

RECENT LEGAL DEVELOPMENTS IMPACTING HEALTH CARE PROVIDER COMPLIANCE OBLIGATIONS

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Agenda

- Spotlight on individual liability in healthcare enforcement
- Update on Medicare's move from provider-based to site-neutral payment rules
- Recent changes in federal and California laws and rules that affect provider licensing and operations
- General Data Protection Regulation (GDPR)
- Questions?

Individual Accountability In Federal Investigations – “The Yates Memo”

- What is the “Yates Memorandum”
 - Issued on September 9, 2016, by then Deputy Attorney General Sally Q. Yates
 - Was formally titled “Individual Accountability for Corporate Wrongdoing” and went into effect immediately.
 - Was widely issued to a number of federal legal divisions, including the civil division, criminal division and all 95 United States Attorney Offices
 - Key component of the Yates Memo was that it increased enforcement focus on individuals in cases of corporate misconduct on the theory that, “one of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing.”

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Individual accountability In Federal Investigations – “The Yates Memo”

- Six Key Takeaways from the Memo
 1. To qualify for cooperation credit, corporations must provide to Department of Justice all relevant facts relating to individuals responsible for the misconduct;
 2. Criminal and civil corporate investigations should focus on individuals from the beginning;
 3. Criminal and civil attorneys should be in routine communication with on another;
 4. DOJ will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation (“extraordinary” circumstances exception)
 5. DOJ attorneys should not resolve matters with corporations without plans to resolve individual cases; and
 6. Civil attorneys should focus on individual and companies based on considerations besides ability to pay.

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Individual accountability In Federal Investigations – “The Yates Memo”

▪ Early Results

- May 2016 Speech by Yates: “[C]ompanies are not only continuing to cooperate, they are making real and tangible efforts to adhere to our requirement that they identify facts about individual conduct, right down to providing what I’m told are called ‘Yates Binders’ . . . that contain relevant emails of individuals being interviewed by the government.” –
- Nov 2016 Speech by Yates: “We’re getting exactly what we wanted— companies showing up to their first meeting with the government with information about who did what.” –
- In 2017, DOJ recovered more than \$60M in actions against individuals that did not involve joint and several liability with the corporate entity.

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Individual accountability In Federal Investigations – “The Yates Memo”

▪ Practical Implications of the Yates Memo for Investigations Involving Health Care Providers

- Prosecutors now have less discretion; may only decline to prosecute an individual with approval from U.S. Attorney;
- Increased demands on corporations when conducting internal investigations, e.g. identifying all potentially culpable individuals, compiling “Yates Binders,” enhanced “Upjohn Warnings,” etc.
- Tensions between executives and corporation itself (do all individuals need separate counsel?)
- Investigations will take time and consume more resources

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Individual accountability In Federal Investigations – “The Yates Memo”

- Practical Implications of the Yates Memo for Investigations Involving Health Care Providers (cont.)
 - Yates Memo increases the importance to health care providers/organizations of evaluating the effectiveness of a corporate compliance program
 - Jan 2017: OIG, in collaboration with HCCA, released, “Measuring Compliance Effectiveness: A Resource Guide,” listing over 400 individual compliance program metrics.
 - Feb 2017: DOJ releases guidance document, “Evaluation of Corporate Compliance Programs,” with common questions the Fraud Section may ask in evaluating a compliance program in a criminal investigation. •
 - Does your organization have a plan for applying these tools?

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Individual accountability In Federal Investigations – “The Yates Memo”

- Clarifications To Date and Possible Future Changes
 - May 2016 Speech by Yates: –
 - “[C]ounsel for the company is not required to serve up someone to take the fall in order for the corporation to get cooperation credit –a hypothetical person sometimes referred to as the ‘vice president in charge of going to jail.’”
 - “[W]e don’t expect a company to make a legal conclusion about whether an employee is culpable, civilly or criminally. We just want the facts.”
 - “The policy specifically requires only that companies turn over all relevant non-privileged information.” Companies are not required “to waive attorney-client privilege.”

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Individual accountability In Federal Investigations – “The Yates Memo”

- Clarifications To Date and Possible Future Changes (cont).
 - DOJ’s FAQs re Yates Memo –What corporations are not required to do:
 - Receiving cooperation credit not contingent on waiving attorney-client or the work product privilege.
 - Companies are expected carry out investigations that are thorough but tailored to the scope of the wrongdoing.
 - A company also is not required to deliver a prosecutable case in order to obtain credit for cooperation. –
 - Corporate counsel is not required to present its legal conclusions or theories to the government. –
 - Company is not required to take specific actions against employees as part of its efforts to obtain cooperation credit.

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Individual accountability In Federal Investigations – “The Yates Memo”

- Clarifications To Date and Possible Future Changes (cont).
 - Speculation that changes would come with new Presidential administration.
 - Yates Memo remains active on DOJ’s website (www.justice.gov/dag/individualaccountability).
 - There have been notable prosecutions of individuals since the memorandum was released, but not as many as originally was feared.
 - General trend to date is that DOJ is putting less resources into pursuing individuals for corporate wrongdoing.
 - October 2017 – Deputy Attorney General Rod Rosenstein announced that DOJ is “reviewing” the Yates Memo.
 - Stay tuned...

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Medicare Provider-Based Status and Site Neutral Payments

- What is Provider-Based Status?
 - A Medicare concept that allows services rendered outside of the main location of a hospital provider to be treated as hospital services for billing, payment and certain other purposes.

Allows a provider-based site to appear on a hospital's Medicare cost report and receive an allocation of the hospital's overhead.

Makes provider-based sites eligible for higher rates of payment as compared to non-hospital settings, like physician clinics and ambulatory surgery centers — subject to new site neutral payment policies.

Certain services, such as partial hospitalization services, must be furnished in certain setting in order to be covered by Medicare.

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Medicare Provider-Based Status and Site Neutral Payments

- What are the Requirements for Obtaining Provider-Based Status?
- Set forth principally at 42 Code of Federal Regulations (“C.F.R.”) Section 413.65; regulation lays out the operational and clinical standards that must be satisfied in order for a site to be considered provider based.
 - Common Licensure - as determined under State law.
 - Financial Integration - must be treated like any other hospital department on Medicare cost report.
 - Clinical Integration - same clinical oversight as any other hospital department, included in unified medical record system, medical staff of hospital have privileges at site/location.
 - Public Awareness - general public must be aware when entering site that it is part of the hospital and they will be treated as hospital patients.
 - Under Arrangements - not all patient care services at the facility/location may be provided under arrangement.

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Medicare Provider-Based Status and Site Neutral Payments

- (Requirements for Provider-Based Status Cont.)
- Special Requirements for Off-Campus Locations
 - Common Ownership - same legal entity and governing body.
 - Administration and Supervision - supervised in the same way as any other hospital department; HR, billing, payroll, benefits, etc., done by same department/employees that service other parts of hospital.
 - Location - within 35 miles of main provider or meet certain other requirements.
 - NOTE: No joint ventures permitted for off-campus sites.

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Medicare Provider-Based Status and Site Neutral Payments

- Once provider-based status is conferred, the location is subject certain compliance obligations :
 - Provider Agreement/Conditions of Participation: All the terms of a hospital's Medicare provider agreement apply equally to a provider-based department, which means deficiencies/non-compliance at any site have implications for the hospital's Medicare participation status.
 - Patient Status: Must treat all patients as hospital outpatients for billing purposes, etc.
 - Notices to Patients: Off-campus provider based locations must advise beneficiaries that they are subject to coinsurance obligations associated with both the professional and facility component of services

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Medicare Provider-Based Status and Site Neutral Payments

- Limiting Impact of Provider-Based Designations and the Move to Site Neutral payments – The Bipartisan Budget Act of 2015
 - Section 603 of the Bipartisan Budget Act: Establishes that provider-based departments established after the date of the statute’s enactment may not be paid under the Medicare Outpatient Prospective Payment System (“OPPS”) for services rendered on or after January 1, 2017.
 - Several Exceptions to General Elimination of OPPS Treatment of “New” provider-based locations:
 - * Dedicated emergency departments;
 - * On-campus provider-based units (within 250 yards of the main campus)
 - * Off-campus provider based department that already was billing under OPPS as of November 2, 2015 (“grandfathered” provider-based units).

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Medicare Provider-Based Status and Site Neutral Payments

- NOVEMBER 14, 2016 FINAL RULE
 - Published by the Centers for Medicare and Medicaid Services on November 1, 2016 after an active comment process with significant input provided by the hospital industry.
 - Establishes what payment methodology applies to facility services rendered at provider-based units that cannot bill under OPPS (the “applicable payment system:”);
 - For CYs 2017 and 2018, professional services rendered in provider-based units paid under the physician fee-schedule; facility services paid at a reduced OPPS rate (50% of normal OPPS payment for 2017, 40% of normal OPPS payment for 2018).
 - Clarifies Scope of Exceptions to Elimination of OPPS Treatment: Among other things, CMS clarifies that provider-based facilities will lose grandfathering status for payment purposes if relocated.
 - Addresses status of provider-based units that were in “mid-build” at the time the BBA of 215 was enacted.

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Medicare Provider-Based Status and Site Neutral Payments

- 21st CENTURY CURES ACT
 - Enacted in 2017.
 - Expands/clarifies grandfathering exception to general elimination of OPPS billing for provider-based units .
 - Under the statute, providers will be deemed to have been billing under OPPS as of November 2, 2015 if that provider submitted to CMS a provider-attestation as of that date. That means, as long as the attestation was filed, the provider-based unit will get grandfathering treatment even if it was not actually providing services and billing under OPPS as of November 2, 2015.

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Medicare Provider-Based Status and Site Neutral Payments

- Where are We Now?
 - Provider-based status is not nearly as financially advantageous as it used to be.
 - Many locations that would have been able to qualify as new off-campus provider-based departments in the past and, consequently, receive both a facility and professional payment for services, no longer qualify for that payment treatment.
 - Even for facilities that meet the exceptions to the site-neutral payment policies, the overall differential in payments has been reduced.
 - Still some positive impact on payment rates for provider-based units that meet exceptions to site-neutral payments.
 - OTHER CONSIDERATIONS – provider-based status still matters for reasons other than payment differential
 - 340B – Off-site hospital locations still must meet provider-based requirements in order to dispense 340B discounted drugs to hospital patients.
 - IME/GME – provider-based status still relevant to what resident rotations factor into IME/GME reimbursement calculations.

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Medicare Provider-Based Status and Site Neutral Payments

- Where Are We Now (cont.)?
- Strategic Considerations
 - Beneficial for entities to develop a process for evaluating potential changes that can put site-neutral exempt status at risk.
 - Facilities should be aware of how all provider-based units are reflected in the Medicare enrollment records – what does CMS consider to be the location of the provider-based unit?
 - Facilities should be able to prove through documentation to demonstrate that certain provider-based units were in operation prior to November 2, 2015 and therefore eligible for grandfathering exemption to site-neutral payments.

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Medicare – Conditions of Participation

Modernization of Home Health Agency (HHA) Conditions of Participation (CoPs)

(42 CFR 409, 410, 418, 440, 484, 485, 488). 82 FR 4504

- Effective January 13, 2018 (originally July 13, 2017).
- CMS' stated goals include:
 - Reflect current HHA practices by focusing on the care provided to patients and the impact of that care on patient outcomes.
 - Assure the protection and promotion of patient rights; enhance the process for care planning, delivery, and coordination of services; and build a foundation for ongoing, data-driven, agency-wide quality improvement.
 - Improve the quality of care furnished through the Medicare and Medicaid programs, while streamlining requirements for providers. HHA (CoP) Final Rule (CMS-3819-F) at Federal Register.

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Medicare – Conditions of Participation

Modernization of Home Health Agency (HHA) Conditions of Participation (CoPs)

(42 CFR 409, 410, 418, 440, 484, 485, 488). 82 FR 4504

- *Historically, we have adopted a quality assurance approach that has been directed toward identifying health care providers that furnish poor quality care or fail to meet minimum Federal standards. Facilities not meeting requirements would either correct the inappropriate practice(s) or would be terminated from participation in the Medicare or Medicaid programs. **We have found that this problem-focused approach has inherent limits.** Ensuring quality through the enforcement of prescriptive health and safety standards, rather than improving the quality of care for all patients, has resulted in expending much of our resources on dealing with marginal providers rather than on stimulating broad-based improvements in the quality of care delivered to all patients.*

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Medicare – Systems Improvement Agreements

- Time-limited contractual arrangement between a Medicare-accredited healthcare organization and CMS. More time to correct deficiencies than might be available after a validation or for-cause survey.
- Historically used for home health agencies, nursing homes, and transplant centers, etc. More recently, hospitals too.
- Western State Hospital.
 - SIA #1, June 2016
 - Survey + 60-day Extension, June 2017
 - 30-day Extension, September 2017
 - SIA #2, November 2017

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Independent Contractor Status In California

- The *Dynamex* Decision
 - Issued by the California State Supreme Court on April 30, 2018.
 - Changes the legal test for determining whether a worker is an employee or independent contract.
 - Effectively creates a presumption that all workers are employees, which an organization has the burden of overcoming by proving certain facts about the relationship between the organization and worker.

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Independent Contractor Status In California

- They *Dynamex* Decision (cont.)
 - California Supreme Court adopted what is being called “the ABC Test” for determining when a worker is an independent contractor.
 - Under the ABC Test, a worker is presumed to be an employee unless the putative employer can prove:
 - That the worker is free from control and direction of the hiring entity in connection with the performance of the work, both under the contract for the performance of the work and in fact;
 - That the worker performs work that is outside of the usual course of hiring of the entity’s business; and
 - That the worker is customarily engaged in an independently established trade, occupation or business of the same nature as the work performed.
 - All of these factors must be satisfied to overcome the employee presumption.

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Independent Contractor Status In California

- The *Dynamex* Decision (cont.)
- Practical Implications
 - Most immediate impact of *Dynamex* relates to wage and hour rules;
 - Will result in many more workers being considered employees than independent contractors, thereby obligating the putative employer to provide certain benefits, etc.;
 - Likely will produce more litigation as certain classes of workers push to take advantage of being designated as employees for wage and hour purposes;
 - Most immediate impact of *Dynamex* relates to wage and hour rules;

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Independent Contractor Status In California

- The *Dynamex* Decision (cont.)
 - Implications outside of the wage and hour uncertain;
 - The Supreme Court's decision in *Dynamex* technically applies only to Industrial Welfare orders, but the expectation is that the "ABC Test" for independent contractor status will be extended to all areas of employment litigation;
 - Health care organizations could be materially impacted by *Dynamex* because they regularly structure relationships with workers as independent contractor relationships due to certain compliance obligations;
 - Organizations will want to review current independent contractor arrangements to determine if those arrangements satisfy the "ABC Test" or the workers would be characterized as employees under the test;
 - Moving forward, organizations will have to assess how frequently to use independent contractor relationships in light of risks/benefits, compliance obligations, etc.

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Provider Licensing & Operations

- **Nonprofit health facilities: Sale of assets (AB 651)**
 - Nonprofit health facilities with a suspended license must obtain attorney general approval before selling to a for-profit corporation. Overturns *Gardens Regional Hospital and Medical Center, Inc.*, a May, 2017, bankruptcy court decision, which held that a closed hospital is not a “health facility” under California law and thus not required to obtain such approval.
 - Nonprofit health facilities must inform the attorney general of the primary languages spoken at the facility before selling to a for-profit corporation. Attorney general may require health facilities to translate specified notices into any of those languages and must consider whether the transaction may create a “significant effect on the availability and accessibility of cultural interests provided by the facility in the affected community.” Corp. Code §§ 5914, 5915, 5916, 5917, 5920, 5921, 5922, 5923, 5926.
- **Whistleblower protections (AB 1102)**
 - As originally drafted, would have prohibited hospitals from disciplining an employee for refusing an assignment (or change in assignment) on the grounds that the assignment would violate the nurse ratio staffing law. A lack of appropriate coverage for meal and rest periods was given as the reason for this bill. Due to opposition bill was amended to instead increase the civil penalty for willful whistleblower violations to \$75,000. Health & Safety Code § 1278.5

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Provider Licensing & Operations

- **Workplace safety prevention (8 CCR § 3342)**
 - Addresses violence: (1) committed by a person with no legitimate business at the work site; (2) directed at employees by customers, clients, patients, inmates, visitors or other individuals accompanying a patient; (3) between two employees or ex-employees; and (4) committed by an individual with no relationship to the workplace other than a relationship with one of the employees.
 - Hospitals must:
 - Report violent incidents to the Division of Occupational Safety and Health of the Department of Industrial Relations;
 - Maintain a violent incident log;
 - Develop a violence prevention plan; and
 - Provide employee training.
- **Procedures of emergency medical services providers (SB 432)**
 - Updates the process for hospitals to notify emergency medical services (EMS) personnel (e.g., paramedics, firefighters and private ambulance employees) that they were exposed to specified communicable diseases. Hospitals and EMS employers must provide employee training and post the title and telephone number of their infection control officer on their website. HSC § 1797.188

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Provider Licensing & Operations

- **Hospital satellite compounding pharmacy (SB 351)**
 - Provides additional options for hospitals to license pharmaceutical services in a satellite or approved service area that is located separate from the hospital's physical plant and that is not under the hospital's consolidated license. Authorizes the Board of Pharmacy to issue a license to a hospital satellite compounding pharmacy. Bus. & Prof. Code §§ 4029, 4127.15, 4400

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Provider Licensing & Operations

- **Remote Dispensing Site Pharmacy/Telepharmacy (AB 401)**
 - A remote dispensing site pharmacy is a licensed pharmacy located in California that is exclusively overseen and operated by a supervising pharmacy and staffed by one or more qualified registered pharmacy technicians who work at the remote dispensing site pharmacy and perform order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks.
 - Supervising pharmacist is located at supervising pharmacy. Uses "telepharmacy" technology to monitor prescription drug dispensing, with drug regimen review and patient counseling by an electronic method such as audio, visual, still image capture or store and forward technology.
 - Must be in a medically underserved area, 150 miles or closer to the supervising pharmacy, and under common ownership of the supervising pharmacy. A supervising pharmacy may supervise only one remote dispensing site pharmacy.
 - Remote pharmacy technicians may not perform tasks such as taking oral prescription orders or compounding drug preparations and must be videotaped receiving any controlled substances. Bus. Prof. Code §§ 4044.3, 4044.6, 4044.7, 4130, et seq.

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Provider Licensing & Operations

- **Clinics in Shared Space (AB 401)**
 - Primary care clinics and specialty clinics licensed under Health & Safety Code § 1204 may operate in shared clinic space with government clinics (exempt from licensure under HSC 1206(b)). Licensed clinic is responsible for any statutory or regulatory violations occurring on the premises.
 - Requirements include:
 - Signage that clearly identifies which clinic is operating during the hours of operation.
 - Separate medical records and drug storage.
 - Both clinics are licensed by the State Board of Pharmacy (Bus. & Prof. Code section 4180.5 added to permit clinics in shared space to obtain license for wholesale purchase and dispensing of drugs).
 - CDPH entitled to access and inspect records of the exempt clinic. Health & Safety Code § 1211.

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Provider Licensing & Operations

- **Confidentiality of Mental Health Records (AB 1119)**
 - Under Lanterman-Petris-Short Act, explicitly permits communication of patient information during the provision of emergency services between a physician, psychologist, social worker with a master's degree in social work, marriage and family therapist, professional clinical counselor, nurse, emergency medical personnel at the scene of an emergency or in an emergency medical transport vehicle, or other professional person or emergency medical personnel at a health facility. Welf. & Inst. Code § 5328
- **Patient Access to Medical Records**
 - SB 241. Aligns state law with federal regulations. Limits amount patients may be charged for copies of their medical record. Explicitly permits certain mental health care providers to disclose patient information to business associates with a HIPAA-compliant business associate agreement and to use and disclose patient information for health care operations purposes. Health & Safety Code §§ 123105 and 123110; Welf. & Inst. Code § 5328
 - SB 575. Requires hospitals, physicians and other health care providers to give a free copy of the relevant portion of the medical record to a patient if needed to support a claim or appeal regarding eligibility for a public benefit program (e.g., Medi-Cal, Social Security disability insurance benefits, Supplemental Security Income). Health & Safety Code § 123110

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Provider Licensing & Operations

- **Involuntary treatment for mental health (AB 191)**
 - Authorizes a marriage and family therapist or professional clinical counselor to sign a notice of certification to extend an involuntary hold beyond 72 hours for a patient’s mental health assessment and treatment. The therapist or counselor must have participated in evaluating the patient, and may only provide the second signature (the first must be provided by a physician or psychologist). Welf. & Inst. Code §§ 5251, 5261, 5270.20
- **Involuntary commitment (SB 565)**
 - Currently, mental health facilities must hold a certification review hearing to extend an involuntary hold by 30 days for intensive mental health treatment services. Now, such facilities must make “reasonable attempts” to notify family members or other persons designated by the patient of the time and place of the certification hearing at least 36 hours before the hearing, unless the patient requests this information not be provided. Welf. & Inst. Code §§ 5260, 5270.15

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Provider Licensing & Operations

- **Opioid addiction**
 - SB 554. Authorizes nurse practitioners and physician’s assistants with specified training to order or furnish, as applicable, buprenorphine (an opioid used to treat opioid addiction) in accordance with the federal Comprehensive Addiction and Recovery Act of 2016. Bus. & Prof. Code §§ 2836.4, 3502.1.5
 - California Prescription Drug Monitoring Program, AB 40. Authorizes prescribers and pharmacists to query the Controlled Substance Utilization Review and Evaluation System (CURES) database through an online portal or through a health information technology system. Will permit the California DOJ to integrate the electronic history of controlled substance dispensing into the patient information system used by emergency department physicians, thus giving emergency physicians efficient access to information needed to help fight prescription drug abuse. Health & Safety Code § 11165.1
 - Pain management, AB 1048.
 - Permits a pharmacist to dispense a Schedule II controlled substance (Health & Safety Code § 11055) as a partial fill if requested by the patient or the prescriber. Beginning January 1, 2019, a health care service plan will be required to prorate an enrollee’s cost sharing for a partial fill of a prescription.
 - Changes requirement that health facilities assess pain each time a patient’s vital signs are obtained; permits such assessment in a manner appropriate for the patient. Bus. & Prof. Code § 4052.10, Health & Safety Code § 1254.7, 1367.43, 1371.1, Ins. Code §§ 10123.145, 10123.203

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Provider Licensing & Operations

▪ Skilled Nursing and Long-Term Care Facilities

- Requirements for changes (AB 275)
 - Extends, from 30 to 60 days, the timeline and notice periods that long-term care (LTC) facilities are required to give residents, their families, and various agencies before they close. Clarifies and strengthens requirements to medically and socially assess residents in order to prevent and reduce transfer trauma. Requires LTC facilities, as part of their relocation plans, to provide specific information regarding the number of residents who do not have the capacity to make decisions for themselves, the availability of alternative LTC beds in the community, and the reason for the proposed closure, among other things. Health & Safety Code §§ 1336, 1336.1, 1336.2, and 1336.3
- Notice of transfer or discharge (AB 940)
 - Requires a skilled nursing facility to send to the local long-term care ombudsman copies of written notices to residents of a facility-initiated transfer or discharge. Noncompliance is a class B violation. Health & Safety Code § 1439.6
- Rights of residents (SB 219)
 - Protects the rights of lesbian, gay, bisexual, and transgender (LGBT) seniors in skilled nursing and assisted living facilities, to prevent those facilities from discriminating against them. Creates the LGBT Long-Term Care Facility Resident's Bill of Rights, making it unlawful for any long-term care facility to take specified actions based on a person's actual or perceived sexual orientation, gender identity, gender expression or HIV status. Health & Safety Code §§ 1569.318, 1338.4

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Provider Licensing & Operations

▪ Hospice Licensure Act (SB 294)

- A hospice may provide any service described in the Hospice Licensure Act, including palliative care, to a patient with a serious illness (as determined by the physician caring for the patient), including a patient who continues to receive curative treatment from other licensed health care professionals.
- A hospice that elects to provide palliative care under this bill must provide CDPH with specified information, including the date of commencement of palliative care, the types and numbers of patients receiving palliative care, and staff qualifications. HSC § 1747.3

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Provider Licensing & Operations

- **Medical Board of California (SB 798)**
 - Midwives
 - Adds licensed midwives and midwifery societies to peer review provisions. Bus. & Prof. Code § 805(a)
 - Authorizes licensed marriage and family therapists to be shareholders, officers, and directors, and employees of professional corporations. Corp. Code § 13401.5.
 - Lists adverse events that must now be reported to MBC by an outpatient setting accredited pursuant to Health & Safety Code Section 1248.1 (surgery centers) within five days from detection of adverse event 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. Bus. & Prof. Code § 2216.3
 - Imposes a \$50,000-\$100,000 fine for a failure to file a required report with MBC. Bus. & Prof. Code § 805
- **Occupational Therapy – Standards of Practice for Telehealth (16 CCR 4172)**
 - Clarifies that once the patient is informed and consents to receive occupational therapy services via telehealth, an occupational therapist does not need to affirmatively obtain the patient's consent each time the OT delivers services.

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CDPH – Immediate Jeopardy Penalties

- **Immediate Jeopardy (IJ): noncompliance with licensing requirements causing or likely to cause serious injury or death.**
- **IJ Penalties in 2017**

Date	# Penalties	# Hospitals	Total Fines
Jan 5	15	14	\$913,550
Apr 20	17	14	\$1,135,980
Aug 31	10	10	\$618,002
Dec 28	10	9	\$549,555
		Total	\$3,217,087

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General Data Protection Regulation (GDPR)

General Data Protection Regulation (2016/679)

- Effective May 25, 2018
- Comprehensive privacy regime across all industry sectors
- Sets high baseline of privacy protections
- Broad definition of “personal data”
 - any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person
 - Examples: address, IP address, credit card number, bank statements, etc.

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Whose Data is Subject to GDPR?

- Customers/Patients
- Business Affiliates (if individual names are used on account)
- Website visitors
- Employees

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What is the GDPR?

- Requires organizations to find a “legal basis” for processing, e.g., consent or “legitimate interest”
- Establishes rules for data transfers from the EU to elsewhere in the world
 - Data transfer mechanisms: EU-US Privacy Shield (US only), standard contractual clauses
 - Note: GDPR compliance ≠ Privacy Shield compliance

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What is the GDPR?

And That’s Not All:

- Notice and Choice
- Access and Deletion Rights
- Data Minimization
- Storage Limitations
- Contractual Obligations with Processors
- Data Protection Officer or Registered EU Representative
- Reasonable Security
- 72-hour Breach Notification

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Questions?

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