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COVID-19 HEALTHCARE PROVIDER UPDATES: PHYSICIAN PRACTICES

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CORONAVIRUS COVID-19



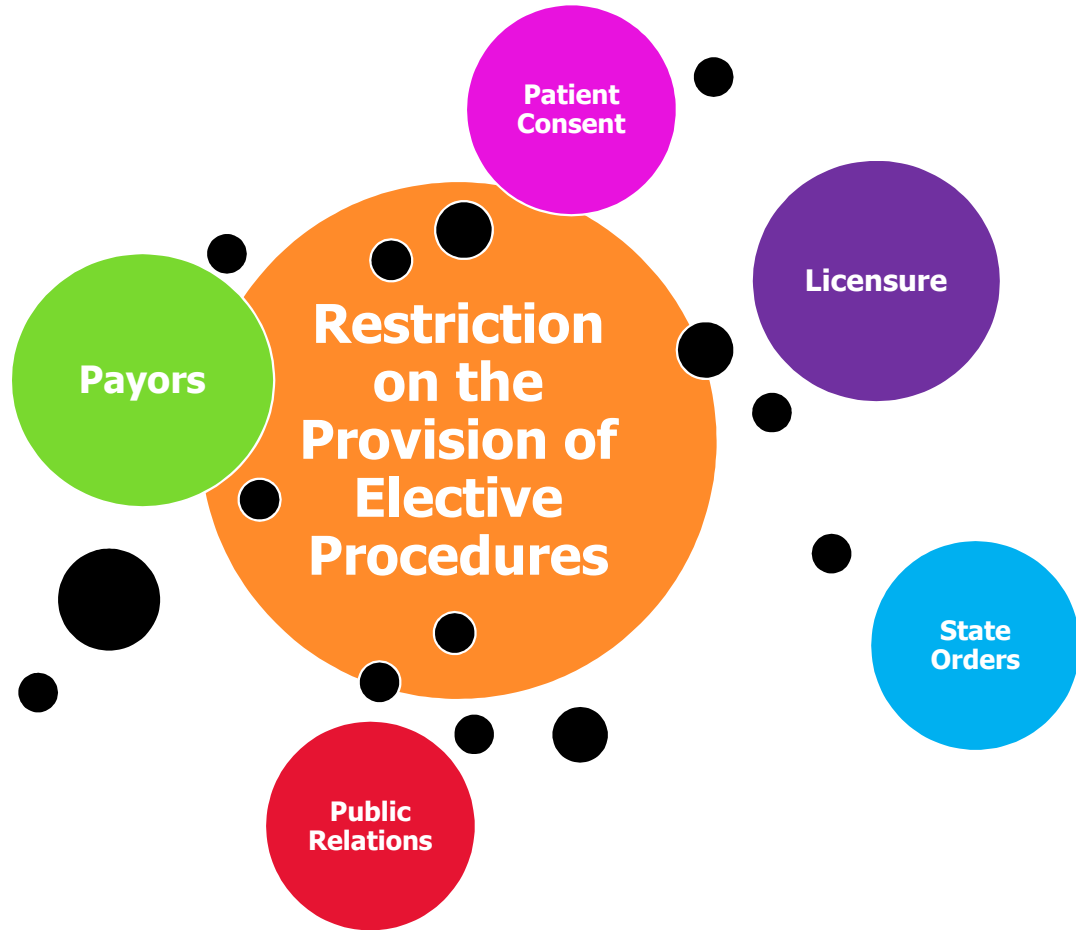
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Agenda

- Provision Of Elective, Non-urgent Surgeries And Procedures
- 1135 Waiver: Stark Law

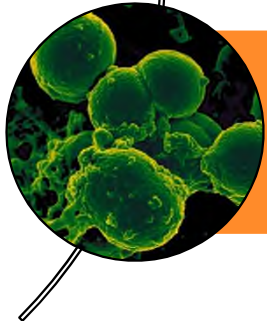
PROVISION OF ELECTIVE, NON-URGENT SURGERIES AND PROCEDURES DURING COVID-19 OUTBREAK



Universal Goals of Restriction



Preserve PPE



Reduce exposure to COVID-19

Payors - Reimbursement

- **Medicare - CMS**

- On March 18, 2020, CMS recommended that all elective surgeries, non-essential medical, surgical, and dental procedures be delayed during the COVID-19 outbreak.
- The [CMS guidance](#) is intended to limit “non-essential adult elective surgery and medical and surgical procedures, including all dental procedures” performed in **any** setting, includes office-based procedures.
- CMS directed providers to analyze “the risk and benefit of any planned procedure,” and “not only must the clinical situation be evaluated, but resource conservation must also be considered.”
- Unclear how “recommendation” will be enforced.
- Monitor MAC and other guidance

CMS Recommendation

- CMS included a [chart](#) to guide decision making and suggests that the following factors be considered as to whether planned surgery or procedures should proceed:
 - Current and projected COVID-19 cases in the facility and region.
 - Supply of PPE to the facilities in the system
 - Staffing availability
 - Bed availability, especially intensive care unit (ICU) beds
 - Ventilator availability
 - Health and age of the patient, especially given the risks of concurrent COVID-19 infection during recovery
 - Urgency of the procedure.

Payors - Reimbursement

- **Commercial Payors**

- Important to *monitor payor provider communications as to coverage/payment* of procedures that may be determined (later) to have been performed in violation of a state or Board of Medicine directive
- Payors may release procedures (by CPT) they would expect to regard as 'urgent.'
- Typical prior authorization procedures may be enhanced
- Commercial payors typically reserve the right to retrospectively review "medically necessary" documentation
- Required documentation for "medically necessary" procedures could rise to a higher standard of "medically *and critically required*" if procedure was performed in possible contradiction of an EO, Medical Board guidance, etc.

State Order – Texas Example

- Governor Abbott issued an [executive order](#) on March 22, 2020.
- The order directed all licensed health care providers to postpone all surgeries and procedures that “are not immediately necessary to correct a serious medical condition of, or to preserve the life of, a patient who without immediate performance of the surgery or procedure would be at risk for serious adverse medical consequences or death, as determined by the patient’s physician.”
- Failure to comply may result in penalties of up to \$1,000 or 180 days of jail time.
- This order is in addition to other executive orders applicable to all businesses, and local (county and city) orders issued in Texas.

Licensure – Texas Example

- Following Texas Governor EO GA-09, on March 24, 2020, the Texas Medical Board (“TMB”) released emergency rules on the provision of non-emergent surgeries and procedures (and has subsequently issued [additional guidance and FAQs](#)).
- The TMB emergency rules apply to procedures performed in any setting, including office based procedures.

TMB – Emergency Rules



Disciplinary Action – [22 Tex. Admin. Code § 187.57](#)

- Causes the performance of a “non-urgent elective surgery or procedure” to be considered a “continuing threat to the public welfare.”
- Violation of this rule may result in a temporary restriction or suspension of a physician’s license.



Mandatory Reporting – [22 Tex. Admin. Code § 178.4](#)

- Imposes an immediate, mandatory reporting requirement on certain individuals and entities, including, physicians and physician assistants.
- Certain individuals and entities must immediately report any physician “scheduling to perform, preparing to perform, performing, or who has performed a non-urgent elective surgery or procedure” to the TMB.

State Order – Oregon Example

- Governor Kate Brown issued [Executive Order No. 20-10](#) on March 19, 2020, mandating that all elective and non-urgent procedures across all settings that utilize PPE, including, but not limited to, hospitals, ambulatory surgery centers, outpatient clinics, dental clinics, and ***veterinary clinics***, to be cancelled, or rescheduled to no earlier than June 15, 2020.
- A procedure is exempt from the limitations if a 3 month delay in the procedure or surgery would put the patient at risk of irreversible harm.
- Criteria for determining whether irreversible harm exists include but are not limited to: (i) threat to the patient's life; (ii) treat of irreversible harm to the patient's physical or mental health; (iii) threat of permanent dysfunction of an extremity or organ system; (iv) risk of metastasis or progression of staging; or (v) risk of rapidly worsening to severe symptoms (time sensitive).
- Violations may result in penalties, including up to 30 days in jail, a fine of up to \$1,250, or both.

Interpreting Multiple Directives

- State Medical Associations and specialty societies working to seek clarifications
- Hospitals working through interpreting directives
- Accreditation bodies working through interpreting directives
- Interpretation critical now, and during 'return to normal' process



Informed Patient Consent

- Consider possible need for changes to or an additional patient informed consent.
- Documenting discussion of risks of exposure to COVID-19, as well as typical risks of a procedure.
- Clear documentation of why the procedure or surgery cannot or can be postponed.

Public Relations

- How will postponing procedures impact a provider from a public relations perspective?

HEALTH

Coronavirus canceled her chemotherapy. Should cancer patients still go to appointments?

HEALTH

Elective surgeries continue at some US hospitals during coronavirus outbreak despite supply and safety worries

1135 WAIVER: STARK LAW

1135 Waiver: Stark Law

- Included in the Secretary's March 13, 2020 1135 Waivers was the following: "Sanctions from section 1877(g) (relating to limitations on physician referrals) under such conditions and in such circumstances as the Center for Medicare & Medicaid Services determines appropriate."
- But this was not a blanket waiver; CMS would grant waivers only on a case-by-case basis, based on the details concerning the actual or proposed financial relationship between the referring physician and entity.
- Unless and until a waiver is granted to the requesting parties, compliance with the Stark Law is required.

1135 Waiver: Stark Law

- Blanket waiver issued on March 30, 2020, with effective date retroactive to March 1, 2020.
- Waivers may be revised or terminated by the Secretary on a prospective basis.
- Waivers do not require submission of documentation or notice to the Secretary in advance of use.
- Parties are encouraged to develop and maintain records relating to the use of blanket waivers and must make records available to the Secretary on request.

1135 Waiver: Stark Law

- Blanket waivers apply only to financial relationships and referrals that are related to COVID-19 emergency.
- Remuneration must be directly between an entity and a physician, the physician's organization, or the physician's immediate family member.
- Remuneration and referrals described in waivers must be solely related to COVID-19 purposes.

1135 Waiver: Stark Law

COVID-19 purposes include:

- Diagnosis or medically necessary treatment of COVID-19 patients.
- Securing the services of physicians and other health care practitioners to furnish medically necessary patient care services, including services not related to COVID-19, in response to the COVID-19 outbreak.
- Ensuring the ability of, and expanding the capacity of, healthcare providers to address patient and community needs due to COVID-19.
- Shifting the diagnosis and care of patients to alternate settings.
- Addressing medical practice or business interruption due to the COVID-19 outbreak in order to maintain the availability of medical care and related services for patients and the community.

1135 Waiver: Stark Law

Waiver for:

- Remuneration from an entity (e.g., hospital) to a physician or immediate family member that is above or below FMV for the services personally performed by the physician.
 - Example: Hospital pays a physician above previously-contracted rate for furnishing services to COVID-19 patients in challenging environments.
- Rental charges paid by entity (e.g., hospital) to a physician or immediate family member that are below FMV for the entity's lease of office space or equipment from a physician.
 - Example: Hospital rents office space or equipment from a physician practice to accommodate patient surge at or below FMV.
- Remuneration from an entity to a physician or immediate family member that is below FMV for items and services purchased from physician.
 - Example: Hospital or HHA purchases items or supplies from a physician practice at below FMV or at no charge.

1135 Waiver: Stark Law

Waiver for:

- Rental charges paid by physician or immediate family member to an entity that are below FMV for lease of office space from entity.
 - Example: Hospital provides free use of office space on campus to allow physician to provide timely and convenient services to patients who come to hospital but do not need inpatient care.
- Rental charges paid by physician or immediate family member to an entity that are below FMV for lease of equipment from entity.
 - Example: Entity provides free telehealth equipment to physician practice.
- Remuneration from physician or immediate family member that is below FMV for use of entity's premises or for items or services purchased by physician from entity.
 - Example: Entity sells PPE to physician at below FMV or provides at no cost.

1135 Waiver: Stark Law

Waiver for:

- Remuneration from a hospital to a physician in the form of medical staff incidental benefits that exceed the limit - \$36 per instance.
 - Example: Hospital provides meals, comfort items, childcare with value greater than \$36 per instance to physician who spends long hours in hospital.
- Remuneration from an entity to a physician or immediate family member in the form of nonmonetary compensation that exceeds the limit - \$423 per year.
 - Example: Entity provides CME related to COVID-19, supplies, food or grocery items, isolation/related needs, childcare, or transportation.

1135 Waiver: Stark Law

Waiver for:

- Remuneration from an entity to a physician or immediate family member resulting from a loan to the physician with an interest rate that is below FMV or on terms not available on the open market (i.e., only available from the hospital).
 - Example: Hospital lends money to a physician practice that furnishes services at the hospital
- Remuneration from physician or immediate family member to entity resulting from a loan to the entity with below FMV interest rate or on terms not available on the open market.
 - Example: Physician owner of hospital lends money to hospital.

1135 Waiver: Stark Law

Waiver for:

- Referral by physician owner of hospital that temporarily expands facility capacity.
- Referral by physician owner of hospital converted from ASC on or after March 1, 2020.
- Referral of Medicare beneficiary to home health agency in which physician or immediate family member has ownership or investment interest.
- Referral of patient residing in rural area by physician to entity with which physician's immediate family member has financial relationship.

1135 Waiver: Stark Law

Waiver for:

- Referral by physician in group practice for medically necessary designated health services furnished by group in location that doesn't qualify as same building or centralized building.
 - Example: Group practice that meets Stark definition furnishes medically necessary MRI or CT services in a mobile unit in parking lot to patients who normally receive the services at a hospital.
- Referral by physician in group practice for medically necessary designated health services furnished by group to patient in private home, assisted living facility, or independent living facility.
 - Example: Physician in group practice that meets Stark definition whose principal medical practice is office-based orders radiology services furnished by group to patient in patient's home.

1135 Waiver: Stark Law

Waiver for:

- Referrals by a physician to an entity with whom the physician has a compensation arrangement that does not satisfy the writing or signature requirements of an applicable exception, but satisfies the other requirements of the exception.
 - This waiver is a regulatory change proposed by CMS as a result of the Regulatory Sprint effort.
 - Accommodates compensation arrangements that can meet the requirements of an applicable exception (e.g., Fair Market Value or Personal Service Arrangements), but for the writing and signature requirements.
 - Examples: A physician provides call-coverage services before the arrangement is documented and signed by the parties.
 - Daughter of a physician begins working as the hospital's paid COVID-19 outbreak coordinator before the arrangement is documented and signed by the parties.

Biography



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Donna Clark advises healthcare providers on issues concerning US federal laws governing the relationships between physicians and other healthcare providers, and the entities to which they refer patients. Donna has practiced healthcare law exclusively for nearly 35 years and is intimately familiar with the potential issues healthcare providers may encounter, as well as the solutions available to them.

Biography



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Joyce A. Cowan has more than 30 years' experience counseling healthcare organizations on transactions, regulatory, compliance, and public policy matters. Her clients include managed care plans and other health insurers, medical device manufacturers, investors, behavioral health and substance abuse providers, clinical laboratories, healthcare providers including hospitals, ASCs, physicians and other providers, and other businesses in the healthcare and life science sectors. Joyce advises clients on healthcare financing, delivery, Medicare, Medicaid, fraud and abuse; she also represents private equity firms, other investors, and emerging businesses in mergers and acquisitions (M&A) and private equity transactions.

Biography



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Albert W. Shay focuses his practice on counseling healthcare companies of all types on regulatory, fraud and abuse, Stark law, Medicare reimbursement, and transactional matters. Al devotes a substantial portion of his practice to corporate compliance issues, including internal and government investigations, and has experience representing clients before regulatory agencies such as the Centers for Medicare and Medicaid Services (CMS), the US Department of Health and Human Services' Office of Inspector General, and the Provider Reimbursement Review Board.

Biography



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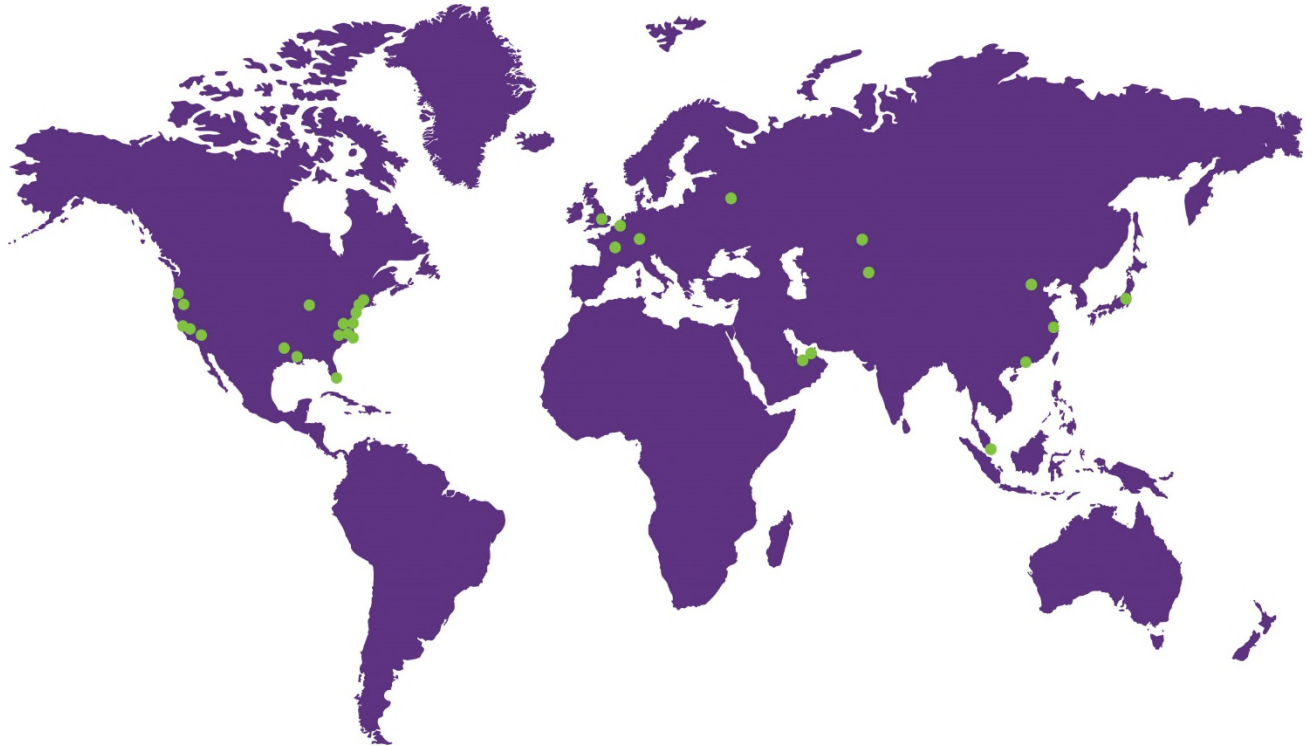
Banee Pachuca focuses her practice on healthcare law, including transactional, regulatory, and compliance matters. She represents hospitals, health systems, academic medical centers, large physician groups, and private equity and financial investor clients in mergers, acquisitions, divestitures, joint ventures, and other collaborative and alignment strategies. Additionally, Banee frequently advises clients with respect to fraud and abuse laws, including the Stark Law and state and federal anti-kickback laws, billing compliance, as well as state and federal privacy laws. She assists healthcare clients with internal investigations, analyzing potential self-disclosures, responding to government subpoenas, and developing compliance programs.

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