CALIFORNIA HEALTH LAW NEWS

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California Health Law News (CHLN) is a quarterly publication of the California Society for Healthcare Attorneys (CSHA). The mission of CHLN and the CSHA Publications Committee is to publish articles that are interesting and useful to health lawyers practicing California law. While the Publications Committee strives to ensure that CHLN articles provide accurate and authoritative information regarding the subject matters covered, the information is provided with the understanding that neither CSHA nor CHLN contributors are engaged in rendering legal services. Contributors to CHLN are not agents of CSHA and the opinions and positions stated in CHLN articles are those of the authors and not of CSHA, its staff, the CHLN editors or Publications Committee members.

EDITORS' NOTE

Carla J. Hartley

Katherine Broderick

Dear CHLN Readers –

Mid-2023 brings a number of changes to the Publications Committee. In addition to Kate Broderick becoming Co-Editor, we also welcome seven new members to the Board of Editors: Lillian Anjargolian, Anna Buono, Sheirin Ghoddoucy, Brandi Hannagan, Katie Howells, Anna Molander and Julia Weisner. In a testament to CSHA's membership, we had a large number of highly qualified candidates.

In this issue, we are pleased to continue our series of articles on the fall out from the *Dobbs v. Jackson Women's Health Organization* decision a year ago with an article on subpoenas seeking abortion records and the first installment of a series on the criminalization of healthcare, California's protections of gender affirming care. In addition, this issue contains timely articles on the end of the public health emergency, AB 890 and the independent practice of nurse practitioners, AB 2338 and surrogate decision makers, California's Physician Ownership and Referral Act, and efforts to limit healthcare executive compensation in Los Angeles.

We continue to be fortunate to receive a broad variety of articles from Committee members and CSHA's membership as a whole. If you are interested in submitting an article or have an idea for timely article with a California connection but no author, please reach out to Kate or me, (kate.broderick@commonspirit.com or cjh@dillinghammurphy.com)

ANNOUNCEMENTS

2023 FALL SEMINAR

Mark your calendar for CSHA's 2023 Fall Seminar, which will be held Friday, November 10, at the Hilton Irvine/Orange County Airport. The Fall Seminar features a variety of educational sessions designed to keep you abreast of important changes and developments in California health law, including the ever-popular Legislative Update to inform you about health-care-related laws signed by the Governor in 2023, so you can advise your clients on how to properly prepare. The program will offer several hours of MCLE credit and feature educational presentations designed to provide you with current and relevant information regarding health care law. Additional information and registration materials will be available in the coming months.

Make your hotel reservations by calling (949) 833-9999. Be sure to mention the "CSHA Fall Seminar" to receive the discounted rate of $169 for single/double occupancy, plus tax. Don't delay – the deadline for reserving rooms at this rate is October 20.

INVITATION FOR SPONSORSHIP: FALL SEMINAR 2023

For the first time, we are opening sponsorship opportunities for our Fall Seminar, expanding beyond our Annual Meeting & Spring Seminar. This event promises engaging discussions, informative presentations, and valuable networking opportunities, attracting approximately 175-200 dedicated health law practitioners.

As a sponsor, your firm will receive prominent recognition, including logo features in the seminar brochure, large signs displayed throughout the event, and inclusion in distributed materials. Attendees from your firm will also be distinguished with "sponsor" ribbons on their name tags, and your firm can place educational materials on a designated table.

To secure your sponsorship, visit www.csha.info/?pg=sponsorship-2023-fall-seminar. Please confirm your $500 commitment by September 26 to be part of shaping this successful event.

We look forward to partnering with you and making the Fall Seminar a success!

SAVE THE DATE!

Mark your calendars for the 2024 Annual Meeting and Spring Seminar, taking place from May 3 to May 5, 2024, at the Everline Resort & Spa, situated in Olympic Valley and just a short distance from North Lake Tahoe. This stunning resort offers numerous amenities, including a championship golf course, cross-country ski center, fly fishing center, ice-skating rink, heated swimming pools, water slide, and scenic hiking and biking trails.

The event will feature a full day of MCLE presentations on Friday and mornings only on Saturday and Sunday, allowing attendees and their families to explore the beautiful Tahoe area and its surroundings during the afternoons. Don't miss the Friday evening Welcome Reception and Saturday evening Annual Dinner, complete with entertainment, providing fantastic opportunities to connect with fellow health law colleagues.

Plan to join this exciting event for an enriching and enjoyable experience!

MEMBER-GET-A-MEMBER CAMPAIGN

Join our Member-Get-A-Member Campaign today by referring a new member to CSHA. For every new member you recruit between May 5 and October 6, you will receive:

- A $25 Amazon gift certificate
- An entry into a drawing for a $100 Amazon gift card

Join us in growing our community and being rewarded for your efforts!

**Campaign Rules: Referring member must be a current member in good standing in order to participate in the Campaign. Past members who have not renewed their membership are not eligible for this Campaign. Referring member's name must be included on new member application. In the event of multiple referring members, only the first referring member's name listed on an application is eligible. Limit of five gift certificates and drawing entries per refer-ring member. Campaign runs from May 5 – October 6, 2023. CSHA reserves the right to substitute Campaign rewards.*

CSHA MENTOR PROGRAM

CSHA is actively seeking members to become mentors for students with a passion for healthcare law. We are thrilled to offer aspiring attorneys the chance to connect with volunteer member attorneys who can share valuable practical knowledge and wisdom in the field of healthcare law. We welcome mentors from diverse practice environments, including large and small firms, corporations, government agencies, academia, research, public interest organizations, and beyond.

If you are interested in becoming an attorney mentor and making a difference in the lives of future legal professionals, please visit www.csha.info and complete the submission form. Your guidance and expertise can have a significant impact on the next generation of healthcare law practitioners.

JOIN CSHA ON LINKEDIN

The California Society of Healthcare Attorneys is on LinkedIn! LinkedIn is the largest online network designed to connect professionals across the globe. Join the CSHA LinkedIn group page now to connect with other CSHA members and build your professional networking profile. We look forward to seeing you there!

NEW MEMBERS

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MEMBER NEWS

AIMEE ARMSBY joined CommonSpirit Health Northern California Division as Senior Counsel in March 2023.

KATHRYN E. DOI has joined Feldesman Tucker Leifer Fidell LLP and will serve as Partner-in-Charge of its new Sacramento office.

ANDREA FREY (San Francisco office), **MATTHEW LAHANA** (San Diego office) and **CATHERINE WICKER** (San Diego office) of Hooper Lundy & Bookman have each been named Senior Counsel as of January 1, 2023.

STEPHANIE GROSS (Los Angeles office) has been promoted to non-equity Partner at Hooper, Lundy & Bookman as of January 1, 2023.

ADAM HEPWORTH was promoted to Partner at Foley & Lardner.

BARBARA LAM has been promoted to Partner at Stephenson Acquisto.

CSHA Board member **PUJA SHAH** recently welcomed Baby Minaxi. Potential future CSHA member, but currently just being adorable.

JESSAMYN VEDRO is now a Partner at Troutman Pepper.

DAVID VERNON (Washington DC office) has been promoted to equity Partner at Hooper, Lundy & Bookman, effective January 1, 2023.

Minaxi Shah Bittner

IMPLEMENTING AB 890 AND NP INDEPENDENT PRACTICE AUTHORITY IN CALIFORNIA

by **Ruby Wood**
Hooper, Lundy & Bookman, P.C.

Ruby Wood serves as the Co-Chair of the Medical Staff Practice Group at Hooper, Lundy & Bookman. She has extensive experience representing medical staffs and other peer review bodies in a variety of matters including credentialing and privileging matters, governance, investigations, corrective actions, and contracting issues, and has served as lead counsel in multiple peer review hearings, appeals and writ petitions as well as other litigation relating to medical staff law.

by **Catherine Srithong Wicker**
Hooper, Lundy & Bookman, P.C.

Catherine Srithong Wicker is Senior Counsel at Hooper, Lundy & Bookman and counsels health systems, hospitals, and medical staffs on various regulatory and litigation matters. She focuses a significant portion of her practice on peer review matters, internal investigations, fair hearing proceedings, and litigation relating to medical staff issues.

by **Erin Sclar**
Hooper, Lundy & Bookman, P.C.

Erin Sclar is an associate at Hooper, Lundy & Bookman, where she represents health care providers on issues related to innovative delivery models, including through the use of allied health professionals. Her involvement in public health predates her legal career, with an extensive Medicaid policy background.

Effective January 1, 2023, the California Board of Registered Nursing ("BRN") promulgated regulations that fully implement California Assembly Bill ("AB") 890. AB 890 granted nurse practitioners ("NPs") greater independent practice authority. California has historically been one of the most restrictive states with respect to NP independent practice, requiring NPs to function pursuant to standardized procedures—policies and protocols developed in collaboration among administrators and health professionals, which specify the way in which NPs may perform certain functions that would otherwise be considered the practice of medicine.

Importantly, AB 890 did not change the use of standardized procedures as they relate to existing NPs. However, it created two new categories of NPs who may operate without standardized procedures within a defined scope of practice: (1) "103 NPs" may practice without standardized procedures in group settings such as clinics, hospitals, medical group practices, home health agencies, and hospices with at least one physician (practicing pursuant to Business and Professions Code section 2837.103[1]) and (2) "104 NPs" may practice without standardized procedures outside of the group setting (practicing pursuant to section 2837.104). Any NP who wishes to practice as either a 103 or 104 NP must meet the minimum requirements set forth by AB 890 and be certified by the BRN; these designations are not automatically applied.

The BRN's regulations set forth the requirements necessary for NPs to apply to practice without standardized procedures. This includes minimum "transition to practice" standards for candidates seeking certification. For an NP to qualify as a 103 NP, they must be able to demonstrate a minimum of three years or 4,600 hours of clinical practice experience and mentorship. These hours must also meet the following requirements:

1. be completed in California;
2. be completed within five years prior to applying to practice as a 103 NP;
3. be completed after certification as an NP; and
4. be in direct patient care in the category in which the NP seeks certification.

An NP must practice as a 103 NP for at least three years before becoming eligible to apply for practice as a 104 NP.

APPLICATION TO PRACTICE WITHOUT STANDARDIZED PROCEDURES

Pursuant to the regulations, NPs who meet the requirements of section 2837.103 may apply online to the BRN for expanded practice authority and, once certified by the BRN, work without standardized procedures as a 103 NP in certain group settings as noted above and in the category in which the NP is certified.[2] The application elements are generally set forth in 16 C.C.R.

section 1482.3 (including proof of completion of transition to practice, proof of NP certification by a national certification organization as an NP, and the NP category, such as neonatal, pediatrics, family/individual across the lifespan, etc.). Accordingly, designation as a 103 NP is not available for all specialties.

Given the additional requirement that 104 NPs first practice as a 103 NP for at least three years, the ability to apply for certification as a 104 NP will not be available until 2026, at the earliest.

MEDICAL STAFF MEMBERSHIP FOR NPS AND UPDATED 805 REPORTING REQUIREMENTS

Another key aspect of AB 890 is that it allows for 103 NPs to serve on medical staff and hospital committees and, beginning in 2026, permits 104 NPs to be eligible for medical staff membership. With respect to serving on medical staff and hospital committees, this codifies an existing practice for many medical staffs and hospitals including, for example, committees directed towards root cause analyses and the Interdisciplinary Practice Committee.[3] However, regarding potential medical staff membership for 104 NPs, AB 890 and the BRN's regulations are silent as to how to read the statute in context with Title 22's requirement that the medical staff "shall be composed of physicians and, where dental or podiatric services are provided, dentists or podiatrists."[4]

Additionally, AB 890 extended section 805's reporting requirements to 103 and 104 NPs.[5] Under section 805, peer review bodies—such as a hospital's medical staff—must file a report with the relevant licensing agency (here, the BRN) when certain corrective actions are taken against a "licentiate" for a "medical disciplinary cause or reason." Specifically, AB 890 expanded the definition of "licentiate" to include 103 and 104 NPs.

In light of AB 890's expanded section 805 reporting requirements, the BRN updated its page with FAQs and a health facility reporting form. Notably, the same reporting form is to be used for permissive reports as well as reports required under AB 890. Therefore, it does not specify 103 and 104 NPs, instead identifying "Nurse Practitioner" and "Nurse Midwife" as the available categories of "licentiate."

Importantly, while AB 890 expanded the definition of licentiate under section 805's reporting requirements, it did not similarly change the definition of licentiate as set forth in section 809 relating to hearing rights. These amendments are consistent with the approach taken with respect to physician assistants, who are included in section 805's definition of licentiates for reporting requirements, but are not identified as a licentiate under section 809 for fair hearing rights.

IMPLICATIONS FOR PROVIDERS

In light of the BRN's regulations, the 103 NP application process, and available guidance about medical staff membership for NPs, providers and medical staffs will need to implement changes in their practice settings. Although not all NPs will pursue practice as 103 or 104 NPs, the BRN expects up to 32,000 NPs to apply for 103 NP certification, therefore providers must be ready.

Key considerations to be addressed include defining the role of the hospital and medical staff in the NPs' application process (especially with respect to certifying qualifying transition to practice hours), establishing contracts with 103 NPs, determining whether to change governing documents (such as Medical Staff Bylaws, Rules and Regulations and policies relating to advanced practitioners), integrating verification of qualifications into credentialing processes, and identifying practices for initial and ongoing assessment of clinical competency.

Other areas of consideration include assessing the implications for clinicians responsible for attesting to an NP's completion of the transition to practice requirements. 103 and 104 NP applications must include one or more attestations regarding "proof of completion of a transition to practice" made by a physician, or a 103 or 104 NP with the same specialization (applicants seeking certification as a 104 NP may only submit attestations from physicians or 104 NPs). The attesting clinician should be someone "who oversaw and provided the mentorship during the transition to

practice period." The attestations are made under penalty of perjury, but it is not clear what other liability, if any, could result from a false attestation.

AB 890 is intended to expand access to healthcare. However, it is clear that 103 and 104 NPs must practice within the scope of their training and within the standard of care. As a result, in addition to being aware of expanded reporting requirements, hospitals and medical staffs must determine how to implement quality assurance processes and protocols, which ensure 103 and 104 NPs are continuously providing quality care to patients.

END NOTES

1 All further statutory references are to the Business & Professions Code.

2 The categories of NPs are listed in 16 C.C.R. § 1481(a).

3 22 C.C.R. § 70706.

4 22 C.C.R. § 70703.

5 AB 890 also extended section 805.5's requirement for health facilities to check for any section 805 reports filed against *all* NPs prior to granting or renewing staff privileges.

AS COVID-19 PUBLIC HEALTH EMERGENCY WAIVERS EXPIRE, SOME HEALTH CARE DELIVERY MODELS WILL NEED TO ADJUST

by **Stacie Neroni**
Davis Wright Tremaine LLP

Stacie Neroni is a partner in the Los Angeles office of Davis Wright Tremaine LLP. Her practice focuses on advising suppliers and providers on how to achieve their business objectives while remaining compliant with the complex governmental regulations related to licensure and payor enrollments.

by **Christine Parkins Johnson**
Davis Wright Tremaine LLP

Christine Parkins Johnson is an associate in the Los Angeles office of Davis Wright Tremaine LLP. Her practice focuses on the regulatory and operational concerns of health care providers, including licensing, Medicare/Medicaid enrollment, certification, and reimbursement.

by **Wei Wei**
Davis Wright Tremaine LLP

Wei Wei was a law clerk in the Seattle office of Davis Wright Tremaine LLP. She is a 2024 J.D. Candidate at the University of Washington School of Law and DWT's first 2L Diversity Healthcare Law Clerk.

Health care providers are diligently working to understand and transition their health care delivery processes in the post-pandemic era as both federal and state waivers expire with termination of the COVID-19 public health emergency declarations. On January 23, 2023, the Biden administration announced that the federal COVID-19 Public Health Emergency (Federal PHE) would end on May 11, 2023.[1] California's COVID-19 State of Emergency (California PHE) expired on February 28, 2023.[2] Since the initial declaration of the Federal PHE in 2020, the federal government and California regulators have used a combination of emergency authority waivers, regulations, enforcement discretion, and sub-regulatory guidance to provide health care providers with greater flexibilities in order to expand facility capacity and maximize resources for responding to challenges created by the COVID-19 pandemic.

Now that the Federal PHE and California PHE have ended, providers must sort through which waivers have expired, which will temporarily remain in effect, and which have or may be made permanent through new legislation. This article presents an update on the end of the California PHE and the Federal PHE, as well as a summary of the key implications for health care providers in California.

HOSPITAL SPACE WAIVERS

Significant for many facilities, the California Department of Public Health (CDPH) provided a "space waiver" that waived various requirements related to the configuration and use of physical space.[3] However, with termination of the California PHE, non-compliant conditions cannot remain in place beyond February 28, 2023.[4] The physical environment must be restored to pre-pandemic conditions by April 11, 2023, and the restoration must be reported to California's Department of Health Care Access and Information (HCAI). Hospitals should identify areas and operations currently in place that benefited from the historic flexibilities and revert to pre-pandemic operations. Facilities that have a continued need for certain flexibilities beyond the end of the California PHE should request program flexibility from CDPH.[5]

At the federal level, CMS temporarily waived certain physical environment requirements under the Medicare conditions of participation, allowing hospitals to use space that is not normally used for patient care to serve as patient care or quarantine areas.[6] By May 11, 2023, hospitals had to de-commission inappropriate use of space for patient care or work with their building and planning department and review applicable building codes to update spaces as needed to ensure they are appropriate for patient care.

Similarly, CMS allowed hospitals to expand capacity by creating new, or relocating existing, provider-based departments (PBDs) during the Federal PHE.[7] Given the end of the PHE, hospitals had to make sure that PBDs are at their original locations or choose to permanently relocate off-campus PBDs, which will be considered new off-campus PBDs and will be required to bill using the "PN" modifier and be paid the PFS-equivalent rate after May 11th. Hospitals may seek an extraordinary

circumstances relocation exception for excepted off-campus locations that have permanently relocated, but the hospitals would need to follow CMS's extraordinary circumstances application process. Furthermore, as of the end of the Federal PHE, hospitals are no longer allowed to utilize Skilled Nursing Facility (SNF) swing beds that are payable under the SNF prospective payment system.

Hospitals also had to assess whether patients are screened at locations offsite from the hospitals' campuses to comply with post-PHE Emergency Medical Treatment and Labor Act (EMTALA) requirements. With CMS's resumption of the enforcement of EMTALA at the end of the Federal PHE, hospitals need to close any existing off-campus screening locations and educate staff in such locations and in hospital departments that direct patients to those locations that offsite locations will no longer be used for screening. Hospitals will also need to reinstate physician's privileges that have expired and ensure that their clinicians are up-to-date and trained on the relevant regulatory changes, including re-implementing the rule that verbal orders must be authenticated within 48 hours.

PHARMACY OPERATIONS

Upon expiration of the California PHE, several of the California Department of Consumer Affairs (DCA) waivers related to pharmacy licensees also expired, including the waiver which permitted pharmacy technicians to administer COVID-19 vaccines.[8] Some of the California State Board of Pharmacy waivers continued pursuant to the Board's own authority until May 28, 2023, including the more general supervision requirement for pharmacy interns administering COVID -19 vaccines and the staffing ratio of pharmacists to pharmacy interns when performing immunization-related activities.

However, much of the vaccine administration authority granted by the DCA waivers was also granted by a Declaration issued by the Secretary of HHS under the Federal Public Readiness and Emergency Preparedness Act (PREP Act).[9] Declarations issued pursuant to the PREP Act preempt any more restrictive state laws.[10] Therefore, any vaccine administration authority granted under the PREP Act would continue beyond the expiration of the California PHE, including the provisions specific to pharmacy technician COVID-19 vaccine administration.[11][12] While the original PREP Act authority for COVID-19 vaccine administration was set to end on May 11, 2023, the Secretary issued an amendment to the PREP Act declaration extending the authority to December 31, 2024.[13]

Another important waiver expiration to keep in mind is the California State Board of Pharmacy "remote processing waiver" which expanded Business and Professions Code section 4071.1(a) to permit licensed pharmacists, licensed technicians, and pharmacy interns to engage in remote order and other data entry and processing activities outside the four walls of a licensed pharmacy. [14] This waiver was especially important during the Covid-19 pandemic and assisted with ensuring social distancing while still operating high volume pharmacy practices. This waiver expired on May 28, 2023 and now only licensed pharmacists are permitted to engage in only data entry activities (for non-controlled meds) outside of licensed space pursuant to Business and Professions Code section 4071.1(a).[15]

Many pharmacies including hospital pharmacies have come to rely on remote data entry by pharmacy technicians to assist with high volume orders and limited pharmacy space and the expiration of the waiver will create a significant burden for those providers. In February 2023, the AB 1557 was introduced which will assist somewhat by amending Business and Professions Code section 4071.1 by allowing licensed pharmacists on behalf of a licensed health care facility to also verify medication chart orders from outside the facility, however, the proposed bill does not apply to licensed technicians.[16]

TELEHEALTH

The use of telehealth expanded exponentially during the pandemic with the federal government encouraging the use of telehealth to promote continuing access to care. Although some telehealth-related waivers will end on May 11th, the federal government has recognized that it will take time to unwind the use of telehealth and extended some telehealth-related waivers through the end of 2023 and other waivers through the end of 2024.[17] In addition, some limited waivers have been made permanent.[18]

Expiration Dates for Other Key CA Waivers[19]				
Personnel	**Remote Processing**	**Prescriber Dispensing**	**Staffing ratio (pharmacists to intern pharmacists) - immunizations**	**Vaccine Administration**
2/28/23	5/28/23	5/28/23	5/28/23	12/31/24
Licensing waivers, including those issued by EMSA allowing out-of-state medical personnel licensure waivers and extending/enhanced scope of practice	Waiver by the California State Board of Pharmacy allowing remote entry of an order or prescription in to a computer from outside of the pharmacy	Waiver of provisions prohibiting a prescriber from dispensing medication to an emergency room patient under certain circumstances	The California State Board of Pharmacy allowed for one or two additional intern pharmacists for each supervising pharmacist under certain circumstances related to administering immunizations	PREP Act 11th Amendment to Declaration covering pharmacy technician administration of COVID-19 vaccinations

Controlled Substances Prescribing

Significantly, the Federal PHE waived the Ryan Haight Act requirement that a practitioner prescribing controlled substances over the internet must have conducted at least one "in-person medical evaluation" of the patient.[20] When the Federal PHE ended on May 11, 2023, the "in-person medical evaluation" was again required unless an exception applies. Many providers view the in-person evaluation requirement as a substantial barrier to care; the American Hospital Association in December 2022 sent a letter to the DEA urging the agency to release proposed rules for virtual prescribing (in the form of a special registration for telemedicine) and grant a permanent exception to separate DEA registrations for practitioners in states that have medical reciprocity requirements.[21]

The Drug Enforcement Administration (DEA) in turn released two proposed permanent rules on February 24, 2023, introducing two potential options for prescribing controlled substances via telemedicine without a prior in-person evaluation.[22] The two options proposed in the two new rules are as follows:

Option 1: A prescriber can issue an initial prescription for a controlled substance without an in-person exam if prescriber:

- Holds a DEA registration in the state where the prescriber and patient are located;
- Conducts an audio-video telemedicine exam;
- Consults Prescription Drug Monitoring Program (PDMP) database in patient's state (if available);
- Issues a 30 day prescription only (or a 7 day prescription if she cannot consult PDMP);
- Prescribes non-narcotic Schedule III, IV, or V controlled substances or buprenorphine for opioid disorder treatment; and
- Annotates the prescription to indicate it was issued pursuant to a telemedicine encounter.

Option 2: A patient who has an initial in-person exam with a practitioner (First Practitioner), may be referred to another practitioner (Second Practitioner) for medically necessary additional treatment to be delivered via telemedicine. The Second Practitioner can conduct a telemedicine exam of the patient and prescribe a controlled substance without having personally conducted

Expiration Dates for Telehealth Waivers			
May 11, 2023	**December 31, 2023**	**December 31, 2024**	**Permanent (No Expiration)**
FDA Controlled Substance Prescribing (but see Proposed Rules)	Expanded List of Medicare-Covered Telehealth Services	Waiver of Rural Location Requirement	FQHCs and RHCs can serve as a distant site provider for behavioral/mental telehealth services.
Remote Evaluation of Patient Images/Video and Virtual Check-Ins for New Patients	Direct Supervision via Telehealth	Waiver of Clinical Location Requirement	Medicare patients can receive telehealth services for behavioral/ mental health care in their home
Remote Physiologic Monitoring for New Patients	Medicare Payment Parity for Telehealth Provided to Hospital Patients	Waiver of Audio-Video Modality Requirement	There are no geographic restrictions for originating site for behavioral/mental telehealth services
Frequency limitations on certain Medicare-covered telehealth services		PTs, OTs, SLTs and Audiologists and Eligible Providers	Behavioral/mental telehealth services can be delivered using audio-only communication platforms
Providing Face-to-Face Encounters for Home Dialysis Patients via Telemedicine		Telephone Only E&Ms	Rural hospital emergency department are accepted as an originating site
Stark and Anti-Kickback Waivers			

an in-person exam of the patient. The Second Practitioner can rely on the in-person exam conducted by the First Practitioner and can prescribe Schedule II-V and narcotic controlled substances if the practitioner:

- Consults the PDMP database in the patient's state; and
- Annotates the prescription to indicate that it was issued pursuant to a telemedicine encounter.
- Comments to the proposed rules were due March 31, 2023.

Medicare Billing

Medicare billing practices related to telehealth will also undergo significant changes as the Federal PHE nears its end. For example, during the Federal PHE, the Centers for Medicare & Medicaid Services (CMS) reimbursed healthcare providers at the same rate for telehealth services as for in-person visits.[23] This payment parity will end on January 1, 2024, leading to reduced telehealth reimbursements outside of facility settings.[24] Likewise, during the Federal PHE, CMS allowed providers to bill for remote evaluation of patient video/images, virtual check-in services, and remote physiologic monitoring (RPM) services furnished to both new and established patients.[25] Once the Federal PHE ended, these services may only be provided to established patients, although RPM can continue to be provided for both acute and chronic conditions without an initiating visit. Furthermore, the modified Medicare physician supervision requirements that allow the supervising physician or practitioner to be "immediately available" through "virtual presence" are set to expire at the end of 2023.

The chart on the previous page summarizes when various telehealth waivers expire, and which waivers will remain permanent.

FRAUD AND ABUSE

The expiration of the Federal PHE has meant the end of the flexibilities for certain portions of the physician self-referral law (the Stark Law). During the Federal PHE, CMS issued blanket waivers of sanctions under Stark Law for 18 types of financial and referral relationships but the relationships had to be related to a COVID-19 Purpose.[26] The waivers have been widely used by Designated Health Services entities and physicians, allowing them, for instance, to protect rent reduction arrangements, expand physician-owned hospital capacity, and provide historical compensation levels despite reduced productivity. As Stark Law waivers have expired, providers using the waivers have had to maintain records and organize documentation evidencing the use of Stark Law waivers. In addition, arrangements should be amended to fit squarely within an exception, including the "set in advance" requirement. Group practices and physician-owned hospitals have had to take special care to determine if any operational changes were made in accordance with the waiver flexibilities and rethink their approaches post-PHE.

During the PHE, the HHS Office of Inspector General (OIG) did not provide waivers related to the Anti-kickback Statute (AKS) or beneficiary inducement provisions of the Civil Monetary Penalties Law. Instead, the OIG issued Policy Statements and FAQs discussing enforcement discretion during the PHE.[27] Flexibilities established by OIG Policy Statements or FAQs will no longer apply after the Federal PHE ends.[28] Providers should make sure they considered whether they relied on any of the OIG guidance and FAQs during the Federal PHE and have made prudent changes to come into compliance with existing federal law.

HIPAA

During the Federal PHE, the Office for Civil Rights (OCR) waived penalties against covered health care providers for the lack of a business associate agreements (BAA) with telehealth platform providers, as well as any other HIPAA violation related to the good faith provision of telehealth during the PHE.[29] Specifically, OCR allowed covered health care providers to use any non-public facing audio or video communication product (*e.g.*, Zoom or Microsoft Teams) to provide telehealth services.

With the Federal PHE ending, it is crucial for covered health care providers to ensure they have a BAA with HIPAA-compliant technology vendors for using telecommunication products. Additionally, providers should review and confirm that reasonable safeguards are in place, such as policies outlining where telehealth sessions may occur, requiring use of approved telehealth platforms, and addressing whether telehealth sessions may be recorded and, if so, what consent is needed. Furthermore, covered health care providers need to address the compliance of their telehealth

platform with the HIPAA Security Rule, such as checking if appropriate encryption technologies are adopted for Protected Health Information (PHI) at rest and in transit.[30] Threats to the confidentiality, integrity, and availability of PHI through telehealth should also be identified, assessed, and addressed in Security Rule risk analysis and risk management processes.[31]

CONCLUSION

As we embark on the third year since the initial outbreak of COVID-19, both federal and California state governments have made the call to transition into the post-PHE era and move forward to reestablishing previous rules and standards. Health care providers in California need to take immediate actions to evaluate their current policies and practices, as well as the flexibilities they have relied on during the PHE, to ensure they are compliant with current law.

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CRIMINALIZATION OF HEALTHCARE SERIES
MAKING CALIFORNIA A SAFE HAVEN FOR MINORS SEEKING GENDER AFFIRMING CARE

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GLOSSARY KEY TERMS	
Gender - Affirming Care	Gender affirming care is a model of care which includes a spectrum of social, psychological, behavioral and medical (including hormonal treatment and surgery) interventions designed to support and affirm an individual's gender identity.
LGBTQ+	Lesbian, Gay, Bisexual, Transgender, Queer (and more).
Non-Binary	Non-binary is an identity embraced by some people who do not identify exclusively as a man or a woman. Non-binary people may identify as being both a man and a woman, somewhere in between or as falling completely outside of these categories. While many individuals who identify as non-binary also identify as transgender, not all do. Non-binary can also be used as an umbrella term encompassing identities such as agender, bigender, genderqueer or gender fluid.
Transgender	A person who has a gender identity different from that traditionally associated with sex assigned at birth.

I. Why Gender Affirming Care Matters

Gender affirming care holistically attends to the physical, mental, spiritual, and social health needs of the gender diverse population while affirming an individual's gender identity. It is important for health care professionals to create and preserve an environment conducive to healing, safety and support. According to the National Center for Transgender Equality 2015 Report, thirty-three percent of gender diverse respondents reported unequal treatment because of gender diversity when seeking care.[1] Additionally, twenty-three percent avoided necessary medical care because of fear of mistreatment.[2] Gender diverse patients frequently experience harassment, discrimination, and violence, which results in marginalization and denial of care based on gender identity or expression.[3] According to the Federal Bureau of Investigation, nearly one in five of any type of hate

crime cases is motivated by anti-LGBTQ+ bias.[4] The Trevor Project has reported that eighty-six percent of transgender and non-binary youth say recent debates around anti-trans bills have negatively impacted their mental health; as a result of these policies and debates in the last year, forty-five percent of transgender youth experienced cyberbullying, and nearly one in three reported not feeling safe to go to the doctor or hospital when they were sick or injured.[5] The Journal of the American Medical Association published new research on gender affirming care for transgender and non-binary youth ages thirteen to twenty, finding that "including puberty blockers and gender affirming hormones, was associated with sixty percent lower odds of moderate or severe depression and seventy-three percent lower odds of suicidality over a twelve month follow-up."[6] Having a supportive healthcare setting where gender diverse people feel welcome to seek care is vital for their physical and mental health, especially for youth seeking gender affirming treatment.

The population under attack has grown significantly in the past decade. In 2020, approximately 700,000 people under the age of twenty-five identified as transgender, according to the Williams Institute, a research center at the University of California, Los Angeles.[7] Additionally, there has been a notable increase in the number of people identifying as non-binary.[8] As an unsurprising corollary, there has also been significantly increased demand for gender affirming care.

Outlined below are the current conservative efforts to limit the rights of minor patients seeking gender affirming care, their families and providers; the efforts in California to create a safe haven for those coming to California to obtain gender affirming care; and the legal considerations providers should be considering when treating an out of state minor patient seeking gender affirming care.

II. Attacks from Lawmakers on Transgender Youth Access to Healthcare

Across the United States in recent years, Republican elected officials have targeted transgender youth by implementing bans on gender affirming care in their respective states. As of the writing of this article, there have been eighty-three anti-trans bills passed out of the 560 proposed across the county in 2023.[9] Of those, seventy-nine have been signed into law and four others have passed and awaiting governor signature or veto.[10] These numbers will likely change as legislative sessions continue throughout the year. According to the Human Rights Campaign, twenty states have enacted laws or policies restricting youth access to gender affirming care and, in some cases, imposing penalties on adults for helping minors to access gender affirming care.[11] In addition to the bans already in place, seven more states are currently considering laws or policies banning gender affirming care, including California's neighboring state of Oregon.[12]

These laws are similar to the tactics currently being employed to restrict legal access to abortions. These laws are contrary to what major medical associations support for transgender youth: the World Health Organization, the American Academy of Pediatrics, the American Medical Association, the American Psychological Association, and the Endocrine Society, all support the use of current evidence-based gender affirming care for minors and emphasize the immediate dangers of denying and criminalizing necessary medical care. [13]

A sampling of bills passed in 2023 includes:

- **Arkansas** signed into law SB 199 (now known as the Act 274) which allows a minor (or a representative of a minor) "injured" by a "gender transition procedure" to bring a civil action against the health professional for declaratory or inductive relief, compensatory damages, punitive damages and attorney's fees and costs for up to fifteen years after the patient turns eighteen.[14]
- **Georgia** signed into law SB 140 which prohibits providing hormone replacement therapy and gender affirming surgery to minors.[15] Doctors and health care providers who do not comply could lose their licenses and potentially be exposed to criminal or civil liability.
- **Idaho** signed into law HB 71 which prohibits gender affirming care, a crime punishable by up to ten years in prison.[16] It aligns gender affirming treatments with female genital mutilation ("FGM").[17] FGM is an internationally recognized violation of human rights where a female has her clitoris and other

parts of her vulva removed for non-medically necessary reasons.

- **Indiana** signed into law HB 1569 which prohibits state and federal dollars to be used for gender affirming surgery for prisoners imprisoned in Indiana.[18] Additionally, it passed SB 480 which prohibits a physician or other practitioner from providing or aiding and abetting other providers offering gender affirming procedures to minors.[19]
- **Iowa** signed into law SF 538 (formally SSB 1197) which prohibits all gender transition procedures, including puberty blockers, hormone therapies and other related surgeries for minors.[20]
- **Kentucky's** General Assembly overrode Governor Beshar's veto of SB 150[21] which bans gender affirming puberty blockers, hormones and surgeries for minors, as well as eliminating discussions of gender identity and sexual orientation in schools.[22] On May 3, 2023, the ACLU has filed a lawsuit on behalf of seven Kentucky families arguing the law is unconstitutional under the Fourteenth Amendment and requesting an injunction on the current ban's enforcement while the case progresses.[23]
- **Mississippi** signed into law HB 1125 which creates civil liability and enforcement by the Attorney General of Mississippi for individuals providing, or aiding and abetting gender transition procedures for minors.[24] Additionally, Mississippi signed into law HB 1733 as part of their expending bill disallowing gender affirming care as a business deduction.[25]
- **Montana** has several healthcare specific anti-transgender bills. HB 303, currently awaiting Governor signature, allows health care providers and institutions to refuse to provide care under religious exemption, even when it is medically necessary and in the best interest of the patient.[26] SB 99, signed into law in May 2023, prohibits health care providers from providing puberty blockers, cross-sex hormones, and a variety of surgeries to minors for the purposes of treating gender dysphoria.[27]
- **North Dakota's** HB 1254 would make any surgical procedure "for the purpose of changing or affirming the minor's perception of the minor's sex" a class B felony; it would also make it a class A misdemeanor for any health care provider to "prescribe, dispense, administer, or otherwise supply" puberty blockers or "cross-sex" hormones. A class B felony carries a maximum sentence of ten years in prison and/or a $20,000 fine. A class A misdemeanor carries a maximum sentence of 360 days in prison and/or a $3,000 fine.[28]
- **Oklahoma**[29] passed SB 613 which bans the use of any medications or surgical procedures for the purpose of gender affirming care to minors with penalties for violation including felony charges, license revocation and civil actions, which can be filed by a parent or guardian.[30] Notably, charges can be brought until the patient is forty-five years old. [31]
- **South Dakota** signed into law HB 1080 which bans certain kinds of health care for transgender youth, including puberty blockers, "cross-sex" hormones and certain surgeries.[32] Violating the law could result in practitioners loss of license and civil penalties.[33]
- **Tennessee's** SB 1 bans minors from accessing gender affirming care such as puberty blockers and hormone therapies, in addition to surgeries.[34] People who received the treatments as minors would also be able to sue parents, guardians and physicians for authorizing the care under a thirty-year statute of limitations under the legislation.[35] The Justice Department filed a complaint alleging SB 1 violates the minor's Fourteenth Amendment's Equal Protection Clause and seeking an immediate injunction order to prevent the law from going into effect.[36]
- **Utah's** SB 16 was the first law to ban gender affirming care to minors.[37] Notably, it allows patients in medical malpractice suits to retroactively withdraw consent.[38]
- **West Virginia's** HB 2007 prohibits gender affirming care to minors. [39]

Alabama, Arkansas, Florida and Texas also passed laws limiting access to gender affirming care. Although in each case, either a court injunction or ruling has been issued to prevent their enforcement.

- **Alabama's** SB 184 prohibits all gender affirming care, including puberty blockers, hormone therapy, and surgical intervention. It makes it a felony to "engage or cause" a minor to receive these treatments, punishable up to ten years in prison.[40] The Justice

Department, on behalf of four Alabama parents, filed a complaint challenging the law as violation of the Fourteenth Amendment's Equal Protection Clause.[41] An Alabama federal district court judge issued a ruling blocking enforcement of the law while legal challenge to the law proceeds.[42] Noteworthy, during the appeal process up to the Eleventh Circuit, defendants, including Alabama Attorney General Steve Marshall, have requested medical and mental health records of the minors involved in the lawsuit.[43] In response, the plaintiffs argued that the records are protected and confidential and disclosing such records could potentially lead to criminal charges.[44] Over twenty medical organizations have filed briefs in support of the plaintiff's claims, including the American Academy of Pediatrics and the American Academy of Child and Adolescent Psychiatry.[45] U.S. District Judge Liles Burke ruled that the records are relevant to the case since the plaintiffs have argued that the treatments their children receive are medically necessary.[46] Both parties previously entered into a protective order that restricts the use and access to the records.[47] While the injunction remains in place a ruling has not been issued to date.[48]

- **Arkansas's** HB 1570 was struck down and permanently enjoined by a federal district court judge.[49] HB 1570 was similar to Alabama's anti-transgender bill on prohibition but differed in punishment by limiting enforcement to licensing discipline for providers.[50] The lawsuit against the ban was brought last year by the American Civil Liberties Union.[51] The suit argued that the ban threatened the health and well-being of transgender youth in Arkansas and was unconstitutional, violating transgender people's rights to equal protection, interfering with parents' rights to make appropriate medical decisions for their children and infringing on doctors' First Amendment rights to refer their patients for medical treatments.[52] The court held that plaintiffs prevailed on all their claims.
- **Florida** signed into law SB 254 which criminalized doctors providing gender affirming care to minors.[53] If found to have violated the law, doctors could spend up to five years in prison.[54] Further, it allows a non-supportive parent to have preferential treatment in child custody disputes in divorce proceedings if the other parent is supportive of their transgender child receiving gender affirming care.[55] Additionally, it imposes new requirements for adults, including written consent for procedures and that the care must be provided in person.[56] Thereafter, a group of Florida families filed a lawsuit challenging the law.[57] On June 6, 2023, a federal court issued a preliminary injunction halting the enforcement of the ban stating that the ban is unconstitutional.[58]
- **Texas** has the highest number of proposed anti-transgender bills, even though it has yet to have actually passed any healthcare specific anti-transgender legislation.[59] In February 2023, Texas Governor Greg Abbott and Attorney General Ken Paxton declared gender affirming care to be a form of child abuse and directed the Texas Department of Family and Protective Services to investigate families simply for supporting their children obtaining gender affirming care.[60] The ACLU, the ACLU of Texas and Lambda Legal filed two legal challenges against the directive and the investigations.[61] In the first challenge, *Doe v. Abbott*, the Texas Supreme Court affirmed that the governor's directive held no legal weight and blocked the families in the case from being investigated.[62] The second lawsuit was filed by the ACLU on behalf of three families who were targeted and investigated by the Department of Family Protective Services (the Texas state agency charged with investigating child abuse cases) based solely on the allegation that their children were receiving care for the treatment of gender dysphoria. [63] PFLAG, which provides peer support, education, and advocacy for LGBTQ+ people and their parents, guardians, and allies, joined the lawsuit.[64] A Texas state court granted relief for all families previously targeted for investigation and expanded that relief to all PFLAG members in Texas.[65]

III. Attacks from Lawmakers on the LGBTQ+ Community Beyond Healthcare

All of this coincides with a proliferation number of other anti-LGBTQ+ discriminatory bills like:

- Bathroom bills, which restrict access to bathrooms or lockers rooms based on

sex assigned at birth; or

- "Don't say gay" bill from Florida that would prohibit classroom discussion on sexual orientation or gender identity; or
- Drag bans, including a bill from Arizona, which would redefine venues that host gender non-conforming entertainment as "adult-oriented" businesses; or
- Pronoun bans, where nine states this year have restricted the [66]use of preferred pronouns in school; or
- Defining "sex" efforts in Montana, Tennessee and Kansas to narrowly defined who is "female" and who is "male" in state law[67]; or
- Sports bans, where at least twenty-one states exclude transgender women and girls from participating in sports consistent with their gender identity.[68] Five of those states extend the bans to transgender boys.[69]

Moreover, there are national efforts currently underway to limit the rights of LGBTQ+ individuals. The Women's Bill of Rights introduced in February that is currently referred to the House Committee on the Judiciary will erase transgender recognition by the federal government, defining sex assigned at birth as an "immutable" definition of man or women, boy or girl.[70] The My Child, My Choice Act introduced in January and currently referred to the House Committee on Education and the Workforce, seeks to prohibit federal education funds from being provided to elementary schools that do not require teachers to obtain written parental consent prior to teaching lessons specifically related to gender identity, sexual orientation or transgender studies, and for other purposes.[71]

In all, the attacks by conservative lawmakers are so concerning that a United Nations expert released his conclusions after a visit to the United States that LGBTQ+ persons, particularly LGBTQ+ persons of color, continue to face significant inequality in relation to health, education, employment, and housing, as well as being disproportionately impacted by violence.[72] He stated "[t]he evidence shows that, without exception, these actions [of the states mentioned above] rely on prejudiced and stigmatizing views of LGBTQ+ persons, in particular transgender children and youth, and seek to leverage their lives as props for political profit."[73]

In addition to the attacks made by lawmakers are the threats and acts of violence targeting children's' hospitals offering gender affirming surgeries. For example, Boston Children's Hospital has received at least three bomb threats in the past year.[74] Boston Children's Hospital is home to the Gender Multispecialty Service (GeMS) program, the first major healthcare program in the United States to focus on gender-diverse and transgender adolescents,[75] and it has become a prime target for anti-LGBTQ+ far right agitators who oppose gender affirming healthcare services.

IV. Transgender and Gender Non-Binary Refuge - Senate Bill 107

On January 1, 2023, Senate Bill 107 ("SB 107") became law in California.[76] SB 107 was written to provide refuge for transgender adolescents and their families seeking care in California. Similar to the way California enacted legislation to protect patients seeking abortion care and providers providing abortion care, SB 107 was designed to make California a safe haven for those seeking gender affirming care. Specifically, SB 107 offers protections in three key ways:

1. Prohibits children from being separated (while in California) from their families who allow their child to receive gender affirming health care.
2. Bars California from complying with out of state subpoenas used to criminalize individuals or families who support their children coming to California to receive gender affirming care.
3. Prevents law enforcement from participating in the arrest or extradition of an individual that is being criminalized for allowing a person to receive or provide gender affirming health care in California.[77]

SB 107 was designed so that California could be a sanctuary state where transgender youth and their families can safely come to California to receive the care they need. While here in California, minors and their families can feel secure in obtaining gender affirming treatment without fear of facing criminal prosecution or having their children taken away. Regardless of its intention, SB 107 has limits and there are many legal implications to consider when someone from out of state comes to California to seek care then returns to their home state, especially when their home state bans such care.

In addition, SB 107 is being

challenged, including most recently by non-profit parental rights group Our Watch who sued California Attorney General Rob Bonta in March 2023.[78] In its complaint, Our Watch argues the law is unconstitutional and interferes with parental rights. The lawsuit was filed by Advocates for Faith & Freedom, a small non-profit law firm specializing in religious freedom issues. No hearing date has been set yet on Our Watch's suit, which was filed in Riverside County Superior Court.[79]

IV. Legal Considerations for Out-of-State Minors Seeking Gender Affirming Care in California

The obvious considerations for providers of minors seeking gender affirming care in California is whether they will be vulnerable to legal action when they return to their home state. As mentioned above, several states have released directives and passed laws imposing criminal and civil penalties to parents and providers. Standard practices, like requesting medical records from primary care providers, should be considered in the perspective of safety for the patients, their families and their home state providers.

Theoretically, when a prosecutor in another state which bans minors from obtaining gender affirming care, the prosecutor will need to collect evidence to support a charge of violating a passed law criminalizing gender affirming healthcare. Therefore, they may serve a subpoena requesting medical records from hospitals and providers in California. Although SB 107 prevents California from complying with out of state subpoenas used to criminalize individuals or families who support their children coming to California to receive gender affirming care, most subpoenas do not declare what charges are being brought against the defendant. Therefore, it is imperative to flag criminal subpoenas from out of state which requests medical records of minors who received gender-affirming care.

Because gender affirming care is critical to the wellbeing of transgender youth, the population seeking gender affirming care is growing and more families are coming to California to access care due to the current conservative efforts to limit the rights of minor patients seeking gender affirming care, it is imperative to understand SB 107 and its limits.

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NAVIGATING SUBPOENAS FOR ABORTION RECORDS IN POST-DOBBS CALIFORNIA

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INTRODUCTION

As providers across the United States continue to grapple with the impact of the U.S. Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, California is paving the way to enhance privacy protections for reproductive health data. In an effort to defend health care providers from a barrage of out-of-state inquiries into care that remain legal in California, the California Legislature enacted several laws last fall that restrict a health care provider's ability to disclose medical information relating to abortion services in response to a subpoena or law enforcement request. These new laws aim to enhance existing privacy protections in California relating to abortion care and require health care providers to analyze the interplay between federal law and these "special" health care data protection state laws when responding to subpoenas or law enforcement requests for such information.

This article will provide an overview of existing federal and California laws relating to subpoena and law enforcement requests for abortion care records, and will address how health care providers should incorporate these new reproductive health care privacy laws into their existing subpoena response processes. This article also will provide readers with a step-by-step questionnaire that can be utilized when presented with a request to disclose this type of sensitive information in response to a subpoena or law enforcement request.

FEDERAL LAW – HIPAA

The federal Health Insurance Portability and Accountability Act ("HIPAA") requires health care providers to ensure the privacy and security of their patient's protected health information ("PHI") and includes specific procedures that health care providers must follow when responding to a subpoena or law enforcement request for PHI. Generally, HIPAA only allows health care providers to disclose PHI without a patient authorization in certain circumstances, as described in the statute.[1] HIPAA allows covered entities to respond to requests for disclosures of PHI as part of judicial or administrative proceedings, and these rules apply when covered entities receive a subpoena or law enforcement request that would disclose PHI.[2] In some cases, HIPAA permits health care providers to disclose PHI in response to a court order or subpoena without the patient's authorization; for example, where the requesting party has provided satisfactory assurances that efforts have been made to protect PHI before the covered entity may disclose PHI.[3] HIPAA also requires health care providers to disclose PHI to law enforcement officials, including when such disclosures are required by law, for limited identification and location purposes, and for reporting emergencies. [4]

HIPAA serves as a federal baseline for protecting PHI and is administered and enforced by the Office for Civil Rights ("OCR") within the U.S. Department of Health and Human Services. There are other federal and California laws that health care providers must analyze when processing a subpoena or law

enforcement request for PHI. For example, if a health care provider maintains substance abuse treatment information protected by 42 C.F.R Part 2, the health care provider may only release those records as specifically authorized by a consent from the patient or valid court order. [5] Similarly, if a health care provider maintains mental health information subject to California's Lanterman-Petris-Short Act, any subpoena or law enforcement request for disclosure of such protected mental health information must comply with the specific limitations of that statute. [6]

After the *Dobbs* decision, the OCR published additional guidance for disclosing information relating to reproductive health care. [7] In the guidance, OCR provided examples of when HIPAA permits, but does not require, health care providers to disclose PHI about an individual without the individual's authorization. Those instances include responding to a subpoena, but only when certain conditions have been satisfied. [8] OCR also recently published a notice of proposed rulemaking to clarify the permitted uses and disclosures of PHI relating to reproductive health care. [9]

CALIFORNIA LAW

The Confidentiality of Medical Information Act ("CMIA") is California's version of HIPAA and protects patient medical information that is maintained by health care providers. Like HIPAA, CMIA prohibits health care providers from disclosing medical information about a patient without a patient authorization, except as permitted by law. [10] CMIA requires health care providers to disclose medical information that is compelled by a court order, a subpoena for a court or administrative agency action, or a subpoena for an arbitration. [11] CMIA also requires health care providers to disclose medical information if the disclosure is compelled by a search warrant lawfully issued by a governmental law enforcement agency. [12] These types of requests are considered compelled disclosures under CMIA and CMIA also includes several categories of permissive disclosures. [13]

California also extends several other protections to reproductive health care information outside of the medical information protected by CMIA. California's Reproductive Privacy Act was initially passed in 2002 and includes a number of reproductive health protections. The Reproductive Privacy Act generally prohibits the state from denying or interfering with a pregnant person's right to choose or obtain an abortion prior to viability of the fetus, or when the abortion is necessary to protect the life or health of the pregnant person. [14]

The California Constitution guarantees a right to privacy, which has been interpreted by California courts to include the right to an abortion as a fundamental right. [15] In 2022, California voters passed Proposition 1, which amended the California Constitution to protect an individual's reproductive freedom as a fundamental right, including the right to choose to have an abortion and to use contraceptives. [16]

Recent Changes to California Law

The California Legislature started enacting reproductive health care protections prior to the Dobbs decision, in order to bolster protection for California patients seeking reproductive health care in the state. Last year, Governor Newsom signed Assembly Bill 2091 into law, which added additional abortion privacy protections to the Reproductive Privacy Act and a new limitation to medical information disclosures under CMIA. AB 2091 amended the Reproductive Privacy Act to provide that a person may not be compelled in any proceeding to identify, or provide information that would identify or that is related to an individual who has sought or obtained an abortion, if the information is being requested based on another state's laws that interfere with a person's right to choose or obtain an abortion, or a foreign penal civil action. [17] AB 2091 added a provision to CMIA which prohibits health care providers from releasing medical information related to an individual seeking or obtaining an abortion in certain circumstances.[18] Health care providers may not release medical information related to an individual seeking an abortion in response to a subpoena or request based on: (1) another state's laws that interfere with a person's rights under California's Reproductive Privacy Act; or (2) a foreign penal civil action.[19] A "foreign penal civil action" means a civil action authorized by the law of a state other than California in which the sole purpose is to punish an offense against the public justice of that state. [20] This restriction on disclosing abortion care information applies to both compelled and permissive disclosures of medical information under CMIA. [21]

Additionally, except as permitted by a lawful subpoena, health care providers may not release medical information to law enforcement that would identify or relate to an individual seeking or obtaining an abortion for either of the following purposes: (1) enforcement of another state's law that would interfere with a person's rights under California's Reproductive Privacy Act; or (2) enforcement of a foreign penal civil action. [22]

TIPS FOR COMPLIANCE AND SUBPOENA RESPONSE CHECKLIST

These changes to California privacy laws will require health care providers to identify whether a subpoena or law enforcement request interferes with a patient's rights under California's Reproductive Privacy Act or relates to enforcement of a foreign penal civil action. Importantly, these changes do not prohibit health care providers from disclosing information relating to abortion services in *all* circumstances. Rather, the new laws prohibit a health care provider from disclosing abortion-related information in a medical record if the underlying purpose of the subpoena or law enforcement request relates to an infringement on an individual's right to seek abortion care (as protected by California's Reproductive Privacy Act), or the enforcement of a civil action in another state. This means that to comply with the statute, health care providers do not need to exclude abortion-related medical information from all subpoena, third-party, or law enforcement requests. Instead, providers need to incorporate a framework into their current subpoena policies to assess whether the subpoena or law enforcement request is seeking abortion-related information for a prohibited purpose.

Health care providers may want to consider enacting technical safeguards in their electronic health record systems to ensure that abortion-related information is separately identified or able to be segregated from the general health record. That way, if a health care provider receives a request for medical information for a purpose that is prohibited by Section 56.108, the provider could consider producing a portion of the medical information in response to the subpoena. In any case, health care providers may want to consider having a way to identify whether a patient's record includes abortion-related services, so that the provider can appropriately scrutinize requests for medical information in accordance with the limitations imposed by Section 56.108.

Below is a checklist of questions that health care providers can incorporate into existing subpoena and law enforcement response policies, which will assist providers in preparing a response to a subpoena for abortion-related services. Note that these checklists are not intended to address all questions relating to a subpoena response, but could be used as a subset of issues to analyze in a response to a subpoena to determine whether portions of a patient's medical record can be produced.

Subpoena Response – *These questions should be incorporated into a health care provider's policy relating to responding to subpoena and third-party requests for medical information.*

1. Does the patient's medical record contain information related to an individual seeking or obtaining an abortion?
    a. If no, then the request does not relate to abortion-related services and the health care provider should follow its standard process for responding to subpoenas.
    b. If yes, is this a subpoena based on another state's law that interferes with the patient's right to obtain an abortion? (Note that it may be challenging to determine the answer to this question, as the source of other state law restrictions on abortion will vary. When evaluating these requests, providers should consider the state where the request originates, the state agency requesting the information, and the status of reproductive care access in the state).
        i. If yes, then the subpoena for records relating to abortion services may be denied based on Cal. Civ. Code § 56.108(a).
        ii. If no, is this a subpoena or request for records based on a civil action authorized by the law of a state other than California to punish an offense in that state?
            1. If yes, then the subpoena for records relating to abortion services may be denied based on Cal. Civ. Code § 56.108(a)

2. If no, then the records relating to abortion services may be released, as long as the subpoena otherwise complies with HIPAA and CMIA's rules relating to subpoena responses.

Law Enforcement Responses – *These questions should be incorporated into a health care provider's policy relating to responding to law enforcement requests for medical information.*

1. Does the patient's medical record identify an individual or relate to an individual seeking or obtaining an abortion?
   a. If no, then the request does not relate to abortion-related services and the health care provider should follow its standard process for responding to subpoenas.
   b. If yes, is the law enforcement request based on enforcement of another state's law that interferes with the patient's right to obtain an abortion? (Note that it may be challenging to determine the answer to this question, as the source of other state law restrictions on abortion will vary. When evaluating these requests, providers should consider the state where the request originates, the state agency requesting the information, and the status of reproductive care access in the state).
      i. If yes, then the request for records relating to abortion services may be denied based on Cal. Civ. Code § 56.108(b)(1).
      ii. If no, is this a request based on enforcement of a civil action authorized by the law of a state other than California to punish an offense in that state?
         1. If yes, then the request for records relating to abortion services may be denied based on Cal. Civ. Code § 56.108(b)(2).
         2. If no, then the records relating to abortion services may be released, as long as the request otherwise complies with HIPAA and CMIA's rules relating to responses to law enforcement requests for medical information.

END NOTES

1 *See* 45 C.F.R. § 164.508.

2 *See* 45 C.F.R. § 164.512(a).

3 *See* 45 C.F.R. § 164.512(e)(1)(ii) (allowing disclosure in response to a subpoena that is not accompanied by a court order if satisfactory assurances are made that either efforts have been made to ensure the patient has been given notice of the request, or a qualified protective order is in place); ***see also*** 45 C.F.R. § 164.512(e)(1)(i) (allowing disclosure of PHI in response to a court order, as long as the covered entity only discloses the PHI expressly authorized by the order).

4 *See* 45 C.F.R. § 164.512(f).

5 *See* 42 C.F.R. §§ 2.31; 2.61(a).

6 *See* Cal. Welf. & Inst. Code § 5328(a)(6) (authorizing disclosure of information to the courts, as necessary to the administration of justice), (a)(16), (a)(18) (authorizing certain disclosures to law enforcement agencies).

7 *See* U.S. Department of Health and Human Services, Office for Civil Rights, "HIPAA Privacy Rule and Disclosures of Information Relating to Reproductive Health Care," https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/phi-reproductive-health/index.html.

8 *Id.* In the guidance, OCR reiterated that these provisions cannot be used to make disclosures to law enforcement officials that are restricted by 45 CFR 164.512(f). See 45 CFR 164.512(e)(2).

9 *See* FR Doc. 2023-07517 Filed April 12, 2023 (to be published in the Federal Register on April 17, 2023).

10 *See* Cal. Civ. Code § 56.10.

11 Cal. Civ. Code § 56.10(a)(b)(1), (b)(3), (b(5).

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13 *See* Cal. Civ. Code § 56.10(c).

14 Cal. Health & Safety Code § 123466(a).

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16 Cal. Const., Art. I § 1.1; Proposition 1, Resolution Ch. 97, 2022.

17 Cal. Health & Safety Code § 123466(b).

18 Cal. Civ. Code § 56.108.

19 Cal. Civ. Code § 56.108(a).

20 Cal. Code Civ. Proc. § 2029.200(b).

21 *See* Cal. Civ. Code § 56.10(b), (c).

22 Cal. Civ. Code § 56.108(b).

CALIFORNIA SELF-REFERRAL LAW (PORA): STILL ALIVE AND KICKING

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In the flurry of excitement over the new federal anti-kickback safe harbors and self-referral ("Stark law") exceptions that allow providers greater flexibility, including opening the door to many value-based arrangements, it can be easy to forget that California's anti-kickback and self-referral laws have not been updated. In fact, California's self-referral law (the Physician Ownership and Referral Act, or "PORA")[1] contains several traps for the unwary, which this article will discuss.

OVERVIEW OF PORA

To place it in context, PORA is comparable to the Stark law, as both target "self-referrals," or referrals made to a provider or entity in which the referring physician[2] has some sort of financial interest. There are, however, some key differences. PORA applies to a narrower range of services, because it does not include all inpatient and outpatient hospital services nor all home health agency services; however, while the Stark law applies only to Medicare referrals, PORA applies to all payors, including self-pay patients. PORA, as with the Stark law, applies to both ownership and compensation arrangements, and to both direct and indirect arrangements. Also, while the Stark law is a civil statute, a violation of PORA is a misdemeanor.

Fortunately for providers, two of the biggest Stark law headaches (*i.e.*, wrestling with the myriad direct and indirect financial relationships of a typical hospital, and applying the labyrinthine definition of "group practice" and the tricky "in-office ancillary services" exception to an actual medical group) are largely avoided in PORA, which has broad exceptions for referrals to a hospital and for referrals within a practice.

The broad exception for referrals to a hospital protects referrals to any "health facility" (including a hospital), and also protects referrals to "any facility owned or leased" by a health facility "if the recipient of the referral does not compensate the licensee for the patient referral, and any equipment lease arrangement between the licensee and the referral recipient ... [satisfies certain] requirements...."[3] The broad exception for referrals within a practice states, in relevant part, that the referral prohibition "... shall not apply to any service for a specific patient that is performed within, or goods that are supplied by, a licensee's office, or the office of a group practice."[4]

While these two broad PORA exceptions can be a blessing when needing to satisfy an exception, PORA can still mystify health care providers (and their lawyers) when it must be applied to more complex or unusual arrangements, because no regulations have been issued to implement or interpret PORA, and there is little sub-regulatory guidance or case law[5] to assist with interpreting any statutory ambiguity that may be encountered.

LACK OF DEFINITIONS OR GUIDANCE FOR PORA

Because PORA lacks regulations, or much other guidance interpreting its application, it is uncertain how

it should be applied to certain arrangements. For example, if a group of referring physicians own a management company that provides turnkey management services to a hospital service line covered by PORA (*e.g.*, diagnostic imaging), then it is uncertain if PORA would be viewed as applying to "referrals" by physician investors solely to the hospital (as would be the case under the Stark law), or also to the management company. Presumably, PORA should be applied to the physicians' referrals to the hospital, because only the hospital is the provider of the diagnostic imaging services. Arguably, the manager is simply a vendor to the hospital, but it is not entirely certain.

Another uncertain aspect of PORA is exactly how it applies to indirect financial relationships. Clearly, PORA extends to such arrangements, because PORA defines "financial interests" that trigger the application of PORA very broadly, stating in relevant part:

> "'financial interest' includes, but is not limited to, any type of ownership interest, debt, loan, lease, compensation, remuneration, discount, rebate, refund, dividend, distribution, subsidy, or other form of direct or indirect payment, whether in money or otherwise, between a licensee and a person or entity to whom the licensee refers a person for a good or service specified in subdivision (a). A ***financial interest also exists if there is an indirect financial relationship*** between a licensee and the referral recipient ***including, but not limited to***, an arrangement ***whereby a licensee has an ownership interest in an entity that leases property to the referral recipient***." (Emphasis added.)[6]

The precise contours of the definition of "financial interest" are uncertain, however, especially given that the definition states that it applies to "indirect" financial relationships, including "but not limited" to cases where physicians own an entity that has a lease with the referral recipient. Accordingly, it is probably prudent to assume a physician-owned management company providing turnkey services to a hospital creates an indirect financial relationship, given that payments would flow from the hospital, to the management company, and then to referring physicians. However, there is another PORA interpretive uncertainty. Although financial relationships triggering the law include indirect relationships, many exceptions are written in a way that makes them appear to apply only to direct relationships between the referring physician and the referral recipient, and thus it is uncertain how they should be applied to indirect arrangements.

For example, the broad "referrals to a hospital" exception (discussed above) protects any referral by a physician to a hospital if the physician "...is not compensated for the patient referral [and]... does not receive any payment ***from the recipient of the referral*** that is based or determined on the number or value of any patient referrals ...." [7] This exception prohibits the referral recipient (presumably, the hospital) from compensating the physician owners for their referrals, or compensating them in a way that is "based or determined on the number or value" of their referrals. Read literally, the hospital would not be compensating the physician owners of the management company at all (it would just be compensating the management company owned by the physicians), and thus this requirement is satisfied.

On the other hand, maybe this requirement of the "referrals to a hospital" exception is meant more broadly to apply to "downstream" compensation arrangements, *e.g.*, when a hospital pays a company owned by physicians. If so, the question arises as to whether a management fee based on a percentage of revenue generated by the service line is permissible. Arguably, the physicians still are not paid for their referrals by any party (rather, they are investors in a company that is paid for services it provides). In further support of this conclusion, it can be noted that if two physicians were to have equal ownership in the management company, and one physician were to refer twice as many patients for the service line as the other, both physicians would receive the same amount in distributions from the management company, hence neither physician is paid for referrals.

PATIENT DISCLOSURE REQUIREMENTS

The Stark law has a very limited patient disclosure requirement, applicable only in the context of the in-office ancillary services exception, and only when furnishing magnetic resonance imaging, computed tomography, or positron emission tomography

services.[8] By contrast, PORA (and its Labor Code counterpart) takes an extremely expansive approach, essentially requiring disclosures of all financial interests to all patients for any "self-interested" referral that is not prohibited by PORA (or its Labor Code counterparts). In other words, if physicians have a financial interest in an entity to which they refer, and the referral is ***permitted*** by PORA, then it must be ***disclosed*** to the patient.

This requirement is explained in recent case law (interpreting the Labor Code counterpart to PORA): "*Banerjee* argues that a physician's compliance with section 139.3(e) for a given patient referral must be interpreted as an exception to, or as excusing the physician's noncompliance with, section 139.3(a) for the same referral because the two statutes are 'in complete conflict' and cannot otherwise be reconciled. The statutes are not in conflict. Section 139.3(a) prohibits a physician from making a financially interested referral of a patient for *services specified* in section 139.3(a), if the services are to be paid pursuant to the workers' compensation system (section 3200 et. seq.). That is, section 139.3(a) prohibits a physician from making a financially interested patient referral, but only for the services specified in section 139.3(a). ***In contrast, the written patient disclosure requirement of section 139.3(e) applies to all financially interested patient referrals, regardless of whether the services for which the patient is referred are specified in section 139.3(a).*** In addition, section 139.3(a) applies 'notwithstanding any other law,' which includes section 139.3(e)."[9]

The same decision also offers some guidance on how to apply this requirement: "A physician may comply with section 139.3(e) by disclosing to the patient in writing at the time of the referral that the physician 'has a financial interest' in the referred or consulted organization. (§ 139.3(e).) ***Nothing in section 139.3(e) requires the physician to disclose the precise nature or extent of the financial interest. In addition, the disclosure of details concerning the financial interest is unnecessary to inform the patient that the physician has a conflict of interest in the referral.*** If the physician's financial interest disclosure form states that the physician has 'a financial interest' in the organization referred or consulted, the physician will have complied with (section 139.3(e))."[10]

MEDICAL FOUNDATIONS

A number of large hospital systems throughout California maintain relationships with medical groups by way of the systems' affiliated medical foundations, which operate clinics exempt from licensure under Health & Safety Code section 1206(l) (referred to herein as "medical foundations" or simply "foundations"). The foundation typically compensates the medical group for services provided to the foundation's patients, likely creating a "financial interest" between the medical group's physicians and the foundation (and possibly the hospital) within the meaning of PORA, and the foundations (or affiliated hospitals) typically offer certain PORA-covered services, like clinical laboratory services and diagnostic imaging. These commonplace arrangements pose particular analytical difficulties under PORA, which does not offer an exception that is necessarily a close fit for such arrangements.

The most obvious choice for an exception for medical foundations appears in Business and Professions Code section 650.02(d), which refers specifically to referrals by physicians to medical foundations, but some of its requirements may be overly restrictive for many foundations. It applies to referrals by licensees to "a nonprofit corporation that provides physician services pursuant to subdivision (*l*) of section 1206 of the Health and Safety Code if the nonprofit corporation is controlled through membership by one or more health facilities or health facility systems...." Notably, the exception also requires that "the amount of compensation or other transfer of funds from the health facility or nonprofit corporation to the licensee is *fixed annually*, except for adjustments caused by physicians joining or leaving the groups during the year, and is not based on the number of persons utilizing [PORA-covered services]."[11]

This exception for medical foundations applies when the foundation's members include a health facility, such as a hospital, and does not apply when the compensation depends on the volume of patients receiving services. Many arrangements between medical groups and foundations will satisfy these requirements. The "fixed annually" requirement, however, poses an analytical challenge because many professional services

arrangements between medical groups and the foundations do provide for payment in an amount that fluctuates based on the volume of services. In the Stark context, many exceptions contain a comparable requirement that compensation be "set in advance," and CMS has made clear in regulations and commentary this requirement is satisfied even if the compensation under the arrangement is based on a formula that depends on productivity, such as wRVU- or hours-based compensation or bonuses, so long as the *formula* is set in advance. [12] In the absence of guidance or regulations, it is unclear whether this PORA exception similarly accommodates arrangements involving a formula, not a set amount of payment. The specific reference to "adjustments caused by physicians joining or leaving the groups during the year" potentially suggests that the use of a formula is limited to these circumstances, and exact dollar amount should otherwise be "fixed" in order for the medical foundation exception to apply.

Another exception to PORA may be available to protect payment arrangements from medical foundations to physicians. For instance, the widely-used exception for referrals to hospitals (discussed above) allows referrals to "any facility owned or leased by a health facility" as well as referrals to "any organization that owns or leases a health facility." [13] These may apply where a foundation's sole member is a hospital or other health facility, as is the case for many foundations across California. In both cases, however, the exception would require the hospital to own or lease the foundation, which is not technically true in the case of a nonprofit organization like a medical foundation. On the other hand, a hospital that acts as the sole corporate member of such an organization, and the resulting control of the organization, are the functional equivalent to ownership and arguably should be treated as such. Again, in the absence of guidance or regulation, it is unclear whether the statute is meant to accommodate this reading.

Another exception to PORA may fit for some medical foundations, depending on the specifics of their arrangements with physicians: under Business & Professions Code section 650.02(b)(6), referrals can be made pursuant to a personal services arrangement between a licensee and the recipient of the referral (such as the foundation). The requirements for the personal services arrangement align with many of the same requirements in the comparable Stark exception. For instance, the agreement must be in a signed writing; it must specify "all services to be provided by the licensee;" the "aggregate services contracted for [cannot] exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;" its term must be for at least one year; the compensation must be set in advance, at or below fair market value, and "not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties;" and the services cannot "involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law." The patient must also receive a written notice regarding the personal services arrangement.

The exception is arguably applicable to the typical professional services arrangement between a medical group and a foundation. Even though the exception, on its face, appears to apply only to agreements with individual physicians (or their family members), a medical group arguably should be able to "stand in the shoes" of licensees who are members of or provide services by way of employment or contract with the group. And while there is no guidance on what it means for compensation terms to be "set in advance" for the purpose of this exception, it would appear that the language is even more flexible than the "fixed annually" requirement applicable to the exception for medical foundations set forth in Business and Professions Code section 650.02(d), and that formulas for compensation based on productivity or hours would fit within the exception. Without further guidance, regulation, or case law, however, it is uncertain whether a foundation's professional services agreement with a medical group necessarily fits within this exception to PORA.

Finally, PORA contains an exception for "any service for a specific patient that is performed within, or goods that are supplied by, a licensee's office, or the office of a group practice." The statute also provides, "the provisions of Section 650.01 shall not alter, limit, or expand a licensee's ability to deliver, or to

direct or supervise the delivery of, in-office goods or services according to the laws, rules, and regulations governing his or her scope of practice."[14] Where the physicians who staff the foundation's clinics do *not* refer outside of the clinic for services (such as PORA-covered services provided by a hospital), this exception may apply such that referrals are permitted notwithstanding the foundation's financial relationship with the medical group. This depends on whether such services are actually performed within the "office of a group practice," which is defined under PORA as "an office or offices in which two or more licensees are legally organized as a partnership, professional corporation, or not-for-profit corporation..." subject to certain other requirements similar to the group practice requirements in the Stark law. For instance, the group must bill for substantially all services provided, except where a medical foundation bills for the group's services, and each licensee must "provide substantially the full range of services that the licensee provides" within the group practice. If these conditions are satisfied, the exception may be applicable to a foundation's arrangement with a medical group, though only for referrals within the clinic itself.[15]

VALUE-BASED ARRANGEMENTS

Value-based arrangements have received considerable attention in recent years, especially as recent federal rulemaking created new regulatory exceptions to the Stark law for such arrangements.[16] These exceptions allow parties to come together to form a "value-based enterprise" with goals like coordinating or improving patient care, or improving cost-efficiency.[17] Such arrangements may involve financial risk-sharing, or payment based on achieving quality metrics. When pursuing such a "value-based purpose" and satisfying the attendant requirements, a value-based enterprise can enjoy the protection of a Stark exception that contains significant flexibilities unavailable outside the value-based context. For instance, it is not necessary for all remuneration paid under the auspices of a value-based arrangement to be fair market value.

No such rulemaking or regulation has taken place in California, however, leaving a potential gap between the federal and state self-referral rules. An arrangement carefully structured to fit within one of Stark's value-based exceptions might not fit within any PORA exception. Oftentimes, however, the exception at Business & Professions Code section 650.02(c) will protect licensees making referrals to a hospital or other health facility with which the licensee has partnered to form a value-based enterprise, and given the limited set of PORA-covered services, this may be sufficient for the parties to mitigate risk moving forward.

While PORA's broad exception for referrals to hospitals generally protects licensees making exceptions to hospitals and other health facilities, it also contains a trap for the unwary: it makes clear that such referrals are exempt from PORA's prohibition only if "the recipient of the referral does not compensate the licensee for the patient referral."[18] In some cases, key features of a value-based arrangement could be characterized as a payment to the licensee for a referral. For example, a value-based arrangement designed around early cancer detection might involve payments to physicians who order screening for their patients. If the value-based enterprise compensates a physician each time he or she orders a mammogram for patients falling into certain categories, this per-mammogram payment might be characterized as compensation *for* the patient referral such that the exception is inapplicable. Although there may be policy reasons to encourage physicians and other providers to establish a cancer detection program in this manner, and such a program would likely be permissible under a new Stark exception (if otherwise designed to satisfy the exceptions' requirements), it is unclear whether such a program would be permitted under PORA.

RISK-SHARING ARRANGEMENTS

Another payment arrangement that is commonly used in California, often without special consideration of PORA, is a risk-sharing or risk-pooling arrangement. The typical risk pool is a contractual arrangement between a hospital and an independent practice association ("IPA"), where the hospital is paid for its services by a health plan on a capitated basis, and the IPA's physicians treat enrollees of the same health plan such that the patients' hospital care is covered by those capitated payments to the hospital. The hospital and IPA enter a risk pool arrangement to develop

a target "budget" for hospital care for the entire population, which corresponds to the amount of the capitation payments. After a set time period, the parties review actual utilization and compare it to the budget. If utilization falls below the target amount, the parties share in the "surplus," but if it exceeds the target amount, the parties are financially penalized. In calculating the dollar amount associated with a particular hospital visit or service, the "rates" assigned to the participating hospital may be lower than those assigned to *other* hospitals to which the physicians may make referrals. In this way, the hospital and IPA share or "pool" risk, and the physicians are motivated not only to manage utilization overall, but to make hospital referrals to the partner hospital (to which lower "rates" are assigned) in hopes of earning a larger surplus payment.

These arrangements arguably give the physicians in the IPA a "financial interest" in the hospital to which the physicians make referrals. Under the Stark law, in determining whether an exception applies, it would presumably be necessary to analyze whether the hospital's payments to the physicians under the risk pool arrangement vary with the "volume or value of referrals" to the hospital. This language appears throughout many of the Stark law's exceptions (including the ever-popular exception for personal services arrangements, which appears in 42 CFR 411.357(d)) and reinforces the notion that physicians should not be financially motivated to refer certain business to hospitals (or other providers of designated health services). Arguably, the arrangements take into account the volume or value of referrals by the physicians to hospitals, because the physicians earn a greater surplus payment if they make fewer referrals overall and drive any referrals to the participating hospital. Though this once posed an analytical challenge under the Stark law, CMS amended the Stark regulations in 2020 to state that an arrangement *only* varies with the "volume or value of referrals" if the equation "used to calculate the physician's… compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's… compensation that positively correlates with the number or value of the physician's referrals to the entity."[19] Thanks to this amendment, it is more clear that a risk pool arrangement *could* fall within a Stark exception that applies only when payment under the arrangement does not vary with the "volume or value of referrals." Notably, the Stark regulations also include an express exception for risk pool payments, found at 42 C.F.R. section 411.357(n).

PORA does not contain an exception that expressly applies to risk pool arrangements, nor do we have commentary or rulemaking comparable to what CMS has provided presenting the view that formula-based payments are only problematic if they are expressly based on referrals. That said, PORA's restrictions are not as broad as Stark's in that it does not apply the "volume or value" prohibition widely across its exceptions. Moreover, two exceptions which do not incorporate that concept are potentially applicable to many risk-sharing arrangements. First, the exception for referrals to any "health facility" (such as a hospital), as well as referrals to "any facility owned or leased" by a health facility "if the recipient of the referral does not compensate the licensee for the patient referral," likely protects referrals to a hospital that shares risk with an IPA pursuant to a risk pool.[20] Second, PORA does not apply to services provided to enrollees of health plans licensed under the Knox-Keene Act.[21] Together, these exceptions should cover most, if not all, risk pool arrangements.

HOW TO ADDRESS VIOLATIONS

Under the Stark law, amounts received from Medicare in violation of the law must be returned within 60 days of discovery. Likewise, Medicare and Medicaid require providers to report and refund any known overpayments within 60 days of discovery. PORA does not provide any specific directions or guidance on how to address PORA violations that are discovered after the fact. However, PORA states that "[n]o claim for payment shall be presented by an entity to any individual, third party payer, or other entity for a good or service furnished pursuant to a [prohibited referral]" and "[n]o insurer, self-insurer, or other payer shall pay a charge… for any good or service resulting from [a prohibited referral]".

Thus, the question arises as to whether amounts received that may have violated PORA must be repaid, particularly if those amounts were received from Medicare (assuming

there is no Stark law violation) or Medicaid. In determining whether amounts received constitute an "overpayment," one might ask, for example, whether a condition of payment or of coverage for the service includes a requirement that the provider comply with applicable state law. If a self-disclosure is made, it should be framed carefully because PORA is a criminal statute, and consideration should be given to whether it might be appropriate to disclose the situation as being potentially problematic, and potentially warranting refunding the amounts received out of an abundance of caution, but without necessarily admitting to the commission of a crime.

Alternatively, if a PORA violation arises from a financial arrangement that fits within a Stark exception (especially a statutory exception), one might consider whether a federal preemption argument is available based on the position that Congress intended for Medicare to pay these claims notwithstanding the existence of such a financial relationship. One might also consider whether one could successfully argue that although PORA might prohibit presenting the claim or paying the claim, it does not contain an express repayment requirement, and thus one should not be inferred. These are all complex issues, to be navigated with great care, after careful consideration.

APPLICATION TO WORKERS' COMPENSATION

It is worth mentioning that California Labor Code sections 139.3 and 139.31 impose similar restrictions on physician referrals to PORA's, but in the context of workers' compensation programs. The rules are not identical, however; for instance the set of services covered by the Labor Code provisions also include pharmacy goods and outpatient surgeries. (These provisions also contain additional exceptions beyond those in PORA.) Arrangements involving referrals for such services that may be paid through workers' compensation programs should be analyzed under these statutes as well as PORA.

CONCLUSION

When presented with a complex or unusual arrangement, PORA can prove to be a challenge to navigate due to lack of regulations, and little sub-regulatory guidance or case law to assist with interpreting any statutory ambiguity. Further complicating matters, there is no clear process to rectify a violation and no clear path to getting answers. In this article, we have sought to identify aspects of particular arrangements that may complicate the application of PORA and to provide some considerations that may assist in proper compliance with the statute.

END NOTES

1 Technically, PORA applies to all payors except workers' compensation; however, a similar California statute covers workers' compensation patients and this article often uses the term PORA to refer to both sets of laws. The primary self-referral statute, PORA, applies to referrals of laboratory, diagnostic nuclear medicine, radiation oncology, physical therapy, physical rehabilitation, psychometric testing, home infusion therapy, or diagnostic imaging goods or services. *See* Calif. Bus. & Prof. Code § 650.01. The workers' compensation statute is similar but slightly broader and is discussed in more detail later in this article. *See* Labor Code §§ 139.3 and 139.31.

2 The Stark law uses the term "physician" and the California self-referral laws use the term "licensee," but both sets of laws define the terms to apply beyond just physicians, and the scope of licensee covered by the Stark law is slightly different from the California laws. In addition to physicians, the California law applies to nurse practitioners practicing independently under Business & Professions Code sections 2837.103 and 2837.104 (commonly referred to as "103 NPs" and "104 NPs," respectively) as well as certified nurse-midwives; these additional categories were added to the statute in 2020.

3 *See* Cal. Bus. & Prof. Code § 650.02(c)(1).

4 *See* Cal. Bus. & Prof. Code § 650.02(f). (The terms "licensee's office" and "office of a group practice" are both defined in PORA, although it is not always clear which definition applies to any particular medical practice.).

5 The most recent case interpreting PORA (although technically it interprets the workers' compensation statutes, not PORA, the provisions interpreted are nearly identical) is *Banerjee v. Superior Ct. of Riverside County* (2021) 69 Cal.App.5th 1093.

6 Cal. Bus. & Prof. Code § 650.01(b)(2).

7 *See* Cal. Bus. & Prof. Code § 650.02(c)(4) (emphasis added).

8 42 U.S.C. § 1395nn(b)(2).

9 *Banerjee v. Superior Ct.* 69 Cal. App.5th at 1113 (emphasis added).

10 *Banerjee* at 1117 (emphasis added).

11 Cal. Bus. & Prof. Code § 650.02(d).

12 42 C.F.R. § 411.354(d)(1); 69 Fed. Reg. 16053, 16066-67,16125 (2004).

13 The statute contains several other requirements: the recipient of the referral cannot "compensate the licensee for the patient referral," and if there is an equipment lease arrangement between the parties, it must comply with Business & Professions Code section 650.02(b)(2).

14 Cal. Bus. & Prof. Code § 650.02(f).

15 Similarly, another exception under Business and Professions Code section 650.02(h) applies "if a licensee is in the office of a group practice and refers a person for services or goods specified in section 650.01 to" a foundation's clinic, as defined in Health & Safety Code section 1206(*l*). This exception poses many of the same limitations as the exception in section 650.02(f).

16 42 C.F.R. § 411.357(aa).

17 42 C.F.R. § 411.351.

18 Cal. Bus. & Prof. Code § 650.02(c). Note that the exception also requires that "any equipment lease arrangement between the licensee and the referral recipient complies with the requirements of paragraph (2) of subdivision (b)" of section 650.02.

19 42 C.F.R. § 411.354(d)(5).

20 *See* Cal. Bus. & Prof. Code § 650.02(c)(1).

21 Cal. Bus. & Prof. Code § 650.02(i).

LOS ANGELES INITIATIVE SEEKS TO IMPOSE $450,000 CAP ON ANNUAL COMPENSATION OF EXECUTIVES IN HEALTH CARE FACILITIES

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INTRODUCTION

An initiative submitted by the Service Employees International Union United Healthcare Workers West (SEIU-UHW) seeking to limit the annual compensation of health care executives in the city of Los Angeles to $450,000 per year is headed to the ballot in March 2024.[1] Entitled the "Limit Excessive Healthcare Executive Compensation Ordinance," the initiative argues that health care executives should not receive higher compensation than the U.S. President, whose compensation is set by federal statute in 3 U.S.C. § 102 (Compensation of the President).[2] Employing a similar legislative strategy, the initiative proposes a cap on the compensation of health care administrative professionals with executive, managerial or administrative duties, i.e., CEOs, CFOs, executive vice presidents and similar administrators, at privately owned health care facilities located in the city of Los Angeles. Covered health care facilities would include licensed general acute care hospitals, acute psychiatric hospitals, skilled nursing facilities, and even residential care facilities for the elderly. Notably, medical professionals that provide medical services, research, patient care, or other non-administrative services are excluded from the compensation cap. The $450,000 executive compensation cap covers, but is not limited to: (1) salary; (2) paid time off; (3) bonuses; (4) incentive payments; (5) lump-sum cash payments; (6) the cash value of housing, automobiles, parking or similar benefits; (7) the cash value of stock option or awards; (8) the cash value of dependent care or adoption assistance; and (9) payments for deferred compensation or severance.

ERISA

Notably, the initiative excludes any compensation or benefit that is provided under an employee benefit plan covered by the Employee Retirement Income Security Act of 1974, as amended (ERISA). These excluded types of compensation may include health coverage and benefits provided under retirement plans, deferred compensation plans, dependent care flexible spending accounts, and severance plans, so long as they are subject to ERISA. While the initiative attempts to include deferred compensation and the cash value of dependent care, if they are provided under an ERISA plan, they cannot be included in the calculation of compensation. Benefits under ERISA plans are excluded because the initiative would otherwise likely be preempted by ERISA.

ENFORCEMENT

If enacted, the initiative would grant the City Attorney authorization to coordinate and implement enforcement measures. The City Attorney would be able to commence a civil action against violators to recover up to $1,000 for each violation. Each day in which a violation is committed would be treated as a separate violation. In addition, individuals who commit a "willful violation" would be subject to additional penalties in the amount of $1,000 per willful violation. Finally, any "covered executive" who receives "covered compensation" in excess of $450,000 would need to refund the excess amount, plus 10% per annum interest on any excess compensation, and pay any applicable penalties.

REPORTING AND CERTIFICATION REQUIREMENTS

Covered health care facilities would also need to maintain records for at least four years showing compliance with the ordinance. Additionally, such facilities will be required to file a certification and annual report documenting compliance, signed under the penalty of perjury. The ordinance also gives the City Attorney audit authority. Facilities that fail to comply with the reporting requirements would be liable for an amount up to $1,000 for each day a report is delinquent.

PREVIOUS RELATED INITIATIVES

Nearly a decade ago, in 2014, the SEIU-UHW proposed a similar initiative seeking to limit executive compensation for health care officials. However, the California Hospital Association (CHA) and SEIU-UHW reached an agreement in that instance resulting in SEIU-UHW removing the proposed ballot initiative.[3]

More recently, in 2022, the Los Angeles City Council opted to enact the Minimum Wage for Employees Working at Healthcare Facilities Initiative as an ordinance rather than sending the initiative to the ballot for voters to decide.[4] However, pursuant to Section 462 of the Los Angeles City Charter, the CHA and Hospital Association of Southern California (HASC) submitted a referendum petition to the City Council, which required the City Council to repeal the ordinance or place the initiative on the ballot.[5] The initiative will now not take effect unless voters approve the initiative. It is expected to be placed on the 2024 ballot.

FAILED RECENT CHALLENGE

To block the current executive compensation initiative, the HASC and CHA petitioned for a writ of mandate on March 14, 2023, in the Superior Court of California, directing the city of Los Angeles to refrain from taking any action to validate the initiative's petition signatures, place it on the ballot, or otherwise adopt it into law. The hospital associations argued that SEIU-UHW presented false and misleading information to voters by inaccurately listing the U.S. President's salary as $450,000 per year, claiming the U.S. President earns closer to $1.2 million per year after factoring in travel expenses, discretionary funds, and residence in the White House. They concluded that it was internally inconsistent to limit the compensation of health care executives to $450,000 when the initiative's own definition of covered compensation is broader and includes items such as transportation and housing. The court disagreed on April 4, 2023.[6] Relying on the plain text of 3 U.S.C. § 102, the court ruled that the initiative's text was accurate and did not warrant invalidation.[7]

NEXT STEPS

The initiative's signed petition was filed with the Los Angeles City Clerk's office on February 14, 2023. [8] The clerk's office confirmed that the petition had enough valid signatures to be placed on the ballot on June 6, 2023.[9] On June 21, 2023, the City Council voted to place the initiative on the March 5, 2024 ballot, instead of adopting the petition outright as an ordinance.[10]

If voters approve the initiative in March 2024, hospitals, skilled nursing facilities and residential care facilities will need to consult with qualified counsel about how best to structure executive compensation packages to attract and retain qualified executive talent. They will also need to carefully comply with annual reporting obligations, which will require certifications under penalty of perjury.

END NOTES

1 *Los Angeles Initiative to Limit Executive Compensation in Healthcare Cleared to Move Forward*, Service Employees International Union United Healthcare Workers West (Apr. 4, 2023) <https://www.seiu-uhw.org/press/los-angeles-initiative-to-limit-executive-compensation-in-healthcare-cleared-to-move-forward/> (as of June 26, 2023).

2 Limit Excessive Healthcare Executive Compensation Proposed Ordinance <https://www.seiu-uhw.org/wp-content/uploads/2023/01/2022-07-14-L.A.-Limit-Healthcare-Executive-Compensation-450K-Cap.pdf> (as of June 26, 2023).

3 Terhune, *Hospitals and union make deal to avoid ballot measure fight*, Los Angeles Times (May 6, 2014) <https://www.latimes.com/business/la-fi-hospital-labor-deal-20140507-story.html> (as of June 26, 2023).

4 City of Los Angeles Ordinance No. 187566 (the effective date of Ordinance No.187566 has been suspended based on the filing of the referendum petition).

5 Los Angeles Charter and Administrative Code, article IV, § 462; *Referendum Against Ordinance No. 187566 (Healthcare Worker Minimum Age)*, City of Los Angeles Office of the City Clerk (Aug. 11, 2022) <https://wagesla.lacity.org/sites/g/files/wph1941/files/2022-08/Healthcare%20MWO%20City%20Clerk%20Suspension.pdf> (as of June 26, 2023).

6 *California Hospital Association, et al. v. Holly Wolcott*, as Los Angeles City Clerk, et al. (Super. Ct. L.A. County, 2023, No. 00760).

7 *Id.*

8 *Petition Status*, Los Angeles Office of the City Clerk (Mar. 14, 2023) <https://clerk.lacity.gov/clerk-divisions/elections/petition-and-measure-info/petition-status> (as of June 26, 2023).

9 *Id.*

10 *Id.*

SUMMARY OF AB 2338

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Karen serves as Assistant General Counsel at MemorialCare, a hospital, and healthcare system based in Southern California, where she has worked since 2004. Karen's in-house practice is broad-based but includes a significant focus on medical staff and peer review matters, as well as licensing, certification, accreditation, consent, bioethics, privacy and security, and clinical research matters across all MemorialCare entities. Karen began her legal career in 1994 at Weissburg and Aronson (subsequently Foley and Lardner), where her practice focused primarily on medical staff and provider operations for hospitals and long-term care facilities. She later joined the in-house legal department of Catholic Healthcare West (now Dignity Health).

Effective January 1, 2023, new California legislation has clarified the order of priority for health care decisionmakers where patients lack capacity to make such decisions themselves. The legislation also for the first time codifies the right of family members or close friends to make health care decisions for patients without capacity where a legally designated decisionmaker does not exist or is unavailable. Health care providers have long relied on family members and close friends to serve as decision makers, but support for that reliance was based on a decades old court decision, and also reflected the lack of other practical options. Further, while the new statute includes a list of individuals on whom a health care provider may rely for health care decisions for patients lacking capacity, the statutory language clarifies that the list is in no particular order of hierarchy.

Under newly enacted Probate Code Section 4712, if a patient lacks capacity to make health care decisions, the following is the order of priority (in descending order) for recognized decision makers:

1. The patient's surrogate, as communicated to a health care provider and documented in the patient's medical record pursuant to Probate Code Section 4711. [1]
2. An agent designated under an advance health care directive or a power of attorney for health care.
3. A conservator or guardian of the patient having the authority to make health care decisions for the patient.
4. One of the individuals designated below in the absence of one of the legally recognized decisionmakers above:
   a. The spouse or domestic partner of the patient.
   b. An adult child of the patient.
   c. A parent of the patient.
   d. An adult sibling of the patient.
   e. An adult grandchild of the patient.
   f. An adult relative or close personal friend.

A health care provider or designee of a health care facility caring for a patient lacking capacity can select an individual from any of the categories above to serve as the health care decisionmaker as long as that individual is an adult, has demonstrated "special care and concern" for the patient, is familiar with the patient's personal values and beliefs to the extent known, and is reasonably available and willing to serve as the decision maker.

END NOTES

1 Probate Code section 4711 states:

(a) A patient may designate an adult as a surrogate to make health care decisions by personally informing the supervising health care provider or a designee of the health care facility caring for the patient. The designation of a surrogate shall be promptly recorded in the patient's health care record.

(b) Unless the patient specifies a shorter period, a surrogate designation under subdivision (a) is effective only during the course of treatment or illness or during the stay in the health care institution when the surrogate designation is made, or for 60 days, whichever period is shorter.

(c) The expiration of a surrogate designation under subdivision (b) does not affect any role the person designated under subdivision (a) may have in making health care decisions for the patient under any other law or standards of practice.

(d) Notwithstanding Section 4685, if the patient has designated an agent under a power of attorney for health care, the surrogate designated under subdivision (a) has priority over the agent for the period provided in subdivision (b), but the designation of a surrogate does not revoke the designation of an agent unless the patient communicates the intention to revoke in compliance with subdivision (a) of Section 4695.

APPELLATE CASE SUMMARIES

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Acute care hospital needed no additional license or approval to operate drug detoxification center

State ex rel. Rapier v. Encino Hospital Medical Center (Dec. 21, 2022, B302426, B303196) __ Cal.App.5th __ [2022 WL 18396584], modified and ordered published Jan. 20, 2023

For about three years, Encino Hospital Medical Center, a licensed acute care hospital, operated at its facility the Serenity Recovery Center to provide acute drug and alcohol detoxification services. Serenity provided no long-term or outpatient services; rather, its patients received round-the-clock care for three to seven days at the hospital. Most patients arrived with a planned transfer to long-term treatment facilities in place. Serenity obtained patients through in-house marketing programs or referrals from entities such as Aid in Recovery, LLC (AIR), which was Serenity's largest referral source. Serenity did not pay for referrals. Mary Lynn Rapier, a former Serenity employee, filed a *qui tam* action against Encino Hospital, alleging employment claims and violations of the Insurance Frauds Prevention Act based on submission of false insurance claims and illegal patient steering. The California Department of Insurance (CDI) intervened and assumed primary responsibility for prosecuting Rapier's claims. Following a bench trial, the court entered judgment for Encino Hospital. CDI appealed.

The Court of Appeal affirmed. First, the court rejected CDI's argument that Encino Hospital made false insurance claims that misrepresented it was licensed to provide detox services when (according to CDI) the hospital had to obtain additional licensing and authorization to provide those services through Serenity. The court explained that general acute care hospitals such as Encino may provide chemical dependency recovery services as a supplemental service without obtaining a separate chemical dependency recovery hospital license. (Health & Saf. Code, § 1250.3, subd. (d)(1).) The governing statute requires the unit of the hospital operating as a detox center to satisfy the criteria for approval as a chemical dependency recovery unit, but it does not require the hospital to obtain separate approval from the California Department of Public Health. Because Encino Hospital did not need any separate license or approval to operate the Serenity detox service, there was no basis for the CDI's false insurance claims cause of action.

Next, the Court of Appeal rejected the CDI's steering claim argument. It is unlawful to employ individuals for the purpose of procuring patients to receive services that will be the basis of insurance claims. (Ins. Code, § 1817.7.) Here, however, there was no evidence that Serenity or Encino Hospital either received compensation for referring patients to residential treating facilities or paid for referrals to the Serenity program. CDI nonetheless argued that Serenity employed AIR by agreeing to honor the referred patients' predetermined treatment plans, which often included transfers to AIR-affiliated long-term care facilities, in exchange for AIR referral of patients to Serenity. Although

no direct evidence of any such agreement existed, CDI argued that the agreement could be inferred because Serenity failed to follow an alleged universal standard that acute detox facilities should refuse to honor preplanned treatment regimens. However, no evidence supported the existence of any such universal standard; rather, the evidence showed it was common for patients to arrive at detox facilities with a predetermined discharge location for long-term care following detox. Because there was no evidence of remuneration, exchanges, or any agreement that Serenity employed AIR to obtain referrals, the CDI's claim steering failed.

A mandatory elder abuse reporter's absolute statutory immunity applies to making a knowingly false report

Valero v. Spread Your Wings, LLC (Jan. 11, 2023, H049119) __ Cal. App.5th __ [2023 WL 1858882]

Lynda Valero shared custodial care duties of dependent elder Michael Barton with Spread Your Wings employee Sabrina Dellard, who was a mandatory reporter of elder or dependent adult abuse. Valero sued Dellard for malicious prosecution, alleging that Dellard knowingly made a false report to law enforcement that she saw Valero attempt to kill Barton and then coerced Barton to corroborate that false accusation. Valero alleged that she was incarcerated for nearly a month before evidence disproved the charges and they were dismissed. Dellard demurred, asserting absolute statutory immunity under the Elder Abuse and Dependent Adult Civil Protection Act. (Welf. & Inst. Code, § 15634, subd. (a).) After the trial court sustained Dellard's demurrer, Valero appealed from the judgment of dismissal.

The Court of Appeal affirmed, rejecting Valero's argument that a mandatory reporter's absolute immunity under section 15634 applies only to reports of *known or suspected* elder abuse, and not to fabricated and knowingly false reports. The court explained that *non-mandatory* reporters have *qualified immunity* that does not extend to *knowingly false* reports, but *mandatory reporters* have *absolute immunity* for all reports. Additionally, the legislative goal of absolute immunity for mandated reporters was intended to increase the reporting of elder abuse and minimize disincentives to reporting, including the fear of getting sued. Accordingly, Dellard enjoyed absolute immunity even as to an allegedly fabricated report. That immunity extended to her alleged post-reporting conduct (coercing Barton to corroborate the false report) because it occurred close in time to the report and concerned the same alleged incident of elder abuse.

Nursing facility's arbitration agreement is unenforceable against cognitively impaired patient

Algo-Heyres v. Oxnard Manor LP (Feb. 28, 2023, B319601) ___ Cal. App.5th ___ [2023 WL 2257761]

Cornelio Algo-Heyres entered Oxnard Manor, a skilled nursing facility, after suffering a stroke. Although Algo-Heyres struggled to communicate and comprehend things, Oxnard Manor had him sign an arbitration agreement waiving his rights to sue for medical malpractice, elder abuse, and other torts. Algo-Heyres lived at Oxnard Manor for nine years. After he died, his successors sued Oxnard Manor for wrongful death, elder abuse, and other causes of action. Oxnard Manor moved to arbitrate the claims. The trial court denied the motion, ruling that Algo-Heyres likely lacked capacity to understand the arbitration agreement that he executed. Oxnard Manor appealed.

The Court of Appeal affirmed, rejecting 's Oxnard Manor's argument that the trial court improperly required it to prove that Algo-Heyres had the capacity to contract. The court first explained that Oxnard Manor had the burden of proving the existence of an enforceable arbitration agreement. Oxnard Manor pointed out that the Probate Code created a rebuttable presumption of capacity and required an incapacity finding to be supported by evidence of deficits in specific areas. (Prob. Code, §§ 810, 811.) But the Court of Appeal found that the more specific guidelines in Civil Code section 39, subdivision (b), governed the controversy. Section 39 establishes a rebuttable presumption that an individual is of unsound mind if he *cannot* manage his own financial resources or resist fraud and undue influence. Here, the trial court reasonably could have found the section 39 presumption applied because Algo-Heyres was unable to solve complex problems like managing a checking account. And even if section 39 didn't apply, substantial evidence supported the trial court's finding that Algo-Heyres lacked the capacity to understand

the arbitration agreement because he struggled with communication, memory, problem solving, following abstract directions, and executive functioning. Accordingly, Oxnard Manor failed to meet its burden of proving the existence of an enforceable agreement.

MICRA applies when ambulance passengers are injured during a collision

Lopez v. American Medical Response West (Mar. 15, 2023, A161951) __ Cal. App.5th __ [2023 WL 2518511]

Ubaldo and Leobardo Lopez were allegedly injured when the American Medical Response West (AMR) ambulance in which Leobardo was being transported collided with another vehicle. Eleven months later, the Lopezes' counsel sent a settlement demand letter to the AMR's claims administrator. Then, a few days before the accident anniversary, the Lopezes' counsel sent a letter directly to AMR stating it constituted notice of the Lopezes' intent to file a lawsuit under Code of Civil Procedure section 364. Eleven weeks later (about 14 months after the accident), the Lopezes' filed a complaint alleging motor vehicle and medical negligence causes of action. AMR moved for summary judgment based on the one-year MICRA statute of limitations (Code Civ. Proc., § 340.5). The trial court found that MICRA applied based on declarations from the emergency medical technicians establishing their EMT certification at the time of the accident. The court treated the initial settlement demand letter as a notice of intent to sue under section 364, so the second letter did not toll the limitations period. The court concluded the lawsuit was untimely and granted summary judgment. The Lopezes appealed.

The Court of Appeal affirmed. First, the court held that the EMTs' declarations established their certification at the time of the accident, so there was no reason for them to submit actual certificates. The court then held that, under *Flores v. Presbyterian Intercommunity Hospital* (2016) 63 Cal.4th 75 and *Canister v. Emergency Ambulance Service, Inc.* (2008) 160 Cal.App.4th 388, transporting a patient by ambulance counts as providing "professional services" under section 340.5. Here, Lopezes' injuries resulted from AMR's alleged negligence in the " 'use or maintenance of equipment . . . integrally related to [plaintiff Leobardo's] medical diagnosis and treatment.' " The court explained that MICRA applies to all injuries resulting from professional medical negligence regardless whether an injured party was receiving medical treatment, so it was immaterial that Ubaldo was not a patient. Finally, the court rejected the Lopezes' argument that their second letter tolled the statute of limitations. The Lopezes' initial settlement demand letter adequately explained the legal basis of their claim against AMR, including details of their alleged injuries. That first letter therefore constituted a section 364 notice of intent to sue, meaning the Lopezes were not permitted to toll the limitations period by sending a second letter.

Plaintiffs suing public entities for medical negligence must meet both Government Claims Act and MICRA deadlines

Carrillo v. County of Santa Clara (Mar. 13, 2023, B322810) ___ Cal. App.5th ___ [2023 WL 2469717]

A nurse for Santa Clara County's Department of Corrections popped a blister on Emilio Carrillo's foot over his objection while he was forcibly detained. Within three days, the wound became infected. Carrillo developed gangrene, became febrile, and went into septic shock. Doctors amputated his foot later that month. Four months later, Carrillo was advised to pursue legal action while visiting the Mexican Consulate for immigration advice. Carrillo waited two months, then filed a claim with the County for negligence, which was rejected the next month. One day shy of six months from the rejection—and 13 months after his foot was amputated—Carrillo sued the County. The County demurred, citing MICRA's one-year statute of limitations. The trial court sustained the County's demurrer and entered a judgment of dismissal. Carrillo appealed.

The Court of Appeal affirmed. Under the Government Claims Act, suits against public entities must be filed within six months after the government rejects the claim. (Gov. Code, § 945.6, subd. (a)(1).) In addition, under MICRA, a plaintiff alleging medical negligence must sue within three years after the injury or one year after the plaintiff knew or should have known of the injury, whichever is earlier. (Code Civ. Proc., § 340.5.) Relying on *Roberts v. County of Los Angeles* (2009) 175 Cal.App.4th 474, 481, Carrillo argued there is always a three-year limitations

period when both the Claims Act and MICRA apply. The court disagreed, construing a statement in *Roberts* about the MICRA three-year period being an "outer limit" for lawsuits against public healthcare providers as meaning that plaintiffs must comply with both the Claims Act and MICRA. Here, MICRA's one-year statute of limitations barred Carrillo's claim because he knew of the nurse's unauthorized blister treatment and his consequent foot amputation, yet he failed to plead specific facts showing that he could not have discovered a connection between those events with reasonable diligence.

Doctor's irregular prescription of controlled substances to family member is good cause for disclosure of family member's private medical information

Kirchmeyer v. Helios Psychiatry Inc. (Feb. 14, 2023, A165128) ___ Cal. App.5th ___ [2023 WL 2518258]

When a patient complained to the Medical Board of California (Board) that Dr. Jennifer Dore—a certified psychiatrist and surgeon—inappropriately prescribed controlled substances, the Board opened an investigation into Dore and her practice. After finding an irregular prescription of Adderall and Klonopin (both controlled substances) to a family member employed by her medical practice, the Board served Dore with an investigative subpoena for the family member's medical records. Dore refused to produce the records. The Board filed in the trial court a petition to compel Dore and her practice to comply with the subpoena and other interrogatories. Dore opposed the petition. The trial court granted the petition. Dore and her practice appealed.

The Court of Appeal affirmed. First, it held that the Board provided sufficient evidence showing that it had compelling interest in reviewing the medical records. The Board's expert declaration explained that treating family members is traditionally outside the scope of standard medical care. Here it was highly unlikely that extenuating circumstances (like an emergency) justified such care. Second, the court held that the Board produced sufficient evidence to support a finding that the family member's records were relevant and material to the Board's investigation, which was narrowly crafted to exclude immaterial records. Moreover, the trial court's failure to make factual determinations was not error because the Board was not obligated to prove wrongdoing. Additionally, the court rejected Dore's claim that the Board's expert declaration should have addressed how often other physicians would have issued similar prescriptions. Last, the court distinguished *Grafilo v. Wolfsohn* (2019) 33 Cal.App.5th 1024, by noting that this case began with a patient complaint (as opposed to one by a third party), the expert declaration described a deviation from the standard of care, and the subpoena was not a fishing expedition.

DHCS has no mandatory duty to "deem audited" any unaudited cost reports and data after three years

Crestwood Behavioral Health, Inc. v. Baass (May 1, 2023, C094882) __ Cal.App.5th __ [2023 WL 3166593]

Some skilled nursing facilities serving Medi-Cal beneficiaries may provide special treatment program (STP) services to patients with chronic psychiatric impairments, for which they receive reimbursement from the Department of Health Care Services based on days of care and type of services provided. Under the Quality and Accountability Supplemental Payment System (QASP), the Department may authorize supplemental payments to facilities meeting certain performance standards, using audited bed days to calculate payment amounts. However, because the Department does not audit STP days, they are not included in QASP calculations. Crestwood Behavioral Health and other facilities providing STP services petitioned for administrative writ relief mandating the Department to include STP days in QASP calculations, which they alleged would result in recovering millions of dollars in QASP payments. The trial court denied writ relief, and the facilities appealed.

The Court of Appeal affirmed, holding that appellants failed to identify an appropriate basis for writ relief. The court explained that Welfare and Institutions Code, section 14170, subdivision (a)(1), which requires the Department to implement an auditing system, does not impose a mandatory or ministerial duty on the Department to "deem audited" the unaudited cost reports and data after three years. Rather, the section vests the Department with discretion to decide which cost reports and data to audit and limits its discretion

by providing that reports and data shall be considered true and correct *unless* audited or reviewed within three years. The Department was not required to take any particular action with respect to the cost reports and data, so writ relief could not be granted to compel the performance of a mandatory, ministerial act. The facilities also failed to demonstrate any abuse of discretion by the Department, because it could reasonably exercise discretion to decline to audit STP days due to its limited resources, and could not exercise discretion to include unaudited STP days in the QASP calculations without violating the State Plan.

Hospital's failure to disclose an ER fee supports a claim under the Consumer Legal Remedies Act

Naranjo v. Doctors Medical Center of Modesto, Inc. (2023) 90 Cal.App.5th 1193

After receiving a bill for emergency medical treatment at Doctors Medical Center of Modesto (Hospital), Joshua Naranjo filed a class action lawsuit seeking declaratory and injunctive relief. Naranjo alleged the Hospital's failure to disclose the emergency room evaluation and management service (EMS) fee included in his bill violated the Consumer Legal Remedies Act (CLRA) and the unfair competition law (UCL). The trial court sustained the Hospital's demurrer and entered a judgment of dismissal. Naranjo appealed.

The Court of Appeal reversed. First, the court held the Hospital had a duty to disclose its EMS fee because it had exclusive knowledge of the fee, which was not reasonably ascertainable by patients, and the Hospital's failure to disclose its EMS fee could support CLRA liability. Departing from three recent appellate decisions holding that hospitals had no duty to disclose EMS fees, the court explained that none of those decisions had addressed the "exclusive knowledge" issue. Next, the court held that, contrary to the rationale of prior decisions, requiring disclosure of the potential EMS fee was consistent with state and federal laws requiring the provision of emergency medical services before questioning the patient or others about payments, and requiring the disclosure of certain fee information. Moreover, those laws do not create a safe harbor from CLRA and UCL claims—a safe harbor exists only if a statutory provision bars the litigation or expressly permits the conduct. Finally, the court held that Naranjo adequately alleged that the Hospital had exclusive knowledge of its EMS fee billing practices (which information he lacked); that the EMS fee was material to his decision to receive emergency treatment; that he would not have consented to the emergency treatment if the EMS fee had been disclosed; and that he sustained damages by paying part of the EMS fee. Accordingly, the trial court erred by sustaining the Hospital's demurrer to Naranjo's CLRA claim and to the UCL claim premised on his CLRA claim.

Kaiser cannot avoid class claims that it failed to provide medically necessary treatments required by the Mental Health Parity Act

Futterman v. Kaiser Foundation Health Plan, Inc. (Apr. 25, 2023, A162323) __ Cal.App.5th __ [2023 WL 3070944], ordered published May 17, 2023

Three plaintiffs sued Kaiser Foundation Health Plan under the Unfair Competition Law alleging the Plan violated the California Mental Health Parity Act by failing to provide coverage for medically necessary mental health treatments for themselves or their dependents. They presented evidence that the Plan denied, or deterred members from obtaining, one-on-one therapy sessions without determining medical necessity. The Plan instead required or recommended group therapy, practices that did not mirror the Plan's treatment of physical health conditions and that, in some instances, were inappropriate clinically. Plaintiffs sought class-wide injunctive relief and statutory penalties. Plaintiffs also invoked the Unruh Civil Rights Act, arguing the Plan intentionally discriminated against persons with mental disabilities or conditions. The trial court granted the Plan's motion for summary judgment on the basis that plaintiffs were seeking relief for actions taken by healthcare providers that contracted with the Plan (but not the Plan itself), and that no contractual benefits were denied for a discriminatory reason. Plaintiffs appealed.

The Court of Appeal reversed (except as to one plaintiff's individual claims). Plaintiffs had presented evidence that the Plan—not medical groups and physicians—arranges and pays for mental health treatment more stingily than for treatment of physical illnesses. Return or repeat appointments were virtually impossible to arrange; doctors were

scheduled in a manner frustrating one-on-one therapy sessions; and the Plan's model emphasized group therapy, even for actively suicidal or psychotic patients for whom group sessions were clinically improper. Together, this and other evidence supported an inference that the Plan was making decisions regarding individual mental health treatment based on criteria other than medical necessity. So too, this evidence supported an inference the Plan was providing less robust coverage for mental health issues than it provides for physical illnesses. Distinguishing several other cases, the court rejected the Plan's argument that plaintiffs were actually seeking to hold the Plan vicariously liable for the actions of doctors, medical groups, and other providers, which the Knox-Keene Act forecloses. The court also determined that plaintiffs could pursue their claims without interfering with the DMHC's regulatory authority. On the Unruh Act claims, the Court of Appeal held that evidence of the Plan's decision not to fund its coverage at a level necessary to provide all medically necessary treatment supported an inference of discrimination against patients with certain mental illnesses. Summary judgment for the Plan was therefore inappropriate.

"Deemed" Public Health Service employees are immune from liability to third parties for conduct related to health services under 42 U.S.C. § 233

Friedenberg v. Lane County, __ F.4th __, No. 21–35078, 2023 WL 3558224 (9th Cir. May 19, 2023)

A municipal court referred Michael Bryant to a jail diversion program (as a condition of probation) and ordered him to report to Lane County Mental Health (LCMH) for treatment. But Bryant stopped taking his medications, leading to a psychotic break during which he killed two people and maimed another. The crime victims (or their estates) sued Lane County, LCMH, and its employees, alleging negligence and wrongful death claims stemming from the defendants' failure to report Bryant's probation violations to the court, which would have incarcerated him. The defendants removed the case to federal court under the Federally Supported Health Centers Assistance Act (FSHCAA), 42 U.S.C. § 233. The defendants argued that, because the FSHCAA deems them Public Health Service (PHS) employees, the Federal Tort Claims Act requires the United States to be substituted in their place as the sole defendant. Plaintiffs moved to remand on grounds the district court lacked jurisdiction under the FSHCAA. The district court granted the remand motion, ruling that, as "deemed" PHS employees (rather than actual PHS employees), the defendants were not entitled to § 233 immunity because plaintiffs were not LCMH patients when they suffered injury. Defendants appealed.

The Ninth Circuit reversed and directed the district court to substitute the United States as the sole defendant. The court explained that Congress enacted the FSHCAA to prevent community health centers serving underprivileged populations from having to use their federal funds to purchase costly medical malpractice insurance. To further this objective, Congress extended the absolute immunity "provided to actual PHS employees in § 233(a) to 'deemed' PHS employees under § 233(g)." Moreover, § 233 immunity does not turn on who brings a claim, but rather whether the claim arose out of the defendants' performance of medical, dental, surgical, or related services—regardless whether the injured plaintiff was a patient. And while Congress's concerns regarding medical malpractice insurance premiums were the driving force behind enactment of FSHCAA, Congress elected not to limit § 233 immunity to malpractice claims when it could have done so. Finally, the court held that the defendants' alleged failure to notify the municipal court of the probation violations was a "'related function'" under § 233, bringing it within the scope of the statutory immunity, because their duty to report Bryant's violations and his potential threat to public safety was tied to their status as medical health professionals.

Corrections officials may not engage in unconsented "patient dumping" of medically compromised parolees

Kern County Hospital Authority v. Department of Corrections and Rehabilitation (May 26, 2023, F083743) __ Cal.App.5th __ [2023 WL 3675914]

The California Department of Corrections and Rehabilitation (CDCR) unsuccessfully attempted to locate skilled nursing facilities to accept four medically compromised inmates approaching their parole dates. CDCR then "paroled" and transported them to the emergency department at Kern Medical Center, a general acute care hospital. Kern County Hospital Authority, which

operates the center, sought and obtained a writ of mandate and a permanent injunction barring CDCR from transferring parolees to the authority's facilities absent advance permission or a medical emergency. CDCR appealed.

The Court of Appeal affirmed, but modified the scope of the injunction. The court recognized the tension between CDCR's duty to the parolees as patients and the parolees' liberty interests. Parolees are entitled to be released, yet CDCR retains statutory discretion to determine a parolee's placement. Some parolees require skilled nursing care. Under California Code of Regulations, title 22, section 79789, however, CDCR may not transfer parolees to another facility unless transfer arrangements are made beforehand. The Court of Appeal rejected CDCR's argument that this regulation covers only inmates, not parolees, as well as CDCR's argument that the facility's advance agreement to accept the parolee was unnecessary. The court also found EMTALA inapplicable because the parolees did not require *emergency* medical care; they needed only skilled nursing care. To vindicate parolees' liberty interests, the Court of Appeal modified the injunction to allow a parolee to decline further care and treatment at the correctional facility, enabling the parolee to choose either to be discharged to a hospital emergency room (regardless of the hospital's prior consent) or continue to receive skilled nursing care at the correctional treatment center while awaiting an agreed placement at a skilled nursing or other medical facility. "What the Department cannot do is drop the parolees off at the emergency department while the parolees remain correctional treatment center patients without making advance arrangements for their admission to the hospital."

"Aggravated identity theft" sentence enhancement is inappropriate in healthcare fraud case based on overbilling Medicare

Dubin v. United States, 599 U.S. __, 2023 WL 3872518 (June 8, 2023)

David Dubin overbilled Medicaid $338 by overstating the qualifications of employees who performed psychological testing. A jury convicted him of healthcare fraud under 18 U.S.C. § 1347 and aggravated identity theft under § 1028A. The Government sought a 2-year prison sentence enhancement for aggravated identity theft under § 1028A(a)(1). That statute applies when "'during and in relation to any [predicate offense, including healthcare fraud]'" a defendant "'knowingly transfers, possesses, or uses, without lawful authority, a means of identification of another person.'" The Government argued that § 1028A(a)(1) applied because Dubin committed healthcare fraud using patients' Medicaid reimbursement number, a "'means of identification.'" The district court was dubious because the crux of the case was fraudulent billing, not identity theft, but nonetheless imposed the sentence enhancement due to controlling Fifth Circuit precedent.

The U.S. Supreme Court granted review to determine "whether in defrauding Medicaid, [Dubin] also committed '[a]ggravated identity theft.'" The Supreme Court reversed the Fifth Circuit, holding that "under § 1028A(a)(1), a defendant 'uses' another person's means of identification 'in relation to' a predicate offense when the use is at the crux of what makes the conduct criminal" and does not merely facilitate the crime. The Court reasoned that the title and language of § 1028A(a)(1) together reflected a targeted meaning that "accurately captured the ordinary understanding of identity theft, where misuse of a means of identification is at the crux of the criminality." Thus, Congress' decision to title § 1028A "Aggravated identity theft" and to separate *identity fraud* crimes from *identity theft* crimes shows the statute "is focused on identity theft specifically, rather than all fraud involving means of identification." Likewise, the verbs used in § 1028A(a)(1) (transfers, possesses, and uses) speak to classic identity theft where the means of identification is the locus of the criminal undertaking. In contrast, the "Government's broad reading, covering any time another person's means of identification is employed in a way that facilitates a crime, bears little resemblance to any ordinary meaning of 'identity theft.'" The statute's list of predicate offenses and its separate 2-year sentence enhancement also reflects an intent to target "situations where the means of identification itself is at the crux of the underlying criminality, not just an ancillary billing feature." Finally, under the rule of lenity, the Court typically eschews broad readings of federal criminal statutes to ensure people have "fair warning" of what conduct is forbidden.

A concurring opinion by Justice Gorsuch opined that § 1028A(a)(1) was unconstitutionally vague, and not merely ambiguous, because it failed to provide even rudimentary notice of what it does and does not criminalize.

State employees do not face § 1983 stigma-plus liability for losses that would have occurred absent state action

Chaudhry v. Aragon, 68 F.4th 1161 (9th Cir. May 23, 2023)

A patient suffered hypoxic brain injury during open heart surgery at a private hospital. The hospital, California Department of Public Health (CDPH), and Centers for Medicare and Medicaid Services conducted separate investigations and found that the lead surgeon, Dr. Pervaiz Chaudhry, left the operating room before the patient was stable and his chest was closed. The hospital suspended Dr. Chaudhry's medical staff membership and clinical privileges, revoked his appointment as Medical Director of Cardiac Surgery and Thoracic Services, and declined to renew consulting services agreements with him and his medical group. Several months later, CDPH published a statement of deficiency on its website, which summarized its findings but did not identify Dr. Chaudhry by name. Thereafter, a hospital employee with independent knowledge about the surgery notified the patient's family of Dr. Chaudhry's potential malfeasance. The patient's family sued the hospital and Dr. Chaudhry for malpractice, securing a $60 million jury verdict. Dr. Chaudhry and his medical group separately sued current and former CDPH employees, alleging a "stigma-plus" due process claim under 42 U.S.C. § 1983. They asserted that CDPH employees violated their Fourteenth Amendment rights by publishing the statement of deficiency without first providing Dr. Chaudhry an opportunity to be heard. They asserted that the publication of the statement of deficiency damaged Dr. Chaudhry's reputation and deprived him of protected employment-related interests. Following a bench trial, the district court entered judgment for the CDPH employees. Plaintiffs appealed.

The Ninth Circuit affirmed, holding that the record supported the district court's finding that publishing the statement of deficiency was not the but-for cause of plaintiffs' loss of positions and contracts with the hospital. The hospital conducted an internal investigation before CDPH began investigating, and the hospital's internal investigation yielded the same conclusions as CDPH's statement of deficiency. Therefore, it was plausible that the hospital would have terminated Dr. Chaudhry's privileges and declined to renew his consulting contract based on those same findings and conclusions. The court rejected plaintiffs' argument that the publication of the statement of deficiency increased his medical malpractice insurance premiums. The court reasoned that Dr. Chaudhry's insurance premiums would have increased regardless of CDPH's publication of the statement of deficiency because there were five unrelated malpractice lawsuits pending against him. The court also rejected plaintiffs' argument that the patient's family sued him because CDPH published the statement of deficiency, agreeing with the district court that the family likely would have sued Dr. Chaudhry (and prevailed in that lawsuit) with or without the statement of deficiency because the family received an anonymous tip about the incident and had access to the hospital's internal findings.

Nursing home residents may sue under 42 U.S.C. § 1983 for FNHRA violations

Health & Hospital Corp. v. Talevski, 599 U.S. __, 2023 WL 3872515 (June 8, 2023)

Family members placed Gorgi Talevski in a county-owned nursing home in Indiana when his dementia progressed to the point they could no longer care for him. His condition quickly deteriorated. The family attributed his decline to the nursing home's use of powerful psychotropic medications. When the nursing home began transferring Talevski to a distant psychiatric hospital for days at a time, the family complained to the state health department. An administrative law judge nullified the transfer, but the nursing home ignored the decision and refused to readmit Talevski. Talevski (via a relative) sued the nursing home's operator (HHC) in federal court under 42 U.S.C. § 1983, alleging that HHC violated his rights under the Federal Nursing Home Reform Act (FNHRA), a statute enacted by Congress under its Spending Clause authority. The district court dismissed the complaint, ruling

that Section 1983 may not be used to enforce the FNHRA. The Seventh Circuit reversed, holding that the FNHRA confers on nursing home residents certain individual rights that may be enforced by litigating under Section 1983.

The Supreme Court granted review and affirmed the Seventh Circuit. The Court explained that Section 1983 supplies a plaintiff with a cause of action against a person (acting under color of state law) who has deprived the plaintiff of rights "secured by the Constitution *and laws*" of the United States. The "laws" enforceable via Section 1983 are not limited to federal statutes focused on civil rights or equal protection, but neither is every federal statute such a "law[ ]." The Supreme Court considers a variety of factors to determine which federal statutes may be enforced under Section 1983. Here, the Court held that FNHRA provisions create Section 1983-enforceable rights because they contain rights-creating, individual-centric language focused on the benefited class (specifically, FNHRA provisions bar unnecessary restraints and mandate predischarge notice). FNHRA provisions also specify that Medicaid-participant nursing homes must respect and honor these rights. In addition, Congress did not provide a private right of action within the FNHRA, and the Act lacks an internal administrative enforcement scheme that could be thought incompatible with enforcement efforts under Section 1983.

Justice Barrett (joined by the Chief Justice) concurred separately to caution that Section 1983 actions should be the exception (not the rule) for violations of federal statutes enacted under the Spending Clause. The typical remedy for non-compliance with Spending Clause statutes is an action by the federal government to terminate funds to the state, not a private lawsuit. Justice Barrett nonetheless found a private lawsuit suitable in the FNHRA context. Justice Thomas dissented on the ground that Spending Clause statutes like FNHRA should not be enforceable under Section 1983. Spending Clause statutes resemble contracts between states and the federal government, not regulations conferring individual rights. A contrary view (he suggested) could enable Congress to commandeer states to administer federal programs that Congress might otherwise lack authority to enact. Finally, Justice Alito dissented to criticize the majority's holding that the FNHRA creates Section 1983-enforceable rights given its unique remedial scheme and grievance process.

Terminating a hospital administrator for refusing to get a flu shot in violation of employer policy is not prohibited by FEHA

Hodges v. Cedars-Sinai Medical Center (2023) 91 Cal.App.5th 894

Deanna Hodges worked for Cedars-Sinai Medical Center in an administrative role with no patient care responsibilities. Cedars terminated her employment because she refused to get a flu vaccine. Cedars's flu vaccine policy made exceptions for employees who established "a valid medical or religious exemption." Employees who declined the vaccine "based on medical contraindication, per CDC guidelines" were required to submit an exemption request completed by their physician. Hodges's doctor wrote a note recommending an exemption based on her history of cancer and general allergies. None of those reasons were medically recognized contraindications, however. Hodges continued to refuse a flu vaccination after Cedars' review panel declined her exemption request, so Cedars terminated her employment. Hodges sued Cedars for disability discrimination and related claims under the Fair Employment and Housing Act (FEHA). The trial court granted Cedars summary judgment, and Hodges appealed.

The Court of Appeal affirmed. Because there was no direct evidence that Cedars acted with a "prohibited motive," the court applied the *McDonnell Douglas* three-step burden-shifting framework commonly used in employment discrimination cases and concluded that Hodges failed to show a prima facie case, the initial step. The court explained that terminating a person because she refused to get a flu shot in violation of employer policy is not prohibited by FEHA. The court noted that there was no evidence that Cedars terminated Hodges because she was "unable" to get the vaccine, or due to any claimed disability. To the contrary, the direct evidence, including the written policy and exemption request form, showed that Cedars had a policy of terminating employees who failed to receive the flu vaccine without a religious exemption or medically recognized contraindication to receive the flu vaccine, and that it followed the

policy here. The court noted that Cedars would have prevailed at other steps of the burden-shifting framework as well: Cedars presented a legitimate, nondiscriminatory reason for terminating Hodges, and Hodges failed to argue the reason was pretextual.

Public health care service plans are not immune from provider reimbursement actions under the Knox-Keene Act

County of Santa Clara v. Superior Court (July 10, 2023) __ Cal.5th __ [2023 WL 4414084]

As required by state and federal law, Doctors Medical Center of Modesto, Inc., and Doctors Hospital of Manteca, Inc., provided emergency medical care to three individuals enrolled in a health care service plan operated by the County of Santa Clara. The hospitals had no contract with the County governing rates payable for emergency services rendered to plan members. The hospitals billed the County for the emergency services rendered, but the County paid only a portion of the billed amounts. The hospitals then sued the County for the balance under a provision of the Knox-Keene Act (and implementing regulations) requiring a health care service plan to reimburse medical providers for the "reasonable and customary value" of the emergency care. (Health & Saf. Code, § 1371.4, subd. (b); Cal. Code Regs., tit. 28, § 1300.71, subd. (a)(3)(B).) After the trial court overruled the County's demurrer, the County petitioned for a writ of mandate, The Court of Appeal granted writ relief, holding that the County was immune from suit under the Government Claims Act's general immunity provision (Gov. Code, § 815). The Hospitals sought and obtained review in the California Supreme Court.

The Supreme Court reversed, holding that the Claims Act does not immunize a public health care service plan from an emergency medical provider's implied-in-law quantum meruit claim seeking reimbursement under the Knox-Keene Act. Noting that the Claims Act does not preclude contract liability, or the right to obtain relief "other than money or damages" (Gov. Code, § 814), the Supreme Court explained that the Claims Act immunizes public entities only from tort claims seeking money damages. The Court rejected the County's characterization of the hospitals' quantum meruit claim as a tort claim seeking money damages, and instead viewed the hospitals' claim as seeking County compliance with the statutory duty of reimbursement. The Court further reasoned that the Knox-Keene Act should apply equally to private and public health care service plans, and that treating public plans differently would risk systemic underpayment of emergency services, which the Legislature had sought to avoid by enacting the Knox-Keene Act's reimbursement provision. The Court also distinguished its decisions predating the Claims Act that barred quasi-contractual recovery against public entities; those cases involved express contracts with public entities that proved to be void for violating applicable statutes or charters. Here, by contrast, the hospitals had no express contract with the County and the hospitals' quasi-contractual claims sought payment required by statute.

GETTING TO KNOW... KAREN KIM

by **Karen Kim**
Toyon Associates, Inc.

Karen is Vice President of Appeals Services at a national healthcare consulting firm. where she advises healthcare organizations on issues related to Medicare/Medicaid reimbursement matters, including appeals and litigation. Before Toyon, Karen was a healthcare litigator at Murphy Austin Adams Shoenfeld LLP, Press Secretary to the California State Assembly Majority Leader, and a reporter for the Los Angeles Times. She is co-chair of the CSHA Diversity Task Force.

1. Where are you currently employed and what is your position?

I am the Vice President of Appeals Services at Toyon Associates, Inc. a healthcare financial consulting firm that specializes in Medicare and Medi-Cal reimbursement.

2. How long have you held that position?

I have been at Toyon Associates for six years.

3. When did you become a member of CSHA?

I've been a member of CSHA since 2011.

4. When did you become a health lawyer?

I became a health lawyer in 2011 when I joined Murphy Austin Adams Schoenfeld in Sacramento. I worked in litigation, representing providers in managed care reimbursement disputes. I also represented providers in reimbursement disputes with Medicare and Medi-Cal.

5. Did you practice in any other area of law before you became a health lawyer, and if so, what area?

I worked in general business litigation and real estate litigation. But I went to law school mid-career. Prior to law, I served as the Press Secretary to the former California Assembly Majority Leader (and former Assembly Health Committee Chairman). I also worked as a newspaper reporter for the Los Angeles Times community news division for several years before I worked in politics.

6. What is your health law sub-specialty and why did you choose it?

I wouldn't say I chose to work in government reimbursement; rather, it chose me. I started out working on managed care disputes, but as laws changed and the Affordable Care Act was passed, government reimbursement just became a more and more critical piece of healthcare providers' business operations. My work sort of naturally shifted in the direction of its current state.

7. What is the biggest challenge in your job?

Medicare and Medicaid reimbursement appeals routinely take years (sometimes decades!) to finally resolve. Working with clients to maintain documentation, staff knowledge, etc., not to mention their patience, is definitely challenging.

8. What do you consider your greatest achievement in your career?

When I was just starting out as a healthcare lawyer, I ended up handling a managed care arbitration largely by myself. The case was a complicated one, spanning close to a decade of payment disputes, and millions of dollars were at stake. The opposing counsel was a seasoned and respected defender of healthcare plans, and I was intimidated to say the least. The night before the arbitration, the health plan proposed a settlement of only 2% what we believed we were owed, which indicated how confident they were in their case. We rejected the deal and went to arbitration for five days. I ended up winning that case fully and recouped the entire amount the hospital was owed. It was an exciting entrance into healthcare law for me.

9. What do you think is the biggest challenge the health care system faces today?

I don't know if it's the biggest, but a challenge I definitely see in my work is the fact that the business offices of hospitals and health systems are sorely understaffed and always the first to get cut when budget cuts need to be made. Meanwhile, maintaining the financial viability of a hospital/health system becomes more and more challenging with each year, and hospitals have to fight to keep their doors open with less and less staff to help.

10. What hobbies do you pursue?

I have two children, ages 6 and 2 years, so I don't always have time for hobbies. But I enjoy sports, reading, writing, cooking, and traveling. I also consider being a foodie a hobby! I love food, reading about it, trying it, seeking out new restaurants, etc.

11. What is your motto?

I'm not sure if it's a motto, but my philosophy has always been to dream as big as possible and shoot for the moon. I know it sounds trite, but my example has always been, "if you aim for an A, you might get and A or you might get a B. But if you aim for a B, you will NEVER get an A." This has been sort of my internal mantra since I was in high school. Always aim higher than you think you can reach!

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