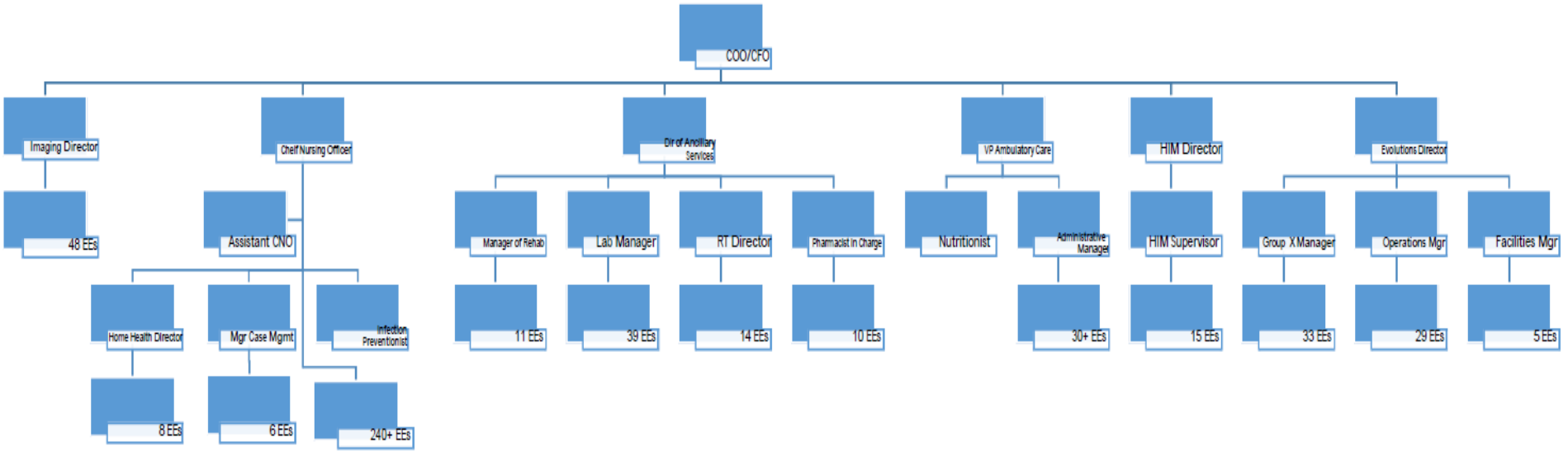
HCCA
Tulare Regional Medical Center

Administration & Leadership



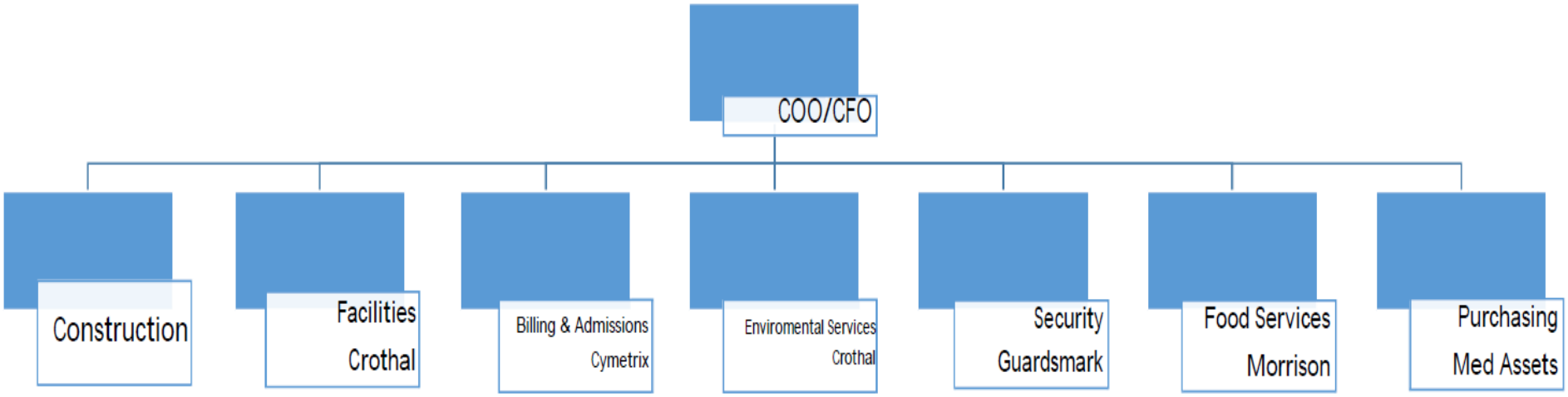
HCCA
Tulare Regional Medical Center

Operations



HCCA
Tulare Regional Medical Center

Third Party Teams



5.5.1.1 Board of Directors Responsibilities

a) TRMC operates in accordance with the best interests of the public health and make and enforce all rules, regulations and bylaws necessary for the administration, government, protection and maintenance of TRMC under their management and property belonging thereto
b) Perform the duties and responsibilities required by the Local Health Care District Law, other public agencies laws applicable to TRMC and applicable state and federal laws and regulations

5.5.1.2 Chief Executive Officer (CEO) Responsibilities

a) Ensures that the requirements of the QMS are implemented, maintained and communicated and ensuring compliance with the requirements of the ISO 9001 standards
b) Ensures adequate resources and trained personnel for management and support of service
c) Direction and administration of all organizational activities
d) Participates in the periodic review of the QMS and the implementation of any identified required improvements

5.5.1.3 Compliance Officer Responsibilities

a) Serves as the focal point for all compliance activities
b) Coordinates and communicates all compliance activities and programs, as well as plans, implements and monitors the compliance program
c) Oversees and monitors the implementation of the compliance program that meets the needs and addresses the risk areas of the organization
d) Reports on a regular basis to Senior Leadership, CEO and compliance committee on the progress of implementation
e) be made

5.5.1.4 Chief Operations Officer (COO) Responsibilities

a) Ensures that the requirements of the QMS are implemented and maintained
b) Ensures that TRMC complies with the applicable requirements of ISO 9001 standards
c) Provides liaison with external bodies on matters relating to the quality system
d) Determines the sequence and interaction of the processes needed to maintain the QMS

e) Participates in periodic review of the QMS and the implementation of any identified required improvements

5.5.1.6 Chief Nursing Officer (CNO) Responsibilities

a) Requests alterations to service as specified in the medical order
b) Ensures adequate definition of medical order
c) Participates in the periodic review of the QMS and the implementation of any identified required improvements
d) Ensures the availability of information necessary to support the operation and monitoring of processes
e) Responsible for implementation and appropriate administration of service in accordance with established policies to ensure service quality
f) Has the authority to identify nonconforming material and equipment and to ensure that all operations are in compliance with established specifications and policies

5.5.1.7 Chief Financial Officer (CFO) Responsibilities

a) Ensures compliance with applicable safety and regulatory requirements
b) Planning and scheduling of customer orders
c) Purchasing of material
d) Participates in the periodic review of the QMS and the implementation of any identified required improvements
e) Revenue Cycle

5.5.1.8 Chief Information Officer (CIO) Responsibilities

a) Participates in the periodic review of the QMS and the implementation of any identified required improvements
b) Supporting the implementation of TRMC's strategic plan related to Information Services
c) Supports Senior Leadership in creating development plans for new information technology
d) Ensures reports are accurate and carries out other analysis or reporting, as needed
e) Ensures the availability and integrity of information necessary to support the operation and monitoring of processes

5.5.1.9 VP Ambulatory Care Responsibilities

a) Participates in the periodic review of the QMS and the implementation of any identified required improvements
b) Ensures reports are accurate and carries out other analysis or reporting, as needed
c) Follow-up on non-payment of bills to include, but not limited to, writing claims inquiries, correcting errors and re-submitting claims
d) Performs coding audits as directed by the CFO to assure the appropriate submission of billing and diagnosis codes

5.5.2 Quality Management Representative

The Quality Manager has been appointed by Senior Leadership as the Management Representative who, irrespective of other responsibilities, is responsible and authorized to:

a) Ensure that processes needed for the QMS are established, implemented and maintained
b) Report, through the CNO, to Senior Leadership on the performance of the QMS and any need for improvement
c) Promote awareness of customer requirements throughout the organization
d) Act as the liaison with external parties on matters relating to the QMS
e) Measures, monitors and analyzes processes and implements actions as necessary to meet goals and to drive continual improvement
f) Ensures that ISO 9001 policies and procedures are being accurately maintained and organized, and calling for changes when they need to

5.5.3 Internal Communication

Appropriate communication processes are established within the organization. Senior Leadership promotes awareness of the Quality Plan, disseminates progress on quality performance and customer satisfaction and changes in the QMS. This promotion may include activities such as:

a) Senior Leadership Meetings
b) Directors Meetings
c) Departmental Meetings
d) Electronic newsletters
e) Information boards

f) Memos and electronic mail

5.6 Management Review

EXHIBIT 7

Management Review Flowchart

5.6.1 General

Senior Leadership reviews the organization's QMS, annually, to ensure its continuing suitability, adequacy and effectiveness in satisfying the requirements of ISO 9001, the Quality Plan and the organizational objectives. The QMS review committee consists of Senior Leadership and other responsible staff as applicable. The QMS review includes:

a) Assessing opportunities for improvement
b) Any change to the QMS
c) Any change to the quality policy
d) Any change to the quality objectives

5.6.2 Review Input

The input to the management review includes information on:

a) Results of audits
b) Customer feedback
c) Process performance and product conformity
d) Status of preventive and corrective actions
e) Follow-up actions from previous Senior Leadership reviews
f) Changes that could affect the QMS
g) Recommendations for improvement

5.6.3 Review Output

The output from the management review includes any decisions and actions related to:

a) Improvement of the effectiveness of the QMS and its processes
b) Improvement of product related to customer requirements
c) Resource needs

6 RESOURCE MANAGEMENT

6.1 Provision of Resources

It is the responsibility of Senior Leadership to ensure proper allocation of the resources that are essential to the achievement of the organization's objectives, including implementing, maintaining and improving the QMS and enhancing customer satisfaction are identified during the planning processes. Resource requirements are usually planned during the budgeting process and adjusted during the year in response to census, customer requirements and other internal needs. Management reviews the adequacy of resources and adjustments shall be made based on identified needs.

6.2 Human Resources

6.2.1 General

Senior Leadership ensures that the qualifications of personnel performing care and service are reviewed upon hire, when staffs change position or the requirements for a position change. Human Resources maintain records of personnel qualifications. If any differences between the qualification and the requirements for the job are found, training or other action is taken to provide the staff member with the necessary competence for the job. Reevaluation of appropriate job competency can be based on:

a) Education
b) Training
c) Skills
d) Experience
e) Mentoring

6.2.2 Competence, Training and Awareness

TRMC takes the initiative to:

a) Determine the necessary competence necessary for personnel performing work functions that could affect conformity to product requirements
b) Provide training or take other action to achieve the competence, where applicable
c) Evaluate the effectiveness of the action taken
d) Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives
e) Maintain appropriate records of:

    1) Education
    2) Training
    3) Skills
    4) Experience

6.2.2.1 Education Department

The Education Department has the responsibility for establishing, maintaining and implementing training programs. Internal training courses are planned, developed and implemented based upon identified needs including but not limited to regulatory and accrediting changes, external reviews, internal data output, and customer feedback.

The effectiveness of a training program is expected to reflect through improvement in job performance and/or service quality. Methods such as audits, employee interviews, supervisory evaluation and performance appraisals may be used.

6.3 Infrastructure

The organization is committed to providing and maintaining a suitable infrastructure to ensure that the service conforms to established requirements and achieves quality conformity. The required infrastructure and resources are identified, which may include:

a) Building facilities, workspace and associated utilities

b) Training and teaching in information systems, both hardware and software
c) Supporting services such as communication media

6.4 Work Environment

Senior Leadership ensures that the appropriate human and physical factors of the work environment are considered and provided, including such factors as noise, temperature, humidity, lighting, weather, etc. TRMC is committed to maintaining its campus in a safe and healthy manner for both personnel and customers.

Items for consideration include:

a) Customer service/feedback
b) Staff input
c) Hygiene and Infection Control standards
d) Housekeeping and cleanliness
e) Nutrition
f) Security and safety of the physical environment

7 PRODUCT REALIZATION

7.1 Planning of Product / Service Realization

The product for our organization is the delivery of Healthcare Services.

The organization designs, plans and develops the processes required for service realization.

In planning for service realization, the organization determines the following:

a) Is consistent with the organization's mission, vision, values, goals, objectives and plans
b) Meets the needs of patients, medical staff, hospital staff and others
c) Incorporates the following:

    1) The results of performance improvement activities
    2) Information about potential risks to patients
    3) When clinical processes are involved, the design is clinically sound and consistent with accepted national and/or community standards of care. (Use of practice guidelines, information from relevant literature and clinical standards)
    4) Incorporates available information from other organizations; especially published data relating to sentinel events/potential risks
    5) The results of any tests are analyzed to determine whether the proposed design or modification is an improvement

6) Leaders shall involve staff, medical staff and patients, as appropriate, in the design of new or modified services or processes.

The output of the planning activities is consistent with the organization's mission, vision, values and quality manual.

7.2 Customer-Related Processes

7.2.1 Determination of requirements Related to the Product

The organization determines:

a) The requirements specified by the customer, including the requirements for delivery and post-delivery activities
b) Necessary services for the specified provision that are not stated by the customer but are standards of practice
c) Statutory and regulatory requirements applicable to a healthcare organization
d) Any additional requirements the organization deems necessary to providing the service

7.2.2 Review of Requirements Related to the Service

A formal system is in place and maintained to ensure that each commitment to supply a service is formally reviewed and controlled. The review is conducted prior to the commitment to supply a service and ensures that:

a) All requirements are defined and documented
b) The service requirements are confirmed before providing the service
c) Any change in the service requirements is documented and the persons affected are notified
d) Requirements from the review are recorded and maintained in appropriate committee minutes

7.2.3 Customer Communication

TRMC recognizes the necessity for customer communication and feedback as a major contributing element of customer satisfaction and has implemented an effective process for communication with customers:

a) Product Information:
    1) Comprehensive website

2) Community focus groups
3) Community outreach groups
4) Community Presentations
5) Social Media
6) Community Events
7) Annual report mailed out to community homeowners
8) Community Tuesday Talks
9) Foundation Board of Trustees
10) Board of Directors

b) Inquiries, contracts or order handling, including amendments:
1) Materials Management
2) Department Directors
3) Senior Leadership
4) Compliance/Risk Management
5) Board of Directors

c) Customer feedback, including customer complaints:
1) NRC Picker
2) Quality Management
3) Risk Management
4) Comprehensive website
5) Community focus groups
6) Community Tuesday Talks
7) Senior Leadership Patient Rounding
8) Foundation Board of Trustees
9) Board of Directors

7.3 Design and Development

TRMC does not perform design and development activities. TRMC provides the services, surgery and treatments, which are accepted worldwide in medical circles.

7.4 Purchasing

7.4.1 Purchasing Process

The organization has a documented procedure, Policy #16-4002 Purchasing of Goods and Services – Invoice Approval and Processing that it follows to ensure that purchased product

conforms to the specified purchase requirements. The procedure outlines the extent of control required for suppliers. Suppliers are evaluated and selected based on their ability to supply product in accordance with the requirements outlined in the procedure. Records of the evaluation and necessary actions are maintained.

7.4.2 Purchasing Information

Purchasing information describes the product or service to be purchased, including, where appropriate:

a) Requirements for approval of product, procedures, service, processes and equipment
b) Requirements for qualification of personnel
c) Quality management system requirements

Purchase orders are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.

7.4.3 Verification of Purchased Product

The verification of purchased products is performed in accordance with the “Blind Receiving Method”, which ensures a more accurate warehouse receipt counts. Verification activities necessary for insuring that the purchased product/service meets the specified purchased requirement is reviewed by the Products Evaluation Committee prior to order.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

The organization plans and implements service processes under controlled conditions which include:

a) Availability of information that describes the characteristics of the service
b) Availability of education, training and work instruction as required
c) Suitable equipment
d) Availability and use of monitoring and measuring equipment
e) Implementation of monitoring and measurement
f) Implementation of service release, delivery and post-delivery activities

7.5.2 Validation of Processes for Service Provision

TRMC requires select process to be carried out on a test basis prior to implementing in the “live” environment.

7.5.3 Identification and Traceability

The organization identifies the service status with respect to monitoring and measurement requirements throughout the service realization. The organization also controls and records the unique identification of the service wherever traceability is a specified requirement.

7.5.4 Customer Property

The organization identifies, verifies, protects and safeguards the customer furnished property provided for use or incorporation into the service, Policy #22-1006 Medical Equipment Management Plan. With respect to safeguarding patient property, the organization has a documented procedure, Policy #10-1117 Securing Patient Monies/Valuables and Property Damage or Loss.

7.5.5 Preservation of Product

Methods used for handling, storing, packaging, preserving and delivery of products to ensure they are not damaged and that they are maintained in an acceptable condition are documented in various policies and procedures. These also apply to any constituent parts of a product. Damaged or nonconforming product is controlled and dispositioned according to documented procedure, Policy # ISO 9001 8.3.

Stock inventory is stored and packaged according to the specification for each product. Storage areas and stockrooms are secure and controlled to prevent damage to the inventory.

7.6 Control of Monitoring and Measuring Equipment

The monitoring and measurement to be undertaken as well as the monitoring and measuring equipment needed to provide evidence of conformity is documented in, Policy #12-5005 Outside Vendor Assistance for Clinical Services.

Documented processes ensure that monitoring and measurement can be carried out in a manner that is consistent with the monitoring and measurement requirements, Policy # 12-5005 Outside Vendor Assistance for Clinical Services.

Records are reviewed and validated by Quality Management when equipment is found not to conform to requirements.

Records of the results are maintained and documented (see 4.2.4). Monitoring and measuring equipment are identified with the following minimum information:

a) Date calibrated
b) Calibration due date
c) Technicians number
d) Identification ID number

Items not used to monitor and/or measure service related processes are identified in an excel spread sheet.

The capability of computer software to satisfy the intended application is undertaken prior to initial use and reconfirmed as necessary, when used in the monitoring and measurement of specified requirements.

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

The organization plans and implements the monitoring, measurement, analysis and improvement processes needed to:

a) Demonstrate conformity to product requirements
b) Ensure conformity of the QMS
c) Continually improve the effectiveness of the QMS

This includes the determination of applicable methods, including statistical techniques and the extent of their use.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the QMS, the organization monitors information relating to customer perception as to whether we have met customer requirements. The method used for obtaining and using this information is from a contracted service who provides real time customer satisfaction scores.

Trends in customer satisfaction and key indicators of customer dissatisfaction are documented and supported by objective information.

8.2.2 Internal Audit

The organization conducts internal audits at planned intervals to determine whether the QMS:

a) is effectively implemented and maintained
b) conforms to the requirements of this International Standard
c) meets the quality management system requirements established by the organization

The responsibility for carrying out internal quality audits falls on the Quality Department. The Quality Management Representativeor delegate plans the audits and ensures that they are carried out according to the plan.

The planned audit program takes into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods will be defined. The selection of auditors and conduct of audits will ensure objectivity and impartiality of the audit process. Auditors will not audit their own work.

A documented procedure has been established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results, reference ISO 9001 8.2.2.

Records of the audits and their results are maintained (see 4.2.4).

Audit results are distributed to the Department Directors for the areas audited or affected. They will ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

Follow-up includes the verification of the actions taken and the reporting of verification results (see 8.5.2).

8.2.3 Monitoring and Measurement of Processes

Results from the quality system audits, coupled with the assessment of customer satisfaction and dissatisfaction are the primary indicators of the effectiveness of the QMS. When audits determine an inadequacy in the implementation of the QMS, appropriate corrective action shall be taken. The corrective action could include, but not limited to:

a) Development and deployment of training to bring actual practice into alignment with documented requirements
b) Change the documented requirements to ensure alignment with current business needs and practices

8.2.4 Monitoring and Measurement of Product

The organization monitors and measures performance to verify that service requirements have been met. This is carried out at all stages of the service process according to planned goals and objectives with the performance results recorded, reviewed and approved by the PI Committee.

Records will indicate the person(s) authorizing release of service for delivery to the customer.

Consent is obtained authorizing the facility to asses, diagnose and treat in accordance with the reason for hospitalization. Service delivery to the customer does not proceed until all planned requirements have been satisfactorily completed, unless life threatening in nature.

8.3 Control of Nonconforming Product

The organization ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure is established to define the controls related responsibilities and authority for dealing with a nonconforming product, reference ISO 9001 8.3.

Where applicable, the organization deals with nonconforming product by one or more of the following ways:

a) taking action to eliminate or correct the nonconformity
b) authorizing its use, release or acceptance under concession by a relevant authority
c) taking action to remove the product/device

When a nonconforming product is corrected, it will be subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained (see 4.2.4).

8.4 Analysis of Data

The organization collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the QMS can be made. This includes data generated as a result of monitoring and measurement activities and other relevant sources:

a) Customer satisfaction (see 8.2.1)
b) Conformity to product requirements (see 8.2.4)
c) Characteristics and trends of processes and service, including opportunities for preventive action (see 8.2.3 and 8.2.4)
d) Suppliers (see 7.4)

e) Regulatory requirements
f) Accrediting requirements

Senior Leadership, on a periodic basis, will evaluate the measurements and goals. All departments will utilize facts, data and quality records for improvement planning, for minimizing repetitive nonconformance situations and for determining corrective/preventive action strategies.

8.5 Improvement

One of the major objectives of the TRMC QMS is to foster improvement in all aspects of our organization. This can be best accomplished by the on-going initiatives to improve the quality and reliability of our services and to improve the operating effectiveness of the equipment and processes.

8.5.1 Continual Improvement

The organization continually improves the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective Action

The organization takes action to eliminate the causes of nonconformity in order to prevent recurrence. Corrective actions are designed to medicate the effects of the nonconformity encountered, reference ISO 9001 8.5.2.

A documented procedure is established to define requirements for:

a) reviewing nonconformities (including customer complaints)
b) determining the causes of nonconformities
c) evaluating the need for action to ensure that nonconformities do not recur
d) determining and implementing action needed
e) records of the results of action taken (see 4.2.4)
f) reviewing the effectiveness of the corrective action taken

8.5.3 Preventive Action

The organization review processes to eliminate potential nonconformities and prevent their occurrence. The focus is usually on high risk, high volume and complex processes. Preventive actions initiated are designed to reduce the probability of a process breakdown, reference ISO 9001 8.5.3.

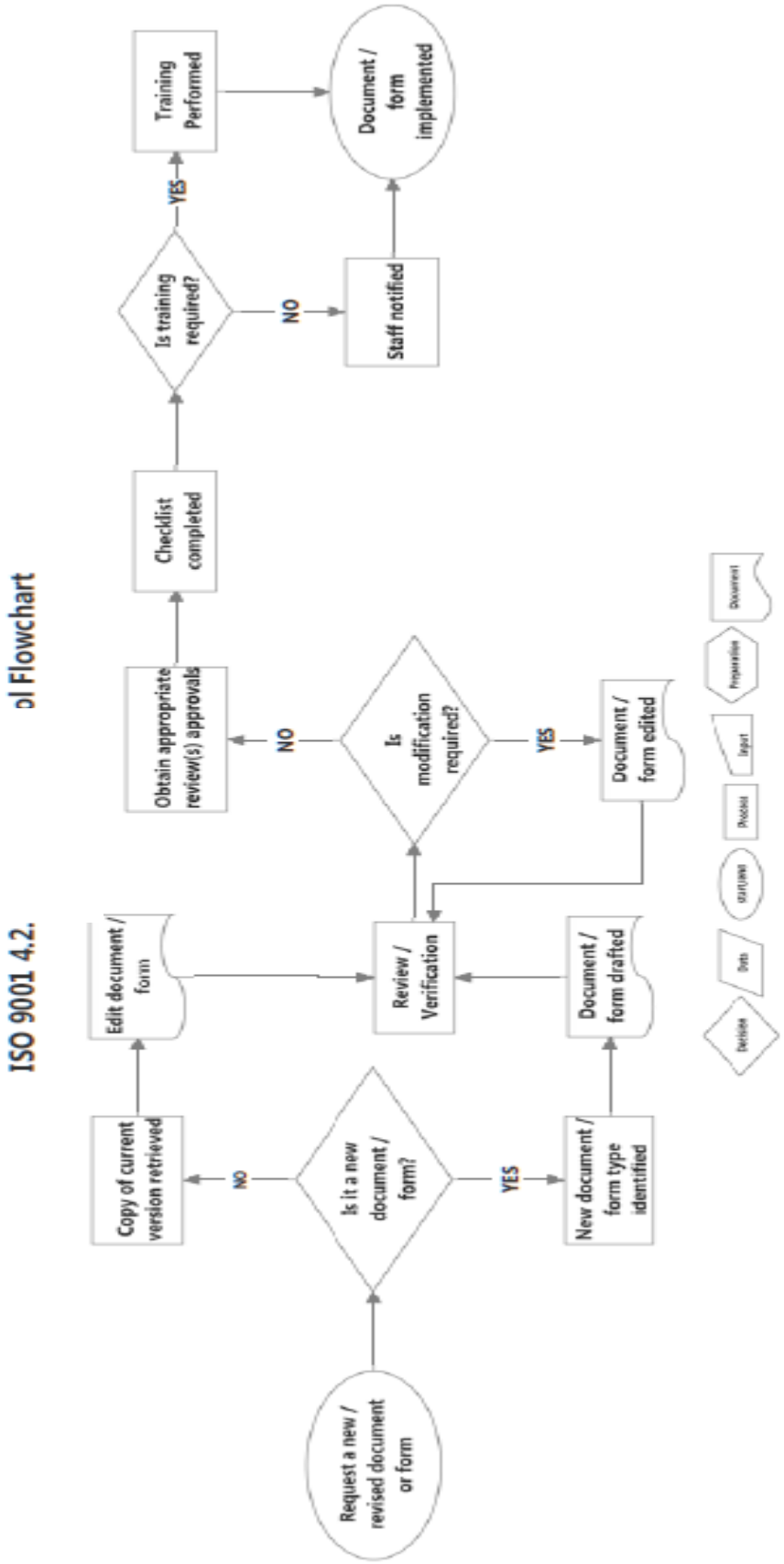
A documented procedure is established to refine requirements for:

a) Determining potential nonconformities and their causes

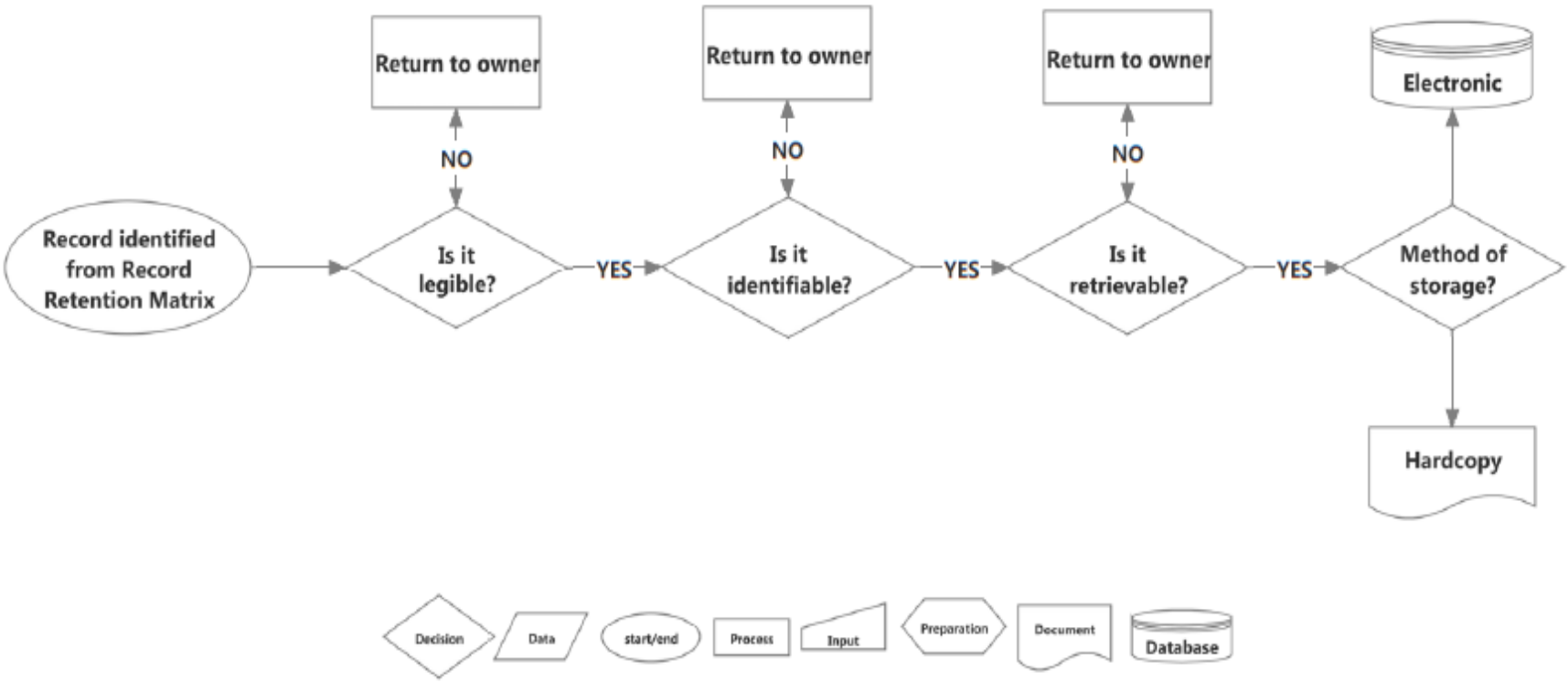
b) Evaluating the need for action to prevent occurrence of nonconformities
c) Determining and implementing action needed
d) Records of results of action taken (see 4.2.4)
e) Reviewing the effectiveness of the preventive action taken

APPENDIX A

ISO PROCESS MAPS

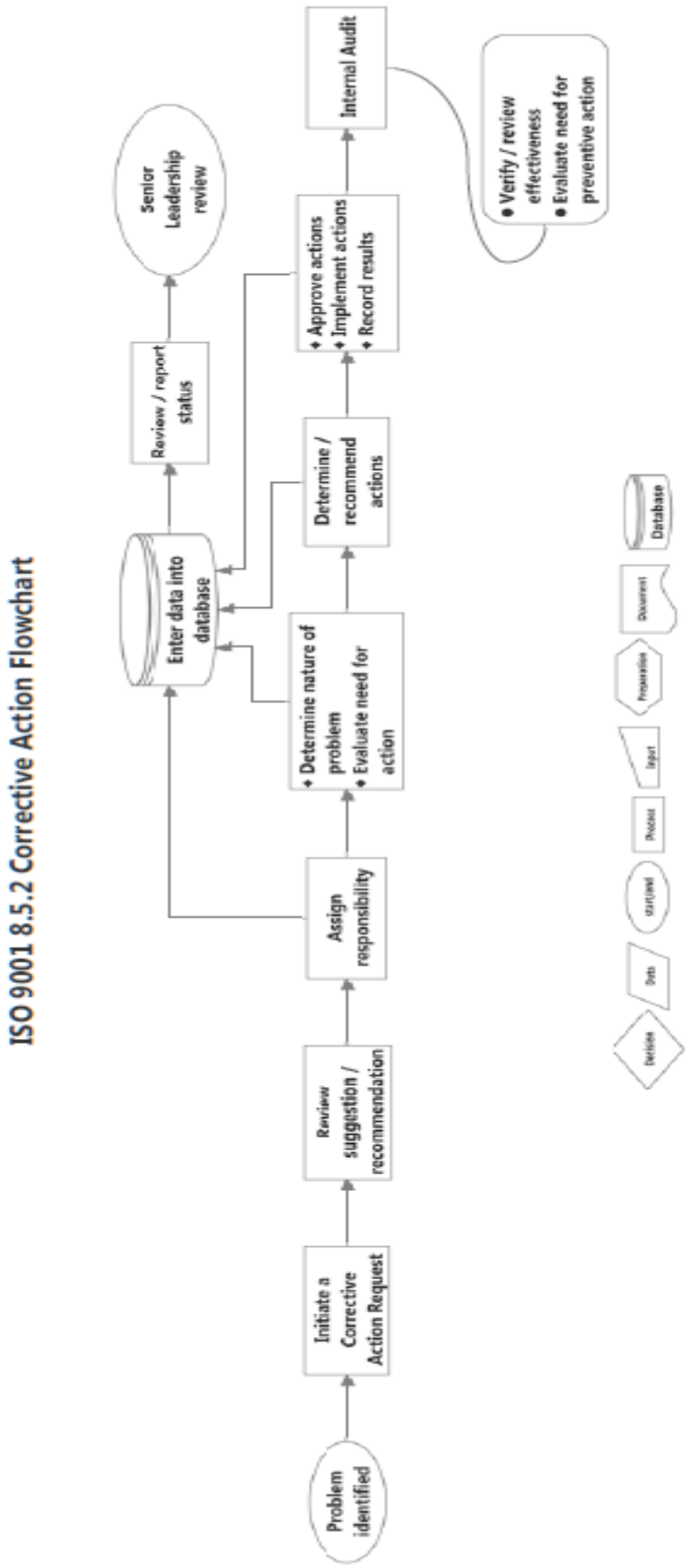

ISO 9001 4.2.
ol Flowchart
Request a new / revised document or form
Is it a new document / form?
NO
YES
Copy of current version retrieved
New document / form type identified
Edit document / form
Document / form drafted
Review / Verification
Is modification required?
NO
YES
Obtain appropriate review(s) approvals
Document / form edited
Checklist completed
Is training required?
NO
YES
Staff notified
Training Performed
Document / form implemented
Decision
Data
Process
Input
Preparation
Document

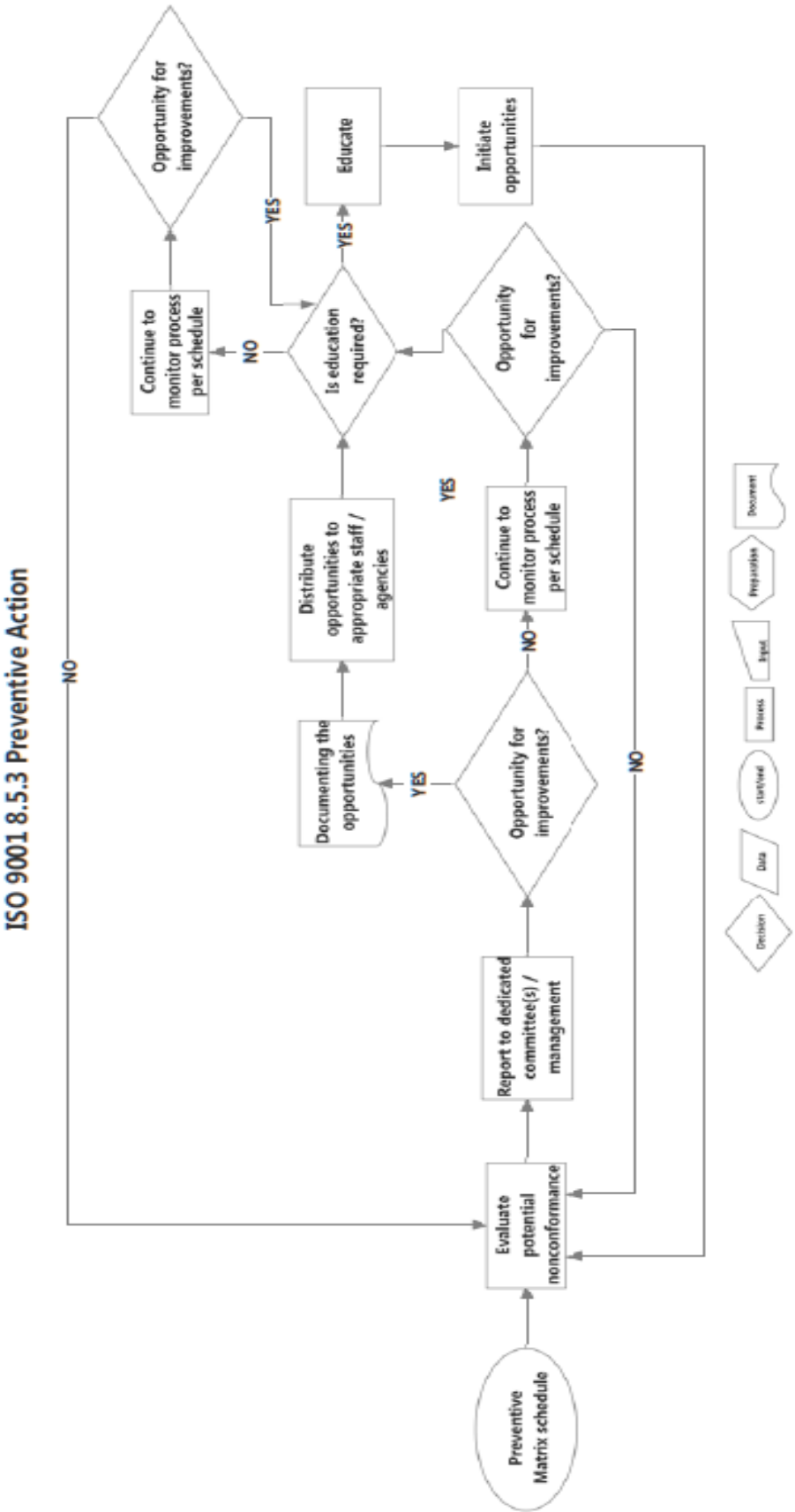
ISO 9001 4.2.4 Record Control Flowchart



ISO 9001 82.2 Internal Audit Flowchart
Schedule Audit
Does an audit plan exist?
YES
NO
Audit Manager plans audit
Notify Department Director (Auditee) and agree on date / time / scope of audit
Perform audit
Does nonconformance exist?
YES
NO
Generate nonconformance / corrective action report
Track follow up
Is response on time?
YES
NO
Schedule follow up with Department Director (Auditee)
Perform audit to ensure implementation / effectiveness of reaction
Is it acceptable?
NO
YES
Escalate
Close audit and file results
Update audit schedule
Management review

ISO 9001 8.3 Nonconforming Product Flowchart
Nonconforming product identified
Segregate nonconforming product
Nonconforming product placed under control of responsible department director
Document nonconforming product
Disposition?
Repair / Fix
Is it conforming?
YES
Use Product
Nonconforming condition is reviewed & corrected
NO
Return to vendor
NO
Scrap


ISO 9001 8.5.2 Corrective Action Flowchart
Problem identified
Initiate a Corrective Action Request
Review suggestion / recommendation
Assign responsibility
+ Determine nature of problem
+ Evaluate need for action
Enter data into database
Determine / recommend actions
+ Approve actions
+ Implement actions
+ Record results
Internal Audit
• Verify / review effectiveness
• Evaluate need for preventive action
Review / report status
Senior Leadership review
Database


ISO 9001 8.5.3 Preventive Action
Preventive Matrix schedule
Evaluate potential nonconformance
Report to dedicated committee(s) / management
Opportunity for improvements?
NO
Documenting the opportunities
YES
Distribute opportunities to appropriate staff / agencies
Continue to monitor process per schedule
Opportunity for improvements?
NO
YES
Is education required?
NO
Continue to monitor process per schedule
Opportunity for improvements?
YES
Educate
Initiate opportunities
Decision
Data
Start/End
Process
Input
Preparation
Document

APPENDIX B

REVISION OF HISTORY

Rev	Revised By	Date	Nature of Revision
0		10/25/12	Initial Release
1	Angie Graziano CNO/ Patti McCowan ACNO		3 year Update

Descriptive Name: Quality Manual System

Committee Review and Approval:	Approval Date:	Comments:
MEC	09/14/16	
Board of Directors		

Effective Date:

Forward To: Policy Binders – (PBX and Administration) and Post to Intranet Site

TULARE LOCAL HEALTH CARE DISTRICT
dba TULARE REGIONAL MEDICAL CENTER

POLICY/GUIDELINE MANUAL

TO: All Employees and Medical Staff

FROM: Administration

SUBJECT: Corporate Compliance Plan

I. STATEMENT OF POLICY OF ETHICAL PRACTICES ("Policy")

A. The DISTRICT has a policy of maintaining the highest level of professional and ethical standards in the conduct of its business. The Hospital places the highest importance upon its reputation for honesty, integrity and high ethical standards. This Policy Statement is a reaffirmation of the importance of the highest level of ethical conduct and standards.

B. These standards can only be achieved and sustained through the actions and conduct of all staff of the Hospital. (For purposes of this policy the terms “staff” and “staff member(s)” includes direct-hire employees, contract workers, physicians and other allied health professionals working on-campus on behalf of the hospital.) Every staff member is obligated to conduct himself/herself in a manner to ensure the maintenance of these standards. Such actions and conduct will be important factors in evaluating a staff member’s judgment and competence. Staff who ignore or disregard the principles of this Policy will be subject to appropriate disciplinary actions, as explained in section IV.C below.

C. Staff must be cognizant of all applicable federal and state laws and regulations that apply to and impact upon the Hospital's documentation, coding, billing and competitive practices, as well as the day-to-day activities of the Hospital and its staff and agents. Each staff member who is materially involved in any of the Hospital's documentation, coding, billing or competitive practices has an obligation to familiarize himself or herself with all such applicable laws and regulations, and to adhere at all times to the requirements thereof. Where any question or uncertainty regarding these requirements exists, it is incumbent upon, and the obligation of, each staff member to seek guidance from a knowledgeable officer of, or attorney for, the Hospital.

D. In particular, and without limitation, this Policy prohibits the Hospital and each of its staff members from directly or indirectly engaging or participating in any of the following:

1. **Improper Claims.**

   a. Presenting or causing to be presented to the United States government, the State of California, or any other health care payer a claim:

      1. Item or Service Not Provided As Claimed:

         For a medical or other item or service that such person knows or should know (1) was not provided as claimed, including a pattern or practice of presenting or causing to be presented a claim for an item or service that is based on a code that such person knows or should know will result in a greater payment to the claimant than the code such person knows or should know is applicable to the item or service actually provided;

   b. False Claim:

      1. For a medical or other item or service and such person knows or should know the claim is false or fraudulent;

   c. Service by Unlicensed Physician.

      1. For a physician's service (or an item or service incident to a physician's service) when such person knows or should know the individual who furnished (or supervised the furnishing of) the service -

         (i) was not a licensed physician;

         (ii) was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing); or

         (iii) represented to the patient at the time the service was furnished that the physician was certified in a medical specialty by a medical specialty board when the individual was not so certified;

   d. Excluded Provider.

      1. For a medical or other item or service furnished

in which such person knows or should know the claimant was excluded from the program under which the claim was made;

e. Not Medically Necessary:

1. For a pattern of medical or other items or services that such person knows or should know are not medically necessary;

2. **False Statement in Determining Rights to Benefits**.

a. Making, using or causing to be made or used any false record, statement or representation of a material fact for use in determining rights to any benefit or payment under any health care program;

3. **Conspiracy to Defraud**.

a. Conspiring to defraud the United States government, the State of California, or any other health care payer by getting a false claim allowed or paid;

4. **Improper Beneficiary.**

a. Is a beneficiary of an inadvertent submission of a false claim to the State, and fails to disclose discovery of the false claim.

5. **Patient Dumping**.

a. Refusing to treat, transferring or discharging any individual who comes to the emergency department, and on whose behalf a request is made for treatment or examination, without first providing for an appropriate medical screening examination to determine whether or not such individual has an emergency medical condition, and, if such individual has such a condition, stabilizing that condition or appropriately transferring such individual to another hospital in compliance with the requirements of 42 U.S.C. § 1395dd.

6. **Provision of care to contract HMO patients**.

a. Knowingly failing to provide covered services or necessary care to members of a health maintenance organization with which the Hospital has a contract.

7. **Health Care Fraud/False Statements Relating to Health Care Matters**.

a. Executing or attempting to execute a scheme or artifice to defraud any health care benefit program, or to obtain, by means of false, fictitious or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program;

8. **Anti-Referral**.

a. Presenting or causing to be presented a claim for reimbursement to any individual, third party payor, or other entity for designated health services(2) which were furnished pursuant to a referral by a physician who has a financial relationship with the Hospital, as such is defined in 42 U.S.C. § 1395nn;

9. **Anti-Kickback**.

a. Except as otherwise provided in 42 U.S.C. § 1320a-7b(b), knowingly and willfully:

1. Soliciting or receiving any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind either:

(i) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program; or

(ii) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program; or

b. Offering or paying any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person either:

1. To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program; or

2. To purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program;

10. **Antitrust**.

a. Engaging in any activity, including without limitation being a member of a multi-provider network or other joint venture or affiliation, which is in restraint of trade or which monopolizes, or attempts to monopolize, any part of interstate trade or commerce; or

11. **Failure to Report Violations to Chief Compliance Officer**.

a. Failing to promptly report to the Chief Compliance Officer (as defined below) any instance described in subparagraphs 1 - 9 above with respect to the Hospital or any of its employees which is known to such person.

II. APPOINTMENT OF CHIEF COMPLIANCE OFFICER

A. The Chief Compliance Officer

1. In an effort to ensure compliance with this Policy, the Board of Directors is adopting a formal Compliance Program. To oversee and implement this program, the Hospital has appointed a Chief Compliance Officer. The Hospital has chosen its Chief Compliance Officer based on an outstanding record of commitment to honesty, integrity and high ethical standards, and on knowledge and understanding of the applicable laws and regulations. The Chief Compliance Officer will provide for education and training programs for staff, respond to inquiries from any staff member regarding appropriate billing, documentation, coding and business practices and investigate any allegations of possible impropriety.

B. Duties and Responsibilities of the Chief Compliance Officer

1. The duties and responsibilities of the Chief Compliance Officer shall include, but not be limited to, the following:

a. Working with the Board of Directors, chief executive officer, chief financial officer and general counsel in the preparation and development of, and overseeing the implementation of, written guidelines on specific federal and state legal and regulatory issues and matters involving ethical and legal

business practices, including, without limitation, documentation, coding and billing practices with respect to requests for payments and/or reimbursements from Medicare or any other federally funded health care program, the giving and receiving of remuneration to induce referrals and engagement in certain business affiliations or pricing arrangements that may affect competition;

(i) Such written guidelines shall address, among other topics:

- Billing for services not actually rendered;
- Providing medically unnecessary services;
- Upcoding;
- DRG Creep;
- Duplicate billing;
- False cost reports;
- Unbundling;
- Billing for discharge in lieu of transfer;
- Patients' freedom of choice;
- Credit balances – failure to refund;
- Hospital incentives that violate the anti-kickback statute or other similar federal or state law;
- Joint ventures that may violate the anti-kickback statute;
- Financial arrangements between the Hospital and Hospital-based physicians;
- Stark physician self-referral issues;
- Knowing failure to provide covered services or necessary care to members of a health maintenance organization;
- Patient dumping.

(ii) Developing and implementing an educational training program for Hospital personnel to ensure understanding of federal and state laws and regulations involving ethical and legal business practices including, without limitation, documentation, coding and billing practices with respect to requests for payments and/or reimbursements from Medicare or any other federally funded health care program, the giving and receiving of remuneration to induce referrals and engagement in certain business affiliations or pricing arrangements that may affect competition;

(iii) Handling inquiries by staff regarding any aspect of compliance;

(iv) Investigating any information or allegation concerning possible unethical or improper business practices and recommending corrective action when necessary;

(v) Providing guidance and interpretation to the Board of Directors, the chief executive officer and Hospital personnel, in conjunction with the Hospital's legal counsel, on matters related to Tulare's Compliance Program;

(vi) Planning and overseeing regular, periodic audits of the Hospital's operations in order to identify and rectify any possible barriers to the efficacy of Tulare's Compliance Program;

(vii) Preparing at least annually a report to the Board of Directors and the chief executive officer concerning the compliance activities and actions undertaken during the preceding year, the proposed compliance program for the next year, and any recommendations for changes in Tulare's Compliance Program;

(viii) Coordinating with the Hospital's human resources department (or its equivalent) to ensure all staff have been verified for ineligibility on the OIG and SAM websites, primary source verification for licensed individuals and employment, criminal, misdemeanor and felony background checks upon new hire. The Compliance Officer shall also coordinate with the Medical Staff Office personnel to ensure physicians,

physician groups and allied health professionals are also verified on the OIG and SAM websites and National Practitioner Data Bank. Annually, all staff shall be verified for ineligibility on the OIG and SAM website and reports forwarded to the Compliance Officer.

(ix) Ensuring that independent contractors and agents who furnish medical services to the Hospital are aware of Tulare's Compliance Program including, without limitation, its policies with respect to the specific areas of documentation, coding, billing and competitive practices; and

(x) Performing such other duties and responsibilities as the Board of Directors may request.

C. **Compliance Committees**

1. The Chief Compliance Officer may create one or more committees to advise the Chief Compliance Officer and assist in the implementation of Tulare's compliance program. Each committee may have one or more members, who may be hospital employees, independent contractors or other interested parties, and such members shall serve at the pleasure of the Chief Compliance Officer. The purpose of providing for such committees is to allow the Hospital and the Chief Compliance Officer to benefit from the combined perspectives of individuals with varying responsibilities in the Hospital such as, by way of example only and not obligation, operations, finance, audit, human resources, utilization review, social work, discharge planning, medicine, coding and legal, as well as other staff members of key operating units.

D. **Reporting by Chief Compliance Officer**

1. In general, recommendations from the Chief Compliance Officer regarding compliance matters will be directed to the appropriate officer or Director of the Hospital. If the Chief Compliance Officer is not satisfied with the action taken in response to its recommendations, he/she will report such concern to the Board of Directors and the chief executive officer. In no case will the Hospital endeavor to conceal Hospital or individual wrongdoing.

E. **Establishment of a Hotline**

1. The Chief Compliance Officer shall have an "open door" policy with respect to receiving reports of violations, or suspected violations, of the law or of the Policy and with respect to answering staff questions concerning adherence to the law and to the Policy. In addition, the Hospital shall establish a Hotline to the Chief Compliance Officer for such reporting or questions. The toll-free telephone number for the Hotline is 1-888-633-9391.Telephone calls to the Hotline may come from Hospital staff, patients of the Hospital or others, whether or not affiliated with the Hospital. All information reported to the Hotline by any staff member in accordance with the Compliance Policy shall be kept confidential by the Hospital to the extent that confidentiality is possible throughout any resulting investigation; however, there may be a point where the reporter's identity may become known or may have to be revealed in certain instances when governmental authorities become involved. Under no circumstances shall the reporting of any such information or possible impropriety serve as a basis for any retaliatory actions to be taken against any staff member, patient or other person making the report to the Hotline.

2. The telephone number for the Hotline shall be posted in conspicuous locations throughout the Hospital.

F. Civil and Criminal Penalties

1. Any person who makes, presents, submits, or causes to be made, presented or submitted a false claim or statement shall be subject to a civil penalty of $10,781 to $21,563 per violation, plus three times the amount of the false claim. In addition to state penalties for medical insurance fraud, in cases that involved national medical insurance such as Medicaid or Medicare, you may also be subject to federal penalties. A conviction under federal law carries a penalty of up to 10 years in prison and a minimum fine of $21,563. If the fraud resulted in the injury to another such as a doctor performing unnecessary surgery to receive a higher insurance payment, the penalty increases to up to 20 years in prison.

G. Whistleblower Provisions.

1. Private plaintiff may file a "Qui Tam" action for violation of the state and federal false claims laws, and recover a portion of the damages. The Hospital may not prohibit or prevent staff member from disclosing false claims to the state or pursuing a Qui Tam claim. The Hospital may not directly, or through its agents, demote, suspend, terminate or threaten a staff member for disclosure to the

state or pursuing a Qui Tam claim. A staff member who is terminated, demoted, suspended or harassed for participating in false claims may recover losses only if the staff member voluntarily disclosed information to the State or pursued a Qui Tam action and the staff member was coerced into fraudulent activity by the Hospital.

III. EDUCATIONAL PROGRAM

A. Purpose of Educational Program

1. Tulare's Compliance Program promotes the Hospital's policy of adherence to the highest level of professional and ethical standards, as well as all applicable laws and regulations. The Hospital will make available appropriate educational and training programs and resources to ensure that all staff are familiar with those areas of law that apply to and impact upon the conduct of their respective duties, including, without limitation, the specific areas of documentation, coding, billing and competitive practices of the Hospital.

B. Responsibility for Educational Program

1. The Chief Compliance Officer, in conjunction with the Hospital's legal counsel, is responsible for implementation of the educational program. The program is intended to provide each staff member of the Hospital with an appropriate level of information and instruction regarding ethical and legal standards, including, without limitation, standards for documentation, coding, billing and competitive practices, and with the appropriate procedures to carry out the Policy.

2. Education and training of all staff shall be conducted on new hire and at least annually. The determination of the level of education needed by particular staff members or classes of staff will be made by the Chief Compliance Officer. Each educational program presented by the Hospital shall allow for a question and answer period at the end of such program.

C. Subject Matter of Educational Program

1. Tulare's training program, at a minimum, shall explain

Tulare's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

2. Other training information may include, but not necessarily required:

   a. the False Claims Recovery Act (Welfare and Institutions Code, Section 14115.75), the Federal False Claims Act (31 U.S.C. § 3729);

   b. the California False Claims Act and related penalties and whistleblower protections (Government Code, Section 12650-12656),the civil and criminal provisions of the Social Security Act (42 U.S.C. § 1320a-7a and § 1320a-7b, respectively);

   c. the patient anti-dumping statute (42 U.S.C. § 1395dd), laws pertaining to the provision of medically necessary items and services that are required to be provided to members of an HMO with whom the Hospital contracts (42 U.S.C. § 1320a-7(b) (6) (D)), criminal offenses concerning false statements relating to health care matters (18 U.S.C. § 1035);

   d. the criminal offense of health care fraud (18 U.S.C. § 1347);

   e. the Federal Anti-Referral Laws (42 U.S.C. § 1395nn);

   f. the Anti-Kickback Laws (42 U.S.C. § 1320a-7b (b)):

   g. the Sherman Antitrust Act (15 U.S.C. §§ 1, 2 and 18).

   h. Fraud Enforcement and Recovery Act of 2009.

   i. The Health Insurance Portability and Accountability Act of 1996 (HIPPA)

   j. The Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009.

   k. Ethics

2. As additional legal issues and matters are identified by the Chief Compliance Officer, those areas will be included in the educational program. Each education and/or training program conducted

hereunder shall reinforce the fact that strict compliance with the law and with the Hospital's Policy is a condition of employment with the Hospital.

D. **Training Methods**

1. Different training methods may be utilized to educate various categories of staff, including but not limited to, lectures, videos, on-line computer eLearning programs, etc.

2. While the Hospital will make every effort to provide appropriate compliance information to all staff members, and to respond to all inquiries, no educational and training program, however comprehensive, can anticipate every situation that may present compliance issues. Responsibility for compliance with Tulare's Compliance Program, INCLUDING THE DUTY TO SEEK GUIDANCE WHEN IN DOUBT, rests with each staff member of the Hospital.

IV. STAFF OBLIGATIONS

A. **The Compliance Policy**

1. The Compliance Policy imposes several obligations on Hospital staff, all of which will be enforced by the standard disciplinary measures available to the Hospital as an employer, or as a contractor.

B. **Staff Obligations**

1. *Reporting Obligation*. Staff members must immediately report to the Chief Compliance Officer any suspected or actual violations (whether or not based on personal knowledge) of applicable law or regulations by the Hospital or any of its staff. Any staff member making a report may do so anonymously if he/she so chooses. Once a staff member has made a report, the staff member has a continuing obligation to update the report as new information comes into his/her possession. All information reported to the Chief Compliance Officer by any staff member in accordance with the Compliance Policy shall be kept confidential by the Hospital to the extent that confidentiality is possible throughout any resulting investigation; however, there may be a point where a reporter's identity may become known or may have to be revealed in certain instances when governmental authorities become involved. Under no circumstances shall the reporting of any such information or

possible impropriety serve as a basis for any retaliatory actions to be taken against any staff member making the report.

C. **Hospital Assessment of Staff Performance Under Tulare's Compliance Program**

1. *Violation of Applicable Law or Regulation*. If a staff member violates any law or regulation in the course of his/her employment, the Hospital shall notify the appropriate contractor who directly employs the staff member. The contractor shall report back to the Chief Compliance Officer the outcome of their own investigation into the matter.

2. *Other Violation of the Tulare's Compliance Program.* In addition to direct participation in an illegal act, staff will be subject to disciplinary actions by their employer for failure to adhere to the principles and policies set forth in Tulare's Compliance Program. Examples of actions or omissions that will subject a staff member to discipline on this basis include, but are not limited to the following:

   a. a breach of the Hospital's Policy;

   b. failure to report a suspected or actual violation of law or a breach of the Policy;

   c. failure to make, or falsification of, any certification required under Tulare's Compliance Program;

   d. lack of attention or diligence on the part of supervisory personnel that directly or indirectly leads to a violation of law; and/or;

   e. direct or indirect retaliation against a staff member who reports a violation of the Compliance Policy or a breach of the Policy.

3. *Possible Sanctions.* The possible sanctions include, but are not limited to, termination, suspension, demotion, reduction in pay, reprimand, and/or re-training. Staff who engage in intentional or reckless violation of law, regulation or Tulare's Compliance Program will be subject to more severe sanctions than accidental transgressors.

C. **Non-Employment or Retention of Sanctioned Individuals**

1. The Hospital shall not knowingly contract with any person or entity, who has been convicted of a criminal offense related to health care

or who is listed by a Federal agency as debarred, excluded or otherwise ineligible for participation in federally funded health care programs. In addition, until resolution of such criminal charges or proposed debarment or exclusion, any individual who is charged with criminal offenses related to health care or proposed for exclusion or debarment shall be removed from direct responsibility for, or involvement in, documentation, coding, billing or competitive practices. If resolution results in conviction, debarment or exclusion of the individual, the Hospital or the contractor employing the individual shall terminate its employment of such individual.

V. RESPONSE TO REPORTS OF VIOLATIONS

A. The Hospital, along with its legal counsel where necessary, shall promptly respond to and investigate all allegations of wrongdoing of Hospital staff, whether such allegations are received through the Hotline or in any other manner.

B. **Investigation**

1. Upon the discovery that a material violation of the law or of the Policy has occurred, the Hospital shall take immediate action to rectify the violation, if possible, and to report the violation to the appropriate regulatory body, if necessary, and to appropriately sanction the culpable staff members(s) of the Hospital. Promptly after any discovered material violation is addressed, the Hospital shall, with the assistance of the Chief Compliance Officer, amend this Policy in any manner that the Hospital or the Chief Compliance Officer feels will prevent any similar violation(s) in the future.

2. If an investigation of an alleged violation is undertaken and the Chief Compliance Officer believes the integrity of the investigation may be at stake because of the presence of staff members under investigation, the staff member(s) allegedly involved in the misconduct shall, at the discretion of the Chief Compliance Officer, be removed from his/her/their current work activity until the investigation is completed. In addition, the Hospital and the Chief Compliance Officer shall take any steps necessary to prevent the destruction of documents or other evidence relevant to the investigation. Once an investigation is completed, if disciplinary action is warranted, the Hospital or its contractor shall take action immediately.

VI. AUDITING AND MONITORING

A. **Importance of Auditing and Monitoring**

1. It is critical to the Hospital's compliance with the Policy for the Hospital to conduct regular auditing and monitoring of the activities of the Hospital and its staff in order to identify and to promptly rectify any potential barriers to such compliance.

B. **Regular Audits**

1. Regular, periodic audits, as periodically as the Chief Compliance Officer shall prescribe, shall be conducted with the assistance of the Hospital's legal counsel at the Chief Compliance Officer's direction. Such audits shall evaluate Tulare's compliance with its Compliance Program and determine what, if any, compliance issues exist. Such audits shall be designed and implemented to ensure compliance with the Tulare's Compliance Program and all applicable federal and state laws.

2. Compliance audits shall be conducted in accordance with the comprehensive audit procedures established by the Chief Compliance Officer and shall include, at a minimum:

   a. interviews conducted by the Hospital's legal counsel with personnel involved in management, operations and other related activities;

   b. reviews, at least annually, of whether Tulare's Compliance Program elements have been satisfied (e.g. whether there has been appropriate dissemination of Tulare's Compliance Program standards, training, disciplinary actions, etc.);

   c. random reviews of Hospital records with special attention given to procedures relating to documentation, coding, billing, the giving and receiving of remuneration to induce referrals and engagement in certain business affiliations or pricing arrangements that may affect competition; and

   d. reviews of written materials and documentation used by the Hospital.

3. All compliance audit procedures shall be conducted with the assistance of the Hospital's legal counsel and all investigations, and the results thereof, are confidential.

C. **Formal Audit Reports**

1. Formal audit reports shall be prepared with the assistance of the Hospital's legal counsel and submitted to the Chief Compliance Officer and the Board of Directors to ensure that management is

aware of the results and can take whatever steps necessary to correct past problems and deter them from recurring. The audit or other analytical reports shall specifically identify areas where corrective actions are needed and should identify in which cases, if any: subsequent audits or studies would be advisable to ensure that the recommended corrective actions have been implemented and are successful.

D. **Compliance with Applicable Fraud Alerts**

1. The Chief Compliance Officer shall regularly and periodically monitor the issuance of fraud alerts by Office of the Inspector General of the Department of Health and Human Services. Any and all fraud alerts so issued shall be carefully considered by the Chief Compliance Officer and by the Hospital's legal counsel. The Hospital shall revise and amend this Compliance Policy, as necessary, in accordance with such fraud alerts. In addition, the Hospital shall immediately cease and correct any conduct applicable to the Hospital and criticized in any such a fraud alert.

E. **Retention of Records and Reports**

1. The Hospital shall document its efforts to comply with applicable statutes, regulations and federal health care program requirements. All records and reports created in conjunction with the Hospital's adherence to Tulare’s Compliance Program are confidential and shall be maintained by the Hospital for at minimum of six (6) years, in a secure location.

NOTES:

1. For purposes of this Policy, the term "should know" means that a person, with respect to information (i) acts in deliberate disregard of the truth or falsity of the information, or (ii) acts in reckless disregard of the truth or falsity of the information.

2. The term "designated health services" means any of the following items or services: clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies home health services; outpatient prescription drugs; or inpatient, outpatient hospital and Rural Health Clinic services.

Questions concerning any aspect of this policy/guideline should be referred to the Chief

Compliance Officerat 559-685-3407.

The policy/guideline replaces and supersedes all previous policy/guidelines and is effective immediately.

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Descriptive Type: Revised

Document Number: 10-1002.2

Attachments: None

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Delbert Bryant, Chief Compliance Officer

Typist: Delbert Bryant

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Forward To: Policy Binders – (PBX and Administration) and Post to Intranet Site

Disposition: Copy and Distribution – Administration

Comments:

TULARE LOCAL HEALTH CARE DISTRICT
dba TULARE REGIONAL MEDICAL CENTER

POLICY / GUIDELINE

TO: All Departments

FROM: Administration

SUBJECT: Organizational Development and Educational Services Plan

I. Purpose:

The Organizational Development and Educational Services Department's purpose is to provide education primarily for Tulare Regional Medical Center (TRMC) staff. The Department also may provide resources for patients, lay and healthcare professionals in the community. We strive to enrich and advance the professional practice and competence of our organization's staff, ultimately affecting the health and well-being of the clients who present to Tulare Regional Medical Center (TRMC) for their health care.

The mission of the department is to function as a team to provide the best quality educational services, in conjunction with current standards, best practices and evidence-based research. The Education Department aligns their goals and strategies to the Mission, Vision and Values of the organization in order to support the provision of "best-in-class, performance-driven, integrated delivery system focused on wellness and improving the health status of the community."

II. <u>Qualifications of Staff</u>

The staff consists of one PT Assistant Coordinator/Secretary and one FT BSN Staff Educator trained in the Principles of Adult Learning.

III. Strategic Initiatives:

Educational Services Strategic Plan includes:

1. Enhance Organizational Development
2. Assure competency at the bedside promoting critical thinking skills
3. Revise the Orientation process from hire to six months employment
4. Promote employees to a higher level of learning
5. Enhance Educational Resources

Effective Date:	(13)	Ancillary Services Educational Services:
Approved:		Organizational Development and Educational Services Plan
Board of Directors:		13-12,001

6. Establish Tulare Regional Medical Center leadership in the community through education and involvement in service.

IV. Standards of Practice

The Education Department integrates its services within the overall organization in the following ways:

- Establishment of a Learning Network.
- Facilitates the process of learning by assessment, planning, development, implementation and evaluation of educational activities.
- Collects data and information related to educational needs (NNSDO, 2010).
- Analyzes issues and trends to determine learning needs and desired outcomes (Professional development Team, yearly).
- Establishes and implements a plan prescribing strategies and resources to achieve expected outcomes (NNSDO, 2012).
- Develops learning objectives considering cognitive, affective and psychomotor domains of learning (Bloom, 1956).
- Designs and employs educational programs through strategies and techniques promoting positive learning and practice environment with the effective use of sound educational principles and evidence-based practice (NNSDO, 2012).
- Evaluates progress toward attainment of outcomes through formative and summative assessments (NNSDO, 2010).
- Promotes learning in the following elements: virtual learning environments, independent self-learning, simulation labs, one's practice environment, classroom and academic (ANCC, 2009).
- Provides consultation to influence plans, enhance the abilities of others and effect change (NNSDO, 2012).
- Participates in multi-disciplinary and interdisciplinary education planning processes to meet the learning needs of the organization.
- Adheres to organization-wide policy and procedure.

V. Customer Service Standards:

A. Provide direct service in a professional, helpful manner Monday through Friday 0800 to 1630.
B. If direct service is not possible (i.e.; instructors teaching a class, in hospital, etc.) voice mail is available with response as soon as possible.
C. Voice Mail service after 1630 each day and weekends .
D. Customer friendly environment utilizing the TRMC **Service Excellence** Program concepts and principles.

VI. Organizational Development/Staff Education/Community Education

A. Organizational Development

The Organizational Development role within the hospital consists of the practice of analysis, problem solving, action planning and evaluation, especially related to organizational change and effectiveness.

B. Staff Education

1. Staff Education programs are categorized into three areas:

    1. Orientation
    2. Staff development
    3. Continuing Education

2. Content and **priority** are based on four key factors:

    1. Essential for helping staff to achieve, enhance or maintain competence to do their assigned job.
    2. Required by an external accreditation, regulatory or licensing agency (i.e., CMS, DNV, OSHA or State).
    3. Identified performance gaps indicting a skill or knowledge deficiency.
    4. Driven by internal organizational standards or requirements.

C. Community Education

In an effort to meet the health education needs of the community, TRMC Educational Services department assesses, designs, implements and evaluates a limited amount of educational programs to promote lifelong learning.

VII. Implementation

A. TRMC Educational Services collaborates, consults and prioritizes with other departmental leaders to facilitate educational programs, which affect all TRMC employees.

B. Department specific educational needs are addressed at the unit level through the unit department leader and designated educator, with assistance from Educational Services.

C. Managers and unit educators organization-wide communicate with the Education Department regarding educational activities in a timely manner (CE offerings >1

month). This assures inclusion in the yearly and monthly calendar and assistance in planning, if needed (i.e., consultation, instructors, room, CE [per Policy # 13-12004 Continuing Education for Clinical Staff], advertising, participant registration, supplies provided, etc.).

D. Regularly scheduled education meetings are conducted through the Professional Development Team, reinforcing a collaborative working relationship and assurance of use of sound educational principles.

E. Departmental leaders will support and schedule time for staff to attend educational opportunities within the organization to assist the employee in maintaining competence.

F. Employees are encouraged to participate in outside professional educational conferences related to their positions. All outside participant attendees should send a copy of the certificate of attendance to the education department for inclusion in the employee's records.

G. TRMC Educational Services plans and provides a General yearly calendar (calendar year). The calendars outline all routine and mandatory classes, as well as continuing education programs.

H. Staff input (yearly and per class) for content and program prioritization is considered in planning all educational events.

I. Educational Services supports and provides classroom space, as well as other resources as necessary to academic programs and students/instructors, when available.

J. All educational programs provided by Educational Services are educationally sound with written curricula (see Educational Program Record). This includes outline, class description, learning objectives, lesson plan, teaching aids, references used, as well as methods of evaluation; which requests input and feedback from participants regarding future learning needs. Appropriate and qualified instructors are chosen.

K. All programs and participants are documented in the "Education Tracker." Reports are provided to department leaders upon request.

VIII. ROUTINE PROGRAMS OFFERED:

A. Organizational Development/Continuing Education/Staff Education:

1. General Orientation **M -** monthly (first Monday)

2. Centralized Annual Update **M** - Once a year (fall)

3. Computer Training

4. Clinical Orientation - monthly (following General Orientation) **M**

5. Nonviolent Crisis Intervention- Twice yearly

6. Advanced Cardiac Life Support - Twice yearly

7. Pediatric Advanced Life Support - Twice yearly

8. Neonatal Resuscitation Program - Twice yearly

9. Vascular Access Device Update - Monthly with Clinical Orientation an yearly with CAU

10. Cardiac Dysrhythmia - Twice yearly

11. Preceptorship - Twice yearly

12. Domestic Violence and Abuse Reporting - Online

13. Infection Prevention and Reduction of HAIs- General Orientation/Annual Update, and online as needed

14. Online Education Modules-*various topics as needed*

15. Fire extinguisher practice, fire lifts/carries – PRN

16. CNA continuing education Classes - As needed

17. Other classes - As designated per need

M-mandatory

B. Community Education:

1. Perinatal Series - Monthly

2. BLS HCP CPR Classes – Monthly

3. Basic Skills Diabetes classes – Monthly

4. Industrial CPR/First Aid – As requested

5. Others identified by need

IX. ON LINE INTRANET EDUCATION

TRMC Educational Services maintains an intranet website related to educational needs of staff. Various classes are listed with descriptive information, healthcare related websites (including cultural diversity), as well as some educational programs and online modules for learning.

Questions concerning any aspects of this policy/guideline should be referred to Administration.

This policy/guideline replaces and supersedes all previous policies/guidelines concerning this matter and is effective immediately.

Descriptive Name: Organizational Development and Educational Services Plan

Descriptive Type: Revised

Document Number: 13-12,001

Attachments: None

Author: Carol Bradford

Typist: Melissa Arend

Creation Date: 11/30/06

Revision Date: 07/19/16

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Committee Review and Approval:	Approval Date:	Comments:
Board of Directors		

Effective Date:

Forward To: Policy Binders – (PBX and Administration) and Post to Intranet Site

Disposition: Copy and Distribution - Administration

Comments:

TULARE LOCAL HEALTH CARE DISTRICT
dba TULARE REGIONAL MEDICAL CENTER

POLICY / GUIDELINE

TO: All Departments

FROM: Administration

SUBJECT: American Heart Association Community Training Center

POLICY:

As a Community Training Center for the American Heart Association, Tulare Regional Medical Center is contracted to provide BLS, PALS, and ACLS classes for the purpose of educating hospital staff, other health professionals in the community, individuals involved in public safety and the general community. Tulare Regional Medical Center agrees to abide by the terms of the contractual agreement and the regulations and guidelines of the American Heart Association.

PROCEDURES:

A. Classes

1. The Training Center Coordinator is responsible for coordinating the Basic Life Support Classes. The Staff Educator coordinates the Advanced Life Support Courses. Class schedules for the year are published in the Education Calendar and distributed to staff and the community.

2. Basic Life Support (BLS, HCP) classes are routinely offered monthly for a fee of $60.00 for HealthCare Provider. Both Advanced Cardiac Life Support (ACLS) and Pediatric Advanced Life Support (PALS) are offered twice a year for a fee of $60 for TRMC employees and $220 for outside healthcare professionals. Re-recognition classes for TRMC employees are $40 and $130 dollars for outside professionals.

3. Class fees are refundable only if the student is not accepted as a participant in the class, class is cancelled or the participant notifies the department of withdrawal at least two working days prior to the scheduled date.

Effective Date: (13) Ancillary Services
Educational Services:
American Heart Association
Community Training Center
13-12,002

APPROVED:

Board Of Directors:

4. Hospital staff attending a BLS class make a ten-dollar deposit, which is refunded when the employee attends the class and returns the loaner book.

B. Instructor Courses/Renewal

1. Instructor Candidates must complete an instructor course at their own expense. Instructor candidates are encouraged to observe one or more CPR classes taught by an experienced instructor.

3. Within 6 months of instructor course completion, the instructor candidate is required to teach a class under the observation of the training center facility or lead instructor. An instructor candidate monitoring form is completed at that time and forwarded to the training center coordinator for processing. An instructor card for the appropriate discipline is issued to the successful candidate.

4. Each instructor is responsible for purchasing and maintaining the instructor manuals and provider text for the courses they teach. Supplemental materials for the courses will be provided by the training center.

5. Instructors must maintain current Provider status and teach a minimum of four (4) courses per 2 -year cycle.

6. Instructors are expected to attend scheduled updates and renewal courses taught by the training center faculty. Each instructor has access to the Instructor Network on the AHA website.

7. Teaching ability will be monitored and documented during the renewal course or on an individual basis every two years.

C. CARDS

1. American Heart Association course cards certify successful completion of the course and are valid for two years.

2. The TC Coordinator or designee is responsible for ordering all course cards.

3. All cards are stored in a locked cabinet for security purposes.

4. Instructors will issue cards on successful completion of the course, or within 30 days of completed paperwork.

5. AHA cards expire on the last day of the month noted for recommended renewal. There is no grace period for expired cards. If a card is expired less than six months, the training center faculty may decide whether the student will be required to attend the initial course or just a renewal session.

6. If an instructor allows his/her card to expire it will be left to the discretion of the training center facility as to whether the instructor must attend a new candidate instructor course.

7. Students requesting a replacement card will be issued a card marked *duplicate* at the top. Copies of duplicate cards will be stored with the copy of the original card.

D. Textbooks/Tool Kits

1. Each student attending an AHA course will have the current appropriate AHA course textbook readily available for use before, during, and after the course. The student can either choose to purchase the book or obtain a loaner. Students who arrive at class without a text will be issued a loaner for use during the class.

2. Instructor *Tool Kits* are stored in the Education Department and are readily accessible to all Instructors.

E. Manikins

1. Manikins are stored in the Educational Services Department.

2. Life Safety manikins will not be loaned or rented to agencies or individuals for the purposes of providing training not solicited or scheduled by the training center.

3. Manikins are to be cleaned following classes as follows:

    a. Using gloves and protective clothing, remove the face, old tubing, and lungs.
    b. Discard the lungs and tubing.
    c. Wash all the mannequin faces, pocket masks and valves with warm soapy water, or disinfectant wipes.
    d. Soak all of the above in disinfectant (Alrkem A-456-N) for 2 minutes. Make the solution with one capful of disinfectant and four quarts of warm water.
    e. Rinse and dry the mannequin faces and allow the masks and valves to air dry on paper towels.

f. Wash the exterior of the mannequins with soap and water, rinse and dry well or use disinfectant wipes.
g. Remove and discard disposable gloves. Put on a new pair of gloves.
h. Insert new lungs and tubing.
i. Replace mannequin faces and connect to tubing. Discard gloves.
j. Place clean mannequins in appropriate storage case and the pocket masks and valves in their respective plastic bags with the "clean" label.

F. Record Maintenance

1. Records for each course taught through the training center will be maintained on file for a minimum of four years. These records will include the course roster, attendance sheets, copies of the course completion cards, individual answer/skill performance sheets, class registration forms, participant evaluations and class data summary sheets detailing the number of participants, learning hours and profit/loss.

2. Each student attending a life safety course will be registered in the Education Tracker software program for tracking purposes.

3. Instructor binders will be kept current and include a signed liability form, instructor/provider record form, copy of the current instructor card, instructor monitor forms and a report of classes taught.

G. Performance Improvement

1. Each student is asked to complete a subjective evaluation form rating, among other things, the instructor's preparation, knowledge and presentation of the material.

2. Evaluation results will be summarized and reported. Ratings below the 90% threshold will be reviewed and recommendations for improvement will be discussed with the instructor.

H. Internal Disputes

1. If a class instructor is unable to resolve a disputed issue during a CPR class, it is the responsibility of the instructor to notify the training center coordinator. The training center coordinator will approach the appropriate training center faculty for resolution.

2. The American Heart Association will only become involved in disputes, complaints or problems that are listed in the current Program Administration Manual (PAM) and according to the procedure outlines.

Questions concerning any aspect of this policy/guideline should be referred to Administration.

This policy/guideline replaces and supersedes all previous policies/guidelines and is effective immediately.

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