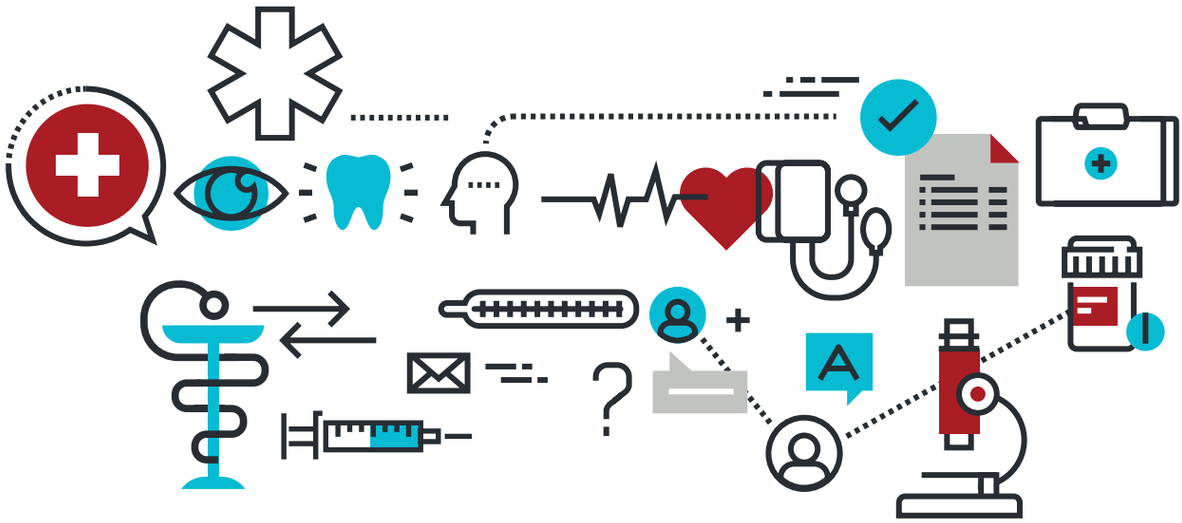

# 2017 Health Care

## Regulatory and Compliance Seminar

March 8, 2017 – Los Angeles, CA

Davis Wright Tremaine LLP

DEFINING SUCCESS TOGETHER

# Agenda

| | |
|---|---|
| 8:00 – 8:30 AM | REGISTRATION & CONTINENTAL BREAKFAST |
| 8:30 – 8:45 AM | **Welcome & Introduction**<br>Presented by Dennis S. Diaz |
| 8:45 – 9:30 AM | **340B Drug Discount Program – Dealing with Compliance Audits and Adverse Audit Findings**<br>Presented by Jordan Keville |
| 8:45 – 9:30 AM | **Health Care Regulatory Enforcement Trends: Ghosts of Past, Present and Yet to Come—the Trump Effect**<br>Presented by Jeffrey B. Coopersmith, Renee Howard and Kerry E. Shea |
| 8:45 – 9:30 AM | **Health IT Challenges for Health Care Providers**<br>Presented by Jane Eckels |
| 9:30 AM – 9:40 AM | BREAK |
| 9:40 AM – 10:25 AM | **Governance Compliance Developments: What Your Board Needs to Know About and Do vis-à-vis Compliance**<br>Presented by Kathleen Drummy and Robert L. Schuchard |
| 9:40 AM – 10:25 AM | **Hospital Litigation Update**<br>Presented by John R. Tate, Anna R. Buono and Loring Rose |
| 9:40 AM – 10:25 AM | **Managing New Risks in Hospital-Physician Relationships – A Potpourri**<br>Presented by Renee Howard and Robert G. Homchick |
| 10:25 AM – 10:35 AM | BREAK |
| 10:35 AM – 11:20 AM | **California's End of Life Option Act**<br>Presented by Terri D. Keville, John P. Krave and Marcia Penido |
| 10:35 AM – 11:20 AM | **Health Information Privacy and Security Update**<br>Presented by Sean. R Baird and Adam H. Greene |
| 10:35 AM – 11:20 AM | **Telemedicine: Recent Developments and Hot Topics**<br>Presented by Dayna Nicholson and Adam D. Romney |
| 11:20 AM – 11:30 AM | BREAK |
| 11:30 AM – 12:30 PM | **Compliance Officers Roundtable**<br>Participants: Christopher Doan, Derek Kang and Cari Toneck, RN, MN<br>Moderator: Dennis S. Diaz |

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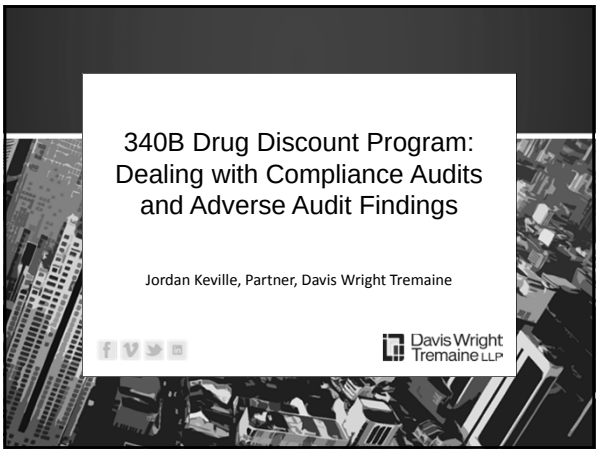
# 340B Drug Discount Program – Dealing with Compliance Audits and Adverse Audit Findings

PRESENTED BY

**Jordan Keville** | Partner




## The 340B Program In a Nutshell

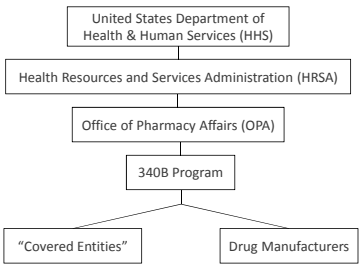
- Federally created program for extending discounts from manufacturers on drugs to various class of safety net health care providers.
  - Was a reaction by Congress to escalating prices for drugs.
  - Program applies to outpatient drugs only.
  - 340B is a price control program – not a reimbursement program.
  - Discounted prices under the program tend to be large, which has caused the program to become a significant factor in the way drugs are purchased and dispensed by eligible entities.
  - There are relatively few compliance obligations under the program, but those obligations are not always simple to satisfy.



## Statutory Basis for Program

- Section 602 of the Veterans Health Care Act of 1992, which added **Section 340B to Public Health Services Act**.
  - Hence the common name, "The 340B Program."
  - The Act is codified at 42 United States Code Section 256b, *et seq*.

## 340B Drug Pricing Program – the Players

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## 340B Drug Pricing Program – How Does It Work?

- Drug manufacturers sign pharmaceutical pricing agreement (PPA) with the Secretary of HHS.
  - Sell outpatient drugs to "**covered entities**" at or below "340B ceiling price".
  - Ceiling price is generally 11% to 35% below average price.
  - Many manufacturers sell to 340B covered entities for even less.
  - Big Savings for Eligible Entities.

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## The 340B Program – By The Numbers

- Total dollars for drug purchases made under the 340B program in 2015[1] — $12 billion.
- Increase of over 67 percent as compared to total for 340B purchases in 2013.
- Projected total 340B purchases for 2017 are $13.9B; $15.2B for 2018; $16.8B for 2019.[2]
- Hospitals are responsible for the majority of 340B drug purchases, at — 86 percent in 2015[3]; As of 2013, there were 970 hospitals participating in the 340B program.[4]
- Office Inspector General recently estimated that 340B hospitals acquire Medicare Part B drugs at a 34% discount as compared to a drug's average sale price (ASP) or 66% of the average price to a non-340B entity.[5]

[1] Drug Channels: 340B Purchases Hit $12 Billion in 2015 – And Almost Half of the Hospital Market, available at http://www.drugchannels.net/2016/02/340b-purchases-hit-12-billion-in.html (visited Feb. 6, 2017).
[2] Berkley Research Group, "Growth of the 340B Program: Past Trends, Future Projections" (Nov. 2014).
[3] Drug Channels.
[4] Berkley Research Group.
[5] Drug Channels.

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## Key Questions Regarding 340B

- What entities are eligible to participate?
- What drugs qualify for discounted prices under 340B?
- What patients can get 340B drugs?
- Does the participating entity use 340B drugs for Medicaid prescriptions?

These questions are critical to the two primary compliance obligations under the 340B program – preventing "diversion" of 340B drugs to ineligible patients and preventing "duplicate discounts" on drugs.



## Provider Eligibility – 340B Covered Entities

- Providers eligible to participate in the 340B Program.

| Grantees | Public or Private Non-Profits |
|---|---|
| FQHCs | DSH |
| Family Planning & STD Clinics | Children's Hospitals |
| Ryan White HIV Programs | Critical Access Hospitals |
| AIDS Drug Assistance Programs | Free-standing Cancer Hospitals |
| TB & Black Lung Clinics | Rural Referral Centers |
| Hemophilia Centers | Sole Community Hospitals |
| Native Hawaiian Health Centers | |
| Urban Indian Organizations | |

- Providers falling within these categories are known as "340B covered entities."



## Provider Eligibility – Procedure for Becoming a CE

- Eligible Entities must register with OPA to participate in 340B.
- Provider cannot buy at 340B prices until listed on Database.
- Database is the primary means manufacturers and wholesalers:
  - Determine whether a provider is eligible to purchase 340B prices.
  - Determine whether a provider bills Medicaid for 340B.
- Registration applies both to Parent Site (on-site covered entity) and Child Sites (off-site components of the covered entity).
- New registrations must be submitted within 15 day windows in October, January, April and July.
- New entities become eligible only at the start of a quarter.

## Provider Eligibility – Potential Pitfalls

- Accounting for "Child Sites".
- Only 340B covered entities are permitted to purchase and provide 340B drugs to persons.
  - The 340B covered entity is the facility registered to participate in the 340B Program according to the OPA Database, but
  - The "covered entity" may include a number of different sites.
- Understanding what the covered entity is becomes important to assuring that 340B drugs are not transferred to an ineligible patient.



## Patent Eligibility – Potential Pitfalls

- OPA looks to the hospital's most recently filed cost report to verify the eligibility of an off-site facility for 340B.
  - Is the OP facility an integral part of the hospital and included as reimbursable on the hospital's Medicare cost report? If not, cannot purchase or dispense 340B drugs.
- Illegal to use or distribute drugs purchased at 340B prices to persons who are not a "patient" of the covered entity.
- Diversion may involve an analysis of at least two (2) issues:
  - Who is a "patient"?
  - What constitutes the "covered entity"?



## Patent Eligibility – Potential Pitfalls

- Who is a "patient"?
- Guidance from Oct. 24, 1996 (61 Fed. Reg. 55156) sets 3 prongs:
  - CE has established a relationship with the individual, such that the CE maintains records of the individual's health care;
  - The individual receives health care services from a health care professional who is either employed by the CE or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the CE; and
  - The individual receives a health care service or range of services from the CE which is consistent with the service or range of services for which grant funding or FQHC look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

## Patent Eligibility – Potential Pitfalls

- Who is not a "patient"? Look critically at these arrangements:
  - The only health care service received by the individual from the covered entity is the dispensing of a drug.
  - Services that are best described as care "management".
  - Professionals providing health services are loosely "affiliated" with the CE.
  - Misuse or misunderstanding of who is the CE and the location of services.
  - "Deeming" employees as patients based upon insurance or administrative circumstances.



## Drug Eligibility

- "Covered OP Drug" is defined at 42 USC § 1396r-8 (k)(2).
- OP drugs used and billed on an OP basis are likely "covered".
- Excluded from the definition is "any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following…":

| | |
|---|---|
| Inpatient hospital services | Hospice services |
| OP hospital services | Dental services (w/ exceptions) |
| Physician services | Renal dialysis |
| Other lab & x-ray services | Nursing facility & ICFMR |



## Drug Eligibility

- GPO Prohibition– 42 USC § 256b (a)(4)(L).
- Certain 340B hospitals cannot purchase any covered OP drug through a GPO or other group purchasing arrangement.
  - Applies to DSH, children's hospitals, free-standing cancer hospitals.
  - Does not apply to CAH, RRC and SCH.
- Attestation upon enrollment in the 340B Program.
- Applies to DSH as part of the definition of a "covered entity".
  - This means compliance with the GPO Prohibition is an eligibility issue.

## Medicaid – Avoiding Duplicate Discounts

- Congress says that Manufacturers should not have to pay both a rebate to state Medicaid agencies and a discount to 340B covered entities on the same drug – *i.e.*, a duplicate discount.
- Providers are prohibited from billing Medicaid for a drug purchased at 340B prices and for which Medicaid seeks a rebate from the manufacturer – 42 U.S.C. § 256b(a)(5)(A).
- Language of the 340B statute places the burden on the 340B covered entity for compliance even though the rebate part of the tripartite relationship is beyond the provider's control.



## Medicaid – Avoiding Duplicate Discounts

- HHS' response was to create a Medicaid Exclusion File.
- Covered entities are asked whether they intend to bill Medicaid for drugs purchased at 340B prices.
- A "Yes" answer to the Medicaid question causes OPA to place the covered entities' Medicaid provider number on the Medicaid Exclusion File.
- State Medicaid agencies use the Medicaid Exclusion File to determine which providers' OP drug claims should be excluded from rebate calculations submitted to manufacturers.
  - Determination at the provider-level, not the claim-level.



## Medicaid – "Carving In" or "Carving Out"

- Medicaid "carve-out" is the name given to a covered entity's pharmacy operations model that chooses to forego the 340B discount for drugs provided to Medicaid patients.
  - Drugs resulting in Medicaid claims cannot be replenished at 340B price.
  - The answer to the Medicaid question should be "No".
  - Provider should not be on the Medicaid Exclusion File.
  - State Medicaid agency should be able to obtain drug rebates on the provider's drug claims without violating the duplicate discount prohibition.
  - Provider is not bound by AAC limitation on billing Medicaid.
  - DSH still cannot purchase OP drugs from GPO.

## Consequences of Not Satisfying 340B Program Rules

- What are the consequences for non-compliance?
  - Repayment of discount – 42 USC § 256b(a)(5)(D).
  - Suspension from the 340B Program.
  - Civil Monetary Penalties for knowing and intentional violations – 42 USC § 256b(d)(2)(B)(v)(I).
  - Potential for false claim liability, including Qui Tam actions.
- Increased audit activity in recent years by OPA and Manufacturers.



## Ongoing Obligation to Comply

- Covered Entities Have an Ongoing Obligation to Update 340B Database Information.
- Covered Entities Also Must Periodically Attest That They Are Complying with Program Requirements. A Covered Entity must represent that:
  - All information listed on the 340B program database for the entity is accurate, complete and correct;
  - It has continuously met all 340B program requirements;
  - It has continuously complied with all compliance requirements, including the prohibitions against diversion and duplicate discounts;
  - Any third-party contract pharmacy arrangements employed by the meet 340B program standards;
  - It will contact OPA as soon as reasonably possible if it materially violates any compliance violations; and
  - If it does not timely notify OPA of compliance violations, the entity acknowledges that it may be required to make refunds to drug manufacturers for prescriptions that did not meet eligibility requirements. The amount of the refund would be the difference between the 340B discount price and what the entity would have paid for the drug without a 340B discount.



## Enforcement of 340B Requirements – Audits and Corrective Action

- Historically, HRSA was not particularly active in monitoring CE compliance with 340B standards.
- Around 2010, due to pressure from Congress and other factors, HRSA started to become more assertive with respect to enforcement efforts.
- 340B statute was amended by Congress through ACA to include additional program integrity standards and auditing expectations. Amendments permit, among other things, drug manufacturers to perform audits of CEs when the manufacturers have "reasonable cause" to believe a CE is out-of-compliance with 340B requirements.
- Now, CEs are routinely subject to audits by both HRSA and drug manufacturers.

## The HRSA-OPA Audit Process

- HRSA-OPA issues a letter to the CE providing notice an audit will be performed.
- Typically, on-site inspection is scheduled; the CE must provide arrangements and workable space for between 1 and 2 HRSA auditors.
- Prior to on-site visit, HRSA-OPA will issue a "pre-audit data request" to the CE. Information requested generally includes:
  - 340B policies and procedures.
  - Most recently filed Medicare cost report.
  - Listing of providers and sites eligible to make 340B drug orders or prescriptions.
  - Listing of 340B purchase orders made during last 6 months.
  - 340B drug orders and prescriptions over 6 month period.
  - Pharmacy service agreements for contract pharmacies that dispense 340B prescriptions for CE.
  - Sample of drug orders and prescriptions.



## The HRSA-OPA Audit Process – Cont.

- Audit interview between HRSA-OPA agents and CE personnel.
- Post-Audit, HRSA-OPA issues a written Final Report of findings to the CE (used to issue a preliminary report first, but dispensed with that practice in 2016).
- The CE has 30 calendar days from the date of the Final Report to either submit a written response to contest the audit findings, if the CE disagrees with them, or to request a corrective action plan or "CAP." If a CAP is requested, it must be submitted by the CE to HRSA within 60 days of issuance of the Final Report.
- HRSA will review the CE's written response to the Final Report. If HRSA agrees with the CE's position on some of the findings, agency may issue a revised Final Report. If HRSA does not agree with the CE's dispute of the audit findings, the CE must move forward with a CAP or risk exclusion from the 340B program.



## The HRSA-OPA Audit Process – Cont.

- If a CE submits a CAP in response to a Final Report, HRSA must approve it (it is typical for a CE to have to submit multiple drafts of a CAP before HRSA approves it).
- There are a few key items HRSA generally expects to see in a CAP with respect to each audit finding of non-compliance:
  - An explanation for how/why the non-compliant practice occurred.
  - The steps that have been taken to ensure the non-compliant practice will not happen again.
  - What steps will be taken, going forward, to ensure that no problems similar to what resulted in the adverse audit findings occur in the future.
  - Identification of the CE staff who will be responsible for oversight of implementation of particular aspects of the CAP.

## The HRSA-OPA Audit Process – Cont.

- Once HRSA reviews and approves a submitted CAP, the CE is required to provide a letter to HRSA that outlines the findings involving diversion and/or duplicate discounts. This letter, once approved by HRSA, will go to manufacturers or wholesalers to notify them that the CE bought drugs from them that were not properly subject to a 340B discount and therefore the CE might owe the manufacturer and/or wholesaler a refund.
  - The manufacturer letter is made publicly available on the HRSA website.
- HRSA closes out an audit of a CE once the CE attests that all refunds to manufacturers, if any, have been resolved and that the CAP has been fully implemented.
- For entities who get a Final Report that necessitates refunds to manufacturers (or, at least, notice to manufacturers of potential refund liability) they will be audited again by HRSA.



## The HRSA-OPA Audit Process – Cont.

- HRSA does not get directly involved with process of a CE submitting refunds to manufacturers; requires only that the CE give notice to impacted manufacturers that they may be owed a refund. After that, it is up to the CE and manufacturer to work out the details of any refund.
  - It is not uncommon for manufacturers not to respond at all to notices from CEs regarding potential refunds. A CE can set a deadline in the notices by which the manufacturers must respond or forfeit their right to any refund.
  - Where manufacturers do respond to a refund notice, a CE can try to negotiate with manufacturer over the amount of the refund. The CE can attempt to get the manufacturer to accept less than the full difference between 340B pricing and regular pricing on the impacted drugs.
  - As mentioned, a CE must achieve some kind of resolution of potential manufacturer refunds or HRSA will not consider an audit concluded.



## Final Thoughts – Maintaining Compliance with 340B Requirements

- CEs or entities considering 340B participation should be familiar with 340B requirements.
- Administration , pharmacy and billing staff should receive training on 340B compliance obligations.
- Adequate systems for tracking purchases and prescriptions are essential – lots of software systems, consultants and other vendors in the market can help Providers with this.
- Ongoing, internal auditing and self-monitoring by CEs should be a goal.
- Continued attention to 340B policy announcements/changes also is important; HRSA is routinely providing guidance and making changes through informal announcements.

## Thank you

# Health Care Regulatory Enforcement Trends: Ghosts of Past, Present and Yet to Come—the Trump Effect

PRESENTED BY

**Jeffrey B. Coopersmith** | Partner
**Renee Howard** | Partner
**Kerry E. Shea** | Partner

# Health Care Regulatory Enforcement Trends: Ghosts of Past, Present and Yet to Come- The Trump Effect

Jeff Coopersmith, Partner, Davis Wright Tremaine
Renee Howard, Partner, Davis Wright Tremaine,
Kerry Shea, Partner, Davis Wright Tremaine

Davis Wright Tremaine LLP

## Overview — Voices of the Past, Present and Future

- Key Fraud and Abuse Reforms of the ACA.
- Repeal and Replace? Impact of ACA Reform on Fraud and Abuse Initiatives.
- False Claims Act Enforcement- Where Are We Now?
- Emerging Enforcement Trends.
  - Improper Disposal of Confidential Information by Healthcare Providers.
  - Narcotics Diversion and Opioid Use.




## Key Fraud and Abuse Reforms of the ACA

- **(1) Claims submitted pursuant to an illegal kickback scheme under the Anti-Kickback Statute, 42 USC § 1320a-7b(b), constitute false claims under the federal False Claims Act, 31 U.S.C. § 3729 *et seq*.**
  - ACA § 6402 (codified at 42 U.S.C. § 1320a-7b(g)).
  - Might not affect cases where provider expressly certified compliance with AKS.
  - Case law prior to ACA already accepted notion that AKS violations were conditions of payment and thus could create liability for false claims submission.

## Key Fraud and Abuse Reforms of the ACA

- **(2) AKS statute clarified to specify that neither actual knowledge of the AKS nor specific intent to violate the AKS is needed to establish AKS liability.**
  - ACA § 6402(f)(2) (codified at 42 USC § 1320a-7b(h)).
  - Full ACA repeal would restore *Hanlester* to its full glory.
  - *But see People v. Duz-Mor Diagnostics Laboratory, Inc.*, 68 Cal. App. 4th 654; 80 Cal. Rptr. 2d 419 (1998) (specific intent to violate the Medi-Cal antikickback statute is not required).



## Key Fraud and Abuse Reforms of the ACA

- **(3) Express provision that failure to report and return overpayments within 60 days is an "obligation" under the False Claims Act's reverse false claims provision and can also result in CMPL liability.**
  - ACA § 6402(a) (codified at 42 USC § 1320a-7k(d)(1)-(2)).
  - Full repeal would not eliminate FCA liability for knowing retention of overpayments, but could nullify CMS rules on "report and return".



## Key Fraud and Abuse Reforms of the ACA

- **(4) ACA amendments to the federal False Claims Act (ACA § 10104(j)).**

Weakened the public disclosure bar by:

- Broadening the sources of information that can be used to bring a FCA qui tam suit to include, for example, state inspection reports;
- Giving the government discretion to waive the public disclosure bar even in cases where it obviously would apply (*e.g.*, a qui tam suit based on a front-page story in the LA Times); and
- Replaces the requirement that a whistleblower have direct knowledge of the fraud with "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions."

## Key Fraud and Abuse Reforms of the ACA

- **(5) Reforms addressing changing health care environment and new payment models.**
  - For example, Civil Monetary Penalties Law revised to add several exceptions to the definition of "remuneration" for purposes of the prohibition against beneficiary inducement.
    - For example, remuneration that "promotes access to care and poses a low risk of harm to patients and Federal health care programs … ."
    - Items or services for individuals determined to be in financial need.



## Key Fraud and Abuse Reforms of the ACA

- Increased funding for the Health Care Fraud and Abuse Control Account for fiscal years 2011 through 2020 (§ 6402).
- Expanded exclusion authority for HHS-OIG in instances of obstruction of program audits and investigations (§ 6408(c)).
- Increased prison time and tougher loss amount calculations for sentencing guidelines (§§ 10606(a)(2)(B)&(C)).
- Civil monetary penalties for slow or false responses to HHS-OIG inquiries (§ 6408(a)(2)-(3)).
- Liability for knowing and intentional overcharging by manufacturers in connection with 340B drug programs (§ 7102(a)).
- Physician Payment Sunshine Act (§ 6002), requiring manufacturers to submit information to HHS about payments to physicians.



## Key Fraud and Abuse Reforms of the ACA

- Requirement that HHS create a self-disclosure protocol for violations of the Stark law, and authorization for CMS to reduce amounts owed for Stark violations (ACA § 6409)
- Broader definition of "health care fraud offense" under 18 U.S.C. § 24(a) to include AKS violations (ACA § 10606(c))
  - Impact if the broader definition was on forfeiture, obstruction of investigations, money laundering charges, and use of administrative subpoenas
- Obstruction of HIPAA administrative subpoenas is equivalent to obstruction of grand jury subpoenas (ACA § 10606(d)(1))
- 42 U.S.C. § 1997, *et. seq.*, providing for DOJ subpoena authority for investigations conducted under the Civil Rights for Institutionalized Persons Act

## Repeal and Replace?



## False Claims Act Enforcement — Where Are We Now?

- *Universal Health Services v. U.S. ex rel. Escobar*
  - SCOTUS addressed implied false certification theory.
  - "Material to government's decision to pay" replaces "condition of payment" rubric.
- *AseraCare* (N.D. Ala.) and other cases dealt a blow to viability of FCA claims based on lack of medical necessity in the absence of objective Medicare/Medicaid coverage standards.
- Statistical sampling to prove liability rather than just damages faces uncertain future.
- FCA per-claim penalty range now adjusted for inflation (currently, $10,781 - $21,563).



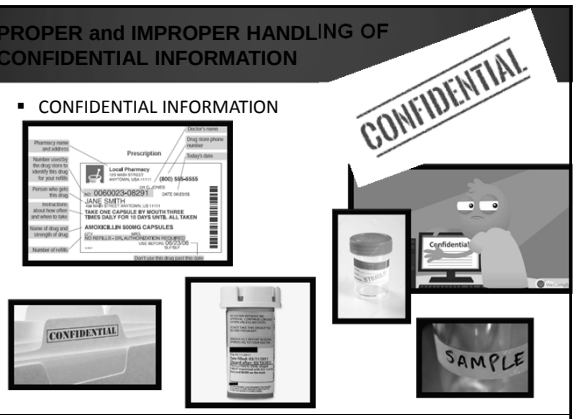
## Two Emerging Enforcement Trends

**(1) Improper Disposal of Confidential Information by Healthcare Providers**

**(2) Opioid Abuse and Diversion**

## PROPER and IMPROPER HANDLING OF CONFIDENTIAL INFORMATION

- CONFIDENTIAL INFORMATION






## Dumpster Dives!



## U.S. Dept. of Health and Human Services – Office of Civil Rights Enforcement Actions

- Actions against HIPAA covered entities
- Improper disposal of Protected Health Information (PHI):
  - CVS Pharmacy, Inc.: **$2.25M** – improper disposal of prescription related PHI in publicly accessible waste containers.
  - Rite Aid Corp. **$1M** – improper disposal of prescription related PHI in publicly accessible waste containers.
  - Affinity Health Plan, Inc.: **$1.2M** – return of photocopiers containing PHI to a leasing company.
  - Cornell Prescription Pharmacy: **$125,000** – improper disposal of prescription related PHI in publicly accessible waste containers.

## U.S. Dept. of Health and Human Services – Office of Civil Rights Enforcement Actions

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## Newscasts / Publicity




## California Investigatory Actions — Dumpster Dives

- California state attorney general.
  - Investigatory powers under Gov't Code §§11180 *et seq.*
  - Performing **inspections** traditionally performed by area-specific agencies such as DTSC, of Health Departments.
  - Issuing **Subpoenas**, without warning.
  - Building cases, more so than protecting health or welfare.
  - **Settlements.**
- Initial focus – hazardous waste.
- Subsequent focus – customer and patient confidential information.

## Cal AG Investigations -- Steps

- Investigation
- Focus on specific industry
  - … Find PHI
- Subpoenas
- Corrective Actions



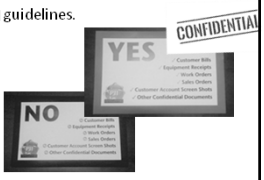

## Cal AG Investigations – Settlements

- Settlements.
  - Wal-Mart Stores, Inc.: **$27M** – illegal transportation and disposal of hazardous waste and other materials.
  - CVS Pharmacy, Inc.: **$13.75M** – improper storage, handling and disposal of medical and pharmacy waste.
  - Target Stores: **$22.5M** – improper disposal of batteries and electronic devices.
  - AT&T: **$21.8M** and Comcast: **$23M** – improper universal waste **and confidential document disposal**.
- Confidential Customer and Patient Information.
  - Beginning in 2014.



## Proper Disposal

- Proper Disposal.
  - No required method – only goals and guidelines.
    - Take appropriate steps. Be prudent.
    - Segregate.
    - Render information.
      - "Essentially unreadable"
      - "Indecipherable"
      - "Otherwise cannot be reconstructed"



## Proper Disposal

- HIPAA Privacy and Security Rules.
  - Apply appropriate administrative, technical and physical safeguards to protect the privacy of PHI. 45 CFR 164.530(c).
- California Civil Code (more than medical).
  - §1798.80 - "Records".
  - §1798.80 – "shall take all reasonable steps".
    - Shredding, erasing or "otherwise modifying" the info to make it.
    - "Unreadable" or "undecipherable".




## Trends and Predictions?



## Emerging Enforcement Trends: (2) Diversion and Opioid Abuse

Joint Statement 2.13.17:

"Because we share a strong concern about the increase in opioid-related deaths, our countries will work together on common solutions to protect our people from opioid trafficking. "

## Diversion and Opioid Abuse

- Two main issues: **public health** and **public fisc.**
- Public health:
  - Quadrupling of opioid related deaths from 1999-2011.
  - Medicaid beneficiaries are prescribed painkillers at 2x the rate of non-Medicaid patients and are 3-6x the risk of overdose.
    - Washington state study found that 45% of opioid overdose deaths were Medicaid enrollees.
  - Methadone accounts for disproportionate share of OD deaths.
- Potential causes: (i) aggressive marketing by pharmaceutical companies; (ii) "pain as the 5th vital sign" campaign, adopted by VA and Joint Commission. *See* California Health Foundation, *The Role of Health Plans in Curbing the Opioid Epidemic* (June 2016).



## Opioids: Protecting Public Health

- Opioid prescribing guidelines.
  - Centers for Disease Control (2016).
  - Agency Medical Directors' Group Interagency Guideline on Prescribing Opioids for Pain (2010) (Washington State).
    - May be used to establish standard of care for **professional licensing cases**.
- Regulations governing treatment of pain.
  - Physicians required to document health histories with various elements, evaluations with required elements, risk screening, treatment plan. WAC 246-919-853, 854.
  - Pain contract required for patients at high risk for abuse. WAC 246-919-856.



## Opioids: Protecting Public Health

- **WAC 246-919-860 Consultation—Recommendations and requirements.**

(1) The physician **shall consider**, and document the consideration**, referring the patient for additional evaluation and treatment** as needed to achieve treatment objectives. Special attention should be given to . . . pain patients who are under eighteen years of age, or who are at risk for medication misuse, abuse, or diversion. . .

(2) **The mandatory consultation threshold for adults is one hundred twenty milligrams morphine equivalent dose (MED)(oral). In the event a physician prescribes a dosage amount that meets or exceeds the consultation threshold of one hundred twenty milligrams MED (orally) per day, a consultation with a pain management specialist** as described in WAC 246-919-863 **is required**, unless the consultation is exempted under WAC 246-919-861 or 246-919-862. Great caution should be used when prescribing opioids to children with chronic noncancer pain and appropriate referrals to a specialist is encouraged.

## Opioids: Protecting the Public Fisc

**Medicare coverage policy**: **Local Coverage Determination (LCD): Controlled Substance Monitoring and Drugs of Abuse Testing (L36668) (CA).** The 25-page coverage policy sets forth:

- "The appropriate indications and expected frequency of testing for safe medication management of prescribed substances in risk stratified pain management patients and/or in identifying and treating substance use disorders;
- Designates documentation, by the clinician caring for the beneficiary in the beneficiary's medical record, of medical necessity for, and testing ordered on an individual patient basis; and
- Provides an overview of presumptive urine drug testing (UDT) and definitive UDT testing by various methodologies."



## Opioids: Protecting the Public Fisc

- State and federal enforcement actions involving urine drug testing (UDT):
  - ***Coastal Spine and Pain*** (FL) paid **$7.4M** to settle FCA allegations involving medically unnecessary confirmatory urine drug testing (Aug. 2016).
    - Regardless of result of less expense qualitative test, Coastal allegedly performed and billed for quantitative drug tests for all patients.
  - ***US v. Acacia Mental Health Clinic*** (E.D. Wisc.) (complaint filed 12/28/16)
    - All patients seen at mental health clinic required to submit to urine drug screening.
    - Medicaid reimbursed on average $474 for the tests, as billed. Acacia accounted for 99% of Wisconsin Medicaid reimbursements for drug tests to mental heath providers.



## Opioids: Protecting the Public Fisc

- San Diego-based **Millennium Health** paid **$256M** to settle allegations related to fraudulent UDTs and genetic tests and physician kickbacks (Oct. 2015).
  - Free point-of-care test cups given to physician customers. DOJ likened the practice to "taping a $5 bill" inside of the cup.
  - Use of "custom profiles" not tailored to specific patients.
  - Speaker program to reward referring physicians .
- Criminal crack down on operators of "pill mills."
  - DEA considers Los Angeles to be one of largest "pill mills".
- Private insurers:
  - **Formulary policies** (remove high dose and high street value drugs).
  - **Limiting prescription quantity per fill and limiting early fills**.
  - **Authorization review** for certain drugs, doses, combinations of drugs.

## Considerations for Health Care Providers

- Professional discipline for providers believed to be over-prescribing opioids or over-ordering UDTs.
- Malpractice risks.
- DEA enforcement.
  - Diversion of narcotics from pharmacies, medication lock boxes.
  - Improper prescribing by providers resulting in diversion.
- State AG / DOJ enforcement.
  - Medically unnecessary prescribing or ordering of diagnostic tests.
  - Improper financial arrangements with testing labs.



## Symptom or Disease?

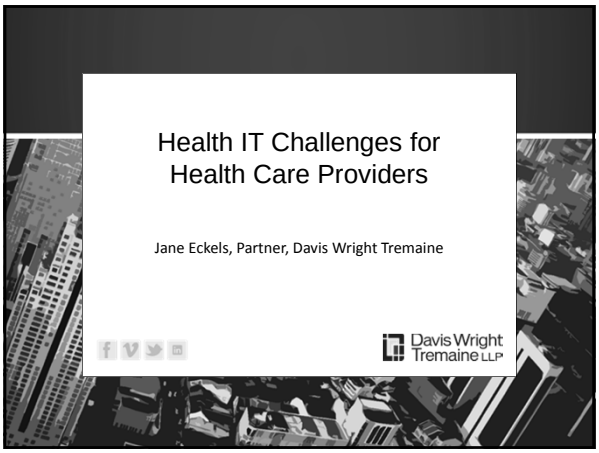
- "Key drivers of overprescribing include insufficient provider training on nonopioid pain management strategies, lack of sufficient nonopioid resources to treat pain (such as easy access to behavioral therapies, physical and occupational therapy, or availability of alternative modality benefits such as chiropractic care or acupuncture), insufficient access to specialists, and lack of time in the short primary care visit to address behavioral or social issues contributing to pain and suffering."
  - California Health Care Foundation, Changing Course: *The Role of Health Plans in Curbing the Opioid Epidemic.*



# Health IT Challenges for Health Care Providers

PRESENTED BY

**Jane Eckels** | Partner




## The End of Meaningful Use?

*"Now that we effectively have technology in virtually every place care is provided, we are now in the process of ending Meaningful Use and moving to a new regime culminating with the MACRA implementation. The Meaningful Use program, as it has existed, will now be effectively over and replaced with. something better."*

Andy Slavitt, Acting CMS Administrator, January 12, 2016

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## The Future of Meaningful Use

- HHS published final rule on October 14, 2016 setting out implementing regulations for Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).
- New program called Quality Payment Program.
- Several provisions directly relate to the use of certified EHR technology.
- "Advancing Care Information category" replaces the Medicare EHR Incentive Program for eligible professionals.
  - Essentially Meaningful Use renamed.

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## Certified EHR Technology

- ONC's 2015 Edition Health IT Certification Criteria established new standards for certified EHR technology (CEHRT).
  - Health IT foundation for meaningful use and Quality Payment Program.
- 2015 Edition CEHRT required for use in 20180
  - 2014 Edition CEHRT may be used during 2017.
- Interoperability-focused standard.
  - Example: Requires EHR vendors to publish application programming interfaces (APIs) for EHRs.
- Transparency of cost.

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## The Future of Meaningful Use

- MIPS Advancing Care Information category replaces only the Medicare EHR Incentive Program for eligible professionals.
- Medicare EHR Incentive Program stays in place for eligible hospitals and critical access hospitals.
- Medicaid EHR Incentive Program stays in place.
  - Eligible professionals.
  - Acute care and children's hospitals.
- *Organizations with both Medicare and Medicaid payments will need successfully to manage both programs simultaneously to maximize reimbursement.*

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## Meaningful Use in 2017

- CMS's Outpatient Prospective Payment System (OPPS)/Ambulatory surgical Centers (ASC) final rule published November 14, 2016.
- Revisions to objectives and measures.
  - Removed clinical decision support and CPOE objectives and measures.
  - Reduced certain thresholds for remaining objectives and measures.
  - New naming conventions.
  - Only applies to hospitals attesting to CMS.
- Changes to 2016 and 2017 reporting period and reporting requirements.
  - 90 day reporting period in 2016 and 2017 for new and returning participants.
- One-time hardship exception for first-time Medicare EPs who are also transitioning to MIPS in 2017.

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## Meaningful Use in 2017

- Modified Stage 2
  - 7 objectives
  - May use 2014 Edition or 2015 Edition CEHRT or combination
  - Reduced threshold to meet Patient Electronic Access objective
    - View/download/transmit (VDT): From 5% to at least 1 patient
- Stage 3
  - 6 objectives
  - Must use 2015 CEHRT
  - Reduced thresholds for several measures
  - Flexibility within certain thresholds
    - Coordination of Care through Patient Engagement and Health Information Exchange
    - Must attest to all three measures, but only required to meet thresholds of two measures



## MU in 2017 – Stage 3 Reduced Thresholds

| Objective | Measure | New Threshold | Change |
|---|---|---|---|
| Patient Electronic Access | Patient access to health information | For >50% unique patients, provide timely access to electronic health information | Reduced from >80% |
| | Patient-specific education | For >10% unique patients, provide access to patient-specific educational resources | Reduced from >80% |
| Coordination of Care through Patient Engagement | View/ Download/ Transmit (VDT) | At least 1 patient views, downloads or transmits health information | Reduced from >5% |
| | Secure messaging | For >5% unique patients, send secure message | Reduced from 25% |
| Health Information Exchange | Send Summary of Care | For > 10% unique patients, create and electronically send summary of care | Reduced from >50% |
| | Request/Accept Summary of Care | For > 10% transitions or referrals, incorporate summary of care into EHR | Reduced from >40% |
| | Clinical Information Reconciliation | For >50% transitions or referrals, perform clinical information reconciliation of medication, medication allergy and known problem list | Reduced from >80% |
| Public Health and Clinical Data Registry Reporting | Report on measures | Any combination of 3 measures | Reduced from any combo of 4 |



## Transition to MACRA

- Meaningful Use folded into MIPS – Advancing Care Information category.
  - In 2017, Medicare eligible clinicians report under Advancing Care Information requirements of MIPS.
- Both Quality Payment Program options for clinicians and groups – MIPS and APMs – require use of CEHRT to exchange information across providers and with patients.
- Continues to emphasize.
  - Clinical effectiveness.
  - Information security and patient safety.
  - Patient engagement.
  - Health information exchange.

## Merit-based Incentive Payment System (MIPS) – Advancing Care Information

- Core component of MIPS.
  - Currently weighted at 25% of MIPS composite score.
- Focus on interoperability.
- Final Rule does not require.
  - Reporting on clinical decision support.
  - CPOE measures.
- Reduces number of measures that clinicians must report.
  - 5 measures focused on interoperability.
  - Reduced from 18 measures in "Stage 3" of "meaningful use" and from 11 measures in the QPP proposed rule.



## MIPS – Advancing Care Information

- Key interoperability goals in Advancing Care Information category.
- Health information referrals.
  - Not only sending ePHI.
  - Receiving and querying ePHI.
  - Incorporation ePHI into patient record.
- Bridging care settings.
  - Use of secure electronic messaging and health information exchange by clinicians to share and obtain information across multiple settings.
  - Incorporating patient generated health data and data from a non-clinical setting.



## MIPS – Advancing Care Information

Key interoperability goals (con't)

- Public health and population health management.
  - Incentives to participate and report on public health and population health.
  - Outcome-related goals: care coordination, participation in public health registries and clinical health registries (includes immunizations), reporting health data related to specialties.
- Streamlining and flexibility.
  - Simplifies reporting.
  - Clinicians select measures and best use of technology for their practices.

## MIPS – Quality

- Bonus scoring opportunity in quality category to encourage electronic clinical quality measure (eCQM) reporting.
- Information exchange: MIPS eligible clinicians using CEHRT to capture, calculate and submit CQMs using structured data standards and automated data exports.
- Options for electronic reporting: electronic submission of data to CMS including: CEHRT, qualified data registries and third parties to calculate and report for providers.



## MIPS – Improvement Activities

- Options to leverage use of CEHRT in implementing clinical practice improvements.
- Many activities may satisfy Improvement Activities category.
  - Examples: capture of social, psychological and behavioral data; generate and exchange electronic care plan.
- CEHRT Bonus.
  - Bonus available under Advancing Care Information category for use of CEHRT in clinical practice improvement activities.
  - Focus on high priority quality measurement, use of CEHRT to support improved patient outcomes and care delivery system reform goals.



## Advanced Alternative Payment Models (APMs)

- Another way to reward clinicians for using CEHRT.
- Advanced APM Criteria: 50% or more of clinicians in an APM entity must use CEHRT to document and communicate clinical care information.
  - Many APM models have requirements exceeding this baseline.
- Other Payer Advanced APM Criteria:
  - Beginning in 2019, other payer APMs will become available.
  - Will also require participants in each entity to use CEHRT.

# Governance Compliance Developments: What Your Board Needs to Know About and Do vis-à-vis Compliance

PRESENTED BY

**Kathleen Drummy** | Partner
**Robert L. Schuchard** | Partner

# Governance Compliance Developments: What Your Board Needs to Know About and Do vis-à-vis Compliance

*(20 Years After CareMark)*

Robert L. Schuchard, Esq., Partner, Davis Wright Tremaine

Kathleen Houston Drummy, Partner, Davis Wright Tremaine

Davis Wright Tremaine LLP

## WHAT IS CORPORATE GOVERNANCE?

Board's Oversight of:

- Corporate Purpose and Mission
- Business and Affairs
- Financial Reporting
- Selection and Oversight of Senior Management
- Compliance
- Medical Staff
- Board Composition and Performance




## STATUTORY STANDARD OF CARE

(Same for Non-Profits and For-Profits)

- In good faith
- Believed to be in the best interest of the corporation
- Reasonable care and inquiry (as an ordinarily prudent person in a like position would use under similar circumstances)

## DUTY OF LOYALTY


- Good Faith
  - Absence of fraud or illegality
  - Honest purpose
  - Constructive skepticism
- Best interests of corporation
  - Absence of conflict of interest
- Confidentiality



## DUTY OF CARE

Two important director functions - due inquiry:

- Decision making
  - Specific decision or board action
- Oversight function
  - Oversight of management and business operations
  - Investigation when put on notice of a potential problem
    - When suspicions are aroused or should be aroused
    - *E.g.,* Extraordinary facts or material governmental investigation



## CONSEQUENCES OF FAILURE TO MEET THE FIDUCIARY DUTIES

- Poor Decisions
- Litigation by Directors, Members, Employees or Shareholders
- Governmental Investigations and Prosecutions
- Loss of Protection of the "Business Judgment Rule"
- Possible Loss of Rights to Indemnification

## CONSEQUENCES OF FAILURE TO MEET THE FIDUCIARY DUTIES *(continued)*

- Personal Liability
  - Reimburse Damages Incurred by the Corporation
    - Fines
    - Personal Benefit
    - Lost Opportunities
  - Removal



## MESSAGE OF CAREMARK, ABBOTT LABORATORIES, *STOVE V. RUTTER*

- Prior Rule:

  Unless had reason to believe there was wrongdoing, duty of care did not require "corporate system of espionage"
- Post Caremark (1996) Rule:

  Need a system to detect and prevent potential violations of law of corporate policy
  - system to track and analyze compliance issues
  - need to address problems have notice of



## CAREMARK INTERNATIONAL

- Facts
  - Kickback issues – contracts with hospitals and MDs
  - 4-year investigation by DHHS and Department of Justice
  - $250 million civil settlement and a plea agreement
- No Cause of Action
  - Internal audit
  - Price Waterhouse investigation

## IN RE CAREMARK INTERNATIONAL DERIVATIVE LITIGATION

- "… It is important that the Board exercise a good faith judgment that the corporation's information and reporting system is in concept and design adequate to assure the Board that appropriate information will come to its attention in a timely manner as a matter of ordinary operations, so it may satisfy its responsibility"
- The level of detail appropriate for such information systems is a matter of Business Judgment
  - Directors are entitled to rely in good faith on officers and employees, as well as consultants in whom such confidence is merited
  - Duty to make reasonable inquiry where facts warrant
  - Preventing all compliance issues is not reasonable



## FEDERAL CRIMINAL SENTENCING GUIDELINES

- Board must be knowledgeable about the content and operation of the compliance program and exercise reasonable oversight (Section 8B2.1)
- Board must assess whether the compliance program is adequate to mitigate risks of noncompliance
- Board should have direct access to compliance personnel



## Compliance Guidance

Compliance Resource Material

"OIG has developed a series of voluntary compliance program guidance documents directed at various segments of the health care industry, such as hospitals, nursing homes, third-party billers, and durable medical equipment suppliers, to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements."

Excerpts from the compliance program guidance documents:

09-30-2008
- Supplemental Compliance Program Guidance for Nursing Facilities (73 Fed. Reg. 56832; September 30, 2008)
  - Compliance Program Guidance for Nursing Facilities (65 Fed. Reg. 14289; March 16, 2000)

01-31-2005
- Supplemental Compliance Program Guidance for Hospitals (70 Fed. Reg. 4858; January 31, 2005)
  - Compliance Program Guidance for Hospitals (63 Fed. Reg. 8987; February 23, 1998)

11-15-1999
- Compliance Program Guidance for Medicare+Choice Organizations (64 Fed. Reg. 61893; November 15, 1999)

10-05-1999
- Compliance Program Guidance for Hospices (64 Fed. Reg. 54031; October 5, 1999)

12-18-1998
- Compliance Program Guidance for Third-Party Medical Billing Companies (63 Fed. Reg. 70138; December 18, 1998)

08-24-1998
- Compliance Program Guidance for Clinical Laboratories (63 Fed. Reg. 45076; August 24, 1998)

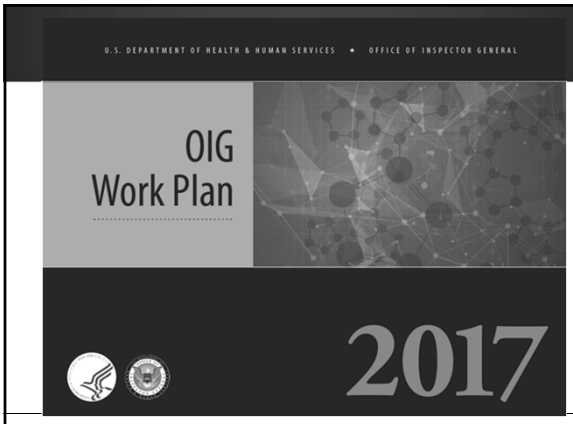
08-07-1998
- Compliance Program Guidance for Home Health Agencies (63 Fed. Reg. 42410; August 7, 1998)

## Compliance Resource Material

Health Care Boards

- 04-20-2015
  - Practical Guidance for Health Care Governing Boards on Compliance Oversight
- 02-27-2012
  - Handout: A Toolkit for Heath Care Boards
- 08-29-2011
  - The Health Care Director's Compliance Duties: A Continued Focus of Attention and Enforcement
- 03-23-2009
  - Driving for Quality in Acute Care: A Board of Directors Dashboard -- Government-Industry Roundtable
- 01-31-2008
  - Driving for Quality in Long-Term Care: A Board of Directors Dashboard - Government-Industry Roundtable
- 09-13-2007
  - Corporate Responsibility and Health Care Quality - A Resource for Health Care Boards of Directors
- 12-02-2004
  - Continuing the Partnership: A Summary of the Government-Industry Roundtable on the Role of Governance in Compliance Programs
- 07-01-2004
  - An Integrated Approach to Corporate Compliance: A Resource for Health Care Boards of Directors
- 04-02-2003
  - Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors



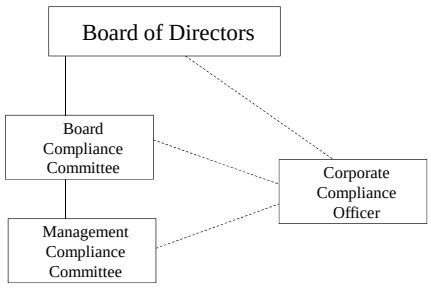





## OIG-AHLA CORPORATE COMPLIANCE RESOURCE

- Directors have a duty to exercise reasonable diligence in overseeing the compliance function
- Board should know structure of program and who are the key employees responsible for its implementation and operation
- Board should receive regular reports

## COMMON COMPLIANCE STRUCTURE SEEN AT HEALTH CARE ENTITIES






## CHANGING ENVIRONMENT FOR COMPLIANCE

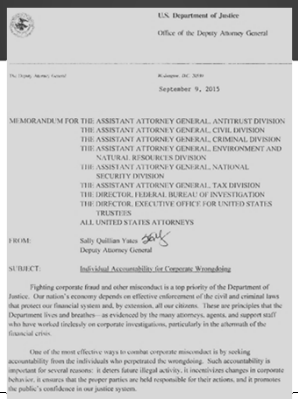
- Case law on board duty of care
  - "inadequate or flawed

    *vs.*
  - "conscious disregard"




## CHANGING ENVIRONMENT FOR COMPLIANCE
*(continued)*

- Heightened attention from regulatory and law enforcement agencies
  - Increase in enforcement activity
  - Expectation that entities need to exceed the minimum standards set forth in the Federal Sentencing Guidelines
  - More public scrutiny
  - Expansion of OIG Exclusion Rules: January 12, 2017 Final Rule
  - Corporate officer individual accountability
    - Yates memorandum



U.S. Department of Justice

Office of the Deputy Attorney General

The Deputy Attorney General

Washington, DC 20530

September 9, 2015

MEMORANDUM FOR THE ASSISTANT ATTORNEY GENERAL, ANTITRUST DIVISION
THE ASSISTANT ATTORNEY GENERAL, CIVIL DIVISION
THE ASSISTANT ATTORNEY GENERAL, CRIMINAL DIVISION
THE ASSISTANT ATTORNEY GENERAL, ENVIRONMENT AND NATURAL RESOURCES DIVISION
THE ASSISTANT ATTORNEY GENERAL, NATIONAL SECURITY DIVISION
THE ASSISTANT ATTORNEY GENERAL, TAX DIVISION
THE DIRECTOR, FEDERAL BUREAU OF INVESTIGATION
THE DIRECTOR, EXECUTIVE OFFICE FOR UNITED STATES TRUSTEES
ALL UNITED STATES ATTORNEYS

FROM: Sally Quillian Yates
Deputy Attorney General

SUBJECT: Individual Accountability for Corporate Wrongdoing

Fighting corporate fraud and other misconduct is a top priority of the Department of Justice. Our nation's economy depends on effective enforcement of the civil and criminal laws that protect our financial system and, by extension, all our citizens. These are principles that the Department lives and breathes—as evidenced by the many attorneys, agents, and support staff who have worked tirelessly on corporate investigations, particularly in the aftermath of the financial crisis.

One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing. Such accountability is important for several reasons: it deters future illegal activity, it incentivizes changes in corporate behavior, it ensures that the proper parties are held responsible for their actions, and it promotes the public's confidence in our justice system.



## CHANGING ENVIRONMENT FOR COMPLIANCE
*(continued)*

- Recommendations on compliance
  - Ethics & Compliance Initiative (ECI): Principles and Practices of High Quality Ethics and Compliance Programs

In April of 2016, the Ethics and Compliance Initiative (ECI) released the final version of its report, Principles & Practices of High Quality Ethics & Compliance Programs. The report was prepared by a Blue Ribbon Panel of prominent ethics and compliance practitioners, academics, white collar and whistleblower attorneys, as well as former enforcement officials. Ethics and compliance practitioners and other members of the public were invited to offer comments on a draft of the report and their feedback was included in the final report.



## HIGH-QUALITY E&C PROGRAMS (HQP) STANDARDS

The final report provides detail about organizations with ethics and compliance programs that go beyond the minimum standard. The report discusses five core principles that are shared by these organizations:

- Principle 1: Ethics and compliance is central to business strategy.
- Principle 2: Ethics and compliance risks are identified, owned, managed and mitigated.
- Principle 3: Leaders at all levels across the organization build and sustain a culture of integrity.
- Principle 4: The organization encourages, protects, and values the reporting of concerns and suspected wrongdoing.
- Principle 5: The organization takes action and holds itself accountable when wrongdoing occurs.

The report also identified specific objectives, practices and pitfalls to avoid that have enabled organizations to raise the bar on ethics & compliance and set themselves apart from their peers.

## EVIDENCE OF NEW COMPLIANCE PRACTICES

- Raising the profile of the Corporate Compliance Officer and the Compliance function
  - Inclusion of Compliance Officer in strategic planning and other top management team meetings
  - Board compliance committee chair meets periodically with the Corporate Compliance Officer
  - Compliance officers included in crisis management team




## EVIDENCE OF NEW COMPLIANCE PRACTICES
(continued)

- Raising the profile of compliance at the board
  - Board compliance committee regularly briefs the board on its activities
  - Submit the Compliance Program to independent review
  - Recruit board members with compliance background
  - Provide board education regarding compliance



## EVIDENCE OF NEW COMPLIANCE PRACTICES
(continued)

- Raising the accountability of Senior Management
  - Compliance risk areas are assigned to business leaders to address
  - Operations managers meet regularly to identify and classify (prioritize) risk areas with some quantitative measurements
  - Management steering committee convenes to give insights to Compliance
  - Leaders periodically discuss the importance of compliance with employees
- Compliance officers and staff participate in trade association activities to learn what others are doing

## EVIDENCE OF NEW COMPLIANCE PRACTICES
(continued)

- Create an environment where "speaking up" is encouraged and not retaliated against
  - Include training of managers as to how to encourage
  - Leaders discuss the importance of raising issues
  - Ombudsman to oversee how reporters are treated/protection of reporters
  - Compliance staff follow up to make sure no retaliation
  - Confidentiality policies and agreements accommodate an employee's right to report to governmental authorities
  - Substantiated retaliation is reported up the chain of command and addressed



## EVIDENCE OF NEW COMPLIANCE PRACTICES
(continued)

- Periodic risk assessments
  - Risks are identified and ranked
  - Policies and the code of conduct are updated
  - Targeted training in areas of highest risk
  - Failures/breaches are monitored for learning and follow up action
  - Leaders are tasked with identifying risk area



## EVIDENCE OF NEW COMPLIANCE PRACTICES
(continued)

- Sufficient resources are allocated to compliance
  - Discussion with board as to how adequacy of resources is determined

## EVIDENCE OF NEW COMPLIANCE PRACTICES
*(continued)*

- Sufficient resources are made available to senior leadership
  - RCOD concerns with personal liability
  - Access to counsel
  - Corporate commitment to compliance
  - Expanded insurance/indemnification/expense advancement coverage, including access to outside counsel



## RED FLAGS

- Accounting firm/auditor warnings
  - management letter
  - special letter
- Compliance program remains largely unchanged from its first implementation
- No reporting on compliance activities
- No clear reporting responsibilities to board or executive leadership
  - compliance officer not seen as a senior leader
- Not meeting compliance plan objectives
  - educating employees
  - not reporting regularly to the board
  - no activity



## RED FLAGS
*(continued)*

- No board compliance education
- No one asking tough questions
  - need some “pleasant skeptics”
  - need objectivity
- Organization does not ask for input from senior leaders or employees regarding compliance issues
- No aggressive follow-up on potential problems
  - need to investigate
  - need to take disciplinary or other action
  - need to report or follow up to wrong doing
- Negative information/suggestions in press stories

## RED FLAGS
*(continued)*

- "Fooling Around"
  - Shredding
  - Altering
  - Back dating
  - Withholding information from the government



## QUESTIONS/COMMENTS

# Hospital Litigation Update

PRESENTED BY

**John R. Tate** | Partner
**Anna R. Buono** | Associate
**Loring Rose** | Associate

# Hospital Litigation Update

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John Tate, Partner, Davis Wright Tremaine

Davis Wright Tremaine LLP

## National Trends and Developments

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## National Trends and Developments

- False Claims Act post-*Escobar*
- False Claims Act imposes liability on
  - Whoever "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A)
  - Whoever "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id*. § 3729(a)(1)(B)
  - Claims can be *factually* false or *legally* false
  - Legally-false certifications can be *express* or *implied*


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## National Trends and Developments

- *Universal Health Services v. United States ex rel. Escobar*
- Case involved claims for mental health counseling services that Universal Health submitted to the Massachusetts Medicaid program.
- Alleged that Universal Health "submitted reimbursement claims that made representations about the specific services provided by specific types of professionals, but that failed to disclose serious violations of regulations pertaining to staff qualifications and licensing requirements for these services."
- *Implied certification* theory of liability



## National Trends and Developments

- Dismissed at the District Court level, but that dismissal reversed on appeal to the First Circuit Court of Appeals.
- First Circuit held that *every* submission of a claim *implicitly represents compliance with relevant regulations*, and that *any undisclosed violation of a precondition of payment* (whether or not expressly identified as such) renders a claim "false or fraudulent."
- Circuit differences with regard to import of implied certification theory.



## National Trends and Developments

- Supreme Court held that "the implied false certification theory can, at least in some circumstances, provide a basis for liability."
- "[*A*]*t least* where two conditions are satisfied:"
  - The claim "does not merely request payment, but also *makes specific representations* about the goods or services provided"; *and*
  - Defendant's failure to disclose its noncompliance "with *material* statutory, regulatory, or contractual requirements makes those representations misleading half-truths."
- The misrepresentation about compliance must be "*material* to the Government's payment decision" to be actionable.
- This "materiality" standard is "rigorous" and "demanding".
  - if the government pays a claim in full despite its actual knowledge that certain requirements were violated, "that is very strong evidence that those requirements are *not material*".

## National Trends and Developments

- Key case: *U.S. ex rel. Rose et al. v. Stephens Institute* (N.D. Cal.)
- Plaintiffs alleged that defendant fraudulently obtained funds from the U.S. Department of Education by falsely alleging compliance with Title IV of the Higher Education Act
- Defendant moved for summary judgment, Judge denied motion
- Is *Escobar*'s two-part implied certification test *mandatory*?
  - Judge says "no," test not necessary for liability
  - "At least" language = *permissive*
  - This would appear to be helpful to plaintiffs, since there can be additional bases to find implied certification



## National Trends and Developments

- What is *material*?
  - Defendant presented evidence that the government rarely revoked Title IV funds for the kinds of compliance allegations alleged and that the government did not initially take action against defendant once the allegations came to light
  - Judge disagreed that this was sufficient to show immateriality, relied on pre-*Escobar* case
- On the request of defendants, Judge certified an interlocutory appeal to the Ninth Circuit—on to the Supreme Court?
- How far can the implied certification theory go?



## National Trends and Developments

- False Claims Act: Statistical Sampling
- Analysis of a representative sample of a provider's claims
- Sample used to draw inferences about the totality of those claims
- Frequently used to prove *damages*, in cases where a claim-by-claim review is not practical
- Less frequently allowed for purposes of *liability*

## National Trends and Developments

- Key case: *United States ex rel. Berntsen* (C.D. Cal.)
- $50 million FCA suit, alleging the falsity of potentially tens of thousands of Medicare claims
- Plaintiff alleged that defendant used fraudulent admissions practices to boost the bills that were sent to Medicare and Medicaid
- Government served subpoenas for documents on a portion of the claims
  - Subpoenaed 131 claims, or about 0.17% of the universe of claims at issue



## National Trends and Developments

- Defendant filed a preemptive motion to exclude statistical sampling evidence to prove *liability*
- *Government has the burden to prove liability*
- Judge thought the motion premature and denied it without prejudice
- Defendant will have the opportunity to re-file motion once government tries to use statistical sampling to show liability
- Government has avoided this fight before—what will happen here?



## National Trends and Developments

- False Claims Act and DOJ Experts
- Key case: *United States ex rel. Paradies v. AseraCare, Inc*. (N.D. Ala.)
- $200 million False Claims Act suit targeting Medicare billing by hospice chain AseraCare
- Alleged that AseraCare billed Medicare for hospice services for patients that were ineligible for end-of-life care, notwithstanding that patients were certified as eligible by physicians
- DOJ's expert disagreed with physicians' conclusions

## National Trends and Developments

- Trial court granted summary judgment to AseraCare
- "When hospice certifying physicians and medical experts look at the very same medical records and disagree about whether the medical records support hospice eligibility, *the opinion of one medical expert alone cannot prove falsity without further evidence* of an objective falsehood."
- Disagreement by DOJ expert over course of care does not equate to false claim—victory for defendants in FCA cases
- Case appealed to Eleventh Circuit



## California Litigation Highlights



## California Litigation Highlights

- Consumer Actions
  - Uniform Practices: Medical Records Charges
  - Variable Practices: Charges Not Covered by Insurance

## California Litigation Highlights

- Medical Records Charges
  - *Nicodemus v. Saint Francis Memorial Hospital*, 3 Cal. App. 5th 1200 (Sept. 14, 2016)
    - Patients requesting copies of their records
    - Statutory fee schedule
    - Claim that medical records management company charged fees in excess of the statutory fee schedule



## California Litigation Highlights

- *Nicodemus*
  - Claims asserted under Evidence Code Section 1158 and the UCL
    - Evidence Code Section 1158 provides that medical providers must promptly provide medical records to lawyers for patients who have consented to release of the records
    - Provides that medical providers can charge the attorneys all reasonable costs incurred in making the patient records available, limited to $.10 per page for copying regular paper, $.20 for microfilm, actual cost of oversize or special processing documents, reasonable clerical costs at a maximum of $16 per hour



## California Litigation Highlights

- *Nicodemus*
  - Class definition sought: Individuals whose attorneys requested patient medical records from a medical provider in California prior to litigation and were charged more than the amounts specified in Section 1158
  - Trial court denied class certification on the basis of ascertainability and predominance of common issues

## California Litigation Highlights

- *Nicodemus*
  - Appellate court directed trial court to allow a class:
    - Document request dataset contained sufficient information to identify attorney requesters.
    - Common question existed regarding whether the *uniform practice* of responding to attorney requests for medical records violated Evidence Code Section 1158.
    - Even if each class member will be required to establish his or her records request was submitted before or in contemplation of litigation does not overwhelm the common question.



## California Litigation Highlights

- Medical Records charges
  - Compare: *Carter v. Healthport Technologies, LLC*, 822 F.3d 47 (2d Cir. May 10, 2016)
  - Similar claim in the Second Circuit, overcharge for copies of medical records.
  - Motion to dismiss granted on grounds of lack of injury-in-fact and standing because attorneys, not plaintiffs, paid for the records.
  - Reversed on the basis that attorneys are agents of the plaintiffs, so the complaint plausibly alleged plaintiffs themselves were injured.
  - Certification not yet raised, but indication is that a class could be made just as in *Nicodemus*.



## California Litigation Highlights

- Distinguishing *Nicodemus*:
  - *Jansky v. Laboratory Corporation of America*, 2017 Cal. App. Unpub. LEXIS 418 (Jan. 20, 2017)
    - Class certification sought relating to charges for laboratory testing not covered by insurance.
    - Three classes requested, all of which the court denied.
    - Unlike the uniform practice of charges for medical records in *Nicodemus*, here the court believed each class member's insurance coverage decisions would have to be reviewed because scope of coverage is neither universal nor dependent on particular ICD Codes.
  - *Leon v. Emergency Medical Group of Watsonville*, 2016 Cal. App. Unpub. LEXIS 5134 (July 11, 2016)
    - Class certification sought relating to balance billing and collections.
    - Certification denied because, like *Jansky*, there were too many variables.

## California Litigation Highlights

- Take Away: Classes pose more exposure, so uniform practices should strictly adhere to requirements of statutes or regulations.




## California Litigation Highlights

- Consumer and Consumer Protection Claims
  - *Moran v. Prime Healthcare Management, Inc.*, 3 Cal. App. 5th 1131 (Sept. 14, 2016)
    - UCL claim alleging hospital emergency department services had been billed at grossly excessive and unconscionable rates.
    - At a motion to dismiss level (based on the pleadings only), excess charges to uninsured ER patients satisfies unfair and unlawful prongs of the UCL.
    - However, discriminatory pricing claim failed because variable pricing is permitted, patient lacked standing as to misrepresentation claim, and reasonable value claim failed because an express contract referenced an ascertainable fee schedule.



## California Litigation Highlights

- Ordinary Negligence or Professional Liability?
  - *Flores v. Presbyterian Intercommunity Hospital*, 63 Cal. 4th 75 (May 5, 2016)
    - Plaintiff injured when hospital bed railing collapsed.
    - Court held the claim sounds in professional negligence, not ordinary negligence.
      - The railing had been raised per the doctor's orders.
      - The allegation was that the hospital negligently failed to inspect and maintain the equipment.
    - Important distinction: Ordinary negligence has a 2 year statute of limitations. Professional liability has a 1 year statute of limitations.
    - Result: Claim barred by the statute of limitations.

## California Litigation Highlights

- Elder Abuse
  - *Fenimore v. Regents of the University of California*, 245 Cal. App. 4th 1339 (March 9, 2016)
    - Elderly Alzheimer's patient with extreme risk of falling transferred to facility on a 5150, then left alone for 15 minutes. He fell. Hospital failed to treat the injury for four days, and he was transferred elsewhere.
    - At the next facility, it was discovered that he had fractured his hip in the fall.
    - He died of his injuries within a short period of time.
    - Family sued the hospital for elder abuse, negligence, negligent hiring and supervision, and wrongful death.



## California Litigation Highlights

- *Fenimore*
  - Key to the allegations were regulatory violations and understaffing that led to a failure to properly supervise and treat the patient.
  - Court of Appeal held that plaintiffs sufficiently alleged elder abuse.
  - Issues for the trier of fact should include whether a **knowing pattern and practice** of understaffing in violation of applicable violations amounts to recklessness.



## California Litigation Highlights

- Anti-SLAPP Motions in Whistleblower Litigation
  - SLAPP: Strategic Litigation Against Public Participation
  - Anti-SLAPP Motions aim to prevent abusive litigation and protect speech and participation rights
  - Filing an anti-SLAPP Motion *stays discovery*
  - *Mandatory* award of attorneys' fees
  - Right to an immediate appeal (in California)
  - Anti-SLAPP Motions have been used to protect peer review proceedings

## California Litigation Highlights

- *Armin v. Riverside Community Hospital*, 5 Cal. App. 5th 810 (Nov. 16, 2016)
  - Two questions of first impression:
    - Is completion of peer review a prerequisite of a section 1278.5 action?
    - Can a physician bringing a section 1278.5 action name individual doctors involved in the peer review as defendants?



## California Litigation Highlights

- *Armin*
  - Is completion of peer review a prerequisite of a section 1278.5 action?
    - Prior California Supreme Court decision (*Fahlen v. Sutter Central Valley Hospitals*, 58 Cal.4th 655 (2014)) held a physician could prosecute a whistleblower action without first having to prevail in an administrative mandate proceeding following a peer review determination, but did not decide whether the physician had to complete the peer review process before filing a section 1278.5 action.
    - Based on *Fahlen* and the Legislative History of Section 1278.5, Court held that completion of peer review is <u>not</u> a requirement.



## California Litigation Highlights

- *Armin*
  - Can a physician bringing a whistleblower action name individual doctors involved in the peer review as defendants?
    - Based on the text of Section 1278.5 and the Legislative History, the Court held that individual doctors may <u>not</u> be named in a section 1278.5 complaint.

## California Litigation Highlights

- *Armin*
  - What does this have to do with anti-SLAPP?
    - Peer review context, so involves protected activity.
    - Physician being reviewed claimed religious discrimination.
    - Was the claim of discrimination so intertwined with the protected activity so as to subject the claims to an anti-SLAPP motion?
    - Anti-SLAPP Motion failed because physician alleged the peer review was initiated *in retaliation* for complaining about discrimination, not because of discrimination during the peer review.
  - NOT a case involving administrative mandamus to set aside discipline after peer review proceedings, so the standard of review was more favorable to plaintiff than defendants.



## California Litigation Highlights

- More Anti-SLAPP
  - *Un Hui Nam v. Regents of the University of California*, 1 Cal. App. 5th 1176 (July 29, 2016)
    - Anesthesiology resident at state university hospital claimed retaliation, discrimination, sexual harassment, wrongful termination.
    - Resident complained about patient care procedures and failure to reciprocate sexual advances.
    - She was subjected to various investigatory leaves and other discipline, all of which exonerated her.
    - Once she returned to work, the residency competency committee decided to dismiss her, and on appeal, it was upheld. The investigator, however, also faulted the anesthesiology department for singling her out for unique treatment.



## California Litigation Highlights

- *Nam*
  - Resident sued, and the hospital filed an anti-SLAPP motion theorizing that the complaint arise from written complaints made in connection with an official proceeding.
  - Court denied the motion, finding the action does not arise from a protected activity. What was said during the hearings appealing her termination is not the basis of the claim.

## California Litigation Highlights

- Anti-SLAPP take away:
  - Legitimate peer review and discipline is protected activity.
  - Conduct occurring prior to such peer review is outside the scope of the protected activity.
  - Key is what conduct is alleged by a plaintiff. Claims based on conduct outside peer review will survive an anti-SLAPP motion.



## Other Trends



## Workplace Policy Issues

- National Labor Relations Board Decision on policy prohibiting "offensive" conduct
  - *Valley Health System LLC*, 363 NLRB No. 178 (May 5, 2016)
    - Policy prohibited employees from "engaging in conduct that brings discredit on the System or Facility or is offensive to fellow employees."
    - NLRB held that the policy violated Section 8(a)(1) of the National Labor Relations Act because it would reasonably tend to chill employees in the exercise of their Section 7 rights.

## Workplace Policy Issues

- *Valley Health*
  - Policy also included a mandatory arbitration agreement requiring employees, as a condition of employment, to waive the right to maintain class or collective actions in all forums, arbitral *or* judicial.
  - Contained an opt-out, but NLRB rejected the notion that the opt-out made it voluntary and held that it violated Section 8(a)(1).



## Workplace Policy Issues

- On the Subject of Arbitration Agreements:
  - *Vasserman v. Henry Mayo Newhall Memorial Hospital*, 2017 WL 491700 (Feb. 7, 2017)
    - Registered nurse brought class action complaint for violations of Labor Code relating to meal and rest breaks, unpaid wages, unpaid overtime.
    - Hospital argued that the collective bargaining agreement required her to arbitrate her claims.
    - Even though the agreement included an arbitration requirement, the requirement did not include an unmistakeable waiver of the right to a judicial forum for claims based on the statute.



## Privacy Issues

- Privacy and Reality Television
- Key case: *Chanko v. American Broadcasting Company, et al.* (New York)
- ABC was in the hospital to film a documentary regarding ERs and trauma treatment, with hospital's knowledge and approval
- Film crew recorded patient's medical treatment and eventual death, with a portion of the footage later broadcast as part of the documentary
- Neither ABC nor hospital had patient's (or family's) approval to film, nor did family know filming was happening

## Privacy Issues

- Dismissed, appealed to New York Court of Appeals
- Claim for breach of doctor-patient confidentiality *allowed to proceed against doctor and hospital*
- *Even though* patient's face was distorted on the broadcast so as to be unrecognizable
- Hospital fined $2.2 million by HHS
- Care must be taken to obtain approval *in advance* of any patient *prior to allowing film crew* in sensitive areas



## Trending Discrimination Issues

- Increase in activity relating to transgender issues
  - *Robinson v. Dignity Health*, 2016 U.S. Dist. LEXIS 168613 (N.D. Cal. Dec. 6, 2016)
  - *Rumble v. Fairview Health Servs.*, 2017 BL 26785 (D. Minn. Jan. 30, 2017)
  - *Tovar v. Essentia Health*, 187 F. Supp.3d 1055 (D. Minn. May 11, 2016)
  - *Fabian v. Hospital of Central Connecticut*, 172 F. Supp. 3d 509 (D. Conn. Mar. 18, 2016)
  - *Brown v. Dept. of Health and Human Services*, 2016 WL 6637937 (D. Neb. Nov. 9, 2016)
  - *Franciscan Alliance, Inc. v. Burwell*, 2016 WL 7638311 (N.D. Tex. Dec. 31, 2016)



## Trending Discrimination Issues

- Main area for litigation: Section 1557 of the ACA preventing discrimination, including on the basis of gender identity
- Gender identity issues are on certiorari before the Supreme Court:
  - *Gloucester County School Board v. Grimm* (whether a school's bathroom policy violates prohibition against sex discrimination in Title IX)
- And a recent nationwide injunction issued preventing enforcement by the DHHS regulation under Section 1557
  - *Franciscan Alliance, Inc. v. Burwell* (healthcare providers challenged regulation under ACA prohibiting discrimination on the basis of gender identity and termination of pregnancy as a violation of Religious Freedom Restoration Act as applied to providers)

## Trending Discrimination Issues

- The current status of *Gloucester* has stayed several of these actions, as a determination on sexual identity discrimination issues under Title IX would be persuasive on Section 1557 application.
- Oral argument has not been scheduled.
- Changes to the ACA may moot some of the issues



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# Managing New Risks in Hospital-Physician Relationships – A Potpourri

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# Managing New Risks in Hospital-Physician Relationships – A Potpourri

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Davis Wright Tremaine LLP

## Overview

- Anti-Kickback, CMPL and Stark Update
- The 60-Day Repayment Rule
- Voluntary Disclosures and Refunds
- Physician Compensation
- Emerging Trends in Fraud Cases Based on Medical Necessity



## Anti-Kickback, CMPL and Stark Update

## Anti-Kickback Statute Developments- New Rules

- Five New Safe Harbors (Dec. 2016 final rule)
  - Waivers of pharmacy cost-sharing
  - Waivers of public ambulance cost-sharing
  - Relationships between Medicare Advantage organizations and Federally Qualified Health Centers
  - Medicare coverage gap discount programs
  - Free or subsidized local transportation services
    - Unlike the other new safe harbors, this can be used by a variety of providers to lower patients' cost of accessing care and ensure that they receive regular, prompt care.



## Civil Monetary Penalty Law Developments- New Rules

- OIG issued new rules clarifying additional exceptions to definition of beneficiary "remuneration." (Dec. 2016)
  - Remuneration that "poses a low risk of harm" and "promotes access to care";
  - Retail reward programs such as coupons or rebates;
  - Remuneration to financially needy individuals; and
  - Co-payment waivers for the first fill of generic drugs.
- OIG increased dollar cap on nominal value gifts (now $15/gift or $75/year, up from $10/$50).



## CMPL Developments- New Rules

Examples of items or services that "pose a low risk of harm" and "promote access to care" include :

- provision of child care during beneficiary appointments;
- free or discounted medications, supplies, or devices;
- technology for reporting health data;
- scales or programmable tools to help with medication dosage or refill reminders;
- telemedicine capabilities; and
- incentives for scheduling, in extenuating circumstances (e.g., at a dialysis facility, an inducement to patient to move appointment in order to promote access by different patient).

## CMPL Developments- New Rules

- For the financially needy patient exception, examples of free items that the OIG believes could be "reasonably connected" to the patient's medical care include:
  - blood pressure cuffs;
  - patient engagement software applications;
  - biomonitoring devices, and;
  - mobile devices as necessary to meet patients' various health needs.

*Basically, exception would permit most items connected to the wellness and health needs of financially needy beneficiaries .*



## CMPL Developments- New Rules

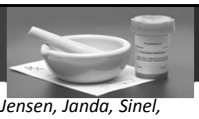
- Civil money penalties have now been adjusted for inflation and will continue to reflect annual adjustments for inflation.
  - For example, penalty for beneficiary inducements was previously $10,000 per violation. Now it is $15,270 for 2017.
  - See penalty adjustment and table at 45 C.F.R. § 102.3



## AKS Developments- Case Law

- California court offers an interpretation of "recommending" under the AKS:
  - *United States ex rel. Brown v. Celgene Corp.*, No. 10-cv-03165, 2016 U.S. Dist. LEXIS 180628 (C.D. Cal. Dec. 28, 2016)
  - Case involved allegations of paying kickbacks to physicians via promotional speaker program and off-label promotion of Celgene drugs.
  - Even if some physician speakers encouraged audience members to prescribe Celgene drugs, "generalized promotion" is not "recommending" under the AKS.
  - Court held: "the term 'recommendation' was only intended to encompass recommendations that pertain to specific patients." *Id*. at *54.

## AKS Developments- Case Law



- Contrast with indictment in *U.S. ex rel. Jensen, Janda, Sinel, Roub and Schoonover* (C.D. Cal. 2016)
  - Grand jury charged owners of La Miranda compounding pharmacy and principals of marketing companies plus one physician for conspiring to violate the AKS
  - Compounding pharmacy paid in excess of $20M over 4 years by federal programs including TRICARE
  - Illegal referral fees were allegedly disguised as commission fees under sham marketing subagent agreements.
  - Marketers allegedly solicited physicians and offered pre-printed prescriptions for signature; marketers or the physicians would deliver prescriptions directly to the compounding pharmacy.



## AKS/CMPL: Recent Advisory Opinions re: Hospitals

- 16:13: University may waive out of pocket cost sharing for clinical study related health care services in order to encourage study enrollment and participant compliance. The NCI study will not benefit any specific product or entity.
- 16-11, 16-05, 16-04, 16-01: Preferred hospital organization may waive Part A inpatient deductibles for Medigap insurance plan members.

- 16:10: Two public health districts may coordinate education and transportation of patients with financial need.
- 16:02: State AMC may provide free transportation and short term lodging to financially needy pregnant women.



## Stark Law Developments – New Rules

- Newest Stark regulations took effect Jan. 2016
  - **Two new exceptions**:
    - Timeshare arrangements
    - Hospital assistance to compensate a non-physician practitioner
  - **Helpful modifications to existing rules**:
    - Multiple writings can make a single contract .
    - Holdovers of personal services and rental of office space arrangements may continue indefinitely on same terms and conditions.
    - For purposes of stand in the shoes, CMS clarified that all physicians in a physician organization are considered parties to the compensation arrangement between the physician organization and DHS entity.

## Stark Law Developments – Cases

- 1/15/2016: Tri-City Medical Center (Oceanside, CA) agreed to pay nearly $3.3M to settle allegations that it violated Stark Law and FCA with respect to arrangements with various community physicians.
  - Five arrangements with Chief of Staff not commercially reasonable or FMV
  - 92 financial arrangements with other physicians and practice groups did not satisfy Stark exception because, among other things, the agreements were expired, missing signatures or could not be located
    - Agreements from 2009-2010 may have been saved by new holdover exception!



## Stark Law Developments – Cases

- Sept. 2016: Former Tuomey CEO Ralph "Jay" Cox III agreed to pay $1M and be excluded for two years to resolve involvement in massive Stark law / FCA case involving Tuomey Health System.
  - Government alleged during the *US ex rel. Drakeford v. Tuomey* trial that Cox "ignored and suppressed warnings from a hospital attorney that the physician contracts were risky and raised red flags", and even pushed Tuomey to enter questionable deals with 19 specialist physicians over fears that it would lose out on patients to a new surgery center.
  - Individual enforcement actions may continue under directives of Yates memorandum.




## Physician Compensations: Legal Framework

- The federal Physician Self-Referral Prohibition *42 U.S.C. §1395nn*
- Anti-Kickback Statute - *42 U.S.C. §1320a-7b(b)*
- Internal Revenue Code prohibition on Private Benefit/ Private Inurement


- Government's arguments and the Courts' analyses of the Stark law are redefining the rules and changing the risk analysis of physician compensation.

## The Three "How's" NB17

- When analyzing physician compensation, three tests are typically involved:
  - **How Much?**
    - Is the compensation within the range of fair market value?
  - **How Calculated?**
    - Is the compensation based on the volume or value of the physician's referrals?
  - **How Come?**
    - Is the compensation commercially reasonable?

3 x ?



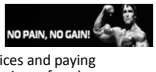
## Stark and FCA: New Duo Hits the Top of the Charts . . .

- US ex rel. Reilly v. North Broward Hospital District
  - $65.9 million settlement in December 2015
  - Allegations of compensation above FMV and commercially unreasonable because it was over the 90th percentile of MGMA survey data
  - Tracking and evaluating "contribution margins"
- US ex rel. Barker v. Tidwell (Columbus Regional)
  - $25 - $35 million hospital settlement
  - $425,000 settlement for physician
  - Allegations included paying above FMV for practice, compensation not commercially reasonable but for physician's referrals



## Recent Big Hits (cont)

- US ex rel. Schaengold v. Memorial Health et al.
  - $9.8 million
  - Allegations included paying compensation above FMV and calculated to reward physicians for referrals within the system
  - Internal Board email: we can't continue to pay these salaries, but can't afford to lose the referrals
- US ex rel. Payne v. Adventist Health System
  - $118.7 million allegations included purchasing practices and paying employed physicians above FMV as a means of capturing referrals
  - Tracking referrals was evidence of wrongfully paying for referrals ("lose the spreadsheet")

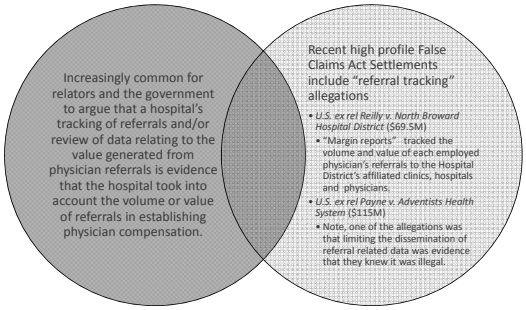


## Physician Compensation: Internal Processes

- To reduce risks consider review of internal processes relating to physician compensation
- How does your organization determine how to pay physicians?
  - Who is in charge?
  - Are compensation decisions data based?
  - What standards are used?
  - What safeguards are in place?
  - What records are maintained?
- Goal should be FMV, commercially reasonable compensation that the organization can defend if necessary.



## Controlling the Conversation: *Referrals*



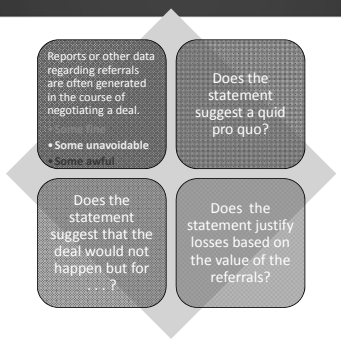



## Evidence of What?


Are you generating evidence that compensation "takes into account" or "otherwise reflects" the v/v of referrals?

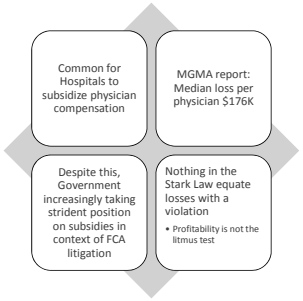
- *Bradford*: Hospital subleased nuclear camera from physician group. Group formerly used camera in office, rather than referring patients to the Hospital. Sublease included a noncompete for range of services.
- Fixed fee lease payments found to reflect v/v of referrals based in part on the fact that the CPA-prepared valuation opinion calculated value of anticipated referrals to the hospital for nuclear camera, CT/MRI services.
- And the CEO said . . .

## The "R" word



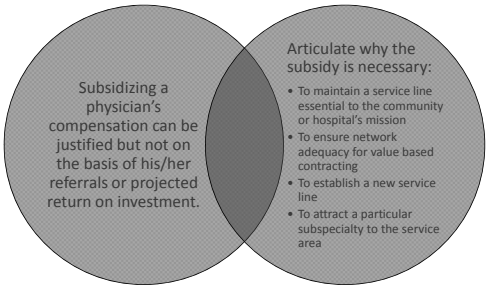



## Controlling the Conversation: *Compensation Subsidies*






## Subsidies . . .



## 60 Day Rule –Voluntary Repayments

- The Statute: Section 6402(a) of the Affordable Care Act (42 USC 1320a-7k(d))
  - An overpayment must be reported and returned by the later of:
    - The date which is 60 days after the overpayment was identified; or
    - The date any corresponding cost report is due, if applicable.



## 60 Day Rule: The Statute (cont)

- Any overpayment retained after the deadline is an "obligation" under False Claims Act:
  - 31 USC 3729(a)(1)(G) and 31 USC 3729(b)(3)
  - Reverse FCA liability
- Civil Money Penalty Law amended to impose CMP on any person who knows of an overpayment and does not report and return as required:
  - Penalties of $10,000 for each item or service plus treble damages
  - Basis for Permissive Exclusion



## Initial "roll-out"

- Statutory requirement to report and return overpayments within 60 days of "identification"
- "Identify" is not defined in the statute

## *U.S. ex rel. Kane v. Continuum*

- In August of 2015 Federal District Court in SDNY issues ruling interpreting what it means to "identify" an overpayment under 60 Day Rule.
- "The sixty day clock begins ticking when a provider is put on notice of potential overpayment, rather than at the moment when the overpayment is conclusively ascertained."
- Tough standard
- Judge acknowledges standard not practical.



## Final Regulations

- Final Regulation published February 2016
- Generally good news
  - "Identified" defined in a more flexible manner
    - An overpayment is *identified* "when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment."
  - 6-year "look-back" period



## Obligation to Investigate?

- Government has sought to avoid an interpretation of the 60 Day Rule that encourages an ostrich defense

- Final regulation provides that a person "should have" determined that an overpayment occurred "if the person fails to exercise reasonable diligence and the person in fact received an overpayment."
- "Reasonable diligence" not defined but commentary explains it includes:
  - Proactive compliance activities conducted in good faith by qualified individuals to monitor for receipt of overpayments
  - Reactive investigations conducted in good faith in a timely manner in response to obtaining credible information of a potential overpayment

## Reasonable Diligence = ?

- The final rule allows provider a period of time to investigate before the "60-Day clock" begins ticking.
- Once a person has credible information. it should exercise reasonable diligence to determine whether an overpayment has been received and to quantify the overpayment amount.
- 60-day period starts to run either once the provider completes the reasonable diligence or the date the provider received credible information if provider fails to conduct reasonable diligence.
- CMS recognizes diligence takes time and that part of identifying an overpayment is quantifying the amount.

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## Reasonable Diligence = ?

- Regulatory text does not define the amount of time a provider may take to conduct its investigation.
- Preamble: reasonable diligence " is demonstrated through the timely, good faith investigation of credible information, which is at most 6 months from the receipt of the credible information, except in extraordinary circumstances." 81 Fed Reg at 7662.
- Total of 8 months

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## Extraordinary Circumstances?

- Extraordinary circumstances may justify more than eight-month delay.
  - Fact-specific question
  - Unusually complex investigations:
    - Stark Violations disclosed under SRDP
    - Natural Disasters
    - State of Emergency
  - Bad Examples
- Maintain records to document reasonable diligence

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## Disclose and Repay

- Providers must use an applicable claims adjustment, credit balance, self-reported refund or other appropriate process to satisfy obligation to report and return overpayments.
- In other words, providers may disclose and make repayment to the Medicare Contractor.
  - Contractors have Voluntary Disclosure Forms
    - Typically posted on websites



## Disclosure under SDP and SRDP

- Providers may disclose under OIG's SDP or CMS SRDP and toll the clock on repayment obligation.
  - If person withdraws from protocol the clock starts to run again.
- Self-disclosure to DOJ or other agencies will NOT toll the 60-day period.
  - Trap for the unwary?



## Voluntary Disclosure: Options

- Carrier
- CMS
- OIG
- AUSA
- DOJ/FTC

# Emerging Trends in Fraud Cases Based on Medical Necessity



## Medical Necessity Cases for Hospitals

- Favorable developments in case law (if you want to roll the dice)
  - *US ex rel. George v. Fresenius Med. Care Holdings, Inc.*, No. 2:12-cv-00877-AKK, 2016 WL 5261666, *3 (N.D. Ala. Sept. 9, 2016) ("**In short, the court declines to find that a difference in medical judgment**—in absence of evidence that a doctor's independent medical judgment was compromised, for instance, through the writing of inefficient prescriptions—**constitutes a false claim**.").
  - *United States v. AseraCare, Inc.*, 153 F. Supp. 3d 1372, 1387 (N.D. Ala. 2015) ("The case law, the regulations, and even the testimony of the Government's witnesses support the court's conclusion that it should have instructed the jury that **a mere difference of opinions among physicians, *without more,* is insufficient to show falsity under the False Claims Act**.") Eleventh Circuit appeal pending.



## Medical Necessity Cases Affecting Hospitals

- *United States ex rel. Polukoff v. St. Mark's Hosp.*, No. 2:16-cv-00304-JNP-ENF, 2017 WL 237615 (D. Utah Jan. 19, 2017)
  - Allegations of unnecessary heart surgeries at two Utah hospitals
  - Court held that difference between a cardiac surgeon's medical opinion and American Heart Association's medical guidelines over whether the surgeries were medically necessary does not create FCA liability.
  - No objective standard concerning when *Medicare* would cover these specific surgeries

## Medical Necessity Cases Affecting Hospitals

- Contrast with DOJ's recent national settlements involving issues of medical necessity:
  - **Defibrillators**: DOJ settled with **457 hospitals** in **43 states** for more than $250M, collectively, between 2013-2015.
    - Issue: ICDs implanted in violation of Medicare National Coverage Determination indications for coverage.

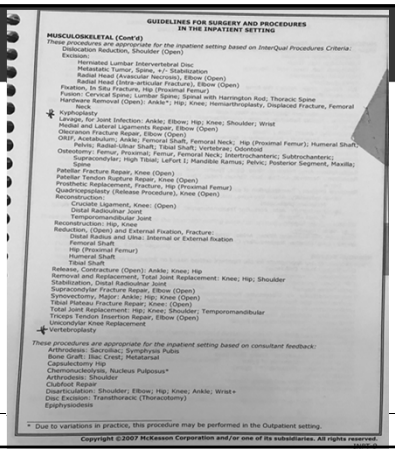
- ICDs implanted within 40 days of a heart attack or 90 days after bypass or angioplasty.
- What happens when NCD does not reflect clinical practice and opinions?



## Medical Necessity Cases Affecting Hospitals

- **Kyphoplasty spine procedure**:
  - 96 hospitals settled with DOJ for over $71M between 2010-2015.
  - Medtronic, which acquired Kyphon, settled with DOJ for $75M in 2008.
  - DOJ alleged that hospitals performed the procedure on an inpatient basis when it could have been performed on an outpatient basis.
  - DOJ pursued case against hospitals despite:
    - Valid physician orders for inpatient admission
    - Interqual Guidelines: Kyphoplasty was appropriate for inpatient setting AND did not denote that it could also be performed in an outpatient setting.





GUIDELINES FOR SURGERY AND PROCEDURES
IN THE INPATIENT SETTING

MUSCULOSKELETAL (Cont'd)

*These procedures are appropriate for the inpatient setting based on InterQual Procedures Criteria:*

Dislocation Reduction, Shoulder (Open)
Excision:
Herniated Lumbar Intervertebral Disc
Metastatic Tumor, Spine, +/- Stabilization
Radial Head (Avascular Necrosis), Elbow (Open)
Radial Head (Intra-articular Fracture), Elbow (Open)
Fixation, In Situ Fracture, Hip (Proximal Femur)
Fusion: Cervical Spine; Lumbar Spine, Spinal with Harrington Rod; Thoracic Spine
Hardware Removal (Open): Ankle*; Hip; Knee; Hemiarthroplasty, Displaced Fracture, Femoral Neck
Kyphoplasty
Manage, for Joint Infection: Ankle; Elbow; Hip; Knee; Shoulder; Wrist
Medial and Lateral Ligaments Repair, Elbow (Open)
Olecranon Fracture Repair, Elbow (Open)
ORIF, Acetabulum; Ankle; Femoral Shaft, Femoral Neck; Hip (Proximal Femur); Humeral Shaft; Pelvis; Radial-Ulnar Shaft; Tibial Shaft; Vertebrae; Odontoid
Osteotomy: Femur, Proximal; Femur, Femoral Neck; Intertrochanteric; Subtrochanteric; Supracondylar; High Tibial; LeFort I; Mandible Ramus; Pelvis; Posterior Segment, Maxilla; Spine
Patellar Fracture Repair, Knee (Open)
Patellar Tendon Rupture Repair, Knee (Open)
Prosthetic Replacement, Fracture, Hip (Proximal Femur)
Quadriceps plasty (Release Procedure), Knee (Open)
Reconstruction:
Cruciate Ligament, Knee: (Open)
Distal Radioulnar Joint
Temporomandibular Joint
Reconstruction, Knee
Reduction, (Open) and External Fixation, Fracture:
Distal Radius and Ulna: Internal or External fixation
Femoral Shaft
Hip (Proximal Femur)
Humeral Shaft
Tibial Shaft
Release, Contracture (Open): Ankle; Knee; Hip
Removal and Replacement, Total Joint Replacement: Knee; Hip; Shoulder
Stabilization, Distal Radioulnar Joint
Supracondylar Fracture Repair, Elbow (Open)
Synovectomy, Major: Ankle; Hip; Knee (Open)
Tibial Plateau Fracture Repair; Knee: (Open)
Total Joint Replacement: Hip; Knee; Shoulder; Temporomandibular
Triceps Tendon Insertion Repair, Elbow (Open)
Unicondylar Knee Replacement
Vertebroplasty

*These procedures are appropriate for the inpatient setting based on consultant feedback:*

Arthrodesis: Sacroiliac; Symphysis Pubis
Bone Graft: Iliac Crest; Metatarsal
Capsulorrhaphy, Hip
Chemonucleolysis, Nucleus Pulposus*
Arthrodesis: Shoulder
Clubfoot Repair
Disarticulation: Shoulder; Elbow; Hip; Knee; Ankle; Wrist+
Disc Excision: Transthoracic (Thoracotomy)
Epiphysiodesis

* Due to variations in practice, this procedure may be performed in the Outpatient setting.

# California's End of Life Option Act

PRESENTED BY

**Terri D. Keville** | Partner
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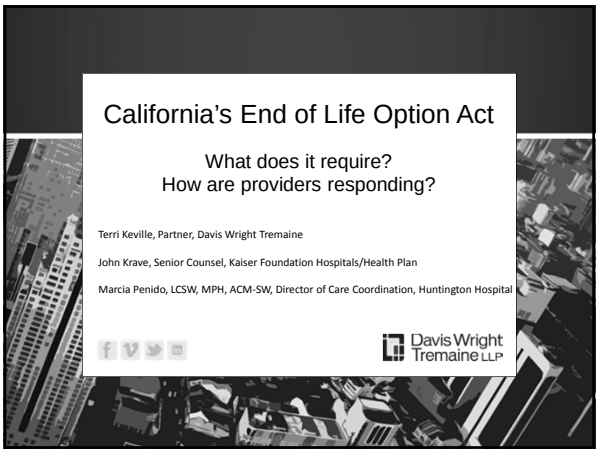
**Marcia Penido** | Huntington Hospital




## Basic Elements of California's End of Life Option Act (EOLOA)

- EOLOA became effective June 9, 2016, and will expire on January 1, 2026 (unless reenacted).
- EOLOA allows a qualified patient to request and receive an aid-in-dying drug, if all of the EOLOA requirements are met.
- EOLOA applies only to adult California residents who have been diagnosed with terminal illnesses and are capable of:
  - making informed health care decisions;
  - communicating health care decisions (the request *cannot* be made by another person on the patient's behalf); and
  - self-administering an aid-in-dying drug.



## Basic Elements of California's EOLOA (cont'd)

- What EOLOA does **not** do:
- EOLOA states expressly that it does **not** authorize lethal injection, mercy killing or active euthanasia.
- The California Legislature does **not** consider EOLOA to authorize physician-assisted suicide.
- Per EOLOA, death resulting from action taken in accordance with the law does **not** constitute suicide—so it has no effect on life insurance.
- Actions in accordance with EOLOA also do not constitute homicide or elder abuse.

## Basic Elements of California's EOLOA (cont'd)

- Procedural Steps/Safeguards
- Two (2) physician assessments, by an attending and consulting physician, are required to establish that a patient is qualified because the patient has a terminal disease with a prognosis of six months or less to live, and is capable of giving informed consent and self-administering the aid-in-dying drug.
- The elements of informed consent for this purpose are specified in EOLOA.
- If either physician sees "any indications of a mental disorder," a third assessment—by a mental health specialist—is required to determine that the patient "has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder."



## Basic Elements of California's EOLOA (cont'd)

- Procedural Steps/Safeguards (cont'd)
- The attending physician must counsel the patient about not taking the aid-in-dying drug while alone, not taking it in a public place, notifying relatives of his/her request for the drug, participating in a hospice program, and keeping the aid-in-dying drug in a safe, secure location.
- The physician must offer the patient multiple opportunities (at specified points in the process) to withdraw the request for the aid-in-dying drug.
- The patient him/herself must make two (2) oral requests for the aid-in-dying drug—at least 15 days apart—plus one (1) written request.



## Basic Elements of California's EOLOA (cont'd)

- Procedural Steps/Safeguards (cont'd)
- The written request must be observed by two (2) adult witnesses who attest in writing that the patient is "of sound mind and not under duress, fraud or undue influence."
- The patient must make a "final attestation" on the mandatory form, within forty-eight hours before he/she ingests the aid-in-dying drug. (After the patient's death, the form should be placed in his/her medical record, unless the patient died without taking the drug and all of it is returned unused.)

## Physician Reporting Requirements

- Within 30 calendar days of writing a prescription for an aid-in-dying drug, the attending physician must submit to the California Department of Public Health (CDPH) a copy of the qualifying patient's written request on the mandatory form, the attending physician's checklist and compliance form, and the consulting physician's compliance form.
- Within 30 calendar days after a qualified patient's death from ingesting a prescribed aid-in-dying drug, or from any other cause, the patient's attending physician must submit the mandatory attending physician follow-up form to CDPH.



## Voluntary Participation

- Participation in EOLOA is entirely voluntary for patients, physicians, and facilities. A provider is not required to participate or to refer an inquiring patient to another provider who is participating.
- No contract, will, or other agreement can be conditioned upon or affected by a person making or rescinding a request for an aid-in-dying drug under EOLOA.
- A health care provider can prohibit its employees, contractors, and other personnel from participating in activities under EOLOA while on premises owned by or under the management or control of that health care provider, or while acting within the course and scope of employment by or contract with the health care provider.
- A health care provider that wants to prohibit its personnel from participating in EOLOA on its premises must first give notice of that policy. A provider that has given notice of a policy prohibiting EOLOA participation on its premises may take action against an employee, medical staff member, etc., who violates the policy.



## Voluntary Participation (cont'd)

- A request under EOLOA cannot be a condition of, or otherwise affect (e.g., with respect to rate), the sale or issuance of any life, health or annuity policy or plan contract or benefit plan.
- Health insurers/plans cannot initiate discussion of EOLOA with enrollees; a health insurer/plan can only respond if asked by a patient, or his/her attending physician at the patient's request.
- Health insurers/plans may not include information about the availability of aid-in-dying drug coverage in any treatment denial communication.
- Although participation is voluntary, and providers are immune from liability for refusing to engage in activities authorized by EOLOA, providers who choose not to participate still should be prepared to respond with information if patients inquire. (See resource list.)

## EOLOA Immunities

- EOLOA provides immunity from civil and criminal liability for a person who is present when a qualified individual self-administers an aid-in-dying drug or prepares the aid-in-dying drug as authorized by EOLOA, so long as the person doesn't also help the patient to ingest it.
- As noted above, providers are immune from liability for refusing to engage in activities authorized by EOLOA.



## EOLOA Penalties

- EOLOA makes it a felony to do any of the following:
  - Knowingly alter or forge a request for drugs to end an individual's life without his/her authorization, with the intent or effect of causing the individual's death;
  - Conceal or destroy a withdrawal or rescission of a request for a drug, with the intent or effect of causing the individual's death;
  - Knowingly coerce or exert undue influence on an individual to request a drug to end his/her life;
  - Destroy a withdrawal or rescission of a request without the individual's knowledge or consent; or
  - Administer an aid-in-dying drug without the individual's knowledge or consent.



## Regulatory Agency Roles

- The mandatory forms for specified activities authorized by EOLOA are posted on the CDPH and Medical Board of California (MBC) websites. (Copies of the forms are also provided in your seminar materials.)
- The MBC can "update" and repost the forms.
- CDPH is required to collect and review information submitted by physicians as required by EOLOA in a manner that protects patient and provider privacy. The information cannot be discovered or subpoenaed.

## Regulatory Agency Roles (cont'd)

- On or before July 1, 2017, and every year after that, CDPH must create a report using the information collected and post the report on the CDPH website. EOLOA specifies information that must be included in the annual report, e.g., the number of people for whom aid-in-dying prescriptions were written, various characteristics of the patients (e.g., age, sex, education level), the number who died, the number of physicians who wrote aid-in-dying prescriptions, etc.
- A person who has custody or control of unused aid-in-dying drugs prescribed per EOLOA after a patient dies must personally deliver the unused drugs for disposal to the nearest facility qualified to dispose of controlled substances, or if no such facility is available, must dispose of the drugs in accordance with California State Board of Pharmacy guidelines or a federal Drug Enforcement Administration approved take-back program.



## Oregon Death with Dignity Act Experience

- Oregon Death with Dignity Act has been in effect since 1998.
- Same eligibility requirements as EOLOA.
- Data published annually through 2015.
- 991 total deaths in 18 years using the DDA mechanism.
- Number of deaths per year has risen gradually over time.
- In 2015, 106 physicians wrote 218 DDA prescriptions.



## Oregon Death with Dignity Act Experience (cont'd)

- 77% of DDA patients were diagnosed with cancer, 90.5% enrolled in hospice.
- 97% white, 51% male, 46% married, 46% college education or higher (only 6% didn't at least finish high school), 94% died at home, median age 75.
- 57% of DDA patients had private insurance, 41% had Medicare and/or Medicaid—only 1% had no insurance.
- Oregon has a much more homogeneous population than California; that difference may result in variations here.

## Oregon Death with Dignity Act Experience (cont'd)

- DDA Patients' End-of-Life Concerns
  - Loss of autonomy
  - Decreased ability to participate in life activities
  - Loss of dignity
  - Loss of control over bodily functions
  - Burden on loved ones
  - Uncontrolled pain
  - Financial concerns



## Oregon Death with Dignity Act Experience (cont'd)

- Oregon Physician Compliance Experience

From 1997 through 2015, 22 physicians were reported to the Oregon Medical Board for possible DDA non-compliance based on issues relating to documentation, consent, witnesses, and the required waiting period.

The Oregon Medical Board did not substantiate any violations.



## Questions?

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# Health Information Privacy and Security Update

PRESENTED BY

**Sean. R Baird** | Associate
**Adam H. Greene** | Partner

# Health Information Privacy and Security Update

Adam Greene, JD, MPH, Partner, Davis Wright Tremaine

Sean Baird, JD, MHS, Associate, Davis Wright Tremaine

Davis Wright Tremaine LLP

## Agenda

- Increased OCR Enforcement Actions
- Recent OCR Guidance
  - Ransomware
  - Cloud Computing
  - Individual's Right of Access
- The HIPAA Audit Program




## Increased OCR Enforcement Actions

## Enforcement Highlights

**45** OCR Settlements

**$58,455,200**
In settlements and CMPs

**3** Civil Monetary Penalty Actions

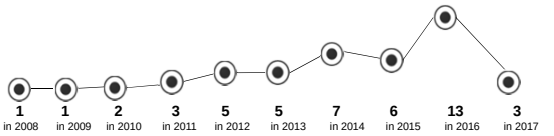
**$1,299,004**
Average settlement amount

**31** of **48**
enforcement actions arose from breach reports to HHS

48
- 6 Required an internal monitor
- 4 Required an external monitor
- 8 **Monitor required in 8 out of 48**

4 dwt.com

## Enforcement Highlights



**1** in 2008 | **1** in 2009 | **2** in 2010 | **3** in 2011 | **5** in 2012 | **5** in 2013 | **7** in 2014 | **6** in 2015 | **13** in 2016 | **3** in 2017

(as of February 1, 2017)

Average minimum length of a corrective plan:
**APPROXIMATELY 2 YEARS**

Average attorney general enforcement action:
$347,909*

*may represent financial settlements associated with claims unrelated to HIPAA violations

**12 actions by state attorneys general/ in just over 6 years:**

| | | |
|---|---|---|
| 5 Massachusetts | 2 New York | 1 Vermont |
| 2 Connecticut | 1 Indiana | 1 Minnesota |

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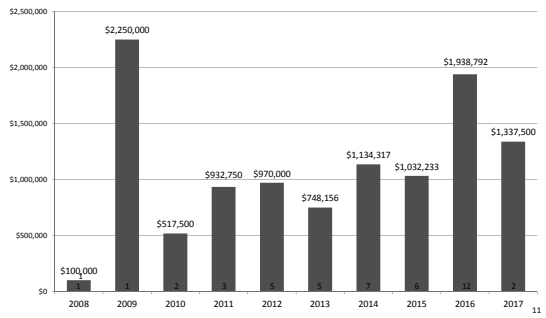
## Average Settlement Amount

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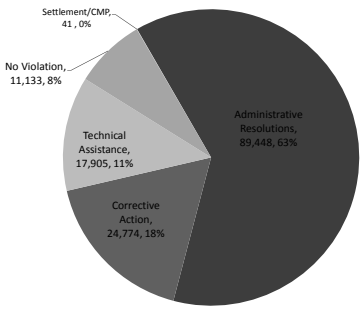
## Enforcement Highlights (as of 12/31/16)






## Current Phase 2 Audit Dates

- March 21, 2016: OCR sends first e-mail verifications
- April 4, 2016: OCR sends first pre-screening questionnaires
- May 20, 2016: OCR sends largest batch of e-mail verifications
- July 11, 2016: OCR sends desk audit requests to 167 covered entities
- July 13, 2016: OCR presents webinar for auditees
- November 2016 – Present: OCR conducting business associate audits
- ~~2017 – Onsite audits to begin~~
- Early 2017: OCR plans to finalize covered entity audits
- May 2017: OCR plans to finalize business associate audits



## Areas to Focus On

- Risk Analysis
  - Encompass all ePHI & data flows?
- Risk Management Plan
  - Corrective actions with dates?
  - Accountable persons?
  - Documentation of implementation?
- Encryption, Encryption, Encryption, Encryption, Encr…
  - You get the point
- Right of Access
  - Support allowable fees?
- Breach Response

# Recent OCR Guidance



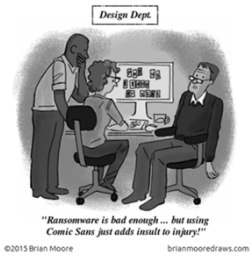
## Right of Access

- Significantly limits permissible fees (e.g., $6.50 as a default)
- Patient Request Form vs. Authorization Form
- Further muddies the water between third-party requests and patient requests
- Access to Media:
  - Allowing news media in treatment areas is a disclosure that may require an authorization.
    - Public vs. treatment areas
    - May preclude filming (and tours?) in ER (authorizations infeasible)
  - What are implications for persons other than media?
    - VIPs (e.g., charitable donors)?
    - Police (and body cams)?
    - Patient visitors?



## Ransomware

- Presence of malware on system with ePHI is disclosure, even without exfiltration of data.
- "Compromise" for purposes of breach notification includes impact on patient care.



## Cloud Computing Guidance

- Cloud service provider ("CSP") is BA, even if ePHI is encrypted and CSP does not have access to key.
- CSP and customer need to understand allocation of security responsibilities.
- Offshoring should be considered in risk analysis.



## For questions …

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# Telemedicine: Recent Developments and Hot Topics

PRESENTED BY

**Dayna Nicholson** | Counsel
**Adam D. Romney** | Partner


## Agenda

1. Back to Basics
2. Recent Developments
3. Hot Topics



## Telemedicine – Back to Basics

1. Telemedicine vs. Telehealth
2. Fundamentals
   A. Licensing & Credentialing
   B. Physician-Patient Relationships
   C. Privacy & Security
   D. Financing

## Telemedicine v. Telehealth

1. Telemedicine is the practice of medicine using electronic communications, information technology or other means between a licensee in one location and a patient in another location with or without an intervening health care provider (Federation of State Medical Boards).
2. Telehealth means the mode of delivering health care services and public health via information and communication technologies to facliitate the diagnosis, consultation, treatment, education, care management, and self-management of a patient's health care while the patient is at the originating site and the health care provider is at a distant site. Telehealth facilitates patient self-management and caregiver support for patients and includes synchronous interanctions and asynchronous store and forward transfers (CA BPC § 2290.5(a)(6)).



## Telemedicine vs. Telehealth

1. Types of Telemedicine:
   A. Non-simultaneous: involve after-the-fact interpretation or assessment, such as teleradiology services
   B. Simultaneous: involve "real-time" interpretation or assessment, such as telestroke and teleICU services
2. (Generally) NOT Telemedicine:
   A. Informal consultations between practitioners
   B. Telephone conversation, e-mail/instant messaging conversation, or fax
3. Telemedicine and telehealth are **tools** in medical practice, not a distinct service.



## Fundamentals – Who provides telemedicine and related services?

1. On Site Provider – health care provider who is with the patient at the time of service (treating provider; AHPs)
2. Remote Provider
   A. Treating Provider – provider who has a treatment relationship with the patient at the originating site
   B. Consulting Provider – provider at a distant site who is being consulted by the treating provider; often specialty telemedicine consultations
3. Technology Vendor
   A. Device – the hardware that is being used to conduct the telemedicine session (*e.g.* iPad, cell phone, computer)
   B. Software/Application – the program or application that is being used to conduct the telemedicine session
4. Payor – Medicare, Medicaid, private payors

## Licensing & Credentialing

1. Practitioner must be licensed in and comply with scope of practice requirements (e.g., patient consent, telepresenter) of the state in which the patient is located.
2. Exception: physician may consult with out-of-state physician (who does not interact with patients); in-state physician has ultimate responsibility for treatment decisions.
3. Licenses to practice medicine across state lines:
   A. Regular license
   B. Licensure by endorsement
   C. Licensure by mutual recognition/reciprocity
   D. Special purpose telemedicine license



## Licensing and Credentialing

4. FSMB Interstate Medical Licensure Compact
   A. To facilitate multi-state licensure
   B. Voluntary pathway for expedited license in Compact-participating states
   C. "Expedited licensing is not yet available but will be soon."


http://www.fsmb.org/state-medical-boards/interstate-model-compact (as of 02/14/17)



## Licensing & Credentialing

1. Distant-Site Hospital: A Medicare-participating hospital that provides the practitioner rendering telemedicine services
2. Distant-Site Telemedicine Entity: Other entities providing telemedicine services, such as teleradiology providers, telepathology providers, ASCs and certain non-Medicare participating hospitals or entities
3. A Medicare-participating hospital or CAH may rely on credentialing and privileging decisions of a distant-site entity pursuant to an acceptable written agreement. 42 CFR §§ 482.22(a)(3) & (4); 485.616(c)(2) & (4)
4. Medical Staff Bylaws must have specific criteria and procedures for the grant and exercise of telemedicine privileges and must comply with CMS's Telemedicine Rule. 42 CFR § 482.22(c)(6)
5. Distant-site telemedicine practitioners must be monitored. Shared information must include all adverse events that result from telemedicine services provided by practitioner to patients, and all complaints the hospital has received about the practitioner. 42 CFR § 482.22(a)(3)(iv), (a)(4)(iv)

***Consider:*** *A telemedicine entity may not be a recognized peer review body under state law and thus not subject to any peer review privilege.*

## Physician-Patient Relationship

1. State laws generally require that patient-provider relationship be established before prescription may be written.
2. Most states: physical examination required
   A. Definition of valid physical examination varies
   B. Some states, prior in-person examination required
   C. Several states allow physical examination by electronic means or telehealth technologies
   D. Most states prohibit prescribing based only on online questionnaire
   E. California: "appropriate prior examination" required (not defined but Medical Board criticizes online questionnaires as substitute for in-person exam)



## Notices and Disclosures to Patients

Key Issues

- Website Terms of Use
- HIPAA Notice of Privacy Practices
- Website Privacy Policy
- Consent to Treatment
- Acceptance of Financial Responsibility
- Assignment of Benefits
- Authorization to Disclose PHI
- Advance Beneficiary Notices



## HIPAA Notice of Privacy Practices

1. Covered Entities must:
   A. Furnish NPP to new patients
   B. Make good faith effort to acknowledge receipt
2. NPP Delivery
   A. Covered Entities may furnish by email with patient consent
   B. Patient requests for hard copy NPP must be honored
3. How to acknowledge receipt of NPP by email
   A. Via checkbox if "the individual is clearly informed . . . of what they are acknowledging and the acknowledgment is not also used as a waiver or permission for something else"
   B. By electronic return receipt "for notice delivered electronically, an electronic return receipt or other return transmission from the individual is considered a valid written acknowledgement of the notice."

## Other Patient Privacy Rights

1. Access
2. Amendment
3. Request protections (e.g., restrictions or communication by alternate means)
4. Accounting of disclosures



## Data Security & Breach

1. Business Associate Relationships
2. Administrative, Physical & Technical Safeguards
3. Ransomeware
4. Breach Investigation and Reporting
5. Cyberliability Insurance



## Telemedicine Recent Developments

1. California laws/regulations
2. TJC: No text messages for patient orders
3. FTC: Protecting telemedicine providers from antitrust
4. FTC: Providing tools for mobile health app developers
5. USDA: Distance Learning and Telemedicine Grants

## California – New/Pending Laws and Regulations

1. Medi-Cal 2020 Demonstration Project Act - SB 815 (Jul 2016)
   One-time access assessment to measure health plan compliance with Knox-Keene network adequacy requirements and Medicaid managed care contracts, including other modalities used for accessing care, including telemedicine
2. Occupational Therapy – Standards of Practice for Telehealth (Apr 2017)
   Clarifies that an occupational therapist does not need to obtain a patient's/client's consent for subsequent telehealth services once the patient/client initially consents to receive occupational therapy services via telehealth (16 Cal Code Regs § 4172)
3. Board of Corrections – Minimum Standards for Local Detention Facilities (Apr 2017)
   Adds resources for facilities to accomplish needed medical or mental health evaluations and provide mental health care by inserting definition for telehealth and allowing a facility administrator for mentally disordered inmates to develop policies and procedures to identify and evaluate inmates through telehealth (15 Cal Cod Regs §§ 1006, 1052)

*Source: California Telehealth Resource Center: http://www.caltrc.org/*



## California – New/Pending Laws and Regulations

4. Board of Behavioral Sciences - Standards of Practice for Telehealth (Jul 2016)
   Establishes requirements for marriage and family therapists, educational psychologists, clinical social workers, and professional clinical counselors who wish to provide psychotherapy services via telehealth (16 Cal Code Regs § 1815.5)
5. Department of Insurance - Provider Network Adequacy (Mar 2016)
   Requires insurers' network adequacy report to describe the implementation and use of triage, telemedicine and health information technology to provide timely access to care; application for waiver of network access standards must explain alternatives that were considered, including telemedicine or phone consultations (10 Cal Code Regs § 2240.5)

*Source: California Telehealth Resource Center: http://www.caltrc.org/*



## TJC – Use of Secure Text Messaging for Patient Care Orders Is Not Acceptable (Dec 2016)

1. Health care organizations should have policies prohibiting the use of unsecured text messaging for communicating protected health information.
2. Computerized provider order entry (CPOE) should be the preferred method for submitting orders as it allows providers to directly enter orders into the electronic health record.
3. In the event that a CPOE or written order cannot be submitted, a verbal order is acceptable.
4. The use of secure text orders is not permitted at this time.

https://www.jointcommission.org/assets/1/6/Clarification_Use_of_Secure_Text_Messaging.pdf

## FTC – Supports Teladoc in Antitrust Suit Against TX Medical Board

1. Teladoc v. Texas Medical Board
   A. Board promulgated rules requiring face-to-face contact with the patient before a physician could write a prescription (Apr 2015)
   B. Teladoc uses phone calls, uploaded photos and questionnaires in lieu of face-to-face consultations; filed suit alleging decision by Board's physician-members was anti-competitive
   C. Injuction issued by U.S. District Court for the Western District of Texas (May 2015) ; TMB's motion to dismiss denied (Dec 2015)
   D. TMB appealed denial of motion to dismiss to U.S. Court of Apeals, Fifth Circuit
2. Dept of Justice and Federal Trade Commission Amicus Brief (Sep 9, 2016)
   A. The District Court's order cannot be appealed (it's too soon in the proceedings)
   B. Texas has not met "active supervision" requirements that are at play because a majority of Board members are "active market participants"

https://www.justice.gov/atr/file/890846/download



## FTC – Guidance for Mobile Health App Developers


https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool



## USDA – Providing Resources for Rural Development of Telemedicine

Rural Development Distance Learning and Telemedicine Grants – 2016

| | | | |
|---|---|---|---|
| CA | College of the Siskiyous | $235,225 | To provide video conferencing equipment at five teaching classrooms at the college and four high schools. |
| CA | Karuk Tribe | $116,677 | To provide video conferencing equipment to support the delivery of specialty care, primary care, and behavioral healthcare services from hub sites in Sacramento and Redding to end-user sites in Happy Camp, Orleans and Yreka. |
| CA | California Telehealth Network | $405,917 | To deliver telemedicine to improve access to specialty health, including psychiatry, endocrinology, dermatology, nephrology, and cardiology as well as health care education to isolated patients with chronic health conditions. |
| CA | Sierra Nevada Memorial Hospital Foundation | $285,129 | To purchase telemedicine carts with accessories for seven healthcare clinics in rural California. |
| CA | Colusa County Office of Education | $493,054 | To add interactive videoconferencing and audio-visual equipment into four school district offices, seven preschools and child care centers, and seven K-12 schools. |
| CA | Lassen Community College | $313,593 | To provide increased access to higher education by establishing video conferencing connections between Lassen Community College and six high schools, including a teen center on the Susanville Indian Rancheria. |
| CA | Landon Pediatric Foundation | $221,230 | To equip rural hospitals and clinics with telemedical carts that will connect them with specialists throughout the state. This project will also create a distance learning certification program to train nurses, physician's assistants and doctors. |

Helps rural communities acquire technologies to connect teachers and medical providers serving rural residents with other teachers, medical professionals and other needed expertise located at distances too far to access otherwise

https://www.rd.usda.gov/programs-services/distance-learning-telemedicine-grants

## Telemedicine Hot Topics

1. The Future of Reimbursement
   A. Medicare
   B. Commercial
2. Billing and Coding Telemedicine Services
3. Direct to Consumer Telemedicine
   A. Can I bill the patient directly?



## Medicare Coverage: The Past

- Medicare Coverage Requirements for Telemedicine
  - Originating site requirements (patient location)
    - Geographic location: HPSA and non-MSA
    - Clinic location: physician office, hospital, RHC, FQHC, SNF or mental health center
  - Distant site requirements (practitioner)
    - Must be a physician, PA, NP, CNS, psychologist, nurse-midwife, LICSW, CRNA or registered dietitian or nutrition professional
  - Approved CPT/HCPCS codes only
  - Interactive audio and video (no phone only)



## Medicare Coverage: The Future

- Bundled Payment for Care Improvement (BPCI) Initiative
  - Overview: Retrospective bundled payment arrangement where actual expenditures for a wide range of clinical conditions are reconciled against a target price for a 30, 60 or 90-day episode of care
  - Geographic location requirement waived for covered telemedicine codes furnished to beneficiaries during a BPCI-Model 2 episode
  - Patient must still present from clinical location
- Next Generation ACO
  - Overview: Initiative for ACOs that are more experienced in accountable care contracts, which allows providers to assume higher levels of financial risk and reward than under the Pioneer or MSSP programs.
  - All originating site requirements waived for covered telemedicine codes furnished to beneficiaries attributed to the ACO

## Medicare Coverage: The Future

- Comprehensive Care for Joint Replacement (CJR)
  - Overview: Holds hospitals financially accountable for the quality and cost of care for services related to lower-extremity joint replacements during a 90-day episode of care
  - All originating site requirements waived for covered telemedicine codes furnished to beneficiaries attributed to the ACO
  - New G-Codes established to report telehealth services
  - Same waivers for mandatory bundles for:
    - The Acute Myocardial Infarction Model ("AMI")
    - The Coronary Artery Bypass Graft Model ("CABG")
    - The Surgical Hip and Femur Fracture Treatment Model ("SHFFT")

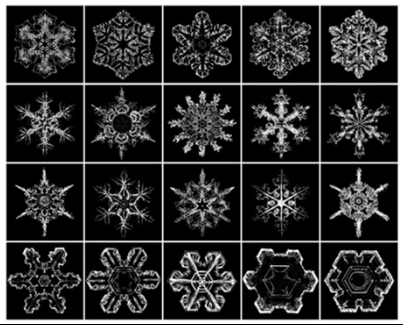


## Medicare Coverage: The Future

- Comprehensive Primary Care Plus (CPC+)
  - Overview: National advanced primary care medical home model for primary care practices. Participants receive enhanced payments from Medicare.
  - Participants must perform "comprehenaive primary care functions" in order to retain enhanced CPC+ payments.
  - Track 2 providers can fullfill "Access and Continuity" functions if they:
    - "Regularly offer at least one alternative to traditional office visits (e.g., e-visits, phone visits, group visits, house calls, expanded hours, etc.)



## Commercial Payors: Today



## Top Questions to Ask Commercial Payors about Telemedicine Reimbursement

**Are you reimbursing all providers for telehealth?**

- Do you reimburse in-network providers?
- Are you reimbursing out-of-network providers as well?
- How will these policies differ?
- Do you reimburse regardless of telehealth vendor/technology platform?

**What provider types are eligible for reimbursement?**

- Physician; Nurse practitioner; Physician assistant; Nurse-midwife; Clinical nurse specialist; Clinical psychologist; Clinical social worker; Registered dietitian or nutrition professional

**What services are covered as a part of the policy?**

- Are you reimbursing for both medical and behavioral health?
- Are you reimbursing E&M and consult codes or a specific set of procedural codes?
- Do you reimburse for both synchronous and asynchronous?

**Are there any other requirements for telehealth payment?**



## Commercial Payors: The Future

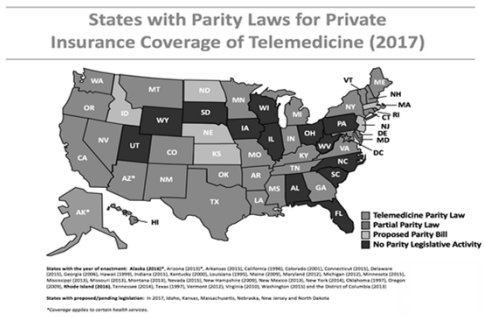
- Telehealth Parity Laws – California Example
  - **Scope:** "No health insurer shall require that in-person contact occur between a health care provider and a patient before payment is made for the services appropriately provided through telehealth…."
  - **Types of Services**: "Health care services" (not defined)
  - **Practitioners:** "A person who is licensed by the Division of Healing Arts" or "A marriage and family support therapist intern or trainee"
  - **Triggering Conditions**:
    - The terms and conditions of the insurers' contracts with providers and insureds shall apply.
    - No "originating site" or "distant site" requirement
    - Store and forward okay
  - **Included Payors:** Any California licensed health plan and Medi-Cal MCOs



## Commercial Payors: The Future

- Can California health plans or Medi-Cal MCOs:
  - Impose an originating site requirement?
  - Limit the categories of providers they will reimburse for telehealth services?
  - Limit coverage of telehealth to certain codes?
  - Cut payment of telehealth to below levels of in-person office based care?
  - Can "prior authorizations" be required for telehealth service when it wouldn't be required for the same service when furnished on an in-person basis?
  - Deny coverage for out-of-network telehealth providers?

## Telemedicine Parity Laws






## Billing and Coding Telemedicine Services

So what are the issues?

- CPT/HCPCS Code Selection
- Maintaining consistent coding practices within your organization
- Avoiding inconsistent coding based on payor



## Example: Physician Office Visits

**Office Consult (99201-215-GT)**
- New or Established Patient
- Medicare covered (for rural patients)

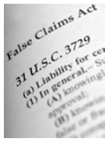
**Online E&M (98969)**
- Non-Physician
- Established Patient
- Non-covered by Medicare

**Online E&M (99444)**
- Physician
- Established Patient
- Non-covered by Medicare

**Miscellaneous E&M (99499)**
- Unlisted evaluation and management service

## Different Codes / Same Service?

- National Correct Coding Initiative
  - "Only the single CPT code most accurately describing the procedure performed or service rendered should be reported."
- False Claims Act
  - Federal
    - U.S. ex rel. Putnam v. Eastern Idaho Regional Medical Center
    - Hospital submits claims for reimbursement to Medicare or Medicaid based on false, misleading, or incorrect CPT codes
  - State False Claims Acts




## Different Rates / Same Code?

- Problems caused by inconsistent charge structures
- Medicare's "substantially in excess" rule
  - Medicare may exclude "[a]ny individual or entity that . . . has submitted bills or requests for payment . . . for items or services furnished substantially in excess of such individual's or entity's usual charges . . . ."
  - Payor's arguments under State False Claims Acts
  - Consumer Protection Act penalties may attach to increase charges more than costs

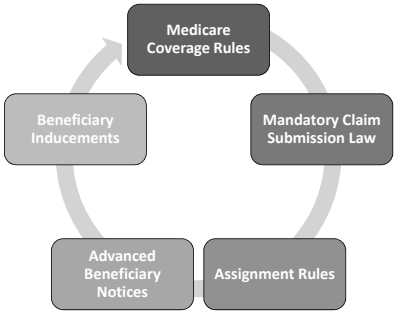


## "Direct to Consumer" Issues

### The Patient's Insurance Matters

- What if the patient is a Medicare Beneficiary?
- What if the patient is a Medicaid Recipient?
- What if the patient receives Tricare?
- What if the provider is "in-network" with patient's health plan?

## What if Patient is a Medicare Beneficiary?

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## Key Medicare Concepts

**1. Medicare Coverage**

- If service is a "covered benefit," Mandatory Claim Submission law applies
- If service is "covered" but denied for medical necessity, Mandatory Claim Submission applies
- If service is "non-covered" or "excluded," no Mandatory Claim Submission

**2. Mandatory Claim Submission Law**

- When applicable, participating providers must submit a bill to Medicare when providing a covered service to a Medicare beneficiary
- Penalties: (1) $2,000 per violation; (2) Medicare termination; (3) OIG exclusion

**3. Assignment Rules**

- Providers agree to bill Medicare on behalf of patients
- Providers may only collect the "Allowed Amount" (Medicare $ + Beneficary coinsurance)
- Penalties: (1) Patient refunds; (2) Medicare termination; (3) civil penalties; (4) OIG exclusion

**4. Advanced Beneficiary Notices**

- Mandatory ABNs: When Medicare denies for lack of medical necessity
- Voluntary ABNs: When Medicare denies because service is "non-covered" or "excluded"

**5. Free Services = Illegal Beneficiary Inducements**

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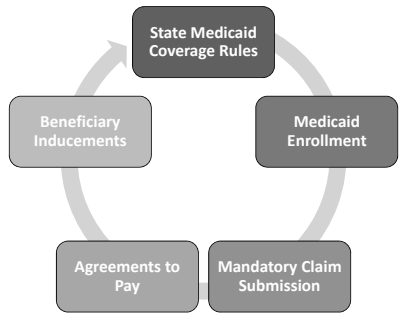
## What if Patient is a Medicaid Beneficiary?

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## Key Medicaid Concepts

**1. State Medicaid Coverage Rules**

- Is service a covered benefit?
- Non-covered or excluded service?

**2. Medicaid Enrollment**

- Do patient billing laws apply only to providers who are enrolled in the state program?

**3. Mandatory Claim** Submission

- Must providers bill Medicaid for covered services?
- Must providers bill Medicaid for non-covered services?

**4. Agreements to Pay**

- May providers enter into "side deals" with patients?

**5. Beneficiary Inducements**

# Additional Resources

# Exposure to Waste Investigations

## What Health Care Facilities Need to Know

Health care facilities dispose of waste pharmaceuticals and sharps, electronic devices, power sources and other hardware and, of course, paper that may contain confidential information. In California especially, improper disposal of any of these items can lead to a multi-million dollar penalty.

Commonly discarded materials, such as electronic devices, batteries, fluorescent bulbs and aerosol cans, is an area of increasing interest in other states as well. These common materials, and others, are collectively known as "universal waste," and there are a number of state and federal requirements regarding the handling/discarding of these materials that may require recycling. Improper disposal of a patient's protected health information (PHI) also can violate HIPAA.

Regulators have shown increasing interest in this area and enforcement actions often are done by first gathering information, without your knowledge, that will support a major penalty.

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Enforcement actions by the California Attorney General addressing these requirements have resulted in large penalties:

» Wal-Mart Stores, Inc.: **$27M** – illegal transportation and disposal of hazardous waste and other materials.

» CVS Pharmacy, Inc.: **$13.75M** – improper storage, handling and disposal of medical and pharmacy waste.

» Target: **$22.5M** – improper disposal of batteries and electronic devices.

» AT&T: **$21.8M** and Comcast **$23M** – improper universal waste and document disposal.

Additionally, the U.S. Department of Health and Human Services Office for Civil Rights (OCR) has brought several enforcement actions against HIPAA covered entities related to improper disposal of PHI:

» CVS Pharmacy, Inc.: **$2.25M** – improper disposal of prescription related PHI in publicly accessible waste containers.

» Rite Aid Corporation: **$1M** - improper disposal of prescription related PHI in publicly accessible waste containers.

» Affinity Health Plan, Inc.: **$1.2M** – return of photocopiers containing PHI to a leasing company.

» Cornell Prescription Pharmacy: **$125,000** - improper disposal of prescription related PHI in publicly accessible waste containers.

OCR has issued guidance specifically focused on disposal of PHI.

Davis Wright Tremaine partners have been dealing with these issues for a wide range of clients in the health care, retail, technology and communications industries and have specific experience in conducting privileged audits of health care facility compliance. Auditing helps clients to avoid costly enforcement. Our nationally-recognized health care privacy and security specialists add their critical expertise when disposal involves devices that have held protected health information.

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# New Year, New Possibilities: OIG Final Rule Amends Beneficiary Inducement Rules

01.13.17

*By Robert G. Homchick, Renee Howard, Adam D. Romney, Christina A. Park, and Sean R. Baird*

The Office of Inspector General ("**OIG**") of the Department of Health and Human Services has issued a final rule[1] ("**Final Rule**") adding new safe harbors to the federal anti-kickback statute, amending existing safe harbors, and revising the definition of "remuneration" under the civil monetary penalty ("**CMP**") law. These are welcome changes providing greater flexibility to industry participants seeking to navigate the prohibitions of the anti-kickback statute and CMP law.

As described in more detail below, the new regulations, which became effective January 6, 2017: (i) allow providers to subsidize patient travel costs incurred to obtain health care services; (ii) give drug manufacturers more flexibility to offer discounts to patients in the Medicare Part D coverage gap; and (iii) establish new safe harbors for Medicare Advantage Organizations, Federally Qualified Health Centers ("**FQHCs**"), pharmacies, and emergency ambulance service providers.

The Final Rule also clarifies the definition of "remuneration," under the CMP law's beneficiary inducement prohibition. Specifically, the OIG clarified that the following shall not be considered "remuneration":

- remuneration that "poses a low risk of harm" and "promotes access to care";
- retail reward programs such as coupons or rebates;
- remuneration to financially needy individuals; and
- copayment waivers for the first fill of generic drugs.

The Final Rule also increased the dollar cap on nominal value gifts.

## 1. New Anti-Kickback Statute Safe Harbors

Due to the broad language of the anti-kickback statute[2], in 1987, Congress directed the Secretary of HHS to create safe harbors to specify certain payment and business practices that would not be subject to criminal prosecution under the statute. An arrangement that fits precisely within the requirements of a safe harbor is immune from prosecution.[3] The Final Rule creates several new safe harbors, which are each discussed further below.

### Free or Discounted Local Transportation

The OIG created a new safe harbor that protects free or discounted local transportation, as well as shuttle services, provided that the programs meet certain requirements.

- **Free or discounted local transportation.** Eligible entities, such as hospitals and clinics, may now furnish certain free or discounted local transportation to "established patients," who are covered by federal health care programs, without implicating the anti-kickback statute. The Final Rule adopted a definition of "established patient" that includes those who have initiated contact to schedule an appointment as well those who have already had an appointment with the provider. The new safe harbor protects free or discounted transportation provided by an "eligible entity." An "eligible entity" is any individual or entity that does not primarily supply health care items, such as durable medical equipment suppliers, pharmaceutical companies, and pharmacies. In commentary to the Final Rule, the OIG clarified that "health plans, MA organizations, MCOs, accountable care organizations (ACOs), clinically integrated

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networks, and charitable organizations are not among the entities excluded from the definition of eligible entity and thus are eligible to provide transportation."[4]

In the past, the OIG has scrutinized free transportation arrangements and issued several Advisory Opinions on the subject. The Final Rule incorporates several requirements for safe harbor protection that preclude, or eliminate, the risk factors the OIG has previously identified.[5] In order to qualify for safe harbor protection, the free or discounted transportation:

- must be set forth in a policy, which is applied consistently by the eligible entity;
- must not be determined in a manner related to the volume or value of federal health care program business;
- must not be publicly marketed or advertised by the eligible entity, and no marketing of health care items and services may occur during the transportation or at any time by the drivers;
- drivers, or others arranging for the transportation, must be not paid on a per-beneficiary-transported basis;
- the transportation is made available for the purpose of obtaining medically necessary items and services;
- the eligible entity does not shift costs of the free or discounted transportation onto federal health care programs, other payors, or individuals; and
- the transportation must not include air, luxury, or ambulance-level transport.

The official commentary indicates that vehicles equipped for wheelchairs (other than ambulances) and third-party transportation, including public transportation, would be protected if they meet the safe harbor criteria.[6] In addition, the Final Rule defined "local" transportation to include anywhere within 25 miles of the health care provider, or 50 miles if the patient lives in a rural area.

- **Shuttle services.** A new safe harbor protects "shuttle services" provided by an eligible entity (defined above). "Shuttle service" is a vehicle that runs on a set route on a defined schedule but excludes air, luxury, or ambulance-level transportation. The safe harbor for shuttle services contains its own requirements that must be satisfied, including:
    - The service must not be marketed or advertised (other than posting necessary route and schedule details);
    - No marketing of health care items and services may occur during the transportation or at any time by the drivers;
    - Drivers, or others arranging the transportation, may not be paid on a per-beneficiary-transported basis;
    - The eligible entity may not shift the burden of the shuttle service costs to federal health care programs, other payors, or individuals; and
    - The eligible entity must make the shuttle service available only within 25 miles from any stop on the route to any location where health care items or services are provided. This distance may be up to 50 miles in rural areas.

Medicare Coverage Gap

The Affordable Care Act amended the anti-kickback statute to protect discounts provided by prescription drug manufacturers under the Medicare Coverage Gap Discount Program. The Final Rule incorporates the statutory exception added by the Affordable Care Act into the safe harbor regulations.

Specifically, the OIG added a provision to protect discounts on "applicable drugs" provided to "applicable beneficiaries" under the Medicare Coverage Gap Discount Program.[7] The terms "applicable drug" and "applicable beneficiaries" are defined in the Affordable Care Act and pertain to drugs that are covered by, and beneficiaries enrolled in, prescription drug plans and Medicare Advantage Prescription Drug ("**MA–PD**") plans.[8] To qualify for safe harbor protection, the drug manufacturer must participate in, and comply with the requirements of, the Medicare Coverage Gap Discount Program.

FQHCs and Medicare Advantage Organizations

In the Final Rule, the OIG incorporates a statutory exception to the anti-kickback statute[9] into the safe harbor regulations. The safe harbor protects remuneration between a FQHC (or an entity controlled by a FQHC) and a Medicare Advantage organization, if:

- The remuneration is provided in accordance with a written agreement between the FQHC and the Medicare Advantage organization[10]; and
- The agreement requires the Medicare Advantage organization to provide a level and amount of payment to the FQHC for FQHC services, which is not less than the level and amount of payment that the Medicare Advantage organization would make for such services if they had been furnished by an entity other than a FQHC. [11]

In commentary to the Final Rule, the OIG stated that the safe harbor protects payments related to FQHCs treating Medicare Advantage plan enrollees and "not arrangements unrelated to MA plan enrollees being treated at the FQHC."[12] The OIG described examples that would not qualify for safe harbor protection, because they are unrelated to FQHC treatment of Medicare Advantage plan enrollees: (i) the provision of free space by the FQHC to the Medicare Advantage organization; and (ii) financial support from the Medicare Advantage organization to the FQHC (for example, for conducting outreach activities, purchasing health information technology, and funding infrastructure costs).[13]

**2. Amended Safe Harbors**

Safe Harbor for Cost-Sharing Waivers

The OIG revised and expanded the existing safe harbor for cost-sharing waivers, which previously protected the reduction or waiver of a Medicare or state health care program beneficiary's obligation to pay coinsurance or deductible amounts if certain requirements were satisfied. The safe harbor now applies to all federal health care program cost-sharing amounts, and the OIG clarified that the types of cost sharing that may be waived include copayments in addition to coinsurance and deductibles.[14] In addition, within the existing safe harbor for cost-sharing waivers, the OIG added two provisions that protect specific types of cost-sharing forgiveness:

- **Cost-sharing waivers by pharmacies.** A pharmacy may reduce or waive cost-sharing amounts imposed under a federal health care program, if it: (i) does not advertise the waiver or reduction; (ii) does not routinely waive or reduce cost-sharing amounts; and (iii) waives the cost-sharing amounts only after determining in good faith that the individual is in financial need, or after failing to collect such cost-sharing amounts after reasonable efforts.
- **Cost-sharing waivers for emergency ambulance services.** An ambulance provider or supplier owned and operated by a state, state political subdivision, or tribal health program, may waive cost-sharing for emergency ambulance services provided that the provider or supplier: (i) offers the reduction or waiver on a uniform basis; and (ii) does not claim that the reduction or waiver is a bad debt under a federal health care program or otherwise shift the cost burden onto a federal health care program, other payors, or individuals.

Amendment to Referral Services Safe Harbor

The OIG also made a technical correction to the safe harbor for referral services[15] and reverted to language

from the 1999 Final Rule[16], which provides that payments from participants to referral services must not be based on the volume or value of referrals to, or other business generated by, "either party for the other party."

**3. CMP Exceptions and Change in Nominal Value Cap**

The Final Rule revised the definition of "remuneration," as the term is used under the CMP law[17], to include several new exceptions. The CMP law prohibits the offering of "remuneration" that is likely to induce or influence federal program beneficiaries to seek or order covered services from a particular practitioner, supplier, or provider. In the Final Rule, the OIG adopts four notable exceptions to the definition of "remuneration" and increases the dollar cap on nominal value gifts.

Remuneration that "Poses a Low Risk of Harm" and "Promotes Access to Care"

The Affordable Care Act amended the CMP law to exclude from the definition of "remuneration" any remuneration that "promotes access to care and poses a low risk of harm to patients and federal health care programs." In the preamble to the Final Rule the OIG describes its view on what promotes a beneficiary's access to care and what poses a low risk of harm to beneficiaries and federal health care programs.

An arrangement "promotes access to care" when it "improves a particular beneficiary's ability to obtain" access to items and services payable by any federal health care program. The OIG adopted its interpretation from its proposed rulemaking that items or services that pose a "low risk of harm" are those that are: (i) unlikely to interfere with, or skew, clinical decision making; (ii) unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) do not raise patient safety or quality of care concerns.[18]

According to the OIG, examples of items or services that may be considered appropriate beneficiary remuneration that both "pose a low risk of harm" and "promote access to care" include offering the following to federal program beneficiaries:

- the provision of child care during beneficiary appointments;
- free or discounted medications, supplies, or devices;
- technology for reporting health data;
- scales or programmable tools to help with medication dosage or refill reminders;
- telemedicine capabilities; and
- certain incentives for scheduling, in extenuating circumstances (for example, at a dialysis facility, an inducement to one patient to move an appointment in order to promote access by a different patient could be protected by the exception).

The OIG makes clear, however, that providing patients with cash or cash equivalent items, or providing rewards just for accessing care, would not fall within this exception.

Coupons, Rebates, or Other Retailer Reward Programs

The OIG also finalized an exception protecting retail coupons, rebates, and other rewards that are made available to the general public, regardless of health insurance status, as long as they are not tied to the provision of other items or services reimbursable by federal health care programs. In the official commentary, the OIG clarifies that "retailers" includes independent or small pharmacies, online retailers, and entities that sell a single category of items, but do not include individuals or entities that primarily provide services (for example, physicians or hospitals).

Items or Services Reasonably Connected to the Medical Care of Financially Needy Individuals

The OIG also finalized an exception to the CMP law for financially needy patients, exempting offers or transfers of items or services (other than cash or cash equivalents) for free or less than fair market value if: (i) the items or services are not offered as part of an advertisement or solicitation; (ii) the offer or transfer is not tied to other services reimbursable by Medicare or Medicaid; (iii) the items or services are "reasonably connected" to the patient's medical care; and (iv) the provider in good faith determines that the recipient is financially needy.

The OIG does not define "reasonably connected" but indicates that the medical provider working with the beneficiary is in the best position to make this determination and that the determination must be made on a case-by-case basis. The OIG indicates that examples which could be reasonably connected to the patient's medical care include the provision of most items connected to the wellness and health needs of patients, such as:

- blood pressure cuffs;
- patient engagement software applications;
- biomonitoring devices, and;
- mobile devices as necessary to meet patients' various health needs.

Note, however, that this exception will not protect items and services that are "essentially for entertainment or other non-medical purposes."

Copayment Waivers for the First Fill of Generic Drugs

Effective January 1, 2018, Part D Plan sponsors or Medicare Advantage plans may waive any copayment for the first fill of a covered Part D generic drug. The hope is that this will encourage the use of lower cost generic pharmaceuticals. Part D Plan sponsors or Medicare Advantage plans that choose to take advantage of this exception must disclose thesewaivers in the benefit design package submitted to CMS.

Gifts of Nominal Value to Beneficiaries

The OIG has indicated that gifts of "nominal value" are not required to meet an exception under the beneficiary inducement prohibition (the "nominal value exception"). The OIG has not changed the nominal value exception threshold since 2002. The Final Rule revises the nominal value exception to raise the value limit from $10 to $15 for an individual gift and from $50 to $75 for the aggregate annual per patient limit.

**4. Takeaways**

The OIG states that the Final Rule "enhances flexibility for providers and others to engage in health care business arrangements to improve efficiency and access to quality care while protecting programs and patients from fraud and abuse."[19] The new and expanded anti-kickback statute safe harbors offer protection for certain arrangements that may allow providers to better serve patients and improve access to care. The new exceptions to the CMP law will promote the use of generic pharmaceuticals and enable providers to reduce barriers to patient care. At the same time, some of the provisions in the Final Rule may not have gone far enough. For example, the exception for certain remuneration to financially needy individuals does not define "reasonably connected" and may lead to confusion amongst providers. Moreover, the increase to the nominal value exception is modest and still relatively low.

**FOOTNOTES**

1 81 Fed. Reg. 88368 (Dec. 7, 2016).

2 42 U.S.C. § 1320a-7b(b). The anti-kickback statute prohibits the knowing and willful solicitation, offer, payment or acceptance of any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind: (1) for referring an individual for a service or item covered by a federal health care program, or (2) for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, service or item reimbursable under a federal health care program. Violation of the anti-kickback statute is a felony, punishable by fines of up to $25,000 and up to five years'

imprisonment.

3 However, an arrangement that does not precisely meet the requirements of a safe harbor does not necessarily violate the anti-kickback statute. Instead, the OIG will evaluate the arrangement based on the totality of facts and circumstances.

4 81 Fed. Reg. 88380 (Dec. 7, 2016).

5 For example, in Advisory Opinion No. 15-13, the OIG listed the following risk factors in free transportation arrangements: (i) the free transportation is offered selectively to certain patients based on their diagnoses, treatments, or type of insurance coverage; (ii) the arrangement is marketed or advertised, and marketing of health care items or services occurs during the course of the transportation or at any time by the drivers; (iii) van drivers are paid on a per-patient basis; (iv) the transportation includes air, luxury, or ambulance-level transport; and (v) free transportation is offered to beneficiaries residing outside the facilities' primary service area.

6 81 Fed. Reg. 88386 (Dec. 7, 2016).

7 Section 3301(d) of the Affordable Care Act.

8 42 U.S.C. §1395w-114A(g)(1)-(2).

9 Section 1128B(b)(3)(H) of the Social Security Act.

10 Section 1853(a)(4) of the Social Security Act.

11 Section 1857(e)(3) of the Social Security Act. This is described at 81 Fed. Reg. 88377 (December 7, 2016).

12 81 Fed. Reg. 88378 (December 7, 2016).

13 *Id.*

14 42 C.F.R. 1001.952(k).

15 42 C.F.R. 1001.952(f).

16 64 Fed. Reg. 63518, 63526 (Nov. 19, 1999).

17 42 C.F.R. Part 1003.

18 81 Fed. Reg. 88368, 88409 (Dec. 7, 2016).

19 81 Fed. Reg. 88368 (Dec. 7, 2016).

**AB-15 End of life.** (2015-2016)

# Assembly Bill No. 15

## CHAPTER 1

An act to add and repeal Part 1.85 (commencing with Section 443) of Division 1 of the Health and Safety Code, relating to end of life.

[ Approved by Governor October 05, 2015. Filed with Secretary of State October 05, 2015. ]

## LEGISLATIVE COUNSEL'S DIGEST

AB 15, Eggman. End of life.

Existing law authorizes an adult to give an individual health care instruction and to appoint an attorney to make health care decisions for that individual in the event of his or her incapacity pursuant to a power of attorney for health care.

This bill, until January 1, 2026, would enact the End of Life Option Act authorizing an adult who meets certain qualifications, and who has been determined by his or her attending physician to be suffering from a terminal disease, as defined, to make a request for a drug prescribed pursuant to these provisions for the purpose of ending his or her life. The bill would establish the procedures for making these requests. The bill would also establish specified forms to request an aid-in-dying drug, under specified circumstances, an interpreter declaration to be signed subject to penalty of perjury, thereby creating a crime and imposing a state-mandated local program, and a final attestation for an aid-in-dying drug. This bill would require specified information to be documented in the individual's medical record, including, among other things, all oral and written requests for an aid-in-dying drug.

This bill would prohibit a provision in a contract, will, or other agreement from being conditioned upon, or affected by, a person making or rescinding a request for the above-described drug. The bill would prohibit the sale, procurement, or issuance of any life, health, or annuity policy, health care service plan contract, or health benefit plan, or the rate charged for any policy or plan contract, from being conditioned upon or affected by the request. The bill would prohibit an insurance carrier from providing any information in communications made to an individual about the availability of an aid-in-dying drug absent a request by the individual or his or her attending physician at the behest of the individual. The bill would also prohibit any communication from containing both the denial of treatment and information as to the availability of aid-in-dying drug coverage.

This bill would provide a person, except as provided, immunity from civil or criminal liability solely because the person was present when the qualified individual self-administered the drug, or the person assisted the qualified individual by preparing the aid-in-dying drug so long as the person did not assist with the ingestion of the drug, and would specify that the immunities and prohibitions on sanctions of a health care provider are solely reserved for conduct of a health care provider provided for by the bill. The bill would make participation in activities authorized pursuant to its provisions voluntary, and would make health care providers immune from liability for refusing to engage in activities authorized pursuant to its provisions. The bill would also authorize a health care provider to prohibit its employees, independent contractors, or other persons or entities, including other health care providers, from participating in activities under the act while on the premises owned or under the management or direct control of that prohibiting health care provider, or while

acting within the course and scope of any employment by, or contract with, the prohibiting health care provider.

This bill would make it a felony to knowingly alter or forge a request for drugs to end an individual's life without his or her authorization or to conceal or destroy a withdrawal or rescission of a request for a drug, if it is done with the intent or effect of causing the individual's death. The bill would make it a felony to knowingly coerce or exert undue influence on an individual to request a drug for the purpose of ending his or her life, to destroy a withdrawal or rescission of a request, or to administer an aid-in-dying drug to an individual without their knowledge or consent. By creating a new crime, the bill would impose a state-mandated local program. The bill would provide that nothing in its provisions is to be construed to authorize ending a patient's life by lethal injection, mercy killing, or active euthanasia, and would provide that action taken in accordance with the act shall not constitute, among other things, suicide or homicide.

This bill would require physicians to submit specified forms and information to the State Department of Public Health after writing a prescription for an aid-in-dying drug and after the death of an individual who requested an aid-in-dying drug. The bill would authorize the Medical Board of California to update those forms and would require the State Department of Public Health to publish the forms on its Internet Web site. The bill would require the department to annually review a sample of certain information and records, make a statistical report of the information collected, and post that report to its Internet Web site.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

## THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

**SECTION 1.** Part 1.85 (commencing with Section 443) is added to Division 1 of the Health and Safety Code, to read:

**PART 1.85. End of Life Option Act**

**443.** This part shall be known and may be cited as the End of Life Option Act.

**443.1.** As used in this part, the following definitions shall apply:

(a) "Adult" means an individual 18 years of age or older.

(b) "Aid-in-dying drug" means a drug determined and prescribed by a physician for a qualified individual, which the qualified individual may choose to self-administer to bring about his or her death due to a terminal disease.

(c) "Attending physician" means the physician who has primary responsibility for the health care of an individual and treatment of the individual's terminal disease.

(d) "Attending physician checklist and compliance form" means a form, as described in Section 443.22, identifying each and every requirement that must be fulfilled by an attending physician to be in good faith compliance with this part should the attending physician choose to participate.

(e) "Capacity to make medical decisions" means that, in the opinion of an individual's attending physician, consulting physician, psychiatrist, or psychologist, pursuant to Section 4609 of the Probate Code, the individual has the ability to understand the nature and consequences of a health care decision, the ability to understand its significant benefits, risks, and alternatives, and the ability to make and communicate an informed decision to health care providers.

(f) "Consulting physician" means a physician who is independent from the attending physician and who is qualified by specialty or experience to make a professional diagnosis and prognosis regarding an individual's terminal disease.

(g) "Department" means the State Department of Public Health.

(h) "Health care provider" or "provider of health care" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act; any person certified pursuant to Division 2.5 (commencing with Section 1797) of this code; and any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of this code.

(i) "Informed decision" means a decision by an individual with a terminal disease to request and obtain a prescription for a drug that the individual may self-administer to end the individual's life, that is based on an understanding and acknowledgment of the relevant facts, and that is made after being fully informed by the attending physician of all of the following:

(1) The individual's medical diagnosis and prognosis.

(2) The potential risks associated with taking the drug to be prescribed.

(3) The probable result of taking the drug to be prescribed.

(4) The possibility that the individual may choose not to obtain the drug or may obtain the drug but may decide not to ingest it.

(5) The feasible alternatives or additional treatment opportunities, including, but not limited to, comfort care, hospice care, palliative care, and pain control.

(j) "Medically confirmed" means the medical diagnosis and prognosis of the attending physician has been confirmed by a consulting physician who has examined the individual and the individual's relevant medical records.

(k) "Mental health specialist assessment" means one or more consultations between an individual and a mental health specialist for the purpose of determining that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.

(l) "Mental health specialist" means a psychiatrist or a licensed psychologist.

(m) "Physician" means a doctor of medicine or osteopathy currently licensed to practice medicine in this state.

(n) "Public place" means any street, alley, park, public building, any place of business or assembly open to or frequented by the public, and any other place that is open to the public view, or to which the public has access.

(o) "Qualified individual" means an adult who has the capacity to make medical decisions, is a resident of California, and has satisfied the requirements of this part in order to obtain a prescription for a drug to end his or her life.

(p) "Self-administer" means a qualified individual's affirmative, conscious, and physical act of administering and ingesting the aid-in-dying drug to bring about his or her own death.

(q) "Terminal disease" means an incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, result in death within six months.

**443.2.** (a) An individual who is an adult with the capacity to make medical decisions and with a terminal disease may make a request to receive a prescription for an aid-in-dying drug if all of the following conditions are satisfied:

(1) The individual's attending physician has diagnosed the individual with a terminal disease.

(2) The individual has voluntarily expressed the wish to receive a prescription for an aid-in-dying drug.

(3) The individual is a resident of California and is able to establish residency through any of the following means:

(A) Possession of a California driver license or other identification issued by the State of California.

(B) Registration to vote in California.

(C) Evidence that the person owns or leases property in California.

(D) Filing of a California tax return for the most recent tax year.

(4) The individual documents his or her request pursuant to the requirements set forth in Section 443.3.

(5) The individual has the physical and mental ability to self-administer the aid-in-dying drug.

(b) A person shall not be considered a "qualified individual" under the provisions of this part solely because of age or disability.

(c) A request for a prescription for an aid-in-dying drug under this part shall be made solely and directly by the individual diagnosed with the terminal disease and shall not be made on behalf of the patient, including, but not limited to, through a power of attorney, an advance health care directive, a conservator, health care agent, surrogate, or any other legally recognized health care decisionmaker.

**443.3.** (a) An individual seeking to obtain a prescription for an aid-in-dying drug pursuant to this part shall submit two oral requests, a minimum of 15 days apart, and a written request to his or her attending physician. The attending physician shall directly, and not through a designee, receive all three requests required pursuant to this section.

(b) A valid written request for an aid-in-dying drug under subdivision (a) shall meet all of the following conditions:

(1) The request shall be in the form described in Section 443.11.

(2) The request shall be signed and dated, in the presence of two witnesses, by the individual seeking the aid-in-dying drug.

(3) The request shall be witnessed by at least two other adult persons who, in the presence of the individual, shall attest that to the best of their knowledge and belief the individual is all of the following:

(A) An individual who is personally known to them or has provided proof of identity.

(B) An individual who voluntarily signed this request in their presence.

(C) An individual whom they believe to be of sound mind and not under duress, fraud, or undue influence.

(D) Not an individual for whom either of them is the attending physician, consulting physician, or mental health specialist.

(c) Only one of the two witnesses at the time the written request is signed may:

(1) Be related to the qualified individual by blood, marriage, registered domestic partnership, or adoption or be entitled to a portion of the individual's estate upon death.

(2) Own, operate, or be employed at a health care facility where the individual is receiving medical treatment or resides.

(d) The attending physician, consulting physician, or mental health specialist of the individual shall not be one of the witnesses required pursuant to paragraph (3) of subdivision (b).

**443.4.** (a) An individual may at any time withdraw or rescind his or her request for an aid-in-dying drug, or decide not to ingest an aid-in-dying drug, without regard to the individual's mental state.

(b) A prescription for an aid-in-dying drug provided under this part may not be written without the attending physician directly, and not through a designee, offering the individual an opportunity to withdraw or rescind the request.

**443.5.** (a) Before prescribing an aid-in-dying drug, the attending physician shall do all of the following:

(1) Make the initial determination of all of the following:

(A) (i) Whether the requesting adult has the capacity to make medical decisions.

(ii) If there are indications of a mental disorder, the physician shall refer the individual for a mental health specialist assessment.

(iii) If a mental health specialist assessment referral is made, no aid-in-dying drugs shall be prescribed until the mental health specialist determines that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.

(B) Whether the requesting adult has a terminal disease.

(C) Whether the requesting adult has voluntarily made the request for an aid-in-dying drug pursuant to Sections 443.2 and 443.3.

(D) Whether the requesting adult is a qualified individual pursuant to subdivision (o) of Section 443.1.

(2) Confirm that the individual is making an informed decision by discussing with him or her all of the following:

(A) His or her medical diagnosis and prognosis.

(B) The potential risks associated with ingesting the requested aid-in-dying drug.

(C) The probable result of ingesting the aid-in-dying drug.

(D) The possibility that he or she may choose to obtain the aid-in-dying drug but not take it.

(E) The feasible alternatives or additional treatment options, including, but not limited to, comfort care, hospice care, palliative care, and pain control.

(3) Refer the individual to a consulting physician for medical confirmation of the diagnosis and prognosis, and for a determination that the individual has the capacity to make medical decisions and has complied with the provisions of this part.

(4) Confirm that the qualified individual's request does not arise from coercion or undue influence by another person by discussing with the qualified individual, outside of the presence of any other persons, except for an interpreter as required pursuant to this part, whether or not the qualified individual is feeling coerced or unduly influenced by another person.

(5) Counsel the qualified individual about the importance of all of the following:

(A) Having another person present when he or she ingests the aid-in-dying drug prescribed pursuant to this part.

(B) Not ingesting the aid-in-dying drug in a public place.

(C) Notifying the next of kin of his or her request for an aid-in-dying drug. A qualified individual who declines or is unable to notify next of kin shall not have his or her request denied for that reason.

(D) Participating in a hospice program.

(E) Maintaining the aid-in-dying drug in a safe and secure location until the time that the qualified individual will ingest it.

(6) Inform the individual that he or she may withdraw or rescind the request for an aid-in-dying drug at any time and in any manner.

(7) Offer the individual an opportunity to withdraw or rescind the request for an aid-in-dying drug before prescribing the aid-in-dying drug.

(8) Verify, immediately before writing the prescription for an aid-in-dying drug, that the qualified individual is making an informed decision.

(9) Confirm that all requirements are met and all appropriate steps are carried out in accordance with this part before writing a prescription for an aid-in-dying drug.

(10) Fulfill the record documentation required under Sections 443.8 and 443.19.

(11) Complete the attending physician checklist and compliance form, as described in Section 443.22, include it and the consulting physician compliance form in the individual's medical record, and submit both forms to the State Department of Public Health.

(12) Give the qualified individual the final attestation form, with the instruction that the form be filled out and executed by the qualified individual within 48 hours prior to the qualified individual choosing to self-administer the aid-in-dying drug.

(b) If the conditions set forth in subdivision (a) are satisfied, the attending physician may deliver the aid-in-dying drug in any of the following ways:

(1) Dispensing the aid-in-dying drug directly, including ancillary medication intended to minimize the qualified individual's discomfort, if the attending physician meets all of the following criteria:

(A) Is authorized to dispense medicine under California law.

(B) Has a current United States Drug Enforcement Administration (USDEA) certificate.

(C) Complies with any applicable administrative rule or regulation.

(2) With the qualified individual's written consent, contacting a pharmacist, informing the pharmacist of the prescriptions, and delivering the written prescriptions personally, by mail, or electronically to the pharmacist, who may dispense the drug to the qualified individual, the attending physician, or a person expressly designated by the qualified individual and with the designation delivered to the pharmacist in writing or verbally.

(c) Delivery of the dispensed drug to the qualified individual, the attending physician, or a person expressly designated by the qualified individual may be made by personal delivery, or, with a signature required on delivery, by United Parcel Service, United States Postal Service, Federal Express, or by messenger service.

**443.6.** Before a qualified individual obtains an aid-in-dying drug from the attending physician, the consulting physician shall perform all of the following:

(a) Examine the individual and his or her relevant medical records.

(b) Confirm in writing the attending physician's diagnosis and prognosis.

(c) Determine that the individual has the capacity to make medical decisions, is acting voluntarily, and has made an informed decision.

(d) If there are indications of a mental disorder, refer the individual for a mental health specialist assessment.

(e) Fulfill the record documentation required under this part.

(f) Submit the compliance form to the attending physician.

**443.7.** Upon referral from the attending or consulting physician pursuant to this part, the mental health specialist shall:

(a) Examine the qualified individual and his or her relevant medical records.

(b) Determine that the individual has the mental capacity to make medical decisions, act voluntarily, and make an informed decision.

(c) Determine that the individual is not suffering from impaired judgment due to a mental disorder.

(d) Fulfill the record documentation requirements of this part.

**443.8.** All of the following shall be documented in the individual's medical record:

(a) All oral requests for aid-in-dying drugs.

(b) All written requests for aid-in-dying drugs.

(c) The attending physician's diagnosis and prognosis, and the determination that a qualified individual has the capacity to make medical decisions, is acting voluntarily, and has made an informed decision, or that the attending physician has determined that the individual is not a qualified individual.

(d) The consulting physician's diagnosis and prognosis, and verification that the qualified individual has the capacity to make medical decisions, is acting voluntarily, and has made an informed decision, or that the consulting physician has determined that the individual is not a qualified individual.

(e) A report of the outcome and determinations made during a mental health specialist's assessment, if performed.

(f) The attending physician's offer to the qualified individual to withdraw or rescind his or her request at the time of the individual's second oral request.

(g) A note by the attending physician indicating that all requirements under Sections 443.5 and 443.6 have been met and indicating the steps taken to carry out the request, including a notation of the aid-in-dying drug prescribed.

**443.9.** (a) Within 30 calendar days of writing a prescription for an aid-in-dying drug, the attending physician shall submit to the State Department of Public Health a copy of the qualifying patient's written request, the attending physician checklist and compliance form, and the consulting physician compliance form.

(b) Within 30 calendar days following the qualified individual's death from ingesting the aid-in-dying drug, or any other cause, the attending physician shall submit the attending physician followup form to the State Department of Public Health.

**443.10.** A qualified individual may not receive a prescription for an aid-in-dying drug pursuant to this part unless he or she has made an informed decision. Immediately before writing a prescription for an aid-in-dying drug under this part, the attending physician shall verify that the individual is making an informed decision.

**443.11.** (a) A request for an aid-in-dying drug as authorized by this part shall be in the following form:

REQUEST FOR AN AID-IN-DYING DRUG TO END MY LIFE IN A HUMANE AND DIGNIFIED MANNER I, ....., am an adult of sound mind and a resident of the State of California.

I am suffering from ....., which my attending physician has determined is in its terminal phase and which has been medically confirmed.

I have been fully informed of my diagnosis and prognosis, the nature of the aid-in-dying drug to be prescribed and potential associated risks, the expected result, and the feasible alternatives or additional treatment options, including comfort care, hospice care, palliative care, and pain control.

I request that my attending physician prescribe an aid-in-dying drug that will end my life in a humane and dignified manner if I choose to take it, and I authorize my attending physician to contact any pharmacist about my request.

INITIAL ONE:

..... I have informed one or more members of my family of my decision and taken their opinions into consideration.

..... I have decided not to inform my family of my decision.

..... I have no family to inform of my decision.

I understand that I have the right to withdraw or rescind this request at any time.

I understand the full import of this request and I expect to die if I take the aid-in-dying drug to be prescribed. My attending physician has counseled me about the possibility that my death may not be immediately upon the consumption of the drug.

I make this request voluntarily, without reservation, and without being coerced.

Signed:.....

Dated:.....

DECLARATION OF WITNESSES

We declare that the person signing this request:

(a) is personally known to us or has provided proof of identity;

(b) voluntarily signed this request in our presence;

(c) is an individual whom we believe to be of sound mind and not under duress, fraud, or undue influence; and

(d) is not an individual for whom either of us is the attending physician, consulting physician, or mental health specialist.

.....Witness 1/Date

.....Witness 2/Date

NOTE: Only one of the two witnesses may be a relative (by blood, marriage, registered domestic partnership, or adoption) of the person signing this request or be entitled to a portion of the person's estate upon death. Only one of the two witnesses may own, operate, or be employed at a health care facility where the person is a patient or resident.

(b) (1) The written language of the request shall be written in the same translated language as any conversations, consultations, or interpreted conversations or consultations between a patient and his or her attending or consulting physicians.

(2) Notwithstanding paragraph (1), the written request may be prepared in English even when the conversations or consultations or interpreted conversations or consultations were conducted in a language other than English if the English language form includes an attached interpreter's declaration that is signed under penalty of perjury. The interpreter's declaration shall state words to the effect that:

I, (INSERT NAME OF INTERPRETER), am fluent in English and (INSERT TARGET LANGUAGE).

On (insert date) at approximately (insert time), I read the "Request for an Aid-In-Dying Drug to End My Life" to (insert name of individual/patient) in (insert target language).

Mr./Ms. (insert name of patient/qualified individual) affirmed to me that he/she understood the content of this form and affirmed his/her desire to sign this form under his/her own power and volition and that the request to sign the form followed consultations with an attending and consulting physician.

I declare that I am fluent in English and (insert target language) and further declare under penalty of perjury that the foregoing is true and correct.

Executed at (insert city, county, and state) on this (insert day of month) of (insert month), (insert year).

X_____Interpreter signature

X_____Interpreter printed name

X_____Interpreter address

(3) An interpreter whose services are provided pursuant to paragraph (2) shall not be related to the qualified individual by blood, marriage, registered domestic partnership, or adoption or be entitled to a portion of the person's estate upon death. An interpreter whose services are provided pursuant to paragraph (2) shall meet the standards promulgated by the California Healthcare Interpreting Association or the National Council on Interpreting in Health Care or other standards deemed acceptable by the department for health care providers in California.

(c) The final attestation form given by the attending physician to the qualified individual at the time the attending physician writes the prescription shall appear in the following form:

FINAL ATTESTATION FOR AN AID-IN-DYING DRUG TO END MY LIFE IN A HUMANE AND DIGNIFIED MANNER I, ....., am an adult of sound mind and a resident of the State of California.

I am suffering from ....., which my attending physician has determined is in its terminal phase and which has been medically confirmed.

I have been fully informed of my diagnosis and prognosis, the nature of the aid-in-dying drug to be prescribed and potential associated risks, the expected result, and the feasible alternatives or additional treatment options, including comfort care, hospice care, palliative care, and pain control.

I have received the aid-in-dying drug and am fully aware that this aid-in-dying drug will end my life in a humane and dignified manner.

INITIAL ONE:

..... I have informed one or more members of my family of my decision and taken their opinions into consideration.

..... I have decided not to inform my family of my decision.

..... I have no family to inform of my decision.

My attending physician has counseled me about the possibility that my death may not be immediately upon the consumption of the drug.

I make this decision to ingest the aid-in-dying drug to end my life in a humane and dignified manner. I understand I still may choose not to ingest the drug and by signing this form I am under no obligation to ingest the drug. I understand I may rescind this request at any time.

Signed:.....

Dated:.....

Time:.....

(1) Within 48 hours prior to the individual self-administering the aid-in-dying drug, the individual shall complete the final attestation form. If aid-in-dying medication is not returned or relinquished upon the patient's death as required in Section 443.20, the completed form shall be delivered by the individual's health care provider, family member, or other representative to the attending physician to be included in the patient's medical record.

(2) Upon receiving the final attestation form the attending physician shall add this form to the medical records of the qualified individual.

**443.12.** (a) A provision in a contract, will, or other agreement executed on or after January 1, 2016, whether written or oral, to the extent the provision would affect whether a person may make, withdraw, or rescind a request for an aid-in-dying drug is not valid.

(b) An obligation owing under any contract executed on or after January 1, 2016, may not be conditioned or affected by a qualified individual making, withdrawing, or rescinding a request for an aid-in-dying drug.

**443.13.** (a) (1) The sale, procurement, or issuance of a life, health, or annuity policy, health care service plan contract, or health benefit plan, or the rate charged for a policy or plan contract may not be conditioned upon or affected by a person making or rescinding a request for an aid-in-dying drug.

(2) Pursuant to Section 443.18, death resulting from the self-administration of an aid-in-dying drug is not suicide, and therefore health and insurance coverage shall not be exempted on that basis.

(b) Notwithstanding any other law, a qualified individual's act of self-administering an aid-in-dying drug shall not have an effect upon a life, health, or annuity policy other than that of a natural death from the underlying disease.

(c) An insurance carrier shall not provide any information in communications made to an individual about the availability of an aid-in-dying drug absent a request by the individual or his or her attending physician at the behest of the individual. Any communication shall not include both the denial of treatment and information as to the availability of aid-in-dying drug coverage. For the purposes of this subdivision, "insurance carrier" means a health care service plan as defined in Section 1345 of this code or a carrier of health insurance as defined in Section 106 of the Insurance Code.

**443.14.** (a) Notwithstanding any other law, a person shall not be subject to civil or criminal liability solely because the person was present when the qualified individual self-administers the prescribed aid-in-dying drug. A person who is present may, without civil or criminal liability, assist the qualified individual by preparing the aid-in-dying drug so long as the person does not assist the qualified person in ingesting the aid-in-dying drug.

(b) A health care provider or professional organization or association shall not subject an individual to censure, discipline, suspension, loss of license, loss of privileges, loss of membership, or other penalty for participating in good faith compliance with this part or for refusing to participate in accordance with subdivision (e).

(c) Notwithstanding any other law, a health care provider shall not be subject to civil, criminal, administrative, disciplinary, employment, credentialing, professional discipline, contractual liability, or medical staff action, sanction, or penalty or other liability for participating in this part, including, but not limited to, determining the diagnosis or prognosis of an individual, determining the capacity of an individual for purposes of qualifying for the act, providing information to an individual regarding this part, and providing a referral to a physician who participates in this part. Nothing in this subdivision shall be construed to limit the application of, or provide immunity from, Section 443.16 or 443.17.

(d) (1) A request by a qualified individual to an attending physician to provide an aid-in-dying drug in good faith compliance with the provisions of this part shall not provide the sole basis for the appointment of a guardian or conservator.

(2) No actions taken in compliance with the provisions of this part shall constitute or provide the basis for any claim of neglect or elder abuse for any purpose of law.

(e) (1) Participation in activities authorized pursuant to this part shall be voluntary. Notwithstanding Sections 442 to 442.7, inclusive, a person or entity that elects, for reasons of conscience, morality, or ethics, not to engage in activities authorized pursuant to this part is not required to take any action in support of an individual's decision under this part.

(2) Notwithstanding any other law, a health care provider is not subject to civil, criminal, administrative, disciplinary, employment, credentialing, professional discipline, contractual liability, or medical staff action, sanction, or penalty or other liability for refusing to participate in activities authorized under this part, including, but not limited to, refusing to inform a patient regarding his or her rights under this part, and not referring an individual to a physician who participates in activities authorized under this part.

(3) If a health care provider is unable or unwilling to carry out a qualified individual's request under this part and the qualified individual transfers care to a new health care provider, the individual may request a copy of his or her medical records pursuant to law.

**443.15.** (a) Subject to subdivision (b), notwithstanding any other law, a health care provider may prohibit its employees, independent contractors, or other persons or entities, including other health care providers, from participating in activities under this part while on premises owned or under the management or direct control of that prohibiting health care provider or while acting within the course and scope of any employment by, or contract with, the prohibiting health care provider.

(b) A health care provider that elects to prohibit its employees, independent contractors, or other persons or entities, including health care providers, from participating in activities under this part, as described in subdivision (a), shall first give notice of the policy prohibiting participation under this part to the individual or entity. A health care provider that fails to provide notice to an individual or entity in compliance with this subdivision shall not be entitled to enforce such a policy against that individual or entity.

(c) Subject to compliance with subdivision (b), the prohibiting health care provider may take action, including, but not limited to, the following, as applicable, against any individual or entity that violates this policy:

(1) Loss of privileges, loss of membership, or other action authorized by the bylaws or rules and regulations of the medical staff.

(2) Suspension, loss of employment, or other action authorized by the policies and practices of the prohibiting health care provider.

(3) Termination of any lease or other contract between the prohibiting health care provider and the individual or entity that violates the policy.

(4) Imposition of any other nonmonetary remedy provided for in any lease or contract between the prohibiting health care provider and the individual or entity in violation of the policy.

(d) Nothing in this section shall be construed to prevent, or to allow a prohibiting health care provider to prohibit, any other health care provider, employee, independent contractor, or other person or entity from any of the following:

(1) Participating, or entering into an agreement to participate, in activities under this part, while on premises that are not owned or under the management or direct control of the prohibiting provider or while acting

outside the course and scope of the participant's duties as an employee of, or an independent contractor for, the prohibiting health care provider.

(2) Participating, or entering into an agreement to participate, in activities under this part as an attending physician or consulting physician while on premises that are not owned or under the management or direct control of the prohibiting provider.

(e) In taking actions pursuant to subdivision (c), a health care provider shall comply with all procedures required by law, its own policies or procedures, and any contract with the individual or entity in violation of the policy, as applicable.

(f) For purposes of this section:

(1) "Notice" means a separate statement in writing advising of the prohibiting health care provider policy with respect to participating in activities under this part.

(2) "Participating, or entering into an agreement to participate, in activities under this part" means doing or entering into an agreement to do any one or more of the following:

(A) Performing the duties of an attending physician as specified in Section 443.5.

(B) Performing the duties of a consulting physician as specified in Section 443.6.

(C) Performing the duties of a mental health specialist, in the circumstance that a referral to one is made.

(D) Delivering the prescription for, dispensing, or delivering the dispensed aid-in-dying drug pursuant to paragraph (2) of subdivision (b) of, and subdivision (c) of, Section 443.5.

(E) Being present when the qualified individual takes the aid-in-dying drug prescribed pursuant to this part.

(3) "Participating, or entering into an agreement to participate, in activities under this part" does not include doing, or entering into an agreement to do, any of the following:

(A) Diagnosing whether a patient has a terminal disease, informing the patient of the medical prognosis, or determining whether a patient has the capacity to make decisions.

(B) Providing information to a patient about this part.

(C) Providing a patient, upon the patient's request, with a referral to another health care provider for the purposes of participating in the activities authorized by this part.

(g) Any action taken by a prohibiting provider pursuant to this section shall not be reportable under Sections 800 to 809.9, inclusive, of the Business and Professions Code. The fact that a health care provider participates in activities under this part shall not be the sole basis for a complaint or report by another health care provider of unprofessional or dishonorable conduct under Sections 800 to 809.9, inclusive, of the Business and Professions Code.

(h) Nothing in this part shall prevent a health care provider from providing an individual with health care services that do not constitute participation in this part.

**443.16.** (a) A health care provider may not be sanctioned for any of the following:

(1) Making an initial determination pursuant to the standard of care that an individual has a terminal disease and informing him or her of the medical prognosis.

(2) Providing information about the End of Life Option Act to a patient upon the request of the individual.

(3) Providing an individual, upon request, with a referral to another physician.

(b) A health care provider that prohibits activities under this part in accordance with Section 443.15 shall not sanction an individual health care provider for contracting with a qualified individual to engage in activities authorized by this part if the individual health care provider is acting outside of the course and scope of his or her capacity as an employee or independent contractor of the prohibiting health care provider.

(c) Notwithstanding any contrary provision in this section, the immunities and prohibitions on sanctions of a health care provider are solely reserved for actions of a health care provider taken pursuant to this part. Notwithstanding any contrary provision in this part, health care providers may be sanctioned by their licensing board or agency for conduct and actions constituting unprofessional conduct, including failure to comply in good faith with this part.

**443.17.** (a) Knowingly altering or forging a request for an aid-in-dying drug to end an individual's life without his or her authorization or concealing or destroying a withdrawal or rescission of a request for an aid-in-dying drug is punishable as a felony if the act is done with the intent or effect of causing the individual's death.

(b) Knowingly coercing or exerting undue influence on an individual to request or ingest an aid-in-dying drug for the purpose of ending his or her life or to destroy a withdrawal or rescission of a request, or to administer an aid-in-dying drug to an individual without his or her knowledge or consent, is punishable as a felony.

(c) For purposes of this section, "knowingly" has the meaning provided in Section 7 of the Penal Code.

(d) The attending physician, consulting physician, or mental health specialist shall not be related to the individual by blood, marriage, registered domestic partnership, or adoption, or be entitled to a portion of the individual's estate upon death.

(e) Nothing in this section shall be construed to limit civil liability.

(f) The penalties in this section do not preclude criminal penalties applicable under any law for conduct inconsistent with the provisions of this section.

**443.18.** Nothing in this part may be construed to authorize a physician or any other person to end an individual's life by lethal injection, mercy killing, or active euthanasia. Actions taken in accordance with this part shall not, for any purposes, constitute suicide, assisted suicide, homicide, or elder abuse under the law.

**443.19.** (a) The State Department of Public Health shall collect and review the information submitted pursuant to Section 443.9. The information collected shall be confidential and shall be collected in a manner that protects the privacy of the patient, the patient's family, and any medical provider or pharmacist involved with the patient under the provisions of this part. The information shall not be disclosed, discoverable, or compelled to be produced in any civil, criminal, administrative, or other proceeding.

(b) On or before July 1, 2017, and each year thereafter, based on the information collected in the previous year, the department shall create a report with the information collected from the attending physician followup form and post that report to its Internet Web site. The report shall include, but not be limited to, all of the following based on the information that is provided to the department and on the department's access to vital statistics:

(1) The number of people for whom an aid-in-dying prescription was written.

(2) The number of known individuals who died each year for whom aid-in-dying prescriptions were written, and the cause of death of those individuals.

(3) For the period commencing January 1, 2016, to and including the previous year, cumulatively, the total number of aid-in-dying prescriptions written, the number of people who died due to use of aid-in-dying drugs, and the number of those people who died who were enrolled in hospice or other palliative care programs at the time of death.

(4) The number of known deaths in California from using aid-in-dying drugs per 10,000 deaths in California.

(5) The number of physicians who wrote prescriptions for aid-in-dying drugs.

(6) Of people who died due to using an aid-in-dying drug, demographic percentages organized by the following characteristics:

(A) Age at death.

(B) Education level.

(C) Race.

(D) Sex.

(E) Type of insurance, including whether or not they had insurance.

(F) Underlying illness.

(c) The State Department of Public Health shall make available the attending physician checklist and compliance form, the consulting physician compliance form, and the attending physician followup form, as described in Section 443.22, by posting them on its Internet Web site.

**443.20.** A person who has custody or control of any unused aid-in-dying drugs prescribed pursuant to this part after the death of the patient shall personally deliver the unused aid-in-dying drugs for disposal by delivering it to the nearest qualified facility that properly disposes of controlled substances, or if none is available, shall dispose of it by lawful means in accordance with guidelines promulgated by the California State Board of Pharmacy or a federal Drug Enforcement Administration approved take-back program.

**443.21.** Any governmental entity that incurs costs resulting from a qualified individual terminating his or her life pursuant to the provisions of this part in a public place shall have a claim against the estate of the qualified individual to recover those costs and reasonable attorney fees related to enforcing the claim.

**443.215.** This part shall remain in effect only until January 1, 2026, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2026, deletes or extends that date.

**443.22.** (a) The Medical Board of California may update the attending physician checklist and compliance form, the consulting physician compliance form, and the attending physician followup form, based on those provided in subdivision (b). Upon completion, the State Department of Public Health shall publish the updated forms on its Internet Web site.

(b) Unless and until updated by the Medical Board of California pursuant to this section, the attending physician checklist and compliance form, the consulting physician compliance form, and the attending physician followup form shall be in the following form:

PRINTER PLEASE NOTE: TIP-IN MATERIAL TO BE INSERTED

**SEC. 2.** The Legislature finds and declares that Section 1 of this act, which adds Section 443.19 to the Health and Safety Code, imposes a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

(a) Any limitation to public access to personally identifiable patient data collected pursuant to Section 443.19 of the Health and Safety Code as proposed to be added by this act is necessary to protect the privacy rights of the patient and his or her family.

(b) The interests in protecting the privacy rights of the patient and his or her family in this situation strongly outweigh the public interest in having access to personally identifiable data relating to services.

(c) The statistical report to be made available to the public pursuant to subdivision (b) of Section 443.19 of the Health and Safety Code is sufficient to satisfy the public's right to access.

**SEC. 3.** The provisions of this part are severable. If any provision of this part or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

**SEC. 4.** No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

# ATTENDING PHYSICIAN CHECKLIST & COMPLIANCE FORM

| A | PATIENT INFORMATION | |
|---|---|---|
| | PATIENT'S NAME (LAST, FIRST, M.I.) | DATE OF BIRTH |
| | PATIENT RESIDENTIAL ADDRESS (STREET, CITY, ZIP CODE) | |

| B | ATTENDING PHYSICIAN INFORMATION | |
|---|---|---|
| | PHYSICIAN'S NAME (LAST, FIRST, M.I.) | TELEPHONE NUMBER<br>( ) — |
| | MAILING ADDRESS (STREET, CITY, ZIP CODE) | |
| | PHYSICIAN'S LICENSE NUMBER | |

| C | CONSULTING PHYSICIAN INFORMATION | |
|---|---|---|
| | PHYSICIAN'S NAME (LAST, FIRST, M.I.) | TELEPHONE NUMBER<br>( ) — |
| | MAILING ADDRESS (STREET, CITY, ZIP CODE) | |
| | PHYSICIAN'S LICENSE NUMBER | |

| D | ELIGIBILITY DETERMINATION |
|---|---|
| | 1. TERMINAL DISEASE |
| | 2. CHECK BOXES FOR COMPLIANCE:<br>☐ 1. Determination that the patient has a terminal disease.<br>☐ 2. Determination that patient is a resident of California.<br>☐ 3. Determination that patient has the capacity to make medical decisions**<br>☐ 4. Determination that patient is acting voluntarily.<br>☐ 5. Determination of capacity by mental health specialist, if necessary.<br>☐ 6. Determination that patient has made his/her decision after being fully informed of:<br>☐ a) His or her medical diagnosis; and<br>☐ b) His or her prognosis; and<br>☐ c) The potential risks associated with ingesting the requested aid-in-dying drug;<br>☐ d) The probable result of ingesting the aid-in-dying drug;<br>☐ e) The possibility that he or she may choose to obtain the aid-in-dying drug but not take it |

## ATTENDING PHYSICIAN CHECKLIST & COMPLIANCE FORM

| E | ADDITIONAL COMPLIANCE REQUIREMENTS |
|---|---|

- ☐ 1. Counseled patient about the importance of all of the following:
- ☐ a) Maintaining the aid-in-dying drug in a safe and secure location until the time the qualified individual will ingest it;
- ☐ b) Having another person present when he or she ingests the aid-in-dying drug;
- ☐ c) Not ingesting the aid-in-dying drug in a public place;
- ☐ d) Notifying the next of kin of his or her request for an aid-in-dying drug. (an individual who declines or is unable to notify next of kin shall not have his or her request denied for that reason); and
- ☐ e) Participating in a hospice program or palliative care program.
- ☐ 2. Informed patient of right to rescind request (1st time)
- ☐ 3. Discussed the feasible alternatives, including, but not limited to, comfort care, hospice care, palliative care and pain control.
- ☐ 4. Met with patient one-on-one, except in the presence of an interpreter, to confirm the request is not coming from coercion
- ☐ 5. First oral request for aid-in-dying: _____/_____/_____ Attending physician initials:_____
- ☐ 6. Second oral request for aid-in-dying:_____/_____/_____ Attending physician initials:_____
- ☐ 7. Written request submitted: _____/_____/_____ Attending physician initials:_____
- ☐ 8. Offered patient right to rescind (2nd time)

| F | PATIENT'S MENTAL STATUS |
|---|---|

Check one of the following **(required)**:

- ☐ I have determined that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.
- ☐ I have referred the patient to the mental health specialist**** listed below for one or more consultations to determine that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.
- ☐ If a referral was made to a mental health specialist, the mental health specialist has determined that the patient is not suffering from impaired judgment due to a mental disorder

Mental health specialist's information, if applicable:

| MENTAL HEALTH SPECIALIST NAME |
|---|
| MENTAL HEALTH SPECIALIST TITLE & LICENSE NUMBER |
| MENTAL HEALTH SPECIALIST ADDRESS (STREET, CITY, ZIP CODE) |

## ATTENDING PHYSICIAN CHECKLIST & COMPLIANCE FORM

| G | MEDICATION PRESCRIBED | |
|---|---|---|
| | PHARMACIST NAME | TELEPHONE NUMBER<br>( ) — |

1. Aid-in-dying medication prescribed:
   - ☐ a. Name:_____
   - ☐ b. Dosage:_____
2. Antiemetic medication prescribed:
   - ☐ a. Name:_____
   - ☐ b. Dosage:_____
3. Method prescription was delivered:
   - ☐ a. In person
   - ☐ b. By mail
   - ☐ c. Electronically
4. Date medication was prescribed:_____/_____/_____

| | | | |
|---|---|---|---|
| | X | PHYSICIAN'S SIGNATURE | DATE |
| | | NAME (PLEASE PRINT) | |

** "Capacity to make medical decisions" means that, in the opinion of an individual's attending physician, consulting physician, psychiatrist, or psychologist, pursuant to Section 4609 of the Probate Code, the individual has the ability to understand the nature and consequences of a health care decision, the ability to understand its significant benefits, risks, and alternatives, and the ability to make

****"Mental Health Specialist" means a psychiatrist or a licensed psychologist.

# CONSULTING PHYSICIAN COMPLIANCE FORM

| A | PATIENT INFORMATION | |
|---|---|---|
| | PATIENT'S NAME (LAST, FIRST, M.I.) | DATE OF BIRTH |

| B | ATTENDING PHYSICIAN | |
|---|---|---|
| | ATTENDING PHYSICIAN'S NAME (LAST, FIRST, M.I.) | TELEPHONE NUMBER<br>( ) — |

**C CONSULTING PHYSICIAN'S REPORT**

| 1. TERMINAL DISEASE | DATE OF EXAMINATION(S) |
|---|---|
| | |

2. Check boxes for compliance. *(Both the attending and consulting physicians must make these determinations.)*

- ☐ 1. Determination that the patient has a terminal disease.
- ☐ 2. Determination that patient has the mental capacity to make medical decisions.**
- ☐ 3. Determination that patient is acting voluntarily.
- ☐ 4. Determination that patient has made his/her decision after being fully informed of:
- ☐ a) His or her medical diagnosis; and
- ☐ b) His or her prognosis; and
- ☐ c) The potential risks associated with taking the drug to be prescribed; and
- ☐ d) The potential result of taking the drug to be prescribed; and
- ☐ e) The feasible alternatives, including, but not limited to, comfort care, hospice care, palliative care and pain control.

**D PATIENT'S MENTAL STATUS**

Check one of the following **(required)**:

- ☐ I have determined that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.
- ☐ I have referred the patient to the mental health specialist**** listed below for one or more consultations to determine that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.
- ☐ If a referral was made to a mental health specialist, the mental health specialist has determined that the patient is not suffering from impaired judgment due to a mental disorder

| MENTAL HEALTH SPECIALIST'S NAME | TELEPHONE NUMBER<br>( ) — | DATE |
|---|---|---|
| | | |

**E CONSULTANT'S INFORMATION**

| PHYSICIAN'S SIGNATURE | DATE |
|---|---|
| | |
| NAME (PLEASE PRINT) | |
| MAILING ADDRESS | |
| CITY, STATE AND ZIP CODE | TELEPHONE NUMBER<br>( ) — |

** "Capacity to make medical decisions" means that, in the opinion of an individual's attending physician, consulting physician, psychiatrist, or psychologist, pursuant to Section 4609 of the Probate Code, the individual has the ability to understand the nature and consequences of a health care decision, the ability to understand its significant benefits, risks, and alternatives, and the ability to make

****"Mental Health Specialist" means a psychiatrist or a licensed psychologist.

# ATTENDING PHYSICIAN FOLLOW-UP FORM

The End of Life Option Act requires physicians who write a prescription for an aid-in-dying drug to complete this follow-up form within **30 calendar days** of a patient's death, whether from ingestion of the aid-in-dying drug obtained under the Act or from any other cause.

**For the State Department of Public Health to accept this form, it must be signed by the attending physician, whether or not he or she was present at the patient's time of death.**

This form should be mailed or sent electronically to the State Department of Public Health. All information is kept strictly confidential.

**Date**: _____/_____/_____

**Patient name**: _____

**Attending physician name**: _____

Did the patient die from ingesting the aid-in-dying drug, from their underlying illness, or from another cause such as terminal sedation or ceasing to eat or drink?

- ☐ **Aid-in-dying drug** (lethal dose) → Please sign below and go to page 2.
  Attending physician signature:_____
- ☐ **Underlying illness** → There is no need to complete the rest of the form. Please sign below.
  Attending physician signature:_____
- ☐ **Other** → There is no need to complete the rest of the form. Please specify the circumstances surrounding the patient's death and sign
  Please specify:
  _____
  _____

Attending physician signature:_____

**PART A and PART B should only be completed if the patient died from ingesting the lethal dose of the aid-in-dying drug.**

Please read carefully the following to determine which situation applies. Check the box that indicates the scenario and complete the remainder of the form accordingly.

- ☐ The attending physician was present at the time of death.

→ The attending physician must complete this form in its entirety and sign Part A and Part B.

- ☐ The attending physician was not present at the time of death, but another licensed health care provider was present.

→ The licensed health care provider must complete and sign Part A of this form. The attending physician must complete and sign Part B of the form.

- ☐ Neither the attending physician nor another licensed health care provider was present at the time of death.

→ Part A may be left blank. The attending physician must complete and sign Part B of the form.

## ATTENDING PHYSICIAN FOLLOW-UP FORM

**PART A: To be completed and signed by the attending physician or another licensed health care provider present at death:**

1. Was the attending physician at the patient's bedside when the patient took the aid-in-dying drug?

- ☐ Yes
- ☐ No

If no: Was another physician or trained health care provider present when the patient ingested the aid-in-dying drug?

- ☐ Yes, another physician
- ☐ Yes, a trained health-care provider/volunteer
- ☐ No
- ☐ Unknown

2. Was the attending physician at the patient's bedside at the time of death?

- ☐ Yes
- ☐ No

If no: Was another physician or a licensed health care provider present at the patient's time of death?

- ☐ Yes, another physician or licensed health care provider
- ☐ No
- ☐ Unknown

3. On what day did the patient consume the lethal dose of the aid-in-dying?
_____/_____/_____ (month/day/year) ☐ Unknown

4. On what day did the patient die after consuming the lethal dose of the aid-in-dying drug?
_____/_____/_____ (month/day/year) ☐ Unknown

5. Where did the patient ingest the lethal dose of the aid-in-dying drug?

- ☐ Private home
- ☐ Assisted-living residence
- ☐ Nursing home
- ☐ Acute care hospital in-patient
- ☐ In-patient hospice resident
- ☐ Other (specify)_____
- ☐ Unknown

6. What was the time between the ingestion of the lethal dose of aid-in-dying drug and unconsciousness?
Minutes_____ and/or Hours_____ ☐Unknown

7. What was the time between lethal medication ingestion and death?
Minutes_____ and/or Hours_____ ☐Unknown

## ATTENDING PHYSICIAN FOLLOW-UP FORM

8. Were there any complications that occurred after the patient took the lethal dose of the aid-in-dying drug?

- ☐ Yes- vomiting, emesis
- ☐ Yes-regained consciousness
- ☐ No Complications
- ☐ Other- Please describe:_____
- ☐ Unknown

9. Was the Emergency Medical System activated for any reason after ingesting the lethal dose of the aid-in-dying drug?

- ☐ Yes- Please describe:_____
- ☐ No
- ☐ Unknown

10. At the time of ingesting the lethal dose of the aid-in-dying drug, was the patient receiving hospice care?

- ☐ Yes
- ☐ No, refused care
- ☐ No, other (specify) _____

Signature of attending physician present at time of death: _____

Name of Licensed Health Care Provider present at time of death if not attending physician:_____

Signature of Licensed Health Care Provider: _____

## ATTENDING PHYSICIAN FOLLOW-UP FORM

### PART B: To be completed and signed by the attending physician

**12.** On what date was the prescription written for the aid-in-dying drug? ____/____/____

**13.** When the patient initially requested a prescription for the aid-in-dying drug, was the patient receiving hospice care?

- ☐ Yes
- ☐ No, refused care
- ☐ No, other (specify) _____

**14.** What type of health-care coverage did the patient have for their underlying illness? (*Check all that apply.*)

- ☐ Medicare
- ☐ Medi-cal
- ☐ Covered California
- ☐ V.A.
- ☐ Private Insurance
- ☐ No insurance
- ☐ Had insurance, don't know type

**15.** Possible concerns that may have contributed to the patient's decision to request a prescription for aid-in-dying drug Please check "yes," "no," or "Don't' know," depending on whether or not you believe that concern contributed to their request (Please check as many boxes as you think may apply)
A concern about . . .

- **His or her terminal condition representing a steady loss of autonomy**
  - ☐ Yes
  - ☐ No
  - ☐ Don't Know
- **The decreasing ability to participate in activities that made life enjoyable**
  - ☐ Yes
  - ☐ No
  - ☐ Don't Know
- **The loss of control of bodily functions**
  - ☐ Yes
  - ☐ No
  - ☐ Don't Know
- **Persistent and uncontrollable pain and suffering**
  - ☐ Yes
  - ☐ No
  - ☐ Don't Know
- **A loss of Dignity**
  - ☐ Yes
  - ☐ No
  - ☐ Don't Know
- **Other concerns** (specify): _____

Signature of attending physician: _____

# Attending Physician Forms Submission Instructions

What Forms Does the Attending Physician Have to Submit to CDPH?

Within 30 calendar days of writing a prescription for medication under this Act, the attending physician must submit the following completed, signed, and dated forms to CDPH:

- A copy of the qualifying individual's written request;
- Attending Physician's Checklist and Compliance form (PDF); and
- Consulting Physician's Compliance form (PDF).

Within 30 calendar days of a qualified individuals' ingestion of the aid-in-dying medication obtained under the terms of the Act, or death from any other cause, whichever comes first, the attending physician shall submit:

- Attending Physician Follow-Up form (PDF).

The forms can be sent to CDPH at the following address:

California Department of Public Health
Public Health Policy and Research Branch
Attention: End of Life Option Act
MS 5205
P.O. Box 997377
Sacramento, CA 95899-7377

The forms can also be faxed to (916) 440-5209.

## REQUEST FOR AN AID-IN-DYING DRUG TO END MY LIFE IN A HUMANE AND DIGNIFIED MANNER

I, _____,
am an adult of sound mind and a resident of the State of California.

I am suffering from _____,
which my attending physician has determined is in its terminal phase and which has been medically confirmed.

I have been fully informed of my diagnosis and prognosis, the nature of the aid-in-dying drug to be prescribed and potential associated risks, the expected result, and the feasible alternatives or additional treatment options, including comfort care, hospice care, palliative care, and pain control.

I request that my attending physician prescribe an aid-in-dying drug that will end my life in a humane and dignified manner if I choose to take it, and I authorize my attending physician to contact any pharmacist about my request.

**INITIAL ONE:**

_____ I have informed one or more members of my family of my decision and taken their opinions into consideration.

_____ I have decided not to inform my family of my decision.

_____ I have no family to inform of my decision.

I understand that I have the right to withdraw or rescind this request at any time.

I understand the full import of this request and I expect to die if I take the aid-in-dying drug to be prescribed. My attending physician has counseled me about the possibility that my death may not be immediately upon the consumption of the drug.

I make this request voluntarily, without reservation, and without being coerced.

**Signed:**_____ **Dated:**_____

## DECLARATION OF WITNESSES

We declare that the person signing this request:

(a) is personally known to us or has provided proof of identity;
(b) voluntarily signed this request in our presence;
(c) is an individual whom we believe to be of sound mind and not under duress, fraud, or undue influence; and
(d) is not an individual for whom either of us is the attending physician, consulting physician, or mental health specialist.

**Witness 1:**_____ **Date:**_____

**Witness 2:**_____ **Date:**_____

**NOTE:** Only one of the two witnesses may be a relative (by blood, marriage, registered domestic partnership, or adoption) of the person signing this request or be entitled to a portion of the person's estate upon death. Only one of the two witnesses may own, operate, or be employed at a health care facility where the person is a patient or resident.

**FINAL ATTESTATION FOR AN AID-IN-DYING DRUG TO END MY LIFE IN A HUMANE AND DIGNIFIED MANNER**

I, _____,
am an adult of sound mind and a resident of the State of California.

I am suffering from _____,
which my attending physician has determined is in its terminal phase and which has been medically confirmed.

I have been fully informed of my diagnosis and prognosis, the nature of the aid-in-dying drug to be prescribed and potential associated risks, the expected result, and the feasible alternatives or additional treatment options, including comfort care, hospice care, palliative care, and pain control.

I have received the aid-in-dying drug and am fully aware that this aid-in-dying drug will end my life in a humane and dignified manner.

**INITIAL ONE:**

_____ I have informed one or more members of my family of my decision and taken their opinions into consideration.

_____ I have decided not to inform my family of my decision.

_____ I have no family to inform of my decision.

My attending physician has counseled me about the possibility that my death may not be immediately upon the consumption of the drug.

I make this decision to ingest the aid-in-dying drug to end my life in a humane and dignified manner. I understand I still may choose not to ingest the drug and by signing this form I am under no obligation to ingest the drug. I understand I may rescind this request at any time.

**Signed:**_____

**Dated:**_____

**Time:**_____

## REQUEST FOR AN AID-IN-DYING - INTERPRETER DECLARATION

I, _____, am fluent in English and _____.
NAME OF INTERPRETER — TARGET LANGUAGE

On _____ at approximately _____,
DATE — TIME

I read the "Request for an Aid-In-Dying Drug to End My Life" to

_____ in _____.
NAME OF PATIENT/QUALIFIED INDIVIDUAL — TARGET LANGUAGE

Mr./Ms. _____
NAME OF PATIENT/QUALIFIED INDIVIDUAL

affirmed to me that he/she understood the content of this form and affirmed his/her desire to sign this form under his/her own power and volition and that the request to sign the form followed consultations with an attending and consulting physician.

I declare that I am fluent in English and _____
TARGET LANGUAGE

and further declare under penalty of perjury that the foregoing is true and correct.

Executed at _____, _____, _____
CITY — COUNTY — STATE

on this _____ of _____, _____.
DAY OF MONTH — MONTH — YEAR

_____
INTERPRETER SIGNATURE

_____
INTERPRETER PRINTED NAME

_____ _____ _____ _____
INTERPRETER STREET ADDRESS — CITY — STATE — ZIP CODE

# Resources

*Participation in the End of Life Option Act is voluntary .*

**The following resources offer additional information and may help guide you to participating physicians and pharmacies:**

- **Coalition for Compassionate Care of California** (CCCC)
http://coalitionccc.org/tools-resources/end-of-life-option-act/
or (916) 489-2222

- **California Department of Public Health**:
http://www.cdph.ca.gov/Pages/EndofLifeOptionAct.aspx

- **American Academy of Hospice and Palliative Medicine** (AAHPM): Advisory Brief: Guidance on Responding to Requests for Physician-Assisted Dying
http://aahpm.org/positions/padbrief

- **California Medical Association**:
http://www.cmanet.org/news/detail/?article=the-end-of-life-option-act-takes-effect-on
or (800) 786-4262

- **National POLST Paradigm**: Distinguishing POLST from death with dignity statutes
http://www.polst.org/distinguishing-polst-from-death-with-dignity-statutes/
or (800) 786-4262

- **UC Hastings College of the Law**: Understanding California's End of Life Option Act
http://www.ucconsortium.org/portfolio-view/end-of-life-care-act-fact-sheet/

- **Compassion and Choices: End of Life Information Center**
https://www.compassionandchoices.org/eolc/
or (800) 247-7421

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# Substance Use Disorder Information: Comments Wanted on Significant Proposed Part 2 Rule

01.23.17

*By Rebecca L. Williams, Adam H. Greene, and Sean R. Baird*

In an unusual action, a Supplemental Notice of Proposed Rulemaking ("SNPRM") accompanied the recent final rule on 42 C.F.R. Part 2 ("Part 2") governing the confidentiality of certain substance use disorder information. On January 18, 2017, the Substance Abuse and Mental Health Services Administration ("SAMHSA") issued the SNPRM seeking public comment on issues either that were not addressed in the final rule or that require further consideration. **Comments are due by 5:00 p.m. Eastern Standard Time on February 17, 2017.**

Specifically, SAMHSA has proposed provisions: addressing the prohibition on re-disclosure; expanding disclosures permitted with written consent and for audits and evaluations; and shortening notifications to recipients of Part 2 information. These proposals are discussed in greater detail below. For anyone who comes into possession of Part 2 information but is not itself a Part 2 program, such as a third party payor or a health care provider coordinating with a Part 2 program, this SNPRM includes very important potential changes. We encourage clients who potentially handle Part 2 information to comment on the SNPRM, including voicing support where appropriate.

**Expanded Disclosures Permitted with Written Consent**

SAMHSA seeks comment regarding a proposal that would clarify the circumstances under which disclosures to contractors, subcontractors, and legal representatives of lawful holders of Part 2 information may receive and use Part 2 information for purposes of carrying out the lawful holder's payment and health care operations activities. Currently, a recipient of Part 2 information, such as a health plan, cannot disclose the information to its subcontractors unless they are identified by name in a patient consent, which often is infeasible or burdensome. SAMHSA proposes to explicitly list and limit the specific types of payment and health care operations activities for which a lawful holder of Part 2 patient information would be allowed to further disclose the information without patient consent. Specifically, SAMHSA proposes that the following would be considered a permissible use or disclosure for payment or health care operations:

- Billing, claims management, collections activities, obtaining payment under a contract for reinsurance, claims filing and related health care data process
- Clinical professional support services (e.g., quality assessment and improvement; initiatives, utilization review and management services)
- Patient safety activities
- Activities pertaining to training of student trainees and health care professionals, assessment of practitioner competencies, assessment of provider or health plan performance, and training of non-health care professionals
- Accreditation, certification, licensing, or credentialing activities
- Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care
- Third-party liability coverage
- Activities related to addressing fraud, waste, and abuse

**RELATED PEOPLE**

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Dayna Nicholson

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- Conducting or arranging for medical review, legal services, and auditing functions
- Business planning and development, such as conducting cost management and planning-related analyses related to managing and operating, including formulary development and administration, development or improvement of methods of payment or coverage policies
- Business management and general administrative activities, including, but not limited to, management activities relating to implementation of and compliance with the requirements of this or other statutes or regulations
- Customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers
- Resolution of internal grievances
- The sale, transfer, merger, consolidation, or dissolution of an organization
- Determinations of eligibility or coverage (e.g. coordination of benefit services or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims
- Risk adjusting amounts due based on enrollee health status and demographic characteristics and
- Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges.

Although these activities are similar to those permitted by HIPAA, they are not identical. Contractors, subcontractors, and legal representatives that would receive data under this proposal would become lawful holders upon receipt of the data and, therefore, would be subject to Part 2. Further disclosures still would require consent.

Additionally, SAMHSA proposes to require that lawful holders of Part 2 information that engage contractors or subcontractors to carry out these payment and health care operations include specific contractual provisions requiring those entities to comply with provisions of Part 2.

SAMHSA seeks comment on whether the proposed listing of explicitly permitted activities identified as payment and health care operations activities is sufficient for the health care industry's purposes while also promoting patient confidentiality. Moreover, SAMHSA seeks comment on the proper mechanisms to convey the scope of a patient's consent to lawful holders, contractors, subcontractors, and legal representatives, including those who are downstream recipients of Part 2 information, given current electronic data exchange technical designs.

**Audit and Evaluation**

Under the recently published final rule, disclosures of patient Part 2 information to accountable care organizations and similar CMS-regulated entities are permissible to carry out Medicaid and Medicare audits and evaluations. In the SNPRM, SAMHSA proposes a provision to clarify that certain contractors, subcontractors, and legal representatives may carry out audit and evaluation activities on behalf of certain CMS–regulated entities, even if the entities themselves are not regulated by CMS.

**Statement Prohibiting Re-Disclosure**

Under current law, any disclosure of information governed by Part 2, made with the patient's written consent, must be accompanied with the following statement:

> "This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains

or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient."

SAMHSA seeks comment on whether an abbreviated, alternative statement prohibiting re-disclosure should be included when making a disclosure. For example, SAMHSA suggests the following, "Data is subject to 42 CFR part 2. Use/disclose in conformance with part 2."

**Comments Requested**

Unlike the final rule published on January 18, 2017, the SNPRM proposes significantly greater flexibility for entities that frequently interact with Part 2 information but are not themselves Part 2 programs. Part 2 programs, lawful holders of Part 2 information, and downstream entities such as contractors and subcontractors that provide services to Part 2 programs are encouraged to submit comments to SAMHSA by 5:00 p.m. Eastern Standard Time on February 17, 2017.

**Disclaimer**

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# Time Waits for No One: OCR Announces First HIPAA Settlement for Lack of Timely Breach Notification

01.12.17

*By Rebecca L. Williams, Adam H. Greene, and Sean R. Baird*

On Jan. 9, 2017, the Department of Health and Human Services Office for Civil Rights ("OCR") announced the first HIPAA enforcement action for failure to timely report a breach. Often investigating and making formal determinations concerning a potential breach can be very time consuming, even when responding promptly and appropriately to the event. The settlement highlights the importance of covered entities and business associates meeting the Breach Notification Rule timing requirements and otherwise having processes in place to respond to potential breaches in a timely manner.

The Breach Notification Rule requires notification of affected individuals and (in some cases) the media without unreasonable delay and in no case later than 60 days after discovery of the breach. OCR must also be notified but the timing depends on the size of the breach. OCR alleges that it took Presence Health 101 calendar days to notify OCR and 104 calendar days to notify affected individuals and media, when the notification should have been made no later than 60 days after discovering the breach.

Presence Health agreed to pay a settlement amount of $475,000. It is noteworthy that Presence Health is a relatively large health system, but the settlement is well below the average of recent settlements (the average 2016 resolution agreement was approximately $2 million). Presence Health also agreed to enter into a two-year corrective action plan, which requires new policies and procedures and training, but does not include internal or external monitoring like some prior settlements. The settlement comes approximately three years after the breach report, which is in line with the timing of past resolution agreements.

Prior to OCR's settlement with Presence Health, the closest enforcement action based on the Breach Notification Rule was with Adult & Pediatric Dermatology, P.C., in which OCR highlighted the covered entity's failure to have written policies and procedures and train members of its workforce regarding the Breach Notification Rule requirements.

OCR's settlements highlight the need for covered entities and business associates to have written breach notification policies and procedures, to train workforce on recognizing and immediately reporting potential breaches to the designated internal person, such as the privacy or security officer, and to educate workforce members on the importance of adhering to the required timeframes.

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# To Settle or Not to Settle – That Is the Question Raised by Recent HIPAA CMPs

02.13.17

*By Adam H. Greene, Rebecca L. Williams, and Sean R. Baird*

On February 1, 2017, the Department of Health and Human Services, Office for Civil Rights ("OCR") announced that the Children's Medical Center of Dallas ("Children's") has paid a civil monetary penalty ("CMP") of $3.2 million to resolve multiple HIPAA violations over several years. This CMP announcement raises a number of questions, such as whether it was financially advantageous to choose to accept a CMP rather than a proposed financial settlement and corrective action plan, and whether imposing millions of dollars in penalties on a non-profit children's hospital strikes the right balance of promoting compliance versus taking funds away from patient care (although OCR applied the minimum CMP amounts available for the violations).

**Take-Away Considerations**

- Covered entities and business associates must conduct a comprehensive risk analysis and must take steps to address gaps identified as part of the risk analysis.
- Policies and procedures should address all required elements of the Privacy and Security Rules.
- "Addressable" does not equal optional. The encryption implementation specification is addressable as opposed to required. Therefore, encryption must be implemented if, after a risk assessment, the entity has determined that the specification is a "reasonable and appropriate" safeguard in its risk management of the confidentiality, integrity, and availability of e-PHI. If the covered entity or business associate concludes that the addressable encryption implementation specification is not reasonable and appropriate, then it must document that determination and implement an equivalent alternative measure.
- Although most entities facing CMPs choose to settle, the costs of a corrective action plan may make accepting a CMP a more attractive alternative, especially if OCR is seeking the minimum level of penalties.

**Summary of OCR's Action**

In January 2010, Children's notified OCR about a breach affecting approximately 3,800 patients due to a misplaced unencrypted BlackBerry device at the Dallas/Fort Worth International Airport. Soon after, OCR initiated an investigation during which Children's provided the results of two external security gap analyses conducted between December 2006 and August 2008. The analyses encouraged Children's to implement encryption on portable electronic devises to reduce exposure of ePHI, noting that data encryption was a "high priority" for Children's. Later in 2010, Children's reported the loss of a resident's unencrypted iPod, which permitted unauthorized access to the ePHI of at least 22 individuals.

Despite these breaches and recommendations to implement encryption, OCR alleged that Children's carried on without implementing encryption and suffered another breach in April of 2013, when an unencrypted laptop was stolen from an operating room. Children's notified OCR of the breach in July of 2013, estimating that breach resulted in the impermissible disclosure of ePHI for 2,462 individuals.

In the Notice of Final Determination, OCR stated that, given the external security gap analyses from 2006 and 2008, Children's had knowledge of the risks to its unencrypted ePHI yet continued to issue mobile devices without encryption. OCR also concluded that Children's failed to implement sufficient policies and procedures governing the receipt and removal of hardware and electronic media that contain ePHI out of its facility, and the movement of those items within the facility. OCR considered two factors in determining the amount of the CMP, namely: 1) the amount of time that Children's continued to use unencrypted devices even after it had actual

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knowledge of the need for encryption; and 2) Children's prior history of non-compliance with the Privacy and Security Rules. OCR chose to apply the minimum CMP amounts ($1,000 per violation), rather than the maximum amount ($50,000 per violation), based on the level of culpability that it assigned (finding that the violations were based on reasonable cause rather than willful neglect). If OCR had sought the maximum penalties, then the CMP would have been more than $13 million after application of the calendar year caps.

This is only the third time that OCR has issued a CMP, which represents formal findings of violations rather than a voluntary settlement. In the first instance, OCR imposed a CMP against Cignet Health for failing to cooperate with an ongoing investigation (and failing to provide patients with access to their records). There is no indication that Children's failed to cooperate here. In the second CMP, Lincare, Inc. chose not to settle and instead appealed OCR's imposition of a CMP, which was subsequently upheld by an Administrative Law Judge ("ALJ"), the first time a covered entity appealed a CMP to an ALJ. In contrast, in this case, Children's did not choose to appeal the proposed CMP after receiving OCR's Notice of Proposed Determination. Because Children's did not request a hearing, the Notice of Proposed Determination is now final, resulting in the imposition of the determined CMP.

It is difficult to say why Children's elected to forgo a hearing. It may be that Children's was concerned about implementing a corrective action plan, which likely would have accompanied the settlement and could have added significant time and costs. Insurance coverage also could be a factor, as a fine may be covered whereas the continuing costs of implementing a corrective action plan may not be.

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# 2017 HEALTH INFORMATION PRIVACY AND SECURITY NEW YEAR'S RESOLUTIONS

To start off the New Year, here are some potential health information privacy and security resolutions. You can use these Annual, Quarterly, and Monthly lists to map out your privacy and security tasks for the year, and then check them off as you complete them. We have included empty rows for you to add your own resolutions.

As with any New Year's resolutions, these are intended to represent potential best practices for the coming year – failing to meet one or more of these resolutions does not necessarily mean that you are out of compliance with HIPAA or other laws.

Additionally, this list is not intended to be comprehensive of all statutory and regulatory requirements. Checking off all these resolutions does not guarantee compliance. While this list is focused on health information privacy and security, we hope that other sectors will also find it useful.

If you have any questions, you may contact Adam Greene at (202) 973-4213 or AdamGreene@dwt.com.

| ANNUAL TASKS | | | |
|---|---|---|---|
| ✓ | Task | Estimated Completion | Actual Completion |
| ☐ | **Insurance Checkup** – Check cybersecurity coverage (including coverage of ransomware) | 1st Quarter | |
| ☐ | **Risk Analysis** – Conduct a Security Rule risk analysis of all confidential/critical information (HIPAA, 45 C.F.R. § 164.308(a)(1)(ii)(A)) | 1st Quarter | |
| ☐ | **Risk Management Plan** – Create or update a risk management plan to reduce identified risks (HIPAA, 45 C.F.R. § 164.308(a)(1)(ii)(B)) | 1st Quarter | |
| ☐ | **Breach Response Table Top** – Conduct breach response table top exercise and update breach response plan accordingly | 1st Quarter | |
| ☐ | **Test Disaster Recovery Plan** – Test backups and disaster recovery plan (HIPAA, 45 C.F.R. § 164.308(a)(7)(ii)(D)) | 1st Quarter | |
| ☐ | **Website Privacy Policy Checkup** – Check website privacy policy(ies) to verify coverage of all collection and use of information collected through website(s) (It doesn't hurt to take another look at the terms of use as well) | 1st Quarter | |
| ☐ | **Internal Privacy and Security Policies Checkup** – Revisit internal privacy and security policies to verify applicability to operations, such as determining whether social media, remote access, and portable media are addressed adequately. Also revisit "problem areas" | 1st Quarter | |
| ☐ | **Evaluation of Security Rule Compliance** – Conduct a review of compliance with the HIPAA Security Rule (if applicable), such as by checking that policies and procedures address all Security Rule requirements (HIPAA, 45 C.F.R. § 164.308(a)(8)) | 1st Quarter | |
| ☐ | **Technical Evaluation** – Perform a penetration test of information security controls (HIPAA, 45 C.F.R. § 164.308(a)(8)) | 1st Quarter | |
| ☐ | **TCPA Checkup** – Check if performing any automated calling and texting and, if so, verify compliance with Telephone Consumer Protection Act | 1st Quarter | |
| ☐ | **Vendor Checkup** – Verify (such as by reviewing accounts payable) that appropriate privacy and security safeguards (including HIPAA business associate agreements, if applicable) are in place with all vendors and that business associate-related risks are included in the Security Risk Analysis | 1st Quarter | |
| ☐ | **Group Plan Checkup** – Check that group health plan documents and privacy, security, and breach notification policies comply with HIPAA, including listing all employees or classes of employees or other persons with access to plan protected health information (HIPAA, 45 C.F.R. § 164.504(f)(iii)(A)) | 1st Quarter | |

| ANNUAL TASKS | | | |
|---|---|---|---|
| ✓ | Task | Estimated Completion | Actual Completion |
| ☐ | **Privacy Officer** – Check that designations for the privacy officer and any privacy contacts are up to date and are reflected in any notice of privacy practices (45 C.F.R. § 164.530(a)) (optional for HIPAA business associates) | 1st Quarter | |
| ☐ | **Security Officer** – Check that designation is up to date (45 C.F.R. § 164.308(a)(2)) | 1st Quarter | |
| ☐ | **HIPAA Hybrid Entity Designation** – Consider whether to designate as a hybrid entity (if you have components unrelated to health care/health plan coverage) or update existing designation (HIPAA, 45 C.F.R. § 164.105(a)) | 1st Quarter | |
| ☐ | **Affiliated Covered Entity Designation** – Consider whether to designate as an affiliated covered entity (if you have multiple legal entities that qualify as HIPAA covered entities) or update existing designation (based on any new acquisitions) (HIPAA, 45 C.F.R. § 164.105(b)) | 1st Quarter | |
| ☐ | **Internal Business Associate Agreements** – If you have legal entities (such as a parent company) that is not a covered entity but supports entities that are, verify that an internal business associate agreement is in place and up to date | 1st Quarter | |
| ☐ | **Small Breach Reports** – Submit all 2016 small breach reports to HHS (HIPAA, 45 C.F.R. § 164.408(c)) | March 1, 2017 | |
| ☐ | **Privacy Training** – Train relevant workforce members on privacy policies and procedures (HIPAA, 45 C.F.R. § 164.530(b)) | 1st Quarter | |
| ☐ | **Security Training** – Train relevant workforce members on security policies and procedures (HIPAA, 45 C.F.R. § 164.308(a)(5)(1)) | 1st Quarter | |
| ☐ | **Breach Notification Training** – Train relevant workforce members on breach notification policies and procedures (HIPAA, 45 C.F.R. § 164.414(a)) | 1st Quarter | |
| ☐ | | 1st Quarter | |
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| QUARTERLY TASKS | | | |
|---|---|---|---|
| ✓ | Task | Estimated Completion | Actual Completion |
| ☐ | **Risk Management Plan Update** – Update most recent risk management plan | 1st Quarter | |
| ☐ | **Encryption** – Document that all devices containing protected health information are encrypted (or that there is documentation for why encryption is not reasonable and appropriate). (HIPAA, 45 C.F.R. § 164.312(a)(1)(ii)(iv)) | 1st Quarter | |
| ☐ | **Vulnerability Scanning** – Conduct a network vulnerability scan (HIPAA, 45 C.F.R. § 164.308(a)(8)) | 1st Quarter | |
| ☐ | | 1st Quarter | |
| ☐ | | 1st Quarter | |
| ☐ | | 1st Quarter | |
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| QUARTERLY TASKS | | | |
|---|---|---|---|
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| ☐ | | 1st Quarter | |

| MONTHLY TASKS | | | |
|---|---|---|---|
| ✓ | Task | Estimated Completion | Actual Completion |
| ☐ | **System Activity Review** – Document review of information system activity (e.g., audit logs) (HIPAA, 45 C.F.R. § 164.308(a)(1)(ii)(D)) | January | |
| ☐ | **Security Reminder** – Send out a security reminder, such as related to password management, phishing, logging off, etc. (HIPAA, 45 C.F.R. § 164.308(a)(5)(ii)(A)) | January | |
| ☐ | | January | |
| ☐ | | January | |
| ☐ | **System Activity Review** – Document review of information system activity (e.g., audit logs) (HIPAA, 45 C.F.R. § 164.308(a)(1)(ii)(D)) | February | |
| ☐ | **Security Reminder** – Send out a security reminder, such as related to password management, phishing, logging off, etc. (HIPAA, 45 C.F.R. § 164.308(a)(5)(ii)(A)) | February | |
| ☐ | | February | |
| ☐ | | February | |
| ☐ | **System Activity Review** – Document review of information system activity (e.g., audit logs) (HIPAA, 45 C.F.R. § 164.308(a)(1)(ii)(D)) | March | |
| ☐ | **Security Reminder** – Send out a security reminder, such as related to password management, phishing, logging off, etc. (HIPAA, 45 C.F.R. § 164.308(a)(5)(ii)(A)) | March | |
| ☐ | | March | |
| ☐ | | March | |

| MONTHLY TASKS | | | |
|---|---|---|---|
| ✓ | Task | Estimated Completion | Actual Completion |
| ☐ | **System Activity Review** – Document review of information system activity (e.g., audit logs) (HIPAA, 45 C.F.R. § 164.308(a)(1)(ii)(D)) | April | |
| ☐ | **Security Reminder** – Send out a security reminder, such as related to password management, phishing, logging off, etc. (HIPAA, 45 C.F.R. § 164.308(a)(5)(ii)(A)) | April | |
| ☐ | | April | |
| ☐ | | April | |
| ☐ | **System Activity Review** – Document review of information system activity (e.g., audit logs) (HIPAA, 45 C.F.R. § 164.308(a)(1)(ii)(D)) | May | |
| ☐ | **Security Reminder** – Send out a security reminder, such as related to password management, phishing, logging off, etc. (HIPAA, 45 C.F.R. § 164.308(a)(5)(ii)(A)) | May | |
| ☐ | | May | |
| ☐ | | May | |
| ☐ | **System Activity Review** – Document review of information system activity (e.g., audit logs) (HIPAA, 45 C.F.R. § 164.308(a)(1)(ii)(D)) | June | |
| ☐ | **Security Reminder** – Send out a security reminder, such as related to password management, phishing, logging off, etc. (HIPAA, 45 C.F.R. § 164.308(a)(5)(ii)(A)) | June | |
| ☐ | | June | |
| ☐ | | June | |

| MONTHLY TASKS | | | |
|---|---|---|---|
| ✓ | Task | Estimated Completion | Actual Completion |
| ☐ | **System Activity Review** – Document review of information system activity (e.g., audit logs) (HIPAA, 45 C.F.R. § 164.308(a)(1)(ii)(D)) | July | |
| ☐ | **Security Reminder** – Send out a security reminder, such as related to password management, phishing, logging off, etc. (HIPAA, 45 C.F.R. § 164.308(a)(5)(ii)(A)) | July | |
| ☐ | | July | |
| ☐ | | July | |
| ☐ | **System Activity Review** – Document review of information system activity (e.g., audit logs) (HIPAA, 45 C.F.R. § 164.308(a)(1)(ii)(D)) | August | |
| ☐ | **Security Reminder** – Send out a security reminder, such as related to password management, phishing, logging off, etc. (HIPAA, 45 C.F.R. § 164.308(a)(5)(ii)(A)) | August | |
| ☐ | | August | |
| ☐ | | August | |
| ☐ | **System Activity Review** – Document review of information system activity (e.g., audit logs) (HIPAA, 45 C.F.R. § 164.308(a)(1)(ii)(D)) | September | |
| ☐ | **Security Reminder** – Send out a security reminder, such as related to password management, phishing, logging off, etc. (HIPAA, 45 C.F.R. § 164.308(a)(5)(ii)(A)) | September | |
| ☐ | | September | |
| ☐ | | September | |

| MONTHLY TASKS | | | |
|---|---|---|---|
| ✓ | Task | Estimated Completion | Actual Completion |
| ☐ | **System Activity Review** – Document review of information system activity (e.g., audit logs) (HIPAA, 45 C.F.R. § 164.308(a)(1)(ii)(D)) | October | |
| ☐ | **Security Reminder** – Send out a security reminder, such as related to password management, phishing, logging off, etc. (HIPAA, 45 C.F.R. § 164.308(a)(5)(ii)(A)) | October | |
| ☐ | | October | |
| ☐ | | October | |
| ☐ | **System Activity Review** – Document review of information system activity (e.g., audit logs) (HIPAA, 45 C.F.R. § 164.308(a)(1)(ii)(D)) | November | |
| ☐ | **Security Reminder** – Send out a security reminder, such as related to password management, phishing, logging off, etc. (HIPAA, 45 C.F.R. § 164.308(a)(5)(ii)(A)) | November | |
| ☐ | | November | |
| ☐ | | November | |
| ☐ | **System Activity Review** – Document review of information system activity (e.g., audit logs) (HIPAA, 45 C.F.R. § 164.308(a)(1)(ii)(D)) | December | |
| ☐ | **Security Reminder** – Send out a security reminder, such as related to password management, phishing, logging off, etc. (HIPAA, 45 C.F.R. § 164.308(a)(5)(ii)(A)) | December | |
| ☐ | | December | |
| ☐ | | December | |

# Speaker Biographies

# Sean R. Baird // ASSOCIATE // SEATTLE


## Seattle

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Sean Baird focuses exclusively on the health care industry and counsels clients in various sectors on health care regulatory compliance matters, including those pertaining to HIPAA (privacy, security, and breach notification), Stark, the federal False Claims Act, and the Anti-Kickback Statute. Sean also advises clients in a variety of transactional issues, including mergers and acquisitions, licensing, and joint ventures. He has a strong background in the industry, having previously worked as a public health professional at Harvard University, Johns Hopkins University, the United States Agency of International Development, and various non-governmental organizations. He has extensive experience managing, designing, and evaluating large domestic and international public health programs.

## Additional Qualifications

- Associate, Holland & Knight, Boston, 2013-2015
- Summer Associate, Holland & Knight, Boston, 2012
- Judicial Intern, Judge O. Rogeriee Thompson, U.S. Court of Appeals for the First Circuit, Boston, 2012
- Judicial Intern, Magistrate Judge James P. Donohue, U.S. District Court for Western Washington, Seattle, 2011
- Program Manager, Harvard University Institute for Global Health, Boston, 2008-2010
- Intern, U.S. Agency for International Development, President's Malaria Initiative, Washington, D.C., 2008
- Intern, Johns Hopkins University Center for Communication Programs, Global Program on Malaria, Baltimore, 2007-2008

## Professional Recognition

- Communications Committee, Health Law Section, Boston Bar Association, 2013-2015
- Pro Bono Attorney, Health Law Advocates, 2013-2015
- Pro Bono Attorney, EdLaw Project, 2013-2015

## Education

J.D., Boston College Law School, 2013, cum laude

M.H.S., Public Health, Johns Hopkins University, Bloomberg School of Public Health, 2009

B.A., Psychology, Western Washington University, 2005

## Related Practices

Health Care
Health Care Mergers & Acquisitions
Health Care Operations
Health Care Regulation & Compliance
Privacy & Security
Telecommunications
Telemedicine

## Admitted to Practice

Massachusetts, 2013
Washington, 2015

## Languages

Spanish

# Anna R. Buono // ASSOCIATE // LOS ANGELES


## Los Angeles

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Anna Buono is a commercial trial lawyer who practices extensively in the health care and financial services industries, as well as handling intellectual property litigation and privacy and security issues across various industries. She represents clients on a wide range of claims, including breach of contract and business torts, antitrust and unfair competition, trademark, copyright, and patent infringement, data breach and security enforcement, as well as employment and franchising disputes.

## Additional Qualifications

- Associate, Arnold & Porter LLP, Los Angeles, 2008-2010
- Associate, Heller Ehrman LLP, Los Angeles, 2004-2008
- Research Assistant, Professor Laurie L. Levenson, Loyola Law School, Los Angeles, 2002

## Education

J.D., Loyola Law School, Los Angeles, 2004, cum laude

B.S., Hospitality Administration, Boston University, 1997, summa cum laude

## Related Practices

Appellate Litigation

Employment Litigation

Food, Beverage, Restaurants & Hotels

Franchising

Intellectual Property Litigation

Theft of Ideas

Health Care Litigation

Litigation

Media & First Amendment

Privacy & Security

Antitrust

White Collar, Investigations, and Government Controversies

## Admitted to Practice

California, 2004

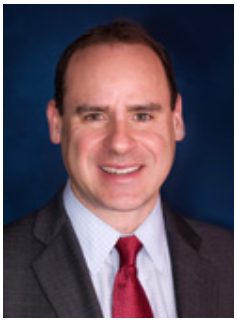
U.S. Court of Appeals 9th Circuit, 2011

U.S. District Court Central District of California, 2004

U.S. District Court Eastern District of California, 2005

U.S. District Court Southern District of California, 2011

# Jeffrey B. Coopersmith // PARTNER // SEATTLE & LOS ANGELES




## Seattle

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Jeffrey B. Coopersmith is a veteran trial lawyer with an extensive practice focusing on civil and criminal matters, internal investigations for private and public entities, and complex commercial litigation. A former federal prosecutor, Jeff has substantial experience as lead counsel representing companies and individuals, both in the U.S. and abroad, in connection with investigations and criminal and civil enforcement proceedings in the areas of health care, securities, FCPA, antitrust, tax, banking, legal ethics, and others. Jeff's internal investigation work has involved representation of Board committees, companies, municipalities, and corporate officers, and he has deep experience with the difficult issues that come up in these matters. Jeff also teaches and writes extensively on these and other topics relating to government controversies and investigations. Jeff currently serves as a member of the firm's Quality Assurance Committee.

## Additional Qualifications

- Faculty, Kessler-Eidson Program for Trial Techniques, Emory University Law School, 2010-present
- Partner, DLA Piper, Seattle, 2005-2012
- Assistant United States Attorney, U.S. Attorney's Office, Western District of Washington, Seattle, 1997-2005
- Covington & Burling, Washington, D.C., 1991-1997
- Law Clerk, The Honorable R. Lanier Anderson III, United States Court of Appeals for the Eleventh Circuit, 1990-1991

## Professional and Community Activities

- Past Member, Board of Ethics, Port of Seattle Commission, 2013-2014
- Washington State Bar Association
- National Association of Criminal Defense Lawyers
- Washington Association of Criminal Defense Lawyers

## Education

J.D., Emory University, 1990, first in class

- Order of the Coif

A.B., Economics, Duke University, 1986

## Related Practices

White Collar, Investigations, and Government Controversies
Arbitration
Appellate Litigation
Government Relations & Litigation
Government Investigations and Crisis Management
Antitrust
Litigation
Health Care Litigation
Health Care Regulation & Compliance
Tax: Federal, State & Local
Securities Litigation

## Admitted to Practice

California, 2007
District of Columbia, 1991
Washington, 2001
U.S. Supreme Court, 1995
U.S. District Court Eastern District of Washington, 1995
U.S. District Court Western District of Washington, 1997
U.S. District Court District of

# Jeffrey B. Coopersmith // PARTNER // SEATTLE & LOS ANGELES

## Professional Recognition

- Named as one of the "Best Lawyers in America" by Best Lawyers, 2011-present
- Selected to "Washington Super Lawyers" by Thomson Reuters, 2010-2016; Selected to "Top 100 Washington Super Lawyers," 2012-2013, 2016
- Thomas C. Wales Performance Award

Columbia, 1991

U.S. Court of Appeals D.C. Circuit, 1991

U.S. District Court Northern District of California, 2007

U.S. Court of Appeals 4th Circuit, 1994

U.S. Court of Appeals 9th Circuit, 1997

U.S. Court of Appeals 10th Circuit, 1995

U.S. Court of Appeals 11th Circuit, 1990

# Dennis S. Diaz // PARTNER // LOS ANGELES


## Los Angeles

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Dennis Diaz is a health care regulatory and transactional lawyer. For more than 25 years, he has represented a wide range of health care providers, including multi-hospital systems, community hospitals, physician-hospital organizations, accountable care organizations, ambulatory surgery centers, and medical groups, in California and nationally. Dennis focuses his practice on regulatory and compliance matters, fraud and abuse, provider transactions including hospital-physician alignment and joint ventures, provider operations, and billing and payment issues. He regularly advises and defends providers against government enforcement actions and leads large-scale internal investigations for providers. He also has served as lead counsel in structuring hospital-physician integrated delivery organizations, including accountable care organizations, medical foundations, and ambulatory surgery centers. Dennis also acts as outside general counsel to hospitals and medical groups.

**Practice Highlights**

- Defending actions brought by the Department of Health and Human Services (DHHS), the Office of Inspector General (OIG), the Centers for Medicare and Medicaid Services (CMS), the California Department of Health Care Services (DHCS), the California Department of Public Health (CDPH), and local governmental authorities
- Internal health care regulatory and compliance matters, including audits and investigations, corrective actions, refunds, and disclosures to the government
- Structuring and negotiating hospital-physician contracts and joint ventures, including strategies for integrated care organizations and hospital-physician alignment
- Federal and state physician self-referral (Stark and PORA), anti-kickback, and fraud and abuse issues in connection with physician contracts and provider operations
- Billing and reimbursement disputes with governmental and commercial payors, including the Medicare and Medicaid programs

## Education

J.D., University of California, Los Angeles, School of Law

B.A., University of California, Santa Barbara, with honors

## Related Practices

Health Care Litigation
Administrative Law Disputes
White Collar, Investigations, and Government Controversies
Health Care Regulation & Compliance
Health Care Mergers & Acquisitions
Health Care Operations
Health Care Finance
Health Care Reimbursement & Payment
Litigation
Hospitals
Physician Groups
Health Care
Health Care Reform

## Admitted to Practice

California, 1980

# Dennis S. Diaz // PARTNER // LOS ANGELES

- Conducting due diligence of health care regulatory and compliance affairs on behalf of buyers, investors, lenders and sellers in acquisitions and financing transactions
- General counsel to community hospitals and medical groups

## Additional Qualifications

- Adjunct Professor of Law, Health Law, University of Southern California Gould School of Law
- Adjunct Professor of Law, Health Law, Loyola University School of Law
- Lecturer, Health Care Law for Managers and Entrepreneurs, University of California, Irvine - Executive MBA Program
- Partner, Sonnenschein Nath & Rosenthal LLP
- Staff Counsel, Office of General Counsel, U.S. Department of Health and Human Services, Washington, D.C.

## Professional and Community Activities

- American Health Lawyers Association

## Professional Recognition

- Named one of "America's Leading Lawyers for Business" in Health Care (California) by Chambers USA, 2010-2016
- Named one of the country's 12 "Outstanding Hospital Lawyers" by Nightingale's Healthcare News, 2007
- Selected by Best Lawyers as Los Angeles' "Lawyer of the Year" in Administrative/Regulatory Law, 2017
- Named one of the "Best Lawyers in America" in Health Care Law by Best Lawyers, 2010-present
- Selected to, "Top Rated Lawyers Guide to Health Care Law," Corporate Counsel
- Highest rating (AV) by peers – Martindale-Hubbell Legal Rating Service


# Kathleen H. Drummy // PARTNER // LOS ANGELES


## Los Angeles

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Kathy Drummy has extensive experience working with health care entities industrywide, from hospitals and skilled nursing facilities, to hospices, home health agencies, FQHCs, PACE providers, and behavioral/mental health care providers, including acute inpatient mental health programs, including specialized psychiatric and geropsychiatric services in freestanding psychiatric programs or those under contract with community acute general hospitals, and residential programs ranging from crisis residential to transitional residential to medically-oriented secure residential (which programs are often focused on older adults). Kathy offers long-standing experience in the regulatory, transactional and litigation aspects of health care law, including issues related to the following: Medicare and Medicaid payment and participation and representation in related administrative/judicial appeals and enforcement actions; federal, state, and local regulatory compliance issues; negotiation and advice as to contracts with governmental agencies. She has handled matters involving various federal, state and local governmental agencies, including: the federal Department of Health and Human Services, CMS (Centers for Medicare and Medicaid Services), the Department of Justice, the Federal Bureau of Investigation, and the Office of Inspector General; the California Departments of Health Care Services, Mental Health (now part of the Department of Health Care Services), Public Health (facility licensing), Social Services, and Education as well as the Board of Pharmacy and the Medical Board; various private accreditation agencies, such as Joint Commission and the Commission on Accreditation of Rehabilitation Facilities; and numerous California counties, including their Departments of Health and Departments of Mental Health.

Ms. Drummy is also the Vice Chair of Research and Website for the AHLA Accreditation, Certification, and Enrollment Affinity Groups of the AHLA Regulation, Accreditation and Payment Practice group, and is a frequent speaker on Medicare and Medicaid payment, participation, and compliance issues, federal, state and local mental/behavioral health legal issues, licensing and certification issues, and special issues relating to Emergency Departments, including EMTALA.

## Education

J.D., University of California, Los Angeles, School of Law, 1977

- Moot Court Honors Program
- Executive Editor, UCLA-Alaska Law Review
- Judicial Internship, U.S. District Court, Judge Harry Pregerson, Central District, California, 1976

M.A., Psychology, University of California, Los Angeles, 1974

B.A., Psychology, University of California, Berkeley, 1973

## Related Practices

Health Care Regulation & Compliance

Health Care Litigation

Health Care Operations

Health Care Reimbursement & Payment

Health Care Mergers & Acquisitions

Health Care

Hospitals

Health Care Reform

## Admitted to Practice

California, 1977

U.S. Court of Appeals 9th Circuit

U.S. Court of Appeals 4th Circuit

U.S. District Court Central District of California

# Kathleen H. Drummy // PARTNER // LOS ANGELES

## Additional Qualifications

- Partner, Musick, Peeler & Garrett LLP
- Partner, McDermott, Will & Emery
- Partner, Memel, Jacobs, Pierno, Gersh & Ellsworth

## Professional and Community Activities

- American Health Lawyers Association

## Professional Recognition

- Named one of "America's Leading Lawyers for Business" in Healthcare (California) by Chambers USA, 2007-2016
- Named one of the "Best Lawyers in America" in Health Care Law by Best Lawyers, 2008-present
- Selected to "Southern California Super Lawyers," Thomson Reuters, 2005-2006, 2008-2016

# Jane Eckels // PARTNER // SEATTLE


## Seattle

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Jane Eckels is a partner in Davis Wright Tremaine's health information and technology transactions groups. Jane represents hospitals, practice groups, trade associations, nonprofit organizations, healthcare technology vendors and others in a full range of health information and technology matters. She supports clients in procurement and implementation of traditional and cloud-based systems, innovation and development of new technologies, information exchange and sharing arrangements for technology and data, licensing and distribution of health technology products and services, as well as mobile and digital health initiatives. With almost two decades of experience, Jane has extensive experience structuring and negotiating complex licenses, commercial agreements and other projects involving software, hardware, data, Internet technologies and services.

## Professional and Community Activities

- Health Information and Technology Group, American Health Lawyers Association
- Legal Aspects of the Enterprise Task Force, Health Information Management Systems Society
- Adjunct Faculty, Seattle University Arts Legal Clinic, 1999-2006
- Volunteer Attorney, Washington Lawyers for the Arts, 1999-2006
- Board Member, Earshot Jazz Society, 2001-2006
- Volunteer Attorney, Northwest Immigrants' Rights Project, 1997-2003

## Professional Recognition

- Named one of the "Best Lawyers in America" in Technology Law by Best Lawyers, 2017-present; also named in Intellectual Property - Litigation, 2017
- Selected to "Washington Rising Stars," Thomson Reuters, 2002-2008

## Education

J.D., University of Michigan Law School, 1997, cum laude

- Note Editor, Michigan Law Review

A.B., French, Dartmouth College, 1994, cum laude

## Related Practices

Corporate and Business Transactions
Intellectual Property
Health Information
Health Information Technology
Startups & Emerging Companies
Tax-Exempt Organizations
Technology Services for Financial Institutions
Technology
Internet & E-Commerce
Communications, Media, IP & Technology
Digital Media
Telecommunications
Health Care
Physician Groups
Cloud Services
Telemedicine
Digital Health

## Admitted to Practice

Washington, 1997
Alaska, 2007

# Adam H. Greene // PARTNER // WASHINGTON, D.C.


## Washington, D.C.

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Adam Greene, a nationally-recognized authority on HIPAA and the HITECH Act, primarily counsels health care systems and technology companies on compliance with the HIPAA privacy, security, and breach notification requirements. Adam is a former regulator at the U.S. Department of Health and Human Services (HHS), where he played a key role in administering and enforcing the HIPAA rules. At HHS, Adam was responsible for determining how HIPAA rules apply to new and emerging health information technologies and he was instrumental in the development of the current enforcement process.

Adam's work at HHS during the evolution of HIPAA and related regulations has given him a keen understanding of agency interactions with the health care community. Adam has written numerous articles on the HIPAA rules and is a frequent speaker on the subject. Adam also serves as the chair of the HIMSS Cloud Security Workgroup.

Adam is a regular contributor to Davis Wright Tremaine's Privacy and Security Law Blog, PrivSecBlog.com. He is also a member of DWT's Breach Response Team (dwt.com/IncidentResponse).

Adam has been recognized as one of the "Top 10 Influencers in Health Information Security" for 2015 by HealthcareInfoSecurity.com and one of the "50 Top Healthcare IT Experts" in 2015 by Health Data Management.

## Additional Qualifications

- Senior Health Information Technology and Privacy Specialist, Office for Civil Rights, U.S. Department of Health and Human Services, Washington, D.C., 2010-2011
- Attorney, Office of the General Counsel, U.S. Department of Health and Human Services, Washington, D.C., 2006-2010
- Health Care Attorney, Powers Pyles Sutter & Verville PC, Washington, D.C., 1999-2006

## Education

J.D., George Washington University, 2000

- The George Washington International Law Review

M.P.H., George Washington University, 2000

- Concentration in Epidemiology

B.A., Biology, The Johns Hopkins University, 1997

## Related Practices

Health Information Privacy, Security & Breach Response
Health Information Technology
Health Information
Health Care
Health Care Regulation & Compliance
Privacy & Security
Incident Response & Breach Coaching
Privacy & Security: Counseling & Compliance
Hospitals
Physician Groups
Cloud Services
Telemedicine

## Admitted to Practice

District of Columbia, 2001

# Adam H. Greene // PARTNER // WASHINGTON, D.C.

## Professional and Community Activities

- Co-founder and General Counsel, Health Care Coalition (HC3)
- Chair, Cloud Security Workgroup, Healthcare Information and Management Systems Society (HIMSS)
- American Health Information Management Association (AHIMA)
- American Health Lawyers Association
- International Association of Privacy Professionals (IAPP)
- Editorial Advisory Board, Report on Patient Privacy
- Editorial Advisory Board, Healthcare Info Security

# Robert G. Homchick // PARTNER // SEATTLE


## Seattle

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**roberthomchick@dwt.com**


Bob Homchick is a partner in Davis Wright Tremaine's national health care practice. As a health care transactional and regulatory lawyer, Bob counsels clients in areas such as physician self-referral (i.e., the federal Stark Law and its state law counterparts), regulatory compliance and fraud and abuse. Bob assists hospitals, physician organizations, ancillary services providers, and others in acquisitions, the formation and operation of joint ventures and in the development and implementation of new care delivery models, including accountable care organizations and other clinically integrated networks. His extensive experience includes defending providers in government audits, investigations, administrative proceedings and assisting providers with voluntary disclosures to federal and state enforcement agencies.

Bob regularly speaks and writes on a variety of health law regulatory topics.

**Practice Highlights**

- Works with hospitals, physician groups, and academic medical centers to resolve Stark Law and anti-kickback issues arising out of physician relationships, organizational structures, and joint ventures
- Advises clients in the formation or acquisition of new entities, the restructuring of existing entities, and creation of alliances or other integration initiatives
- Directs internal investigations of compliance issues and advises clients regarding corrective action and the voluntary disclosure processes
- Represents both physician groups and hospitals in practice and service line acquisitions, co-management agreements, and other integration strategies
- Works with providers, managers, and private equity funds in connection with the formation of specialized joint ventures (i.e., stereotactic radiosurgery, intraoperative monitoring, nuclear medicine, wound care and various types of imaging)
- Assists providers, investors and creditors in assessing the regulatory risks of mergers, acquisitions, affiliations or investments

## Education

J.D., University of Notre Dame Law School, 1982, summa cum laude

B.A., University of Puget Sound, 1979, summa cum laude

## Related Practices

Health Care

Health Care Regulation & Compliance

Health Care Mergers & Acquisitions

Health Care Operations

Health Care Reimbursement & Payment

Health Care Litigation

White Collar, Investigations, and Government Controversies

Litigation

Hospitals

Physician Groups

Health Care Reform

## Admitted to Practice

District of Columbia, 2013

Washington, 1983

# Robert G. Homchick // PARTNER // SEATTLE

- Serves as an expert witness on health care regulatory and compliance issues

## Professional and Community Activities

- Past Chair, Practice Group on Fraud and Abuse, Self-Referrals and False Claims, American Health Lawyers Association
- Past Chair, Health Law Section, Washington State Bar Association
- Past President, Western District of Washington, Federal Bar Association

## Professional Recognition

- Named Fellow of the American Health Lawyers Association, 2016
- Named the "Seattle Best Lawyers Health Care Lawyer of the Year" for 2012 by Woodward/White
- Named one of the "Best Lawyers in America" in Health Care Law by Best Lawyers, 2001-present
- Selected to "Washington Super Lawyers," Thomson Reuters, 2004-2016
- Named as one of "155 Top Lawyers" by Seattle Magazine and Seattle Business Monthly, 2007
- Recipient of the "Patricia Meador Leadership Award," Practice Group on Fraud and Abuse, Self-Referrals and False Claims, American Health Lawyers Association, 2009

# Renee Howard // PARTNER // SEATTLE


## Seattle

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Renee Howard is a seasoned health care attorney with nearly two decades of experience in regulatory and litigation matters. She counsels a wide range of health care providers and suppliers, including hospitals, health systems, physicians, imaging centers, laboratories, medical device manufacturers and distributors, and behavioral health agencies. Renee represents clients in federal False Claims Act, Anti-Kickback, and Stark law matters, FDA issues, Medicare and Medicaid reimbursement litigation, and professional licensing investigations and complaints. She also advises on internal investigations pertaining to fraud and abuse and routinely counsels clients on regulatory compliance matters.

## Additional Qualifications

- Partner, Perkins Coie, Seattle, 2012-2016
- Associate and Shareholder, Bennett Bigelow & Leedom, P.S., Seattle, 2006-2012
- Associate, Jones Day, Washington, D.C., 2000-2005
- Associate, Honigman, Miller, Schwartz & Cohn, Detroit, 1999-2000

## Professional and Community Activities

- Health Law Section, American Bar Association
- Editorial Board Member, ABA Stark and Anti-Kickback Toolkit

## Professional Recognition

- Named the "Seattle Best Lawyers Health Care Lawyer of the Year" for 2015
- Named one of the "Best Lawyers in America" in Health Care Law by Best Lawyers, 2013-present

## Education

J.D., University of Notre Dame Law School, 1999, magna cum laude

- Executive Articles Editor, Notre Dame Law Review

B.A., Government/Philosophy, University of Notre Dame, 1996, magna cum laude

## Related Practices

Health Care
Health Care Litigation
Health Care Regulation & Compliance
Health Care Reimbursement & Payment
Health Care Operations
Health Information
Physician Groups
Medical Staff

## Admitted to Practice

Washington, 2006
U.S. Court of Appeals 9th Circuit
U.S. District Court Western District of Washington

# Jordan Keville // PARTNER // LOS ANGELES


## Los Angeles

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Jordan B. Keville has a practice that focuses on reimbursement and regulatory issues for a number of health care provider categories that include hospitals, physicians, Federally Qualified Health Centers ("FQHCs"), pharmacies, and physical therapists. He has also regularly advised transplant centers and organ procurement organizations on reimbursement and compliance issues. As a part of his work with these types of clients, Mr. Keville offers general advice and litigates at both the court and administrative level.
Mr. Keville also advises clients on various regulatory matters. His areas of focus include the federal "340B" drug discount program, with respect to which he assists clients with, among other things, negotiating and executing third-party pharmacy contracts and responding to 340B-related audits by the Health Resources and Services Administration and pharmaceutical manufacturers. Mr. Keville also regularly works with clients on issues relating to medical education, particular special Medicare payments available for direct graduate medical education ("GME"), and indirect graduate medical education ("IME").

## Additional Qualifications

- Partner, Hooper, Lundy & Bookman, PC, Los Angeles, California, August 2001-October 2016

## Professional Recognition

- Recognized as a Southern California Rising Star by Super Lawyers, 2009
- Recognized as an Outstanding Young Healthcare Lawyer by Nightingale Healthcare News, 2008

## Education

J.D., Loyola Law School, Los Angeles, 2001

- Order of the Coif
- St. Thomas More Honors Society

B.A., English and Anthropology, University of California, Santa Barbara, 1998

- Highest Honors
- Phi Beta Kappa

## Related Practices

Administrative Law Disputes
Appellate Litigation
Litigation

## Admitted to Practice

California, 2001

# Terri D. Keville // PARTNER // LOS ANGELES


## Los Angeles

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Terri Keville advises health care clients on credentialing, peer review and other medical staff issues, consent (including end-of-life issues), confidentiality (HIPAA and CMIA), emergency care requirements (EMTALA), clinical research, and other operational matters. Terri concentrates on helping clients avoid and minimize problems and disputes. When litigation cannot be avoided, her litigation practice emphasizes case-dispositive motions and appeals involving hospitals, physician groups, and other health care clients. Terri has made new favorable law for California health care organizations in cases involving physician peer review, Medicare and ERISA preemption, and California's Unfair Competition Law.

**Practice Highlights**

- Advises numerous hospital clients such as Dignity Health and Huntington Hospital on complex peer review and patient-care issues, including dealing with impaired and disruptive practitioners, sexual harassment allegations against medical staff members, clashing medical groups and medical staff factions, and difficult end-of-life decision-making
- Reviews and revises medical staff bylaws, rules and regulations, and policies to keep them in compliance with evolving legal and accreditation standards for multiple health care providers
- Advises medical staffs on issues relating to credentialing for appointment, reappointment and new privileges for multiple health care providers
- Assists medical staffs in addressing clinical and behavioral deficiencies of their members, including by serving as an advocate or hearing officer in peer review hearing proceedings for multiple health care providers
- Defends hospitals, medical staffs, and physician groups against claims by individual physicians for wrongful exclusion that involve complex issues of alleged disability discrimination, substance abuse, peer review duties and procedural rights, and the interplay of those elements with physician employment or partnership agreements

## Education

J.D., University of Southern California Law School, 1992

- Order of the Coif
- Articles Editor, Southern California Law Review

Graduate Studies, Philosophy, California State University, Northridge, 1974

B.A., Philosophy, University of Pennsylvania, 1972

## Related Practices

Medical Staff
Health Care Regulation & Compliance
Health Information Privacy, Security & Breach Response
Health Information
Health Care Operations
Health Care Litigation
Appellate Litigation
Health Care
Health Care Reform
Telemedicine

## Admitted to Practice

California
U.S. Supreme Court
U.S. Court of Appeals 9th Circuit
U.S. Court of Appeals 1st Circuit
U.S. District Court Central District of California
U.S. District Court Northern District of

# Terri D. Keville // PARTNER // LOS ANGELES

California

## Professional and Community Activities

- Vice Chair, Substance Use Disorders and Mental Health Interest Group (previously Task Force), 2014 – Health Law Section, American Bar Association
- Member; President, 2004-2005 – California Society for Healthcare Attorneys
- President, 2008-2012; Board of Directors, 2005-present – Friends of the Los Angeles County Law Library
- Co-chair, Joint Committee on Biomedical Ethics, Los Angeles County Medical Association and Los Angeles County Bar Association
- Executive Committee, Appellate Courts Section; Past Member and Co-chair, Bioethics Committee, 2000-2002; Member, Healthcare Law Section – Los Angeles County Bar Association
- American Health Lawyers Association
- Vice Chair, Oct. 2014-Sept. 2015; Member, Oct. 2011-Sept. 2015 – California State Bar Health Law Committee

## Professional Recognition

- Selected by Best Lawyers as Los Angeles' "Lawyer of the Year" in Health Care, 2014
- Named one of the "Best Lawyers in America," in Health Law by Best Lawyers, 2007-present
- Named one of "America's Leading Lawyers for Business" in Health Care (California) by Chambers USA, 2007-2016
- Selected to "Southern California Super Lawyers" by Thomson Reuters in Health Care, 2004-2016; in Appellate, 2004-2016; in Business Litigation, 2004-2016
- Named in Who's Who in America, 2006-present
- Named in Who's Who in American Law, 2005-2011
- Named in Who's Who of American Women, 2007, 2010

# Dayna Nicholson // COUNSEL // LOS ANGELES


## Los Angeles

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Dayna C. Nicholson focuses her practice on health care-related matters, such as licensing and other regulatory compliance, peer review and credentialing, and corporate and medical staff governance. Her clients include hospitals, medical staffs, managed care organizations, medical groups, medical device retailers, and other health care providers. Dayna also has experience in patient information privacy issues, appeals of state-issued administrative penalties, Medicare and Medi-Cal certification, emergency care requirements, and litigation arising out of peer review matters.

Dayna has significant experience counseling health care organizations regarding operational issues and regulatory and litigation matters. She has reviewed or drafted numerous policies, rules and regulations, bylaws, and other procedural documents, and regularly assists clients in interpreting and following such guidance. In the area of credentialing and peer-review, she is well-versed in state, federal and accreditation requirements, as well as the roles, responsibilities, and concerns of an organization's leadership, including medical directors and chief medical officers, credentialing and peer review committees, individual reviewers, and support staff. In such matters, Dayna makes every effort to communicate a clear, accurate assessment of the legal landscape, and to provide realistic, effective resolutions.

**Practice Highlights**

- Counsels clients regarding credentialing best practices, including structuring information flow, decision-making criteria, communication activities, etc.
- Develops/ revises multiple credentialing policies and procedures.
- Creates and presents training materials to credentialing/peer review committees and administrative staff.
- Attends credentialing and peer review meetings.
- Counsels clients in corrective action, including suspension and termination, and handles all aspects of peer review hearings.

## Education

J.D., Georgetown University Law Center, 2003, cum laude

M.P.H., Johns Hopkins University, Bloomberg School of Public Health, 2003

B.S., Business Administration, Pepperdine University, 1993

## Related Practices

Corporate Finance & Securities

Health Care

Health Care Mergers & Acquisitions

Health Information Privacy, Security & Breach Response

Privacy & Security

Digital Health Law

## Admitted to Practice

California, 2003

## Additional Qualifications

- Associate, Pepper Hamilton, LLP, Los Angeles, 2013-2016
- Associate, Norton Rose Fulbright, Los Angeles, 2003-2013
- Summer Associate, Norton Rose Fulbright, Los Angeles, 2002
- Summer Associate/Law Clerk, Duane Morris, LLP, Washington, D.C., 2001-2002

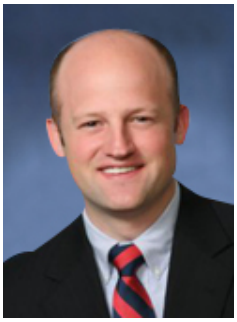
## Professional and Community Activities

- Board Member and Past President, Women in Health Administration of Southern California
- Chair, Executive Committee, Health Law Section of the Los Angeles County Bar Association, Los Angeles County Bar Association
- American Health Lawyers Association
- Health Law Section, American Bar Association
- California State Bar
- California Society of Health Care Attorneys
- Executive Committee Member, The Johns Hopkins University's Los Angeles Alumni Chapter

## Professional Recognition

- Pro Bono Champion, American Health Lawyers Association, 2014
- Selected to “Southern California Rising Stars,” Thomson Reuters, 2007, 2009, and 2013

# Adam D. Romney // PARTNER // SEATTLE & LOS ANGELES




## Seattle

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Adam Romney is a partner at Davis Wright Tremaine and works from the firm's Seattle and Los Angeles offices. He supports health care providers on a variety of issues including:

- Complex health care regulatory, reimbursement, and compliance matters
- Telemedicine services and technology issues
- Clinically integrated networks, ACOs, bundled payments, and other innovative payment models

Adam is a member of the Washington State Telemedicine Collaborative and has worked for the Office of the General Counsel at the U.S. Department of Health and Human Services and the Office of Medicare Hearing and Appeals. He also worked as a legislative staffer specializing in Medicare and Medicaid issues.

## Additional Qualifications

- Associate, Caplan & Earnest LLC, Boulder, Colo.
- Office of Medicare Hearings and Appeals; Office of General Counsel – U.S. Dept. of Health & Human Services
- Staff member for U.S. Congressman Jim Matheson (Utah 2nd)

## Professional and Community Activities

- American Bar Association
- American Health Lawyers Association
- Washington State Society of Healthcare Attorneys
- Health Care Financial Management Association
- Health Care Compliance Association

## Education

J.D., University of Colorado Law School, 2005

B.A., Political Science, French, University of Utah, 2001, cum laude

## Related Practices

Health Care Regulation & Compliance
Antitrust
Litigation
Health Care
Health Care Operations
Health Information
Health Information Privacy, Security & Breach Response
Health Care Mergers & Acquisitions
Health Care Reform
Physician Groups
Digital Health
Telemedicine

## Admitted to Practice

Washington, 2013
Colorado, 2006
California, 2009

# Loring Rose // ASSOCIATE // LOS ANGELES


## Los Angeles

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Loring Rose has handled all aspects of general civil litigation. His practice includes entertainment, real estate, and environmental matters, as well as title insurance defense and contract and partnership disputes. Loring has extensive experience with electronic document review and production, and has worked on a full range of legal research and documentation, including settlement agreements and appellate briefs. Prior to his legal career, Loring spent nearly a decade in information technology, working with banks, Internet startups, and software and insurance companies.

## Additional Qualifications

- Associate, Litigation, Glaser, Weil, Fink, Jacobs, Howard & Shapiro, LLP, Los Angeles, 2007-2010
- Summer Associate, Litigation, Law and Motion, Murchison & Cumming, LLP, Los Angeles, 2006
- Volunteer Advocate, Workers' Rights Self-Help Center, Neighborhood Legal Services of Los Angeles County, Los Angeles, 2005-2007

## Education

J.D., Loyola Law School, Los Angeles, 2007, cum laude

- Order of the Coif
- Scott Moot Court Honors Board
- Staff Member, Loyola Law Review
- Dean's Honor List
- St. Thomas More Law Honor Society
- First Honors: Introduction to Appellate Advocacy, Trial Advocacy, Supreme Court Seminar

M.F.A., Acting, DePaul University, 1995

B.A., Communications, English, North Carolina State University, 1991

## Related Practices

Litigation

## Admitted to Practice

California, 2007

U.S. District Court Central District of California, 2007

U.S. Court of Appeals 9th Circuit, 2009

# Robert L. Schuchard // PARTNER // LOS ANGELES


## Los Angeles

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865 South Figueroa Street
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Bob Schuchard concentrates his practice primarily in the health care industry, advising clients on general business, mergers and acquisitions, governance and board relations, joint ventures, contracts, and financing matters. His extensive experience includes many high-profile health care merger and affiliation transactions. Bob also draws on his diverse transactional and commercial practice to advise clients in other industries, including education, insurance, trade associations, social service organizations and equipment maintenance.

**Practice Highlights**

- Advising clients in the purchase and sale of businesses, mergers and management agreements, corporate governance and executive compensation in diverse industries, including manufacturing, service, insurance and health care
- Advising numerous hospitals, health care systems and physician groups in general corporate, governance, corporate structure, contracts with top executives, commercial and health care matters
- Representing clients before the charitable trust division of the California Attorney General's office
- General corporate and commercial matters, including loan transactions, corporate structure, negotiating agreements for equipment and real property sales and leases, commercial joint ventures and structuring and negotiating general and limited partnerships and limited liability companies
- Advising nonprofit health care facilities and systems and other charitable organizations, with particular focus on the corporate, fiduciary duty, tax and charitable trust issues facing such organizations

## Additional Qualifications

- Partner, Sonnenschein, Nath & Rosenthal LLP, Los Angeles
- Partner, Musick, Peeler & Garrett LLP, Los Angeles

## Education

J.D., Santa Clara University School of Law, 1977

- Business Editor, Santa Clara Law Review

B.A., Political Science, Stanford University, 1974

## Related Practices

Health Care
Health Care Mergers & Acquisitions
Health Care Finance
Corporate Governance
Corporate Finance & Securities
Mergers & Acquisitions
Administrative Law Disputes
Hospitals
Education
Health Care Reform
Tax-Exempt Organizations

## Admitted to Practice

California, 1977

# Robert L. Schuchard // PARTNER // LOS ANGELES

## Professional and Community Activities

- Member, Board of Directors of the Los Angeles Trust for Children's Health
- Past Chair, Committee on Nonprofit and Unincorporated Organizations, State Bar of California
- American Health Lawyers Association
- Business Law Section, State Bar of California
- Previously served on the Board of Directors, Public Counsel

## Professional Recognition

- Named one of "America's Leading Lawyers for Business" in Health Care (California) by Chambers USA, 2005-2016
- Named "Healthcare Sector M&A Attorney of the Year in California," Global Award, Corporate Intl Magazine, 2014
- Selected to "Southern California Super Lawyers," Thomson Reuters, 2004, 2006-2016
- Named an "Outstanding Healthcare Transaction Lawyer" by Nightingale's Healthcare News, 2008
- Named one of the "Best Lawyers in America" in Health Care Law by Best Lawyers, 2010-present

# Kerry E. Shea // PARTNER // SAN FRANCISCO


## San Francisco

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Kerry Shea practices in the fields of environmental permitting, counseling, compliance and litigation. She represents clients in governmental investigations regarding disposal of hazardous waste as well as incidental waste of confidential information. She advises clients on project development, financing, environmental due diligence and permit issues, and also assists them in negotiations with governmental agencies.

Kerry's clients include: Comcast Cable, Calpine, Liberty Utilities, BART, and other confidential investigation targets.

Kerry is a frequent contributor to DWT's Energy & Environmental Law Blog.

## Professional and Community Activities

- Editorial Board, Environmental Liability, Enforcement and Penalties, 2000-2007
- Biomass Power Association, 2009-2012
- California Biomass Energy Alliance, 2009-2012

## Education

J.D., University of California, Los Angeles, School of Law, 1989

- UCLA Law Distinguished Advocate, 1988
- Moot Court Team, State Tournament, 1988

B.A., Economics, University of California, Berkeley, 1985

## Related Practices

Energy Transactions
Environmental & Natural Resources
Environmental Litigation
Energy Project Development & Finance
Climate Change
Property Development: Brownfields
California Public Utilities Commission (CPUC)
Renewable Energy
Electric Power
Telecommunications
Petroleum
Product Stewardship

## Admitted to Practice

California, 1989
Federal Courts 9th Circuit, 1989
U.S. District Court Northern District of California, 1989
U.S. District Court Central District of California, 1989
U.S. District Court Southern District of California, 1989

# John R. Tate // PARTNER // LOS ANGELES

Co-chair, Health Care Litigation Group


## Los Angeles

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John Tate is a commercial trial lawyer who practices extensively in the health care and financial services industries, as well as real estate and insolvency-related litigation. He represents clients on a wide range of claims, including commercial torts, unfair competition, breach of fiduciary duties and creditor's rights, as well as issues specific to the health care and real estate finance industries.

### HEALTH CARE LITIGATION

**U.S. ex rel. ProTransport-1 LLC v. Kaiser Foundation Health Plan**
Obtained early dismissal of False Claims Act and retaliation claims asserted by an ambulance service relator. (N.D. Cal. 2013)

**Enki Health and Research Systems, Inc. v. County of Los Angeles, State of California, et al. and 18 related actions**
Chief trial counsel representing 18 mental health providers seeking payment of claims in excess of $18 million for mental health services provided to Short-Doyle/Medi-Cal beneficiaries that were not paid due to defects in the claims processing systems of the state and county. (L.A. Cnty. (Cal.) Super. Ct. Ongoing)

**Bernard v. City of Oakland; Martinez v. City of Union City**
Prevailed in defense of the California Public Employees' Retirement System in an action by retired firefighters seeking to alter the premium contribution obligations of contracting public agencies under the Public Employees' Medical and Hospital Care Act (California Government Code sections 22751, et seq.). 202 Cal.App. 4th 1563 (2012)

**Erin Brockovich v. Sisters of Charity of Leavenworth Health System, Inc.**
Defense of two hospital systems in qui tam actions purporting to enforce Medicare's Secondary Payor provisions (42 U.S.C. § 1395y(b)(3)). Plaintiff sought recovery of all Medicare funds paid to treat alleged but unspecified hospital malpractice injuries. The cases were dismissed while on appeal to the 9th Circuit

## Education

J.D., Vanderbilt University Law School, 1976
A.B., Government, Dartmouth College, 1973, cum laude

## Related Practices

Health Care Litigation
Real Estate Finance
Arbitration
Financial Services
Health Care
Hospitals
Appellate Litigation

## Admitted to Practice

U.S. Supreme Court, 1983
California, 1977
U.S. Court of Appeals 9th Circuit
U.S. District Court Northern District of California
U.S. District Court Central District of California
U.S. District Court Southern District of California

Court of Appeals. (C.D. Cal.)

**Fraud actions against former employee of large regional hospital**
Represented large regional hospital in multiple actions arising from theft and kickbacks perpetrated by a former employee and his associates. Obtained judgment and/or settlement against multiple defendants, recovering substantial portion of funds taken. Cooperated with criminal prosecution resulting in conviction of principal participants. (2012)

**Defense of national pharmacy chain against pharmacy seller**
Represented acquirer of three pharmacies against seller's claims for breach of sale agreement arising from disputed reimbursement claims. (2010)

**Defense of hospital chain arising from failed hospital sale**
Defended regional hospital system in litigation disputing responsibility for failure to close the sale of a hospital. Plaintiff voluntarily dismissed case. (2012)

**Defense of indemnity claims by former corporate officers**
Represented regional hospital system against claims for former officers for reimbursement involving California Labor Code §2802 and California Corporations Code §317 for expenses incurred in legal defense of criminal investigations. (2012)

**Promise Hospital of East Los Angeles v. Providence Health System**
Defense of hospital in dispute over responsibility for charges incurred by patients transferred under letter of agreement. (2012)

**Defense of civil enforcement action alleging wrongful transportation, treatment and billing of indigent patients**
Represented regional hospital system charged with violating California Business and Professions Code §17200 by the Los Angeles city attorney arising from allegations of improper patient referrals. (2012)

**CHA Hollywood Medical Center v. Kravitz**
Represented hospital and skilled nursing facility in successful eviction of patient refusing discharge. (2010)

## Additional Qualifications

- Partner, Litigation Department, Arter & Hadden LLP, 1994-2003
- Partner, Head of Litigation Department, McDermott & Trayner, 1987-1994
- Partner, Gendel, Raskoff, Shapiro & Quittner, 1983-1987

Guest Speakers

KAISER PERMANENTE

# John Krave

Kaiser Foundation Hospitals / Kaiser Foundation Health Plan, Inc.

*Senior Counsel*

John Krave has been a practicing health care attorney since 1982. He has represented hospitals and health care systems on a wide variety of issues, including general corporate advice, health care privacy, mergers and acquisitions, and health care fraud and abuse. Since 2008, he has been Senior Counsel for Kaiser Foundation Hospitals and Kaiser Foundation Health Plan, Inc., where he has specialized in provider-related issues, most notably including health care privacy, release of information, general consent and other operational matters, as well as medical staff privileging and credentialing. He is a member of the Board of Trustees of the ALS Association.

# Marcia Penido, LCSW, MPH, ACM-SW

Huntington Hospital

*Director of Care Coordination*

Marcia is an LCSW with almost 30 years of experience in clinical social work in hospitals, and has been at Huntington Hospital for over 17 years. She holds three Masters degrees with emphases in Criminal Justice, Social Work Administration and Health Care Management. After 16 years experience with patients at the end of life, she managed the development and launch of Huntington Hospital's Palliative Care program in 2007. For the past 6 years, she has been Huntington's Director of Care Coordination, currently overseeing the departments of Social Work, Case Management, Spiritual Care, Palliative Care and Health Navigation.

Marcia represents Huntington's Palliative Care program to the San Gabriel Valley End-of-Life Care Coalition, Coalition for Compassionate Care of California and the Palliative Care Quality Network. The program has been the recipient of several grant-funded initiatives, including the Palliative Care Action Community and the Greater Pasadena Area POLST Coalition, of which Marcia served as the Project Director implementing POLST in the Western San Gabriel Valley. In addition, Marcia is an active member of the Society for Social Work Leaders in Health Care (SSWLHC) and the American Case Management Association (ACMA).

Marcia's expertise is the legal and ethical issues surrounding patient rights, advance care planning, organ donation and end of life care.