

General Acute Care Hospital Relicensing Surveys (GACHRLS)

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Objectives:

- State the purpose of the GACHRLS
 - Understand the GACHRLS process
 - Find and identify the GACHRLS survey tools
 - Know how to access the GACHRLS resources
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Why are we doing the GACHRLS?

- Required by statute H & S 1279
- Promote and ensure quality of care in hospitals
- Verify compliance with State statutes and regulations
- Ensure program-wide consistency in the survey methodology
- To work smarter with limited staff



When are we doing the GACHRLS?

- Hospitals shall be surveyed no less than every three years
- Currently, we are following the consultant pharmacists' schedule for MERP surveys.
- CDPH will not provide GACHs with advance notice of the survey.



How long should a survey take?

- Currently, the Department believes that the surveys will take 3 to 5 days.
- Factors to consider:
 - ▶ Work schedules of the district office
 - ▶ Some offices work a 4 day workweek, some do a 90-8-80, and some do 5 day workweek
 - ▶ Size and complexity of the hospital
 - ▶ Initial findings and the emergence of concerns.

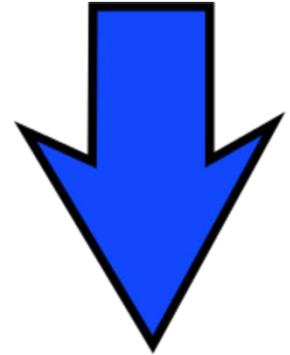
GACHRLS Implementation Plan:

Phase I- Development & Beta Testing
Completed June 2015

Phase II- Pilot testing for 5 District Offices
Completed September 2015

**Phase III- Finalization of the GACHRLS Process
for all District Offices** **Completed January 2016**

Phase IV- Full Roll-Out **Starting March 2016**



GACHRLS

- Surveys shall evaluate the facility's compliance with statutory and regulatory requirements, particularly those addressing quality of care.
- Each survey will consist of a review of nursing, pharmacy, and identified compliance concerns obtained during offsite preparation.
- Each survey will consist of a review current staffing when visiting a nursing unit. Ensure that it meets the requirements.

GACHRLS survey team size

Size of Hospital	Recommended Minimum Survey Team
Small – 100 beds or less	<ul style="list-style-type: none"> • Registered Nurse (RN) (Team Coordinator) • Medical Consultant * • Nutrition Consultant* • Pharmaceutical Consultant • Additional RN surveyor with experience, if the Team Coordinator does not have knowledge and experience in evaluating hospital administration and environment • Additional team members as indicated
Medium – 101 –199 beds	<ul style="list-style-type: none"> • Registered Nurse (RN) (Team Coordinator) • Medical Consultant * • Nutrition Consultant* • Pharmaceutical Consultant • Two additional RN surveyors, at least one with experience, if the Team Coordinator does not have knowledge and experience in evaluating hospital administration and environment • Additional team members as indicated
Large – 200 or more beds	<ul style="list-style-type: none"> • Registered Nurse (RN) (Team Coordinator) • Medical Consultant * • Nutrition Consultant* • Pharmaceutical Consultant • Three additional RN surveyors, at least one with experience if the Team Coordinator does not have knowledge and experience in evaluating hospital administration and environment. Additional team members as indicated
	<p>* Medical Consultant and Nutritional Consultant may be onsite or remote.</p>

GACHRLS Sample Size and Selection

- Surveyors will select patients from the service areas to which the surveyors are assigned.
- A total sample size will consist of 6 to 10% of the current inpatient census with a minimum of 30 patients for patient record review, and expand the sample size as necessary.



GACHRLS

Survey Protocols

- Task 1 Off-site survey preparation
 - Task 2 Entrance activities
 - Task 3 Information gathering and investigation
 - Task 4 Preliminary decision making and analysis of findings
 - Task 5 Exit conference
 - Task 6 Post-survey activities
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Task 1 is offsite preparation

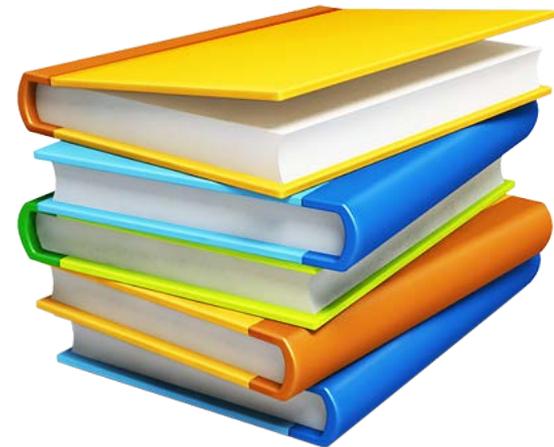
Purpose of Task 1:

- Analyze compliance information
- Base compliance history on the past 3 years
- Develop a list of concerns
- Develop a plan of investigation



What's in a facility file?

- List of basic services
- List of supplemental services
- List of outpatient services and location
- Number of beds and layout
- Program flex approvals
- Newest construction/added services



What databases do we look at?

- ELMS facility profile. ELMS stands Electronic Licensing Management System
- Administrative Penalties, served or pending
- Substantiated AEs
- Past MERP and Patient Safety Survey results
- Substantiated Complaints and ERIs
- Recert or validation surveys
- Current situation reports



An example of a surveyor's prepared report for offsite meeting

Smithsonian Hospital:

- ▶ GACH ELMS DATA BASE and FILE review for the period June 1, 2011 through June 15, 2014.
- ▶ 55 complaints/ERI on file – 18 of the most recent do not have any data attached, meaning there is no information related in the assigned category area if substantiated or unsubstantiated. No program flexes in the file.
- ▶ The following categories were substantiated and issues deficiencies. There was no documented information on administrative penalty assessments per file review or CDPH website for hospital AP's.
- ▶ Patient rights
- ▶ PHI Breach 11/2011 dc instructions to wrong patient
- ▶ PHI Breach 11/2011 the wrong patient was dispensed a bottle of blood pressure medication from the Outpatient pharmacy.
- ▶ PHI Breach 1/2012 patient info faxed to wrong location
- ▶ PHI Breach 3/2012 the wrong patient was dispensed a medication, which was intended for Patient 1, from the outpatient pharmacy
- ▶ PHI Breach x 2 4/2012 Dc instructions and fax
- ▶ PHI Breach 8/2012 wrong documents
- ▶ PHI Breach x 3 9/2012 prescription labels wrong patient
- ▶ PHI Breach 10/2012 fax
- ▶ PHI Breach 11/2012 photo
- ▶ PHI Breach 12/2012 pharmacy
- ▶ PHI Breach 2/2013 fax
- ▶ Formal grievance 1/2013 no response in writing from hospital

An example of a prepared report for offsite meeting cont...

- ▶ Surgical service
 - ▶ 10/2011 – no documentation in the perioperative nursing notes that a portion of a surgical instrument broke off during a surgical procedure and was unintentionally retained in Patient 1's left leg.
 - ▶ 6/2012 – wrong knee implant
 - ▶ 11/2012 – broken implant, no x-ray
- ▶ Pharmacy service
 - ▶ 11/2011 – **outpatient pharmacy** policies and procedures were developed and implemented; pharmacists were not trained and competent with the facilities outpatient pharmacy processes and protocols. A bottle of blood pressure medication was dispensed to the wrong patient in the outpatient pharmacy.
 - ▶ 3/2012 – **outpatient pharmacy**, Patient 1 was given Patient 2's medication.
 - ▶ 6/2012 – meds expired and available for use – emergency crash cart on the medical/surgical unit contained 2 expired syringes.
- ▶ Nursing service
 - ▶ 12/2011 – fall FX – no care plan update
 - ▶ 6/2012 – outpt colonoscopy mishandled specimen, nursing documentation of event
 - ▶ 7/2012 – care planning – dialysis done at wrong rate, charge nurse assigned patients and counted in ratio
 - ▶ 5/2013– nursing competency related to auto infusion device

An example of a prepared report for offsite meeting cont...

- ▶ Physician Services
- ▶ 6/2012 – md not follow rules and regs regarding colonoscopy specimen. Md placed scope in vagina by mistake and removed tissue samples. COP complaint validation survey triggered from the incident and deficiencies same as state.

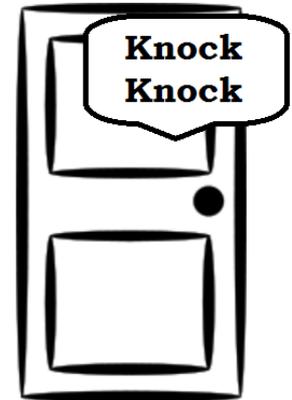
- ▶ Physical plant
- ▶ 7/2012 – preventive maintenance overdue dialysis machine
- ▶ Recommended tools for surveyors to bring:
 - ▶ Medication Pass worksheet
 - ▶ PSLS smart tools, 22 pages
 - ▶ T 22 GACH regs
 - ▶ IJ critical pathway

- ▶ Please note the kitchen was inspected on 5/28/14. The kitchen that serves the 57 GACH also is the kitchen for the 122 bed DP/SNF. The cite for that survey facility failed to maintain sanitary conditions for food preparation that had the potential to affect all residents in the facility. Specifically, water temperature for a 3 step process to manually wash dishware was not hot. This had the potential for harm to all residents in the facility due to contamination of dishware used to prepare resident meals.

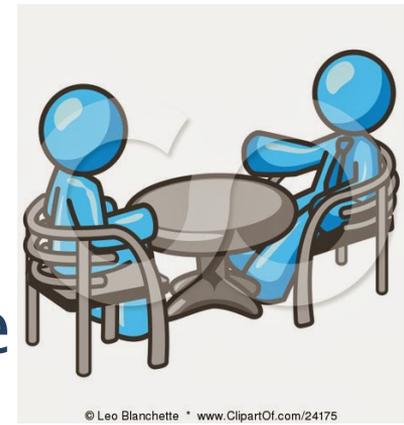
Task 2 is Entrance Conference

Purpose of Task 2:

- Explain the survey process to the hospital representatives
- Introduce the survey team members, present business cards.
- Obtain information and documents needed to conduct the survey
- Provide a survey activity schedule to the facility



Entrance Conference Basics



- Establish expectations for both side regarding communications
- Inform the facility whether consultants or other team members will join the survey at a different time
- Information shared should be specific, brief, and accurate

Essential steps of an Entrance Conference

- Ask for introductions of attending staff
- Explain what a GACHRLS is
- Announce whether complaints and ERIs will be done during the survey (District Office could send complaints and ERIs with the team)
- Discuss medical record access needs
- Acknowledge that survey interviews will be conducted confidentially



Essential steps of an Entrance Conference cont...

- Have the hospital select a staff member to go over the entrance list. Not all items on the list is needed.
- Verify license information, such as, services provided, and locations of services and/or campuses
- Set up a meeting for a later time to go over the program flexes
- Indicate that hospital tours are unnecessary
- Clarify that since this process is State, there is no acknowledgement of past non-compliance.



Program Flex discussion example



CDPH Program Flexes

Flexes Still in Effect

Date	Unit/Area	Flex Type	Regulation(s)
12/20/1993	Dietetic Services	15 hour time span between evening meal and breakfast; Staffing for breakfast meal delivery; and nourishing bedtime snack	§ 70273 (a) (2)
6/16/1994	Transport	Staff required for neonate transport; physician/staff for certain conditions	§ 70483 (a) (4)
3/6/1997	Cardiovascular surgery	PA/RN in place of 3rd surgeon for identified cardiovascular procedures	§ 70435 (b) (2)
10/1/1998	PICU	Increased patient accommodation; rooms 2501, 2503, 2504, 2505, 2506, 2524 and 2525	§ 70495 (d) (e)
8/6/2003	Satellite Units; Hanford, Merced, St Agnes	Staffing ratios for Intermediate Care continue 1:3	§ 70217
9/3/2003	Family Center East ICU	Staffing – ratio change	§ 70217
1/30/2004	Staffing	Nurse staffing during meals and breaks	§ 70217 (a)
9/22/2004	CMCC (Rural Health Clinic)	Employee TB testing	§ 70723
11/2/2005	Medical Records	Approval for off-site medical record storage – change of address	§ 70751 (f)
10/25/2011	Cath Lab	List of approved diagnostic procedures	§ 70438.1 (b)

Per discussion 8/6/2014 with CDPH Survey Team during CDPH Beta Test Licensing Survey
8/4-8/2014

Program Flex discussion example

CDPH Program Flexes

Flexes to be Retired

Date	Unit/Area	Flex Type	Regulation(s)
5/28/1976	Pharmaceutical Services	Verbal orders	§ 70263 (g) § 71233 (g)
2/8/1990	Observation	Provision of observation services for up to 24 hours	§ 70525
9/8/1994	Supplies	Dating/out dating of sterilized materials	§ 70833 (c) (3)
2/27/2002	NICU	Co-bedding of twins and multiple infant	§ 70487 (a) (1)

Per discussion 8/6/2014 with CDPH Survey Team during CDPH Beta Test Licensing Survey
8/4-8/2014

Program Flex discussion example

CDPH Program Flexes

Expired/Revoked Flexes

Date	Unit/Area	Flex Type	Regulation(s)
6/15/1998	Medical Records	Approval for off-site medical record storage	§ 70751 (f)
11/25/2000	NICU	Increased patient accommodation	§ 70485 (d)
9/19/2002	NICU	Increased patient accommodation	§ 70485 (d)
6/3/2003	Medical Records	Approval for off-site medical record storage – change of address	§ 70751 (f)
6/2/2003	ED	Extension of flex allowing a temporary conversion of a separate ED waiting room into a patient treatment area. – 90 day interim use + 90 day extension	
9/9/2003	ED	Extension of flex allowing a temporary conversion of a separate ED waiting room into a patient treatment area. – 90 day interim use + 90 day extension	
10/16/2003	ICU Space	Use of Rooms 2501, 2516, 2508 and 2610 during high census	§ 70499 (a)(1)(3)
12/3/2003	ED Minor Care	Utilization of Day Surgery for ED Care	
12/15/2003	ED	Utilization of Day Surgery Area for ED Care.	
8/15/04	NNN	Increased accommodation through weekend	§ 70485 (d)

Per discussion 8/6/2014 with CDPH Survey Team during CDPH Beta Test Licensing Survey
8/4-8/2014

Program Flex discussion example

CDPH Program Flexes

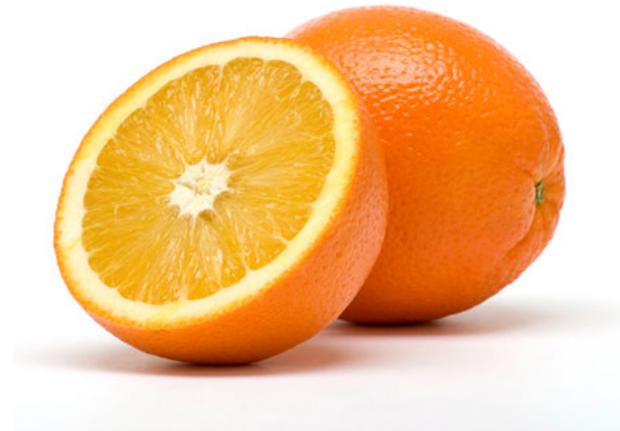
**Program Flex Request; No CDPH Response Documentation Available in Records
Request for status update or re-issue**

Requested Date	Unit/Area	Flex Type	Regulation(s)
7/30/2004	Endoscopy	Endoscopy suite conversion; specific procedures performed	
5/15/2012	NICU	Flexibility for Bedding and staffing lower acuity patients	

Per discussion 8/6/2014 with CDPH Survey Team during CDPH Beta Test Licensing Survey
8/4-8/2014

Feedback from Providers

- Communication is key
- Make sure that both sides are talking about the same thing
- Apples are apples and oranges are oranges





- Services
- Health Information
- Certificates & Licenses
- Publications & Forms
- Data

Home > Programs > Licensing and Certification > **General Acute Care Relicensing Survey - Coming Soon**

General Acute Care Relicensing Survey

The purpose of a GACH Relicensing Survey (GACHRLS) is to promote quality of care in hospitals, verify compliance with State regulations and statutes, and ensure a program wide consistency in the hospital survey methodology. The GACH Relicensing Survey, when fully implemented, will merge California's licensing regulation and statute requirements with elements of the former stand-alone Medication Error Reduction Plan (MERP) survey and Patient Safety Licensing Survey (PSLS) into one survey process.

These documents are in draft form at this time. Any modifications made to these documents will be uploaded after they are approved. The date of modification will be indicated on the document's title and the document. Full implementation of the GACH Relicensing Survey is anticipated for early 2016.

[Process Guidance](#)

The Process Guidance document provides the regulatory authority for the GACH Relicensing Survey, the design of the survey protocols, methods of information gathering for the surveyors, and the mechanics of surveyors' non-compliance decisions. The core elements of the survey will be the provision of nursing and medical care, the provision of medications, and previous non-compliance issues identified during a three year lookback of the file history of the facility. Included in this lookback would be State and Federal survey deficiencies, substantiated complaints and/or entity reported events, and administrative penalties

(Revised 5-21-2015)

[Regulations with Survey Procedures](#)

The Regulations with Survey Procedures document contains a comprehensive listing of California's laws and regulations for surveyors' reference with recommended surveyor procedures

(Revised 5-8-2015)

[General Entrance List](#)

The Entrance List is a checklist of documents and policies that may be requested from the facility at the start of a survey. A surveyor will go over the list with hospital staff during the entrance activities.

(Revised 5-26-2015)

[Pharmacy Entrance List](#)

The MERP Entrance List is a checklist of documents and policies that may be requested from the facility by the pharmaceutical surveyor at the start of a survey

(Revised 5-21-2015)

[Survey Activity Schedule](#)

The Tentative Timeline provides a preliminary overview of the anticipated survey activities

(Revised 5-21-2015)

[Medication Pass Worksheet](#)

The Medication Pass Worksheet provides a preliminary overview of the anticipated survey activities

Task 3 is Information Gathering and Investigation:

Purpose of Task 3:

- Determines compliance with statutory and regulatory requirements
- Review and verify supplemental services listed in the facilities file and on license



Survey Locations may include:

- Various department services and locations
- Inpatient/Outpatient Care areas
- Complex outpatient care/
supplemental service
locations



Patients and facility systems review

- Observations of care/services provided
- Interviews – verify observations
- Document / Record reviews



Surveyor and hospital staff misconduct

- Conflicts and misunderstanding can occur with any human interaction
- Please feel free to bring your concerns regarding the behavior of a surveyor to the survey's team coordinator. Unless, the team coordinator is the problem, then contact the district office supervisor, administrator, or manager.
- If you prefer not to talk to the team leader, contact the district office supervisor for any surveyor concerns
- No retaliation is allowed or tolerated

When could a survey “flip” from being a State process to a Federal process of both?

- The rule of thumb is that the CMS (Federal) must be contacted if the team identifies sufficient violations to consider that a Condition of Participation (COP) is not met
- CMS must also be notified if an IJ situation has been identified
- Once involved, CMS may call for a Federal survey and directs the focus and direction of the Federal survey. Concurrent or separate?
- The State survey process will finish and a 2567 will be generated for that survey



Task 4 is Preliminary Decision Making Analysis of Information

Purpose of Task 4:

- Review findings as a team
- Determine potential Administrative Penalties
- Prepare for exit conference



In The Survey Process...

The survey team must do the following during Task 4:

- Each deficiency must be assessed for AP
- Consider deficiency severity category:
Scope and Severity Matrix
- If above Severity Level 2 review for AP



Must consider Administrative Penalties

Administrative Penalties

Title 22, Division 5, Chapter 1.

Article 10

Health and Safety Code

1280.3



Article 10 . Administrative Penalties

- Became law April 1, 2014
- “The department shall...establish...criteria to assess...administrative penalty against a health facility...”

Severity and Scope Matrix

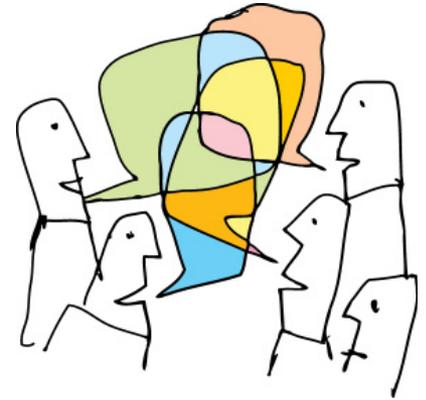
	AP Type	Description of Severity Level	SCOPE		
			Isolated	Pattern	Widespread
S E V E R I T Y	IJ AP	Severity Level 6 – Immediate jeopardy to patient health or safety that <u>caused the death</u> of a patient	100%	100%	100%
		Severity Level 5 – Immediate jeopardy to patient health or safety that <u>caused serious injury</u> to a patient	60%	70%	80%
		Severity Level 4 – Immediate jeopardy to patient health or safety that is <u>likely to cause serious injury or death to a patient</u>	40%	50%	60%
	non-IJ AP	Severity Level 3 – <u>Actual patient harm</u> that is not immediate jeopardy	60%	80%	100%
		Severity Level 2 – No actual patient harm but with potential for more than minimal harm, but not immediate jeopardy (non-IJ harm)	20%	50%	70%
	No AP	Severity Level 1 – No actual patient harm but with potential for no more than minimal harm	No Penalty		
		Minor Violation	No penalty		

New Criteria for Assessing AP Amounts

Adopted regulations provide a methodology for calculating the appropriate final AP amount based upon the eight specific criteria listed in Health and Safety Code 1280.3 paragraph (b):

- 1) The patient's physical and mental condition.
- 2) The probability and severity of the risk that the violation presents to the patient. – (Reflected in Scope and Severity Matrix)
- 3) The actual financial harm to patients, if any.
- 4) The nature, scope, and severity of the violation. – (Reflected in Scope and Severity Matrix)
- 5) The facility's history of compliance with related state and federal statutes and regulations.
- 6) Factors beyond the facility's control that restrict the facility's ability to comply with this chapter or the rules and regulations promulgated thereunder.
- 7) The demonstrated willfulness of the violation.
- 8) The extent to which the facility detected the violation and took steps to immediately correct the violation and prevent the violation from recurring.

Task 5 is exit conference:



Purpose of Exit Conference:

- To inform hospital staff of the survey team's preliminary findings
- Gives the hospital more time to understand the proposed deficient practices and start their POC right away.

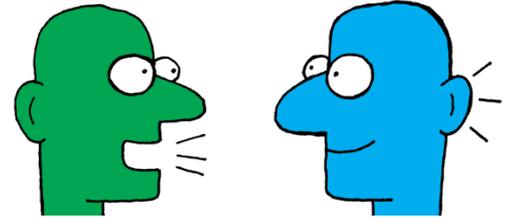
Team and facility preparations for the exit conference

- Some team members may conduct their exit conference ahead of the full team.
- Before starting, establish whether there will be an audio or visual recording of the exit. Survey team must leave with a copy!



Exit Conference Basics

- Introduce survey team members and have hospital representatives introduce themselves
- Thank everyone
- Establish expectations for both sides regarding communications. Questions during presentation or at the end?



Exit Conference Basics cont...

Explain the following:

EXPLAIN
THIS



- Information shared are preliminary findings
- All official findings will be mailed in writing within 10 working days (or 30 days if a non-IJ found during survey)
- The facility may offer addition information prior to leaving the premises

Exit Conference Basics cont...

- Present the findings, avoid specific regulations by number
- Do not reveal staff or patient names while discussing findings
- If complaints and ERIs were done during the survey, what is the status of them upon exit.

CONFIDENTIAL

Exit Conference Basics cont.....

- If an immediate jeopardy or non-immediate jeopardy was found during the survey, which might rise to an administrative penalty, use the script provided in the AP P & P

<http://cdphintranet/sites/Incintranet/Pages/PPManualVolumeandFacilityType.aspx>

Facility must be informed a penalty may be given

- At the conclusion of the exit, encourage that the facility complete the licensing survey evaluation available on line.

Public Web Site

▶ <http://www.cdph.ca.gov/programs/LnC/Pages/GeneralAcuteCareRelicensingSurvey-ComingSoon.aspx>

▶ Questions:

