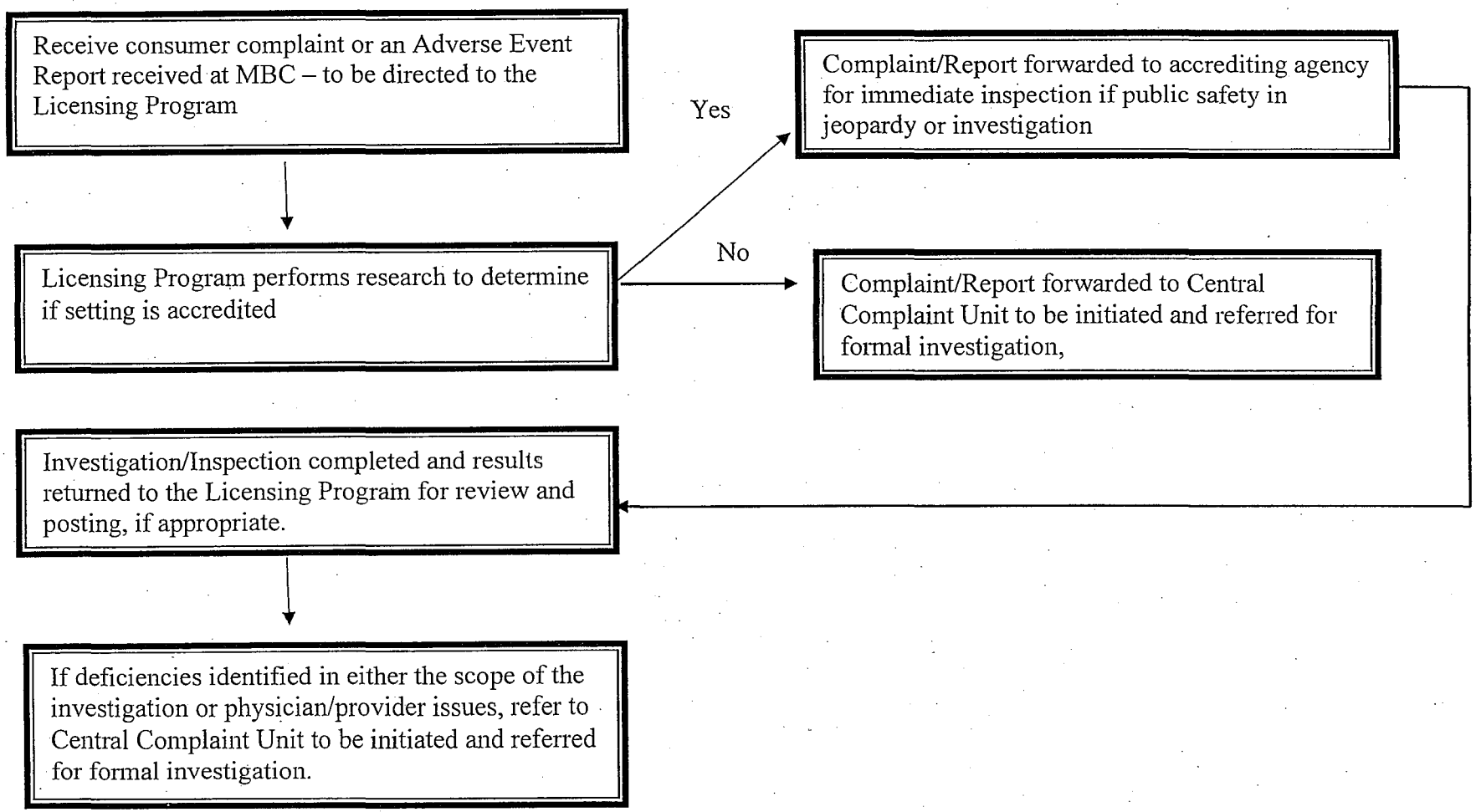
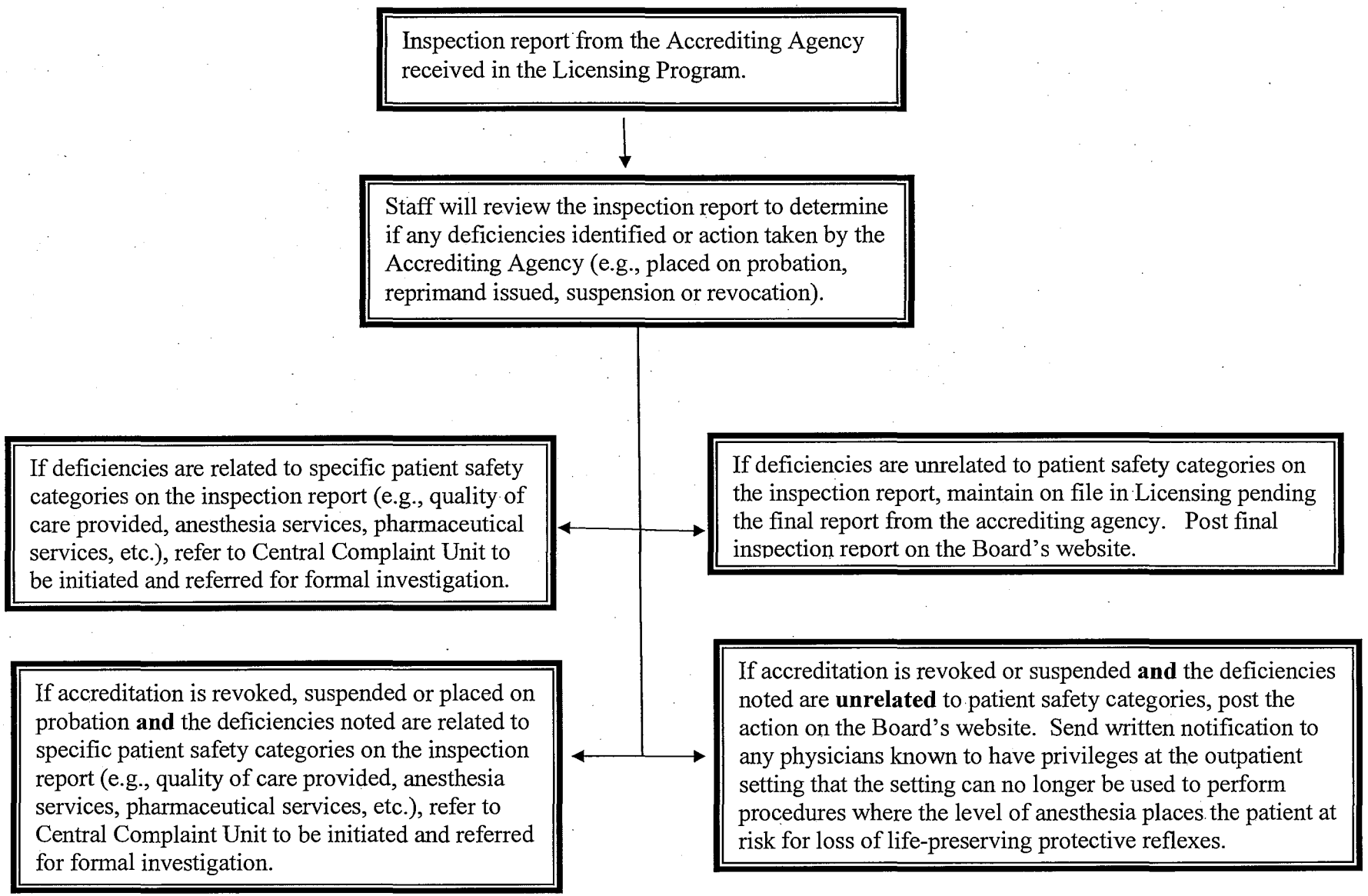
Complaint Process



Enforcement Response to Action taken by an Accrediting Agency



ADVERSE EVENT REPORT
OUTPATIENT SURGERY CENTERS

Health and Safety Code Section 1248.15 makes outpatient settings subject to the adverse events reporting requirements mandated in Health and Safety Code Section 1279.1 as follows; Facilities shall report an adverse event no later than **five days** after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or **safety** of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. The outpatient setting must also report the incident to the affected patient or the patient's representative by the time of notification to the department.

Facility Information			
Facility Name			
Facility Address			
Contact Person Preparing Report:			
Contact Phone Number:			
Practitioner Information			
Name of Practitioner Performing Procedure:			
License No/License Type			
Patient Information			
Patient Name	**Last Name**		**First Name**
Patient Address Information			
Patient Identifier (enter one of the following)			
Medical Record No.		Social Security No	Patient ID No.
Adverse Event Information			
Date and Time Event Occurred		**Date of Report**	
Date and Time Event Detected		**Date Patient/Pt. Rep. Notified**	
Adverse Event Category	o Surgical Event o Product/Device Event o Patient Protection Event	o Care Management Event o Environmental Event o Criminal Event	
Description of Event:			

Signature of Person Preparing Report **Date**

If a licensee fails to report an adverse event pursuant to Section 1279.1, the department may assess a civil penalty in the amount not to exceed $100 for each day that the adverse event is not reported pursuant to Health and Safety Code Section 1280.4

ADVERSE EVENT DETAIL

Surgical Event, including but not limited to:

- o Surgery performed on a wrong body part inconsistent with the documented informed consent
- o Surgery performed on the wrong patient
- o Wrong surgical procedure performed on a patient
- o Retention of foreign object in a patient after surgery or other procedure
- o Death during or up to 24 hours after induction of anesthesia in a normal, healthy patient
- o Other_____

_____

_____

Product or device events, including but not limited to:

- o A patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the facility
- o A patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this section, "device" includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.
- o A patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism
- o Other _____

_____

_____

Patient protection events, including but not limited to:

- o A patient death or serious disability associated with patient disappearance for more than four hours
- o A patient suicide or attempted suicide resulting in serious disability while being cared for in a facility
- o Other _____

_____

_____

Care management events, including but not limited to

- A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration
- A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
- A patient death or serious disability due to spinal manipulative therapy performed at the facility

- Other _____.

_____

_____

Environmental events, including but not limited to

- A patient death or serious disability associated with an electric shock while being cared for in a facility
- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance.
- A patient death or serious disability associated with a burn incurred from any source while being cared for in a facility.
- A patient death associated with a fall while being cared for in a facility.
- A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a facility

- Other _____

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Criminal events, including but not limited to

- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
- Sexual assault on a patient within or on the grounds of a facility.
- The death or significant injury of a patient or staff member resulting from a physical assault that occurred within or on the grounds of the facility.

- Other_____

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