Client Alert: Is Your Professional Information Being Sought From Your Licensing Agency? Do You Know Your Rights?

California Court of Appeal Decision in *Board of Registered Nursing v. Superior Court of Orange* Draws A Line In the Sand: Health Care Professionals Must Be Notified When Their Professional Information Is Sought From An Administrative Body

Stemming from California's ongoing legal battle against pharmaceutical companies for deceptive marketing schemes in relation to the opioid epidemic (think Purdue), the issue of health care professionals' privacy rights came to the forefront when the State of California subpoenaed administrative records (including disciplinary records) and investigatory files (including complaints) about these professionals from their licensing boards, including the Medical Board, Nursing Board, Pharmacy Board, and Department of Justice.

In Board of Registered Nursing v. Superior Court, January 15, 2021, ___ Cal.App.5th ___ [2021 WL 140983], the administrative and governmental agencies referenced above took the position that the subpoenas issued by the State, demanding a broad swath of documents, were invalid because the State failed to provide notices to consumer (i.e., health care professionals) that their professional information was being sought. The agencies further maintained that the scope of categories demanded was protected by the official information privilege, deliberative process privilege, and constitutional right to privacy.

When the trial court ordered the agencies to produce documents in response to the State's subpoenas, despite the arguments above, the agencies sought and were granted writ relief by the Court of Appeal.

The Court of Appeal made the following findings, among others:

- Health care professionals (doctors, nurses, pharmacists, etc.) whose identities would be disclosed in an agencies' administrative records, investigatory files, and coroners report must be given notice of the subpoena.

The Court of Appeal denied the State's argument that the Information Practices Act of 1977 (IPA) allowed administrative and governmental agencies to comply with subpoenas without providing notice to consumer. Instead, it held that, because the subpoenas sought "the personal information of investigated or disciplined health care professions, without redaction, [the State] was required to provide notice to these persons."

- Requests for complete administrative records, investigatory files, and CURES data absent notice to consumer (i.e., health care professionals) was a violation of the constitutional right to privacy and the statutory official information and deliberative process privileges.

The Court of Appeal held that the private and public interest in confidentiality of the requested materials (which included investigatory files, administrative records, and CURES data) is substantial. "The health care professionals named in the investigatory files and disciplinary proceedings have a legally protected privacy interest in their personal information reflected in the records…This right to privacy is especially salient for those professionals who were investigated but never accused of wrongdoing…"

Take Away:

The arguments and assertions made by the administrative and governmental agencies in Board of Registered Nursing v. Superior Court in response to the State's subpoenas are the very same arguments and assertions that can and are raised when the same agencies issue similar requests/subpoenas to health care professionals. Health care professionals must keep a close eye on whether these administrative and governmental agencies are providing notice to consumer, whether the consumer is a health care professional or a patient, before turning over any records.

When you receive a subpoena or similar request, even if it is for your own administrative records or investigatory file, notice to consumer needs to be provided. If you did not receive notice or if you received notice, but do not know how to respond, contact an attorney immediately to discuss how to best protect your privacy rights. Statutory deadlines require a quick response to subpoenas or similar requests, so time is of the essence.

If you have any questions or would like to discuss how to protect your privacy interests, the attorneys at Nelson Hardiman are here to answer your questions. Feel free to contact Sara Hersh or Miriam Mackin at 310-203-2800.

Contact Us

This article is provided for educational purposes only and is not offered as, and should not be relied on as, legal advice. Any individual or entity reading this information should consult an attorney for their particular situation.

8 Nelson Hardiman Attorneys Named to the 2021 Southern California Super Lawyers List

Nelson Hardiman is proud to announce that Attorneys Rob Fuller, Mark Hardiman, Sara Hersh, John A. Mills, Harry Nelson, Jonathan Radke, Zachary Rothenberg, and Alan J. Sedley were named to the 2021 Southern California Super Lawyers list. Each candidate is evaluated on 12 indicators of peer recognition and professional achievement. Only 5% of attorneys in Southern California receive this distinction.

2021 marks the *11th consecutive year* that Co-Founder and Managing Partner Harry Nelson has been named as one of Southern California's Super Lawyers.

Congratulations to all for the selection to this prestigious list!

Client Alert: Certain "Just-in-Time" Inventory Practices Overruled for General Acute Hospitals; Hospitals Required to Maintain Stockpile of

Personal Protective Equipment under AB 2537

NEW LAW REQUIRES REPORTING OF 2019 DATA BY THIS WEEK

Cal OSHA and OSHA regulations mandate that health care workers be protected from hazards at the workplace in hospitals, but these requirements merely address the general need “to furnish employment and a place of employment that was safe and healthful” and “to have an effective injury prevention program in place.” As such, hospitals were free to manage their inventory of personal protective equipment (“PPE”) much as any other inventory, including the ‘just-in-time’ practice of prior day delivery of supplies for cost controls.

These minimal inventory practices, while cost-effective, proved disastrous in the pandemic.

While common sense in normal operations might prevail to increase PPE supplies over time against the reoccurrence of a pandemic, the California legislature has stepped in and passed AB 2537, that requires hospitals to have ready stockpiles of PPE for their workers exposed to hazards, including infectious disease.

Specifically, AB 2537 requires both private and public employers operating general acute hospitals to supply PPE to health care workers who provide direct patient care or provide services that directly support patient care in areas exposed to potential hazard. Hospitals are also required to conduct periodic training in the use PPE.

Additionally, beginning on April 1, 2021, the hospitals must maintain a supply of specified equipment (respirators, particulate filters or cartridges, surgical masks, isolation gowns, eye protection, and shoe coverings) in quantities equal to three months of normal consumption. Hospitals must document the management of this stockpile, including written policies and procedures for periodically reviewing and adjusting the par levels of inventory for all types of equipment to meet the three-month requirement.

A list of the Hospital's PPE stockpile (with par levels) and a copy of its written policies and procedures must be provided to the Division of Occupational Safety and Health upon request. Failure to maintain the required stockpile may come with a civil penalty of up to $25,000 per violation. Please note that these obligations extend to all hospital facilities, and responsibilities fall on owners, operators, and management companies.

On or before January 15, 2021, general acute care hospitals (with the exception of hospitals under the jurisdiction of the State Department of State Hospitals) must also be prepared to report to the Department of Industrial Relations, under penalty of perjury, their highest 7-day consecutive daily average consumption of PPE during the 2019 calendar year.

If you have any questions about this new PPE Stockpile law, please contact Nelson Hardiman attorneys Miriam Mackin, Lara Compton, or Rob Fuller for further advice (310)203-2800.

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Major Payers Slow to React to

AMA Attack on High-Deductible Plans

Partner Rob Fuller was interviewed by health payer specialist to discuss the nation's leading payers high-deductible health plans in the aftermath of the American Medical Association's indictment of the products and the growing crisis of affordable coverage.

From the article:

> *Because they are designed to have consumers pay between $1,400 to $7,000 for medical care before insurance kicks in, these types of plans can be "a very bad trap for the unwary," says Rob Fuller, attorney with Nelson Hardiman in Los Angeles and co-author of the book From ObamaCare to TrumpCare.*
>
> *Fuller says that the plans exploded in popularity over the past 15 years as employers started asking for a lower-cost benefi. But the crisis of affordability, rendered more sharply by the pandemic, is leading to calls for change.*
>
> *Read Full Article: Major-Payers-Slow-to-React*

Cal/OSHA Adopts Emergency COVID-19 Prevention

Regulation

INTRODUCTION

In response to the recent surge in COVID-19 cases throughout California, Cal/OSHA adopted temporary emergency standards aimed at employers, the intent of which is to provide greater protection to workers in the workplace from health hazards related to COVID-19. The regulation went into effect statewide on November 30, 2020. Most California employers are required to implement and follow the new standards, with a few noted exceptions.

In short summary, the new emergency regulation focuses upon the following key employer responsibilities and obligations within the workplace:

- Creation of a detailed, written COVID-19 Prevention Plan
- Implementation of COVID-19 prevention methods (including physical distancing, mask usage and compliant air filtration systems)
- Specific methodology for identifying and correcting COVID-19 hazards
- Reporting obligations of COVID-19 workplace incidents to health agencies
- Required protocol for handling workers infected with, or exposed to COVID-19
- Delineated 'return-to-work following quarantine' criteria

The new emergency standards (Title 8, Division 1, Chapter 4, subchapter 7 – *General Industry Safety Orders*) are divided into five sections:

- COVID-19 Prevention [3205]
- Multiple COVID-19 Infections and COVID-19 Outbreaks [

3205.1]
- Major COVID-19 Outbreaks [§ 3205.2]
- Prevention in Employer Provided Housing [3205.3]
- COVID-19 Prevention in Employer-Provided Transportation to and From Work [§ 3205.4]

An overview of each of the sections is set forth, below. Those interested in reviewing the emergency regulation and its mandated requirements are encouraged to access the full text at this link here.

COVID-19 Written Prevention Plan

Employers should promptly review its existing Cal/OSHA COVID-19 prevention plans as well as its current Injury and Illness Program, and, either by integration into those existing plans, or by placing in a separate and readily identifiable document, prepare a **written** COVID-19 Prevention Plan (Plan) including appropriate policies and procedures to ensure adherence with this emergency regulation. A summary of the requirements for the Plan includes:

- **A system for communicating to employees**: The employer shall, together with employees' participation and input, develop/implement and notify each employee of its current as well as new COVID-19 policies and procedures to include; the manner in which to report to the employer (without fear of reprisal) COVID-19 symptoms and possible exposure; policies for accommodating those with medical or other conditions that put them at increased risk of severe COVID-19 illness; information about access to COVID-19 testing.
- **Procedures for identifying and evaluating COVID-19 hazards**: The employer shall develop and implement plans for – screening procedures for employees; a process to promptly respond to employees with COVID-19 symptoms to prevent or reduce the risk of transmission in the workplace; a method to identify potential COVID-19

hazards and hazard locations at the workplace suspected by employer and/or employees (including close contact locations such as work desk, bathrooms, hallways, breakrooms, and common areas); maximizing the existing indoor workplace ventilation system by increasing filtration efficiency and maximizing the flow of outdoor air into the work space; evaluating existing COVID-19 prevention controls at the workplace, adding additional or different controls where appropriate; conducting periodic inspections to identify unhealthy conditions and work practices and procedures related to COVID-19, and ensure compliance with its COVID-19 policies and procedures.

- **Procedures for Investigating and Responding to COVID-19 cases in the workplace:**

Employers shall have in place an effective procedure to – (a) investigate and verify workplace COVID-19 case status, (b) receive information regarding test results and the onset of symptoms and, (c) identify and record COVID-19 cases.

Employers shall also take the following actions when there has been a COVID-19 case in the workplace – (d) determine the day and time the COVID-19 case was last present in the workplace and to the extent possible, the date of the positive COVID-19 test and/or diagnosis, and additionally, the date the COVID-19 case first had one or more symptoms; (e) through contact tracing, determine who in the workforce onsite may have had COVID-19 exposure; (f) give broad notification (per AB 685) of the potential COVID-19 exposure within one business day (without revealing personal identifying information of the affected individual) to all employees and individuals (including third parties visiting the workplace) who may have had exposure, and (g) for such potentially exposed individuals, the employer must offer COVID-19 testing to all such individuals at no cost, and provide employees who may have been exposed with next options and information on work absence benefits (see below).

- **<u>Procedures for correcting COVID-19 hazards</u>:** The employer's Plan must provide for the implementation of effective policies and procedures for correcting COVID-19 related hazards identified during an investigation after learning of a COVID-19 case and/or health and safety concerns raised by employees.
- **<u>Training and Instruction</u>:** The employer must include policies in the Plan for the effective training and instruction to employees that include the following:
  - Describing the employer's COVID-19 Plan
  - The benefits that are available to employees in the event of a COVID-19 infection, including any benefits available under workers' compensation laws, the federal Families First Coronavirus Response Act, Labor Code sections 248.1 (COVID-19 supplemental paid sick leave) and 248.5 (penalties for non-adherence), Labor Code sections 3212.86 through 3212.88 (requirements entailing a rebuttable presumption that certain employee's COVID-19 exposure occurred in the workplace). Local governmental requirements, employer's own leave policies, and leave guaranteed by contract. This provision is designed in part to persuade employees to report COVID-19 exposure and positive test results.
  - Methods on how the virus may be transmitted in the workplace (e.g., an infected employee who sneezes, coughs or even vocalizes); touching a contaminated object then touching one's eyes, nose and mouth; the fact that an infectious person might display no symptoms while in the workplace; methods on how to best prevent COVID-19 exposure in the workplace (social distancing, use of face covering, and frequent hand washing guidelines), procedures and rules for enforcement of social distancing and

face covering requirements), and guidelines pertaining to avoidance of entering the workplace to take a COVID-19 test should the employee already has symptoms.
- Alternatives when face coverings are not possible, or when respirators are required.
    - **Engineering controls, administrative controls and personal protective equipment:**

Provisions speak to:

- Employer’s duty to install solid partitions or other physical barriers between working stations when physical distancing is not possible.
- Maximization of outside air flow when feasible
- Employers responsibility to implement cleaning and disinfecting procedures, with focus upon frequently touched surfaces and objects (e.g., doorknobs, equipment, tools, handrails, elevator buttons and bathroom surfaces), particularly in areas and surfaces used by a COVID-19 case during the high-risk exposure period.
- Drafting policies and procedures for prohibiting the sharing of commonly used items (e.g., phones, headsets, tools, desks) and where such prohibition

Is not feasible, ensuring that sharing of commonly used items is kept to a minimum. Clean and disinfect shared items and equipment between uses by different individuals.

- Employer’s responsibility to provide employees with appropriate personal protective equipment (PPE) to prevent exposure to COVID-19 hazards, such as gloves, safety goggles and face shields. The employer shall also evaluate the need for respiratory equipment (e.g., N95’s), and if it is determined that such equipment is required, the employer shall create a respiratory protection program which will include fit testing, and a medical test to clear an employee’s use of such gear.

- **<u>Reporting obligations, recordkeeping, and access</u>:** The employer must adopt strict procedures for recordkeeping and tracking of all COVID-19 cases within the workplace, including the procedures for notifying the Department of Public Health (DPH) of any COVID-19 cases at the workplace, The employer is also responsible for notifying DPH of any COVID-19 related serious illness or death, and shall maintain records of the steps taken to implement its written COVID-19 Prevention Plan. The employer shall make its written Plan available at the workplace for viewing by employees.
- **<u>Exclusion of COVID-19 cases</u>**: This subsection of this emergency regulation is designed to limit transmission of COVID-19 in the workplace.
  - Employers must ensure that COVID-19 cases are excluded from the workplace until return-to-work requirements (below) are met. This subsection requires that, and consistent with the Center for Disease Control COVID-19 guidelines, employers shall require that exposed employees be excluded (quarantined) from the workplace for 14 days after the last known exposure to a COVID-19 case. <u>The requirement includes that the employer allow employees so excluded from the workplace to maintain their earnings, seniority and all other employee rights and benefits including the right to return to his/her former job status, thus a “protected leave” similar to that under the ADA and other such similar protections</u>. Employers may use employer-provided employee sick leave benefits for this purpose.
- **<u>Return to work criteria</u>:** The regulation mandates that an employer include in its Plan a requirement

that COVID-19 cases with COVID-19 symptoms shall not return to the workplace until at least 24 hours have passed since a fever of 100.4 or higher has resolved, symptoms have improved, and at least 10 days have passed since COVID-19 symptoms first appeared. Additionally, COVID-19 cases who test positive but never develop COVID-19 symptoms are not to return to the workplace until a minimum of 10 days have passed since the date of their first positive COVID-19 test. Note, however that the regulation does not require a negative COVID-19 test be taken prior to an employee returning to the workplace so long as all other provisions of quarantine are first met.

Multiple COVID-19 Infections and COVID-19 Outbreaks

In addition to drafting and maintaining a written COVID-19 Prevention Plan, the regulation also requires that an employer take additional steps to those otherwise stated previously in the instance that there are; (a) <u>three or more</u> COVID-19 cases ("outbreak") in an exposed workplace *within a 14-day period*, or (b) if the local health department has identified the workplace as the location of a COVID-19 outbreak. Such additional steps include:

1. Provision of free COVID-19 testing to all workplace employees (employees absent from the workplace during the times of an outbreak are excluded), and;
2. Specific testing requirements, including follow up testing at specified intervals are delineated as well.

Bearing in mind that an employer must follow with great diligence those requirements stated previously regarding exclusion of COVID-19 cases from the workplace and investigation of workplace COVID-19 cases, in the specific instance of a COVID-19 <u>outbreak</u>, the employer's investigation previously outlined must now also include a thorough review of unabated COVID-19 hazards, including a re-examination of its existing employee leave policies and practices, testing policies, sufficiency of outdoor air flow into the workplace and workplace filtration, and whether its social distancing policies must be adjusted. This re-examination of its policies and practices must be updated every 30 days that the outbreak continues, and the employer must implement changes to its Plan based up each review where such changes are deemed necessary and appropriate.

- **Notifications to the local health department:** In the instance of a COVID-19 outbreak (i.e., three or more cases) in the workplace, the employer should contact the local health department immediately, but in any event no longer than 48 hours after the employer, through the exercise of reasonable diligence, learns of the outbreak. There is a listing in the regulation of required information that the employer must provide to the health department, including the total number of cases in the outbreak, identifying information of the affected employees, and other information as requested.

Major COVID-19 Outbreaks

In the instance when there are 20 or more COVID-19 cases in an exposed workplace *within a 30-day period,* the following provisions shall apply until there are no new COVID-19 cases detected in the workplace for a 14-day period;

1. Employers shall provide twice a week free COVID-19 testing to all employees present at the workplace during the relevant 30-day period and who remain at the workplace.
2. Employees shall ensure that COVID-19 cases and employees who are so exposed are excluded from the workplace pursuant to the quarantine requirements so stated previously.
3. More stringent safety protocol than previously mentioned

is mandated in the instance of a major COVID-19 outbreak, including re-investigation of the workplace, hazard corrections, re-analyzing engineering controls and a review and modification of workplace protection protocol as deemed necessary.
4. Employer shall notify the local health department as required for any outbreak of COVID-19 in the workplace.

Prevention in Employer-Provided Housing

Prevention in Employer-Provided Transportation to and from Work

The new regulation sets forth a multitude of safety requirements in instances where the employer provides housing [§ 3205.3], or to-and-from work transportation [§ 3205.4]

to employees. The reader is encouraged to review the requirements set forth in these sections of the regulation should either or both these circumstances exist to ensure full compliance with these provisions.

Final Takeaway

A reading of the new COVID-19 emergency regulation makes it abundantly clear that California state and local officials are taking the current (and largest to date) surge in COVID-19 cases in a most resolute fashion and the resulting requirements for workplace safety and health protocols to an extreme level. In several instances, the mandated requirements place such great onus upon the employer towards the health and safety of its employees that it might be said that the employer assumes a near caregiver-like responsibility towards its workplace employees.

In addition to the suggestion that the employer carefully revisit its current Injury and Illness Prevention Program, employers must, wherever appropriate, augment that program by creating an additional written COVID-19 Plan that addresses workplace hazard identification, evaluation and correction; periodic investigations, and in the instance of COVID-19 outbreaks, more in-depth additional investigations; employee COVID-19 prevention training; physical distancing, hygiene and face covering requirements, administrative and engineering controls, reporting and recordkeeping, and return-to-work criteria. Atop all this, the employer must come to terms with the daily prospect that its workplace could suffer an immediate reduction of on-site employees through an exposure to a multiple or major COVID-19 outbreak, which could require expulsion of several from the workplace all at once, and for a lengthy period of time.

There is also the looming prospect that should an employer inadvertently fail to adhere to the letter of the regulation, it could face deficiency notices and penalties from state or local agencies whom we can expect will order its agents to conduct workplace inspections for Plan compliance, and who will be trained to identify any deficiencies and violations.

The best advice one might give to employers in these particularly onerous times is for each to initiate a review of this newly enacted emergency COVID-19 regulation, focusing carefully upon those requirements that apply to its specific workplace environment. The employer should ensure that it has a written COVID-19 Plan in place, goes to great lengths to adhere to the Plan, and together with its team of employees, maintain safe and common sense workplace health practices while exercising great vigilance and providing healthy doses of patience and thoughtfulness towards the workplace environment until such time that the virus is finally behind us.

Nelson Hardiman stands ready to provide additional information on the regulation as necessary. In the interim and given the enormity of the burden this emergency regulation places upon employers, feel free to contact your regular Nelson Hardiman contact or the author of this Client Alert, Alan J. Sedley, should you have any questions or concerns.

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Stark and Anti-Kickback Rules Finalized

Stark and Anti-Kickback Rules Finalized
After considering comments responding to the proposed rule published in October 2019, the Centers for Medicare and Medicaid Services ("CMS") and Office of the Inspector General ("OIG") finalized extensive changes to the Stark and Anti-Kickback regulations (the "Stark Final Rule" and "AKS Final Rule") and the Civil Monetary Penalties ("CMP") Law (collectively, the "Final Rules") as part of the "HHS Regulatory Sprint to Coordinated Care" aiming to remove barriers to coordinated care and value-based care. These Final Rules went on display at the *Federal Register* on November 20, 2020 and were published in the Federal Register on December 2, 2020. Generally, the Final Rules will take effect on January 19, 2021. A brief overview of the Final Rules is below, the AKS Final Rule (with CMP) is available here and the Stark Final Rule is available here.

Electronic Health Records (EHR) and Cybersecurity Changes

The Final Rules revised the electronic health record ("EHR") Stark exception and Anti-Kickback safe harbor and eliminated the sunset provisions. The Stark and AKS Final Rules clarify that donations of certain cybersecurity software and services are permitted under the EHR exception and also permit physicians to pay their portion of EHR costs at reasonable intervals rather than requiring payment in advance prior to receipt of items and services. The Final Rules also made changes to be consistent with the 21st Century Cures Act with respect to interoperability and information blocking. Notably, the Final Rules also remove the requirement that donors must ensure they are not providing equivalent EHR technology, in order to allow for "replacement" of EHR technologies.

New Value-Based Model Stark Exceptions and Anti-Kickback Safe Harbors

In the Final Rules, CMS and OIG acknowledge that the Stark and AKS laws originally contemplated a "fee for service" payment environment, which resulted in an unnecessary chilling effect on certain risk-sharing models. The Final Rules aim to facilitate certain risk-based payment structures by creating three new "value-based" permissible payment methodologies under both Stark and AKS. The value-based payment methodologies are:

- Full financial risk;
- Value-based arrangements with meaningful downside financial risk to the physician; and
- Value-based arrangements.

These new "value-based model" exceptions and safe harbors involve similar arrangements and terminology (but the requirements do not exactly mirror each other) and support arrangements designed to achieve one or more of the following purposes:

- Coordinating and managing the care of a target patient population;
- Improving the quality of care for a target patient population;
- Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or
- Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

Notably, the new value-based Stark exceptions *do not* require that compensation be set in advance, consistent with fair market value, or determined in manner that does not take into account the volume or value of the physician's referrals or other business generated by the physician.

Unlike the new Stark value-based exceptions, the new Anti-Kickback safe harbors impose restrictions on the parties eligible to use the new value-based safe-harbors. According to the OIG, certain entities which are not on the front line of care coordination are ineligible for protection under certain of the new safe harbors. These entities include: pharmaceutical manufacturers, distributors, and wholesalers; PBMs; laboratory companies; pharmacies that primarily compound drugs or primarily dispense compounded drugs; manufacturers of devices or medical supplies; entities or individuals that sell or rent DMEPOS (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); physician owned distributors ("PODs"); and medical device distributors and wholesalers. In certain situations, manufacturers of devices or medical supplies and DMEPOS may qualify for protection under the care coordination arrangements safe harbor.

Other Stark Changes Related to Value-Based Models

In addition to creating new exceptions, CMS further modified the compensation rules to allow for group practices to compensate physicians through certain risk-bearing arrangements and value-based incentives as further described below.

Indirect Compensation. In some cases, a physician compensation model under a value-based arrangement might take into account the volume or value of referrals or other business generated by the physician to the entity or may not be fair market value for specific items or services provided by the physician which created issues with related to satisfying the requirements of the indirect compensation exception under 42 C.F.R. §411.357(p). In order to address this issue the Stark Final Rule allows a physician's referrals to an entity when an indirect compensation arrangement includes a value-based arrangement to which the physician (or the physician organization in whose shoes the physician stands) is a direct party, provided the link closest to the physician is a compensation arrangement that meets the definition of "value-based arrangement" as defined in the Stark Final Rule.

Additionally, compensation made under risk-sharing arrangements may not always be consistent with fair market value. CMS narrowed "indirect compensation arrangements" to include only those arrangements where the individual unit of compensation is not fair market value, or the individual unit of compensation received by the physician is calculated using a formula that varies with the referrals of the physician or varies with the other business generated by the physician in a way that positively correlates to the compensation received by the physician as indirect compensation. While CMS acknowledged this could create many more unbroken chains of financial relationships not requiring a writing, CMS cautioned that best practice is to have a written agreement.

Group Practice Compensation. CMS finalized changes to the group practice compensation rules for profit sharing and productivity bonuses deeming profits directly attributable to a physician's participation in a value-based enterprise as not relating to the "volume or value" of the physician's referrals. CMS delayed the effective date of this change until January 1, 2022 to allow group practices time to modify their compensation arrangements.

Additionally, CMS confirmed that groups may use the "component of five" rule allowing for distribution of overall profits of all DHS for the whole group or any component of the group of five or more physicians so long as profits are aggregated before distribution. CMS rejected comments that DHS could be distributed to "components of five" based on a service-by-service basis, such as laboratory tests or x-rays.

Key Stark Concepts Clarified

Commercial reasonableness, fair market value, and the volume or value of services are concepts common to many Stark exceptions. CMS confirmed in the Stark Final Rule that each of these terms are separate and distinct and attempted to provide additional clarity regarding each of these concepts, which historically have not been well defined.

Commercial Reasonableness. In determining commercial reasonableness, CMS commented that the key consideration is whether the arrangement makes sense in accomplishing the parties' goals. As a result, a commercial reasonableness assessment must be a fact-specific analysis from the perspective of the parties involved in the arrangement. CMS specified that determination of commercial reasonableness does not involve valuation nor does it require that the arrangement will be profitable. Rather, under the Stark Final Rule the definition of "commercially reasonable" means an arrangement that furthers a legitimate business purpose of the specific parties to the arrangement and is sensible, considering the size, type, scope, and specialty of the parties.

Volume or Value Standard and the Other Business Generated Standard. CMS still has not defined volume or value but did codify the meaning of the term "volume or value of referral and other business generated" within the special rules on compensation to and from physicians. According to the Stark Final Rule, physician compensation "takes into account the volume or value of referrals or other business generated" only when the formula used to calculate compensation to or from a physician includes the volume or value of referrals or other business generated as a variable, either increasing or decreasing the amount of compensation in a way that directly correlates with referrals or other business generated.

Fair Market Value and General Market Value. The Stark Final Rule finalized the definition of "fair market value" to mean the value in an arm's-length transaction consistent with the "general market value" of the subject transaction. In other words, the valuation should not take into account the particular value between the parties. For example, when evaluating equipment, fair market value must be determined considering the value created by its intended use. Similarly, while in reality real estate valuation often revolves around "location, location, location!" an office space lease valuation for Stark purposes should focus on use of the space for general commercial purposes without any adjustment to reflect the additional value the prospective lessee or lessor would attribute to patient convenience or proximity to a particular referral source.

The Stark Final Rule also finalized the definition of "general market value" related to each type of transaction (asset acquisition, compensation for services, and rental of equipment or office space) but did not include its proposal to equate general market value with market value. All definitions are based on the bona fide bargaining between a well-informed buyer and seller that are not in a position to refer to each other.

Notably, CMS indicated that there may be legitimate reasons for why arm's length negotiations between parties may result in a different amount of compensation than what the market typically pays. For example, a salary survey indicating that compensation of $450,000 per year would be appropriate for an orthopedic surgeon in the geographic location of the hospital. However, if the orthopedic surgeon with whom the hospital is negotiating is one of the top orthopedic surgeons in the country and is highly sought after by professional athletes with knee injuries due to his specialized techniques and success rate; this particular physician may command a significantly higher salary and according to CMS compensation substantially above $450,000 per year may be fair market value for this particular orthopedic surgeon.

Other Changes to Stark Regulations

In addition to value-based model changes, CMS finalized several new rules and revised several others which will be helpful in addressing administrative and other historically problematic or confusing Stark compliance issues. We think several of these will be very useful in addressing common Stark compliance challenges and recommend a careful review of the regulatory language and commentary.

Reconciliation of Compensation Errors. CMS added a new rule that allows parties to reconcile compensation errors for up to 90 days after a compensation arrangement ends. 42 C.F.R. §411.353(h).

Limited Remuneration to a Physician. This new exception allows for the provision of limited remuneration to a physician if certain requirements are met, including instances when the amount of, or a formula for, calculating the remuneration is not set in advance of the provision of items or services and the remuneration does not exceed an aggregate of $5,000 per calendar year. 42 C.F.R. §411.357(z). We note this exception could be helpful in addressing compensation to a physician without a signed agreement and CMS specifically stated this exception may be used in conjunction with the special rules that allow 90 days to document and sign an arrangement.

Electronic Signatures. CMS has included a new provision specifically allowing electronic signatures that are valid under federal or state law. 42 C.F.R. §411.354(e)(3).

Patient Choice and Directed Referrals. Under the special rule for directed referrals, an entity is permitted to direct a physician who is a bona fide employee, independent contractor, or party to a managed care contract, to refer to a specific provider, practitioner, or supplier. CMS finalized its proposal to add specified conditions designed to preserve patient choice, comply with insurer’s determinations, and protect the physician’s judgment as to the patient’s best medical interests requirements to §411.354(d)(4) as an element of the exceptions for the following:

- § 411.355(e) for academic medical centers;
- § 411.357(c) for bona fide employment relationships;
- § 411.357(d)(1) for personal service arrangements;
- § 411.357(d)(2) for physician incentive plans;
- § 411.357(h) for group practice arrangements with a hospital, §411.357(l) for fair market value compensation, and
- § 411.357(p) for indirect compensation arrangements.

CMS also added a condition that neither the existence of a compensation arrangement nor the amount of compensation may be contingent on the volume or value of referrals to a particular provider, practitioner, or supplier. However, an arrangement, may require that the physician refer an established percentage or ratio of the physician’s referrals to a particular provider, practitioner, or supplier.

Compensation Documentation and Set in Advance. CMS added the ability to document and sign agreements within 90 days of the beginning of the arrangement to the special rules on compensation arrangements. The arrangement must satisfy all requirements of an applicable exception except for the writing and signature, and the 90-day period does not apply to agreement modifications/amendments.

The Final Stark Rule also added flexibility to the “set in advance” requirements so that compensation may be amended during the term of an agreement so long as the new compensation is not based on the volume or value of referrals. Importantly, the change can occur at any time, including the first year, as long as all of the requirements of an applicable exception are met as of the date of the amendment; the new compensation (or formula) is set prior to the furnishing of the items, services, office space, or equipment; and the new compensation (or formula) is set forth in writing in sufficient detail so that it can be objectively verified. Importantly, the new compensation need not remain in place for a year and there is no limit to the number of times that the compensation may be amended during the term of an agreement.

Revisions to Definitions. CMS finalized revisions to several definitions including: (i) designated health services; (ii) physician; (iii) referral; (iv) remuneration; and (v) transaction. Importantly, CMS confirmed that an isolated transaction does not include a single payment for multiple services over an extended period of time, but does include a payment made to forgo compensation in a bona fide dispute.

Fair Market Value Compensation Exception-Office Space. CMS finalized extending the exception for fair market value compensation arrangements to office space leases. The prohibitions on per unit of service and percentage-based arrangements are incorporated into the fair market value exception for office space leases, but notably a one-year term is not required (unlike many other Stark exceptions).

Eliminated Period of Disallowance. CMS finalized its proposal to delete the rules on the period of disallowance in their entirety due to the confusion surrounding the ways it had been interpreted.

Removing Link to AKS and other Laws. CMS stated generally compliance with the AKS and federal and state laws or regulations governing billing or claims submission are no longer necessary requirements of the exceptions to the physician self-referral law. Accordingly, the Stark Final Rule removes this requirement from all physician self-referral law exceptions other than the fair market value exception at 42 C.F.R. §411.357(l).

Anti-Kickback Statute Safe Harbor Changes

In addition to creating new safe harbors, the OIG finalized various changes and clarifications to existing safe harbors, as further described below.

Personal Services and Management Contracts Safe Harbor. In addition to creating new value-based exceptions, the OIG made changes to the personal services and management contracts safe harbor to address potential issues that could be created by risk-sharing arrangements.

The personal services and management contracts safe harbor was revised to permit certain outcome-based payment arrangements, which must be based on the achievement of measures with clinical evidence or credible medical support. The safe harbor requires that payments for any such arrangement measurably improve or maintain care or materially reduce costs. The safe harbor does not cover:

- Outcomes measures related solely to patient satisfaction or patient convenience;
- Outcomes-based payments that relate only to internal cost savings; and
- Relationships with pharmaceutical manufacturers, distributors, wholesalers, PBMs, laboratory companies, compound pharmacies, certain device manufacturers, and durable medical equipment suppliers.

In addition, the “set in advance” requirement for this safe harbor was modified so that the only compensation methodology (and not the aggregate payment) need be set out in advance. Also, the OIG removed the requirement that part-time arrangements have a schedule of services specifically set out as part of the written agreement.

Modification to the Warranty Safe Harbor. This safe harbor was modified to allow protection for a bundle of one or more items and related services, provided the items and services are all paid for by the same payor and under the same payment, subject to a cap for compensation paid under the warranty at the amount paid for the item(s) or bundle of items and services. The safe harbor does not cover:

- Population-based warranties that do not receive safe harbor protection; and
- Service-only warranties.

Modification to Local Transportation Safe Harbor. The AKS Final Rule finalized modifications to this safe harbor with some changes to the proposed rule. The OIG expanded the mileage limits up to 75 miles (from 50 miles in the Proposed Rule) for residents in rural areas and eliminated any distance requirement for conveying inpatients to their residence upon discharge. Additionally, the finalized modifications permit ride-sharing arrangements.

ACO Beneficiary Incentive Program Safe Harbor. The Balanced Budget Act of 2018 included a statutory provision excluding incentive payments made to a beneficiary who receives such payments as part of the ACO Beneficiary Incentive Program. The OIG codified the Balanced Budget Act provision as a new safe harbor without modification at 1001.952(kk), which protects incentive payments made by an ACO to an assigned beneficiary under a beneficiary incentive program established under Section 1899(m) of the Act if the incentive payment is made in accordance with the requirements found in Section 1899(m) of the Act.

Civil Monetary Penalty ("CMP") Changes

The Final Rules amend Beneficiary Inducements CMP regulations at 42 CFR 1003 to allow for providing telehealth technologies to end-stage renal disease (ERSD) patients receiving home dialysis treatment without violating beneficiary inducement prohibitions. "Telehealth technologies" are defined (more broadly than in the proposed rule) to include hardware, software, and services that support distant or remote communication between the patient and provider, physician, or renal dialysis facility for the diagnosis, intervention, or ongoing care management. The Final Rules modify the OIG's proposed rule by removing most of the additional proposed conditions and proposed regulatory text language that were not in the exception set forth in the Creating High-Quality Results and Outcomes Necessary to Improve Chronic Care Act of 2018. For example, the OIG did not finalize the following requirements:

- The technology "is not of excessive value";
- The technology is not duplicative of technology that the beneficiary already owns if that technology is adequate for the telehealth purposes; and
- The provider of services or a renal dialysis facility does not bill Federal health care programs, other payors, or individuals for the telehealth technologies, claim the value of the telehealth technologies as a bad debt for payment purposes under a Federal health care program, or otherwise shift the burden of the value of the telehealth technologies onto a Federal health care program, other payors, or individuals.

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Modern Counsel: Lara Compton Has Attained Off-Script Success

Partner [Lara Compton] was featured in the October 2020 Healthcare issue of [Modern Counsel]. Modern Counsel is a distinguished publication featuring a network of today's most influential in-house counsel. Their stories shape the business of law.

From the article:

> *"Lara Compton carved out an unusual path to law. Now, she brings her passion for wellness to Nelson Hardiman, where she tackles the complexities of healthcare regulation.*

> If there's one lesson Lara Compton has learned on her way to becoming a partner at Nelson Hardiman, a healthcare and life sciences law firm based in Los Angeles, it's that life doesn't always go as planned. But that doesn't mean you can't be successful.
>
> A premed student in college, Compton originally had set her sights on becoming a doctor. After graduation, she worked at a blood bank and conducted HIV vaccine research at an R&D laboratory.
>
> "I applied to medical school twice, and after being waitlisted both times, I realized it was time to reevaluate my plans," she recalls. "It was pretty disheartening. I was trying to figure out what to do next, since it didn't look like medical school would be an avenue for me."

A friend suggested that Compton could take all her training and flip it around, citing coworkers who had used their knowledge to become patent attorneys.

“It had never occurred to me that there were so many different types of lawyers. When I pictured practicing law in my mind, I thought of litigation, and I knew I didn’t want to do that,” Compton says. “I sat in on a few law school classes and discovered I really liked the subject matter and the critical thinking involved. I also liked that I could build upon my love for science and healthcare rather than leave it behind.”

She was twenty-nine when she started law school and did “surprisingly well.” Although Compton thought she would focus on patent law, once she took a class on healthcare law and learned about the regulations involved, a new passion was born.

A friend encouraged her to apply for a clerkship at the California Department of Managed Healthcare. As a clerk, she helped draft regulations and opinion letters. Along the way, she soaked up knowledge about HIPAA regulations and other areas she found fascinating.

As luck would have it, when Compton finished law school in 2006, a small hospital system in Fresno was looking for a new graduate. Her clerk experience helped her land the job.

“It was the best experience I could have had as a young lawyer. We did everything in the legal department for several hospitals, and I got to see it all,” Compton says, who became a trusted go-to lawyer for healthcare regulatory work. “I learned HIPAA frontward and backward. There were several pieces of substantial hospital licensing that had been passed, and I was charged with interpreting and implementing those requirements.”

“I felt I was really contributing to the communities involved by assisting with the continued operation of the distressed hospitals as the COVID-19 crisis unfolded. We made it through the initial phases of the pandemic. It was definitely an interesting time to be hospital counsel."

Today, at Nelson Hardiman, Compton advises traditional health care clients and works with innovative products and technology. She also collaborates with healthcare providers amid the increasing push toward telehealth and the incorporation of more technology within the healthcare industry.

"In addition to my practice, I'm managing the regulatory practice as a whole, monitoring regulatory trends and making sure folks are aware of all the different changes happening," she notes. This work grew more important during the initial months of the COVID-19 pandemic. "We had to help our clients who either had not considered using telehealth due to various limitations or were not yet prepared to use telehealth quickly pivot to the use of telehealth technology. The infrastructure seemed to be built overnight."

Additionally, for more than a year, Compton served as special regulatory counsel for a major hospital system going through one of the largest bankruptcy filings in history. The engagement involved providing regulatory compliance support for the hospital system's day-to day operations, including serving as outside compliance officer as well as extensive regulatory work on the sale of the system's assets. That took up a lot of her time in 2020. Happily, she navigated the transition of ownership successfully, even as the pandemic unfolded and she dealt with multiple competing priorities.

> *"I felt I was really contributing to the communities involved by assisting with the continued operation of the distressed hospitals as the COVID-19 crisis unfolded,"*

> *she explains. “We made it through the initial phases of the pandemic. It was definitely an interesting time to be hospital counsel.”*

> While Compton notes she was a little “crushed” when she didn’t get into med school, she has no complaints now and is happy to be making a difference by helping her clients navigate difficult healthcare regulatory issues.
>
> “I love having a front row seat to healthcare innovation as it evolves, for example, software, telehealth platforms, and AI,” she enthuses. “I love doing this kind of work because it’s new and different and most of the time there isn’t an obvious answer. I love solving that puzzle.” “

Read Full Article

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Bloomberg Law: Organized Crime Claims Won’t Fly in San Francisco’s Opioid Trial

Managing Partner, Harry Nelson, was interviewed by Bloomberg Law regarding opioid litigation. A federal judge in California allowed San Francisco’s opioid lawsuit to move forward but dismissed the city’s racketeering claims.

From the article:

The court’s decision to let San Francisco’s unfair competition claims proceed could offset some of the lost potential of the

RICO claims, said Harry Nelson, a partner and founder of Nelson Hardiman LLP, a health care-focused firm in Los Angeles. That's because California has a strong unfair business practices law, he said.

"You're entitled to disgorge all the profits associated with" actions found to run afoul of the law, Nelson said. "That opens up a new level of potential damages risk. It's a legal theory that's been very threatening to businesses in California– it's been fuel to the plaintiff's bar here."

Read Full Article

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Client Alert: Beginning 2023, Nurse Practitioners will be eligible for Independent Practice and Medical Staff Membership

On September 29, 2020, Gov. Gavin Newsom signed into law AB 890, which grants Nurse Practitioners expanded scopes of practice in certain settings, with a three-year transition period, enabling NPs to engage in independent practice beginning 2023.

Existing law authorizes Nurse Practitioners to perform certain acts in collaboration with a physician and pursuant to a standardized procedure. AB 890 reflects Nurse Practitioners' hard fought changes to the Business and Professions Code – most notably, allowing certified NPs to practice independently of physicians and without standardized procedures; prohibiting the referral of patients to persons or entities with whom the NP has a financial interest; and including NPs in the definition of "licentiates" for membership on hospital medical staffs and participation in certain medical staff committees. Mandatory reporting by hospital medical staffs to the Board of Registered Nursing will be triggered when NPs are disciplined for reasons related to the NPs' patient care. Unlike physician members, NPs will not be afforded hearing rights under the statutory framework.

The bill also creates a Nurse Practitioner Advisory Committee to advise the Board of Registered Nursing on matters relating to NPs, including setting minimal standards for NPs to transition to independent practice, advising on license disciplinary matters and certification standards, and determining the need for supplemental examination requirements or waivers.

If you have any questions regarding the changes noted above, Nelson Hardiman attorneys are here to answer your questions. Feel free to contact [Sara Hersh]() or [Miriam Mackin]() at 310-203-2800.

The Business and Professions Code will amend Sections 650.01, 805, and 805.5 of, and add to Article 8.5 (commencing with Section 2837.100) to Chapter 6 of Division 2 of, the Business and Professions Code, relating to healing arts.

This article is provided for educational purposes only and is not offered as, and should not be relied on as, legal advice. Any individual or entity reading this information should *consult an attorney for their particular situation.*