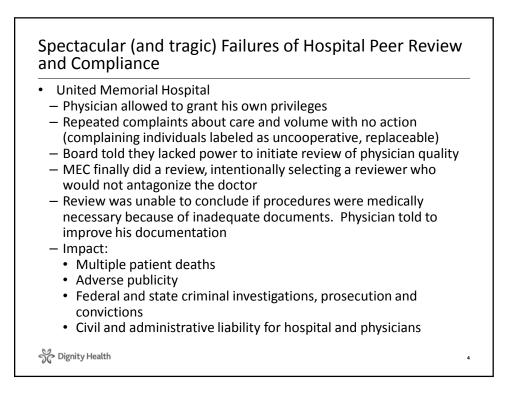


Overview: Peer Review, Compliance and FCA Risk Management

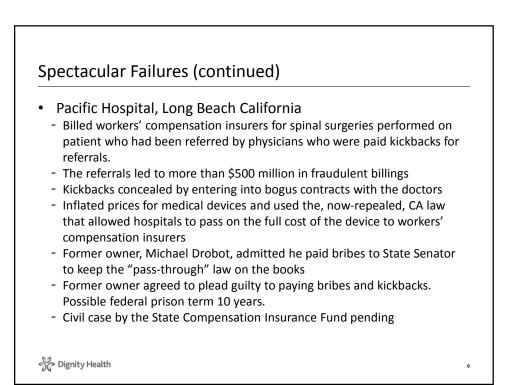
- Three Different Worlds that Intersect and Overlap with Increasing Frequency
- Emerging issues

 Real Life Experiences!
 Affirmative Reporting Obligations
 Quality of Care CIA's
 Governance
 Peer Review/ Case Law Update
- Differing Worlds and Perspectives
- Coordinating Investigations
- Preserving Confidentiality
- Practical Approaches



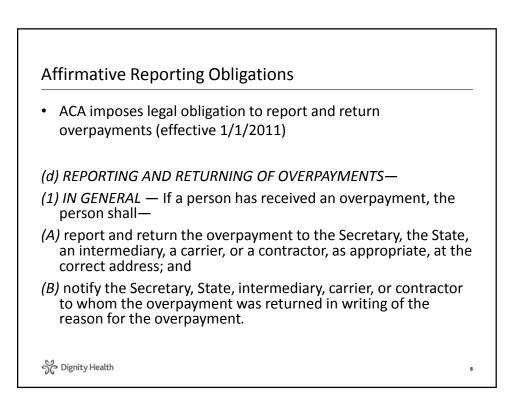
Spectacular Failures (continued)

- Tenet Healthcare Redding Memorial
 - 10 years of complaints regarding volume and medical necessity with little action
- 4 CMS, Licensing, and Joint Commission surveys all noting peer review problems (including condition level deficiency)
- FBI Raid
- Impact
 - Hundreds of unnecessary procedures performed
 - Divestiture of hospital
 - \$54 Million FCA settlement from Tenet and hospital
 - \$32.5 Million from physicians
 \$205 Million to cottle moderal malaractica lawsuits
 - \$395 Million to settle medical malpractice lawsuits
- More Recently:
 - King's Daughters Medical Center in Ashland Kentucky agrees to pay almost \$41 million to settle false claims and Stark allegations stemming from medically unnecessary coronary stents and diagnostic catheterizations. May 2014



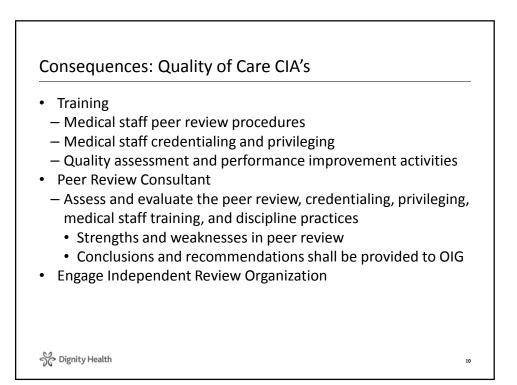
Spectacular Failures (continued)

- Physician Owned Distributorships (PODs)
 - Device companies that have surgeons as owners or investors. Hospitals, where the physicians have staff privileges, purchase the devices and the physician owners may use the device in surgery (typically commodity spine products such as screws and plates)
 - OIG issued special fraud alert in 2013 warning about both patient safety and fraud risks of buying surgical products from PODs
 - OIG reports show hospitals purchasing from PODs performed more than 28% more spinal surgeries than hospitals that did not purchase from PODs
 - DOJ conducting a False Claims Act investigation against at least one neurosurgeon who practiced in California and Michigan.
 - Government alleges that physician's ownership interest caused him to perform unnecessary surgeries
 - Physician insists that he was never paid to use specific equipment





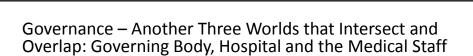
- Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an **obligation** (as defined in the False Claims Act)
- False Claims Act (as amended in 2009) imposes liability for a person who "knowingly conceals or knowingly and improperly avoids or decreases an **obligation** to pay or transmit money or property to the Government"
- "knowingly" includes reckless disregard, deliberate ignorance



Consequences: Quality of Care CIA's

- Physician Executive
 - Responsible for oversight of medical staff quality, including performance improvement, quality assessment, patient safety, utilization review, medical staff peer review, medical staff credentialing and privileging, medical staff training, medical staff discipline
- Physician executive shall be a member of senior management of the hospital
- Physician executive shall maker periodic (at least quarterly) reports regarding quality of care directly to the Board of Directors
- Minimum 1.0 FTE
- Policies
 - Medical staff credentialing and privileging procedures including collecting, verifying, and assessing current licensure, education, relevant training, experience, ability and competence
 - Monitoring practitioners with current privileges
 - Review by Physician Executive and Medical Staff Executive Committee
 - Reporting to the Governing Board credentialing and privileging activities

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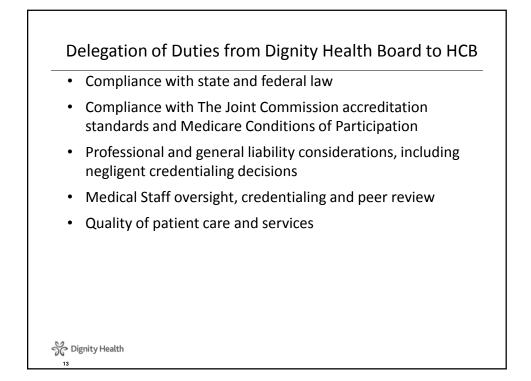


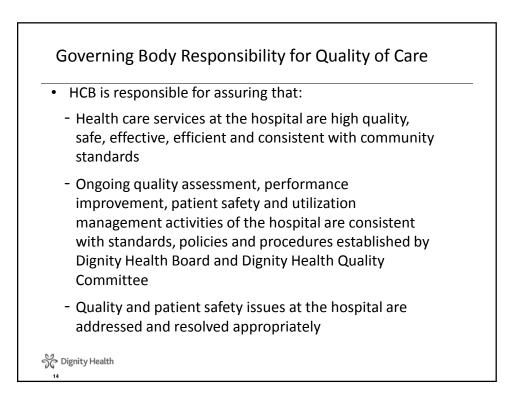
- General duties of Dignity Health Board of Directors
- Delegation of duties from Dignity Health to HCB
- HCB's roles and responsibilities
 - California hospital licensure law
 - The Joint Commission accreditation standards
 - Medicare Conditions of Participation
 - Medical Staff Bylaws
- Oversight of the medical staff credentialing and peer review functions
- Oversight of quality of care

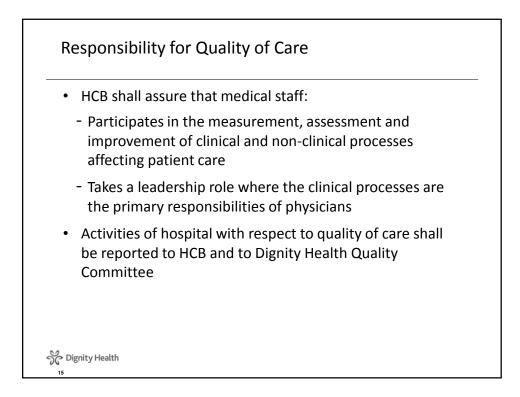
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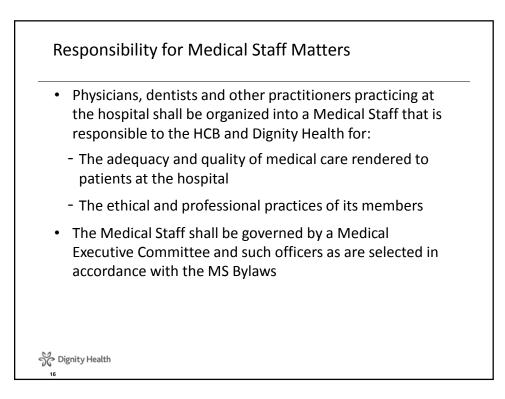
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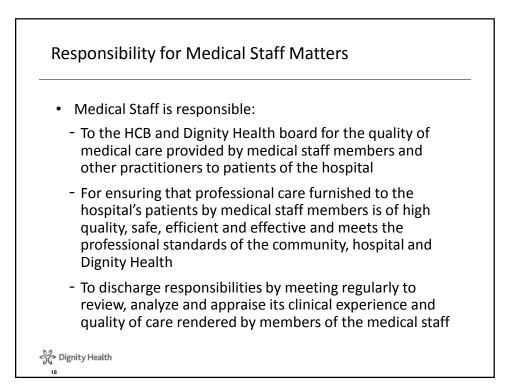


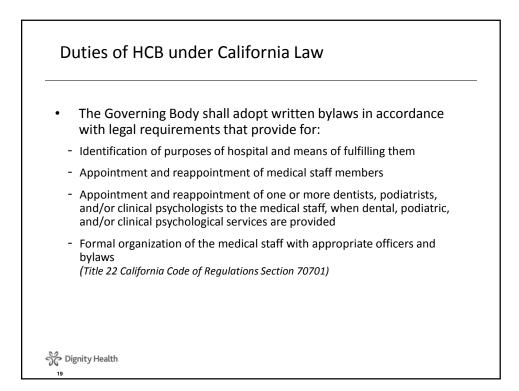


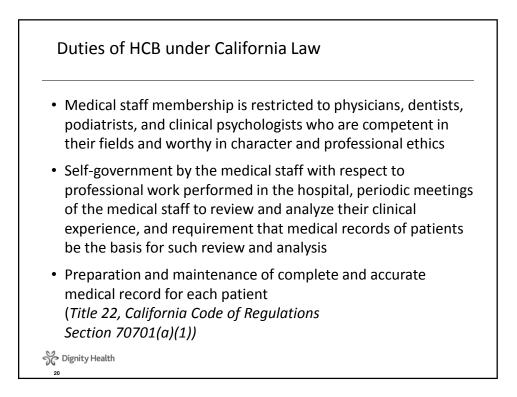


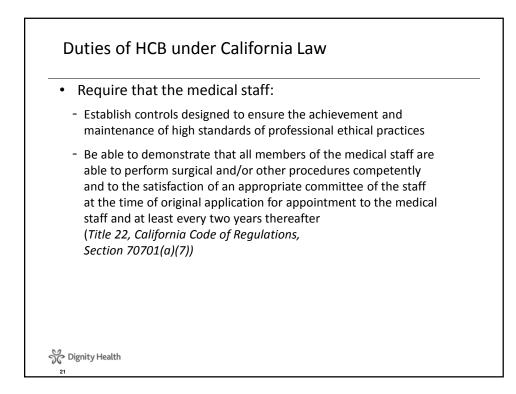


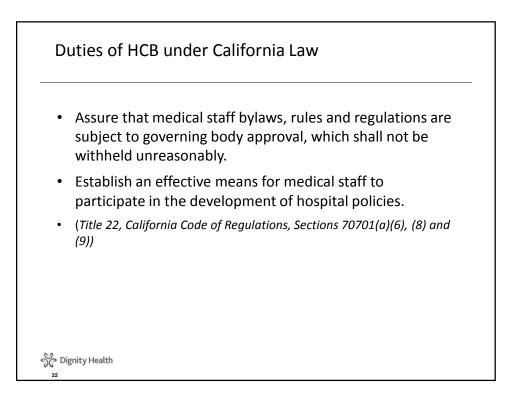


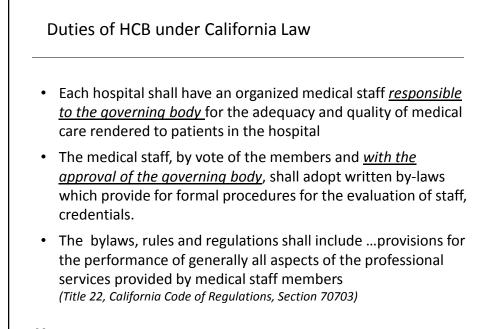






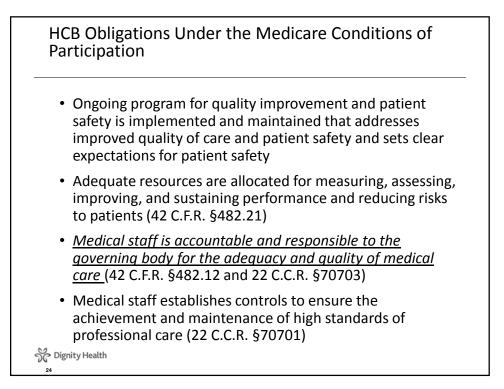


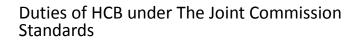




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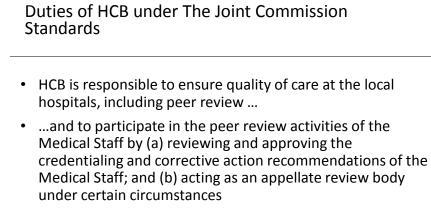
- Leadership Standards (LD) applied to the governing body includes the safety and quality of care, treatment, and services including:
 - A culture that fosters safety as a priority for everyone who works in the hospital
 - The planning and provision of services that meet the needs of patients
 - The availability of resources for providing care, treatment and services
 - The existence of competent staff and other care providers

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Duties of HCB under The Joint Commission Standards

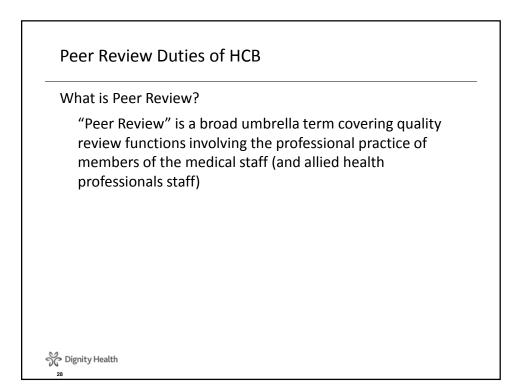
 The self-governing organized medical staff provides oversight of the quality of care, treatment and services delivered by practitioners who are credentialed and privileged through the medical staff process...and responsible for the ongoing evaluation of the competency of practitioners who are privileged...<u>subject to the</u> <u>ultimate authority and responsibility of the governing</u> <u>body for the oversight and delivery of healthcare rendered</u> <u>by licensed practitioners credentialed and privileged</u> <u>through the medical staff process</u>

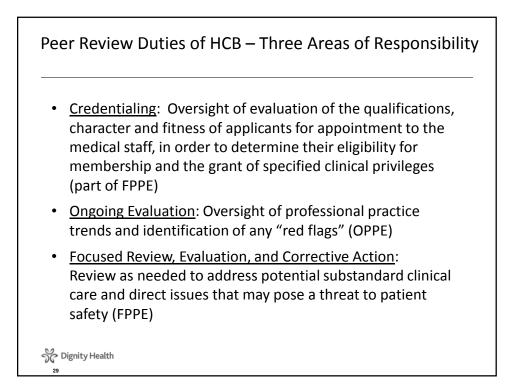


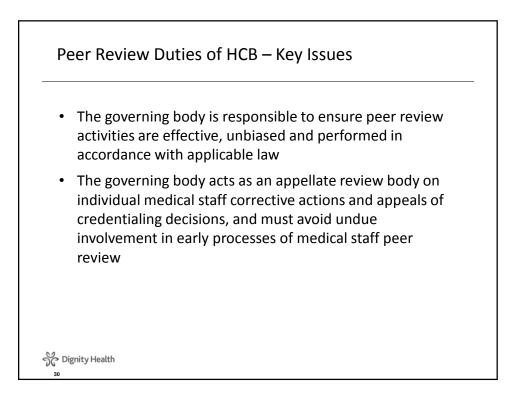
- FPPE Focused Professional Practice Evaluation
- OPPE Ongoing Professional Practice Evaluation

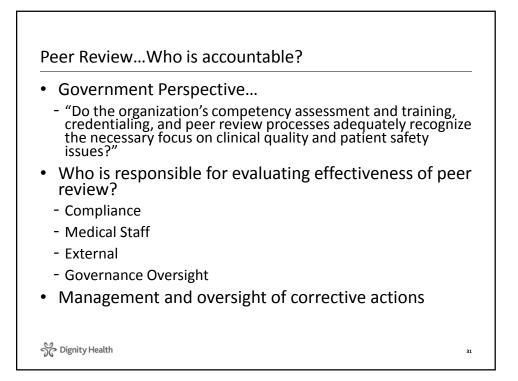
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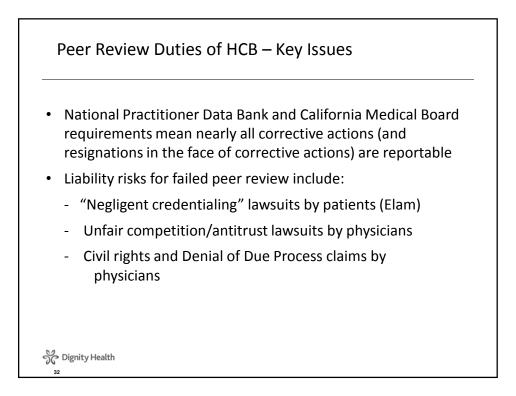
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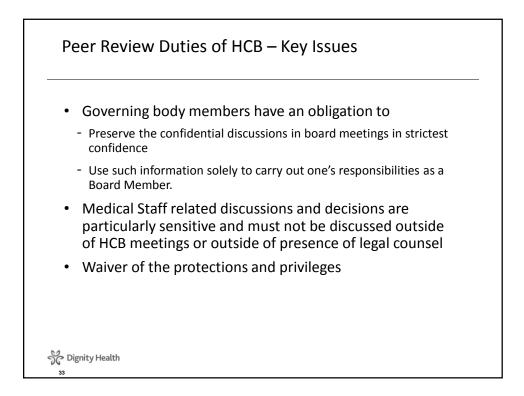


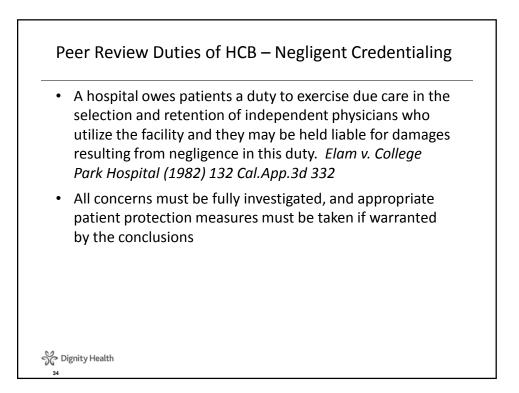


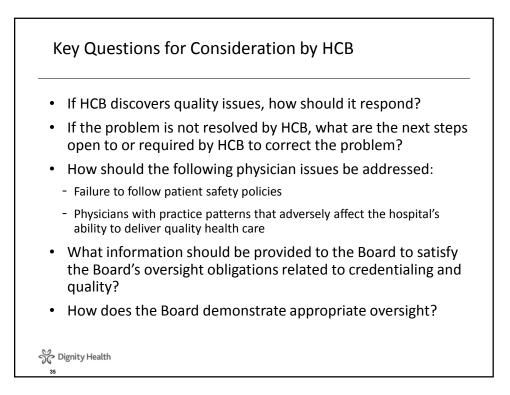


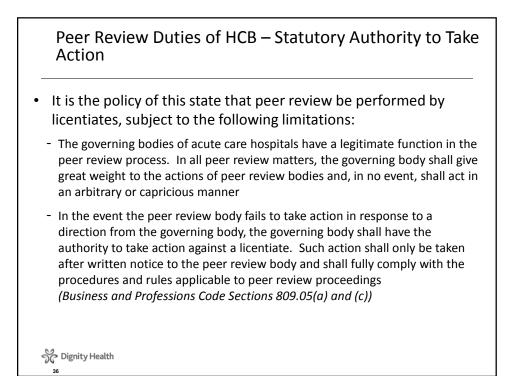






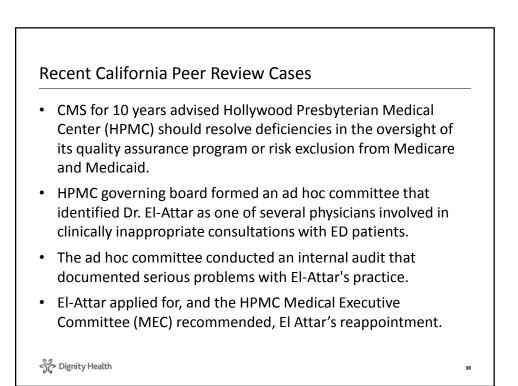






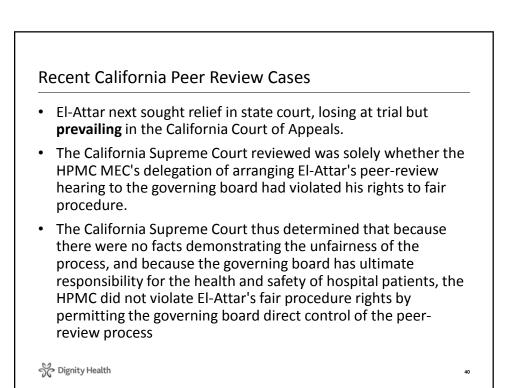


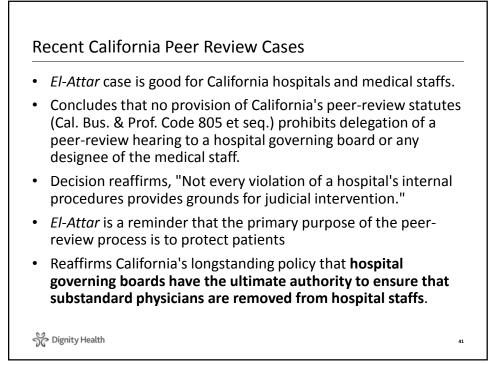
- On June 6, 2013, the California Supreme Court ruled unanimously in *El-Attar v. Hollywood Presbyterian Medical Center* that the delegation of a peer-review matter to the hospital's governing board did not violate a physician's common law right of fair procedure.
- In *El-Attar*, the California Supreme Court determined that while a hospital's governing board must give great weight to the actions of the medical staff, it may take unilateral action if warranted. It also clarified that the standard by which any bylaws deviations would be reviewed is "fairness" and importantly found that it is not inherently unfair for the governing body to appoint a hearing committee.

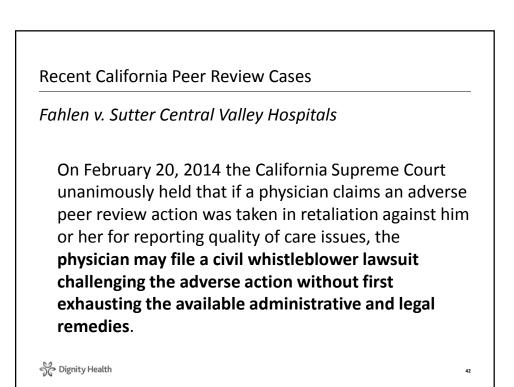




- The HPMC governing board denied El-Attar's reappointment, overruling the HPMC MEC.
- El-Attar requested a hearing and the HPMC MEC advised the governing board that "since the MEC did not summarily suspend [El-Attar's] privileges, did not recommend any adverse action relating to [El-Attar] ... and since the requested hearing would be to review actions by the Governing Board; it should be the Governing Board and not the MEC which arranges and prosecutes the requested hearing."
- The governing board impaneled a judicial review committee (JRC) comprised of six medical staff physicians.
- The JRC held a hearing and determined that the denial of El-Attar's reappointment was reasonable and warranted because his medical skills were dangerously substandard, and he had behavioral problems. On appeal, the governing board concurred with the JRC's findings.

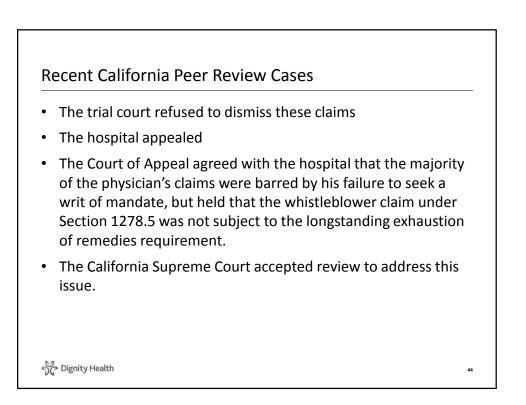


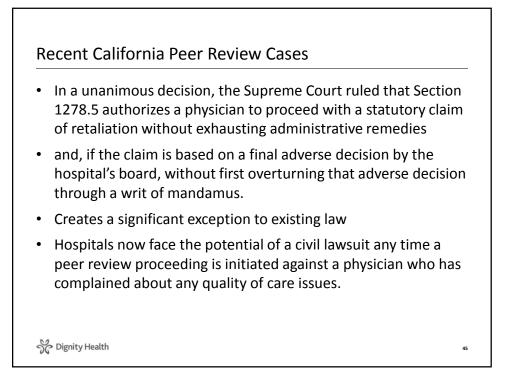


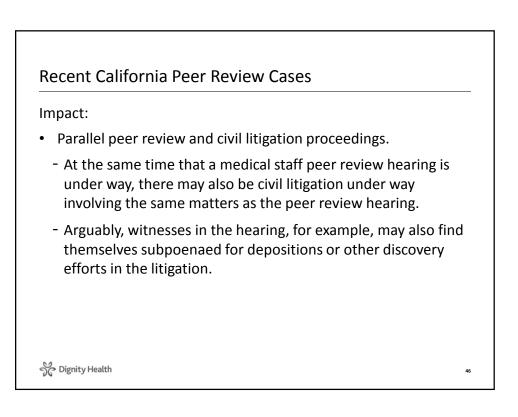


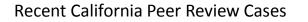
Recent California Peer Review Cases

- *Fahlen* was denied reappointment by a final decision of a hospital's board, and filed a lawsuit challenging that adverse decision without first obtaining court review through a writ of mandate proceeding.
- The lawsuit included a whistleblower claim under Health & Safety Code Section 1278.5, relying on a 2007 amendment to that statute that added physicians to the list of individuals authorized to bring a claim of alleged retaliation for reporting quality of care concerns.
- A number of statutory and common law claims that California courts have long held damages claims are precluded unless and until an adverse peer review action has been overturned through a writ proceeding.









Recommendations:

- Investigate promptly and vigorously every complaint by a physician regarding quality of care issues
- address any quality of care complaints made by the physician in written decisions including whether the complaints had merit, and whether the proceeding was retaliatory in any way
- Analyze for the factors necessary to establish immunity under HCQIA and California Civil Code Section 43.7 — and be sure that those factors are being met.

