Morgan Lewis

FAST BREAK: ELECTIVE PROCEDURES

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June 23, 2020

Agenda

1. Overview of Centers for Medicare and Medicaid Services (CMS) guidance on providing elective procedures and surgeries during COVID-19

2. Overview of various state-level approaches to providing elective procedures and surgeries during COVID-19

3. How the interaction of federal and state law and guidance affects providers in practice

OVERVIEW OF CMS GUIDANCE ON PROVIDING ELECTIVE PROCEDURES AND SURGERIES DURING COVID-19

CMS Guidance on Elective Surgeries and Nonessential Procedures During COVID-19

- CMS has provided a number of guidance documents with respect to the provision of elective surgeries and nonessential procedures during COVID-19:

March 18 Guidance and April 7 Guidance – For providers operating in communities that have not yet entered Phase 1

April 19 Guidance – For providers operating in communities that have entered Phase 1

June 8 Guidance – For providers operating in communities that have entered Phase 2

- The guidance documents provide various recommendations for providers operating in regions with different incident rates of COVID-19.

CMS Guidance on Elective Procedures and Surgeries: A Flexible Approach for Health Officials and Providers

March 18 Guidance: Communities continuing to experience a high number of cases

April 19 Guidance: Communities experiencing a decline in cases

June 8 Guidance: Communities continuing to maintain a low number of cases

Approach for Communities with a High Case Rate

(Not Yet in Phase 1), Based on March 18 Guidance

On March 18, 2020, CMS recommended that all elective surgeries, nonessential 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."

CMS has indicated that this guidance is to be followed by communities that are not yet in Phase 1 of the White House's Guidelines for Opening Up America Again.

Approach for Communities with a Declining Case Rate (Phase 1), Based on April 19 Guidance

On April 19, 2020, CMS published guidance providing a flexible approach for state and local health officials, healthcare facilities, and healthcare providers determining whether they should allow or perform elective surgeries and procedures.

CMS Administrator Seema Verma indicated that the recommendations specifically target communities that are in Phase 1 of the White House's Guidelines for Opening Up America Again.

Approach for Communities with a Declining Case Rate (Phase 1), Based on April 19 Guidance

Careful planning is required to resume in-person care of patients requiring non-COVID-19 care.

- All aspects of care must be considered.

Maximum use of telehealth is encouraged.

Non-COVID-19 care should be offered to patients as clinically appropriate and within a state, locality, or facility that has the resources to properly provide such care and the ability to quickly respond to a surge in COVID-19 cases, if necessary.

Approach for Communities Maintaining a Low Case Rate (Phase 2), Based on June 8 Guidance

On June 8, 2020, CMS published new guidance providing recommendations for re-opening facilities to provide nonemergent, non-COVID-19 care.

The guidance indicates it targets communities that are in Phase 2 of the White House's Guidelines for Opening Up America Again.

The guidance reiterates recommendations made in the April 19 guidance, including:

- Careful planning to resume in-person care of patients requiring non-COVID-19 care.
- All aspects of care to be considered.
- Maximum use of telehealth.
- Non-COVID-19 care to be offered to patients as clinically appropriate and within a state, locality, or facility that has the resources to properly provide such care and the ability to quickly respond to a surge in COVID-19 cases, if necessary.

Approach for Communities Maintaining a Low Case Rate (Phase 2), Based on June 8 Guidance

CMS recommends that general considerations should include:

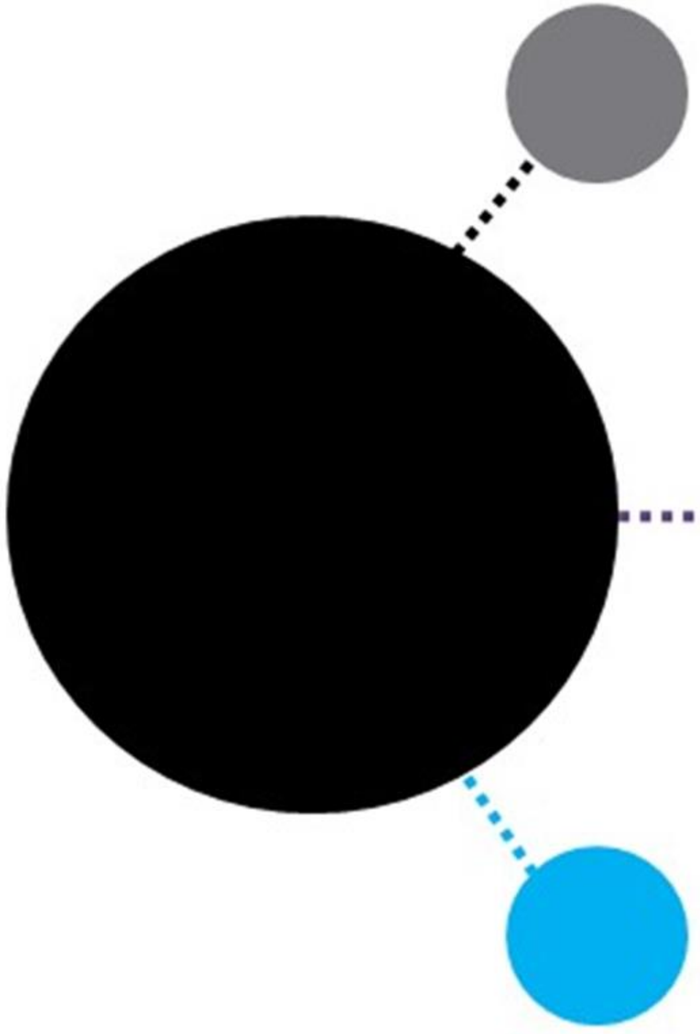
1. **Evaluate the incidence and trends for COVID-19 in the area where in-person care is being considered, including metrics related to local and regional healthcare system capacity.**
   - **In Phase II, the state or region should have no evidence of a rebound and have already satisfied the Gating Criteria.**
2. **Evaluate the necessity of the care based on clinical needs:**
   - **Prioritize services that, if deferred, are most likely to result in patient harm.**
   - **Prioritize at-risk populations who would benefit most from those services.**
3. **Establish non-COVID care (NCC) zones where patients can be screened for symptoms of COVID-19, including temperature checks.**

Approach for Communities Maintaining a Low Case Rate (Phase 2), Based on June 8 Guidance

4. Sufficient resources should be available to the facility across phases of care (e.g., post-acute and long-term care), including PPE, sufficient healthcare workers, facilities, supplies, and screening and testing capacity, without jeopardizing surge capacity.
5. Participation in a registry or national data collection system, such as the National Healthcare Safety Network, is strongly encouraged to help track patient outcomes, facility and system impacts, and resource allocation.
   - Note: COVID-19 reporting is required in some facilities (e.g., nursing homes).

OVERVIEW OF VARIOUS STATE-LEVEL APPROACHES TO REGULATING THE PROVISION OF ELECTIVE PROCEDURES AND SURGERIES DURING COVID-19

State Orders and Guidance Subsequent to CMS Guidance



After CMS issued its guidance, many states issued orders and guidance concerning the provision of elective, nonurgent procedures.

Healthcare facilities and providers should remain current with state and local executive orders and other applicable law.

State and local laws will dictate options that are available to healthcare facilities and providers and may or may not defer to CMS guidance.

Texas Executive Orders Affecting Elective Procedures

In Texas, Governor Greg Abbott issued a series of executive orders affecting elective, nonurgent procedures.

March 22
Executive Order GA-09 – requiring the postponement of all surgeries and procedures not medically necessary to diagnose or correct a serious medical condition or to preserve the life of a patient.

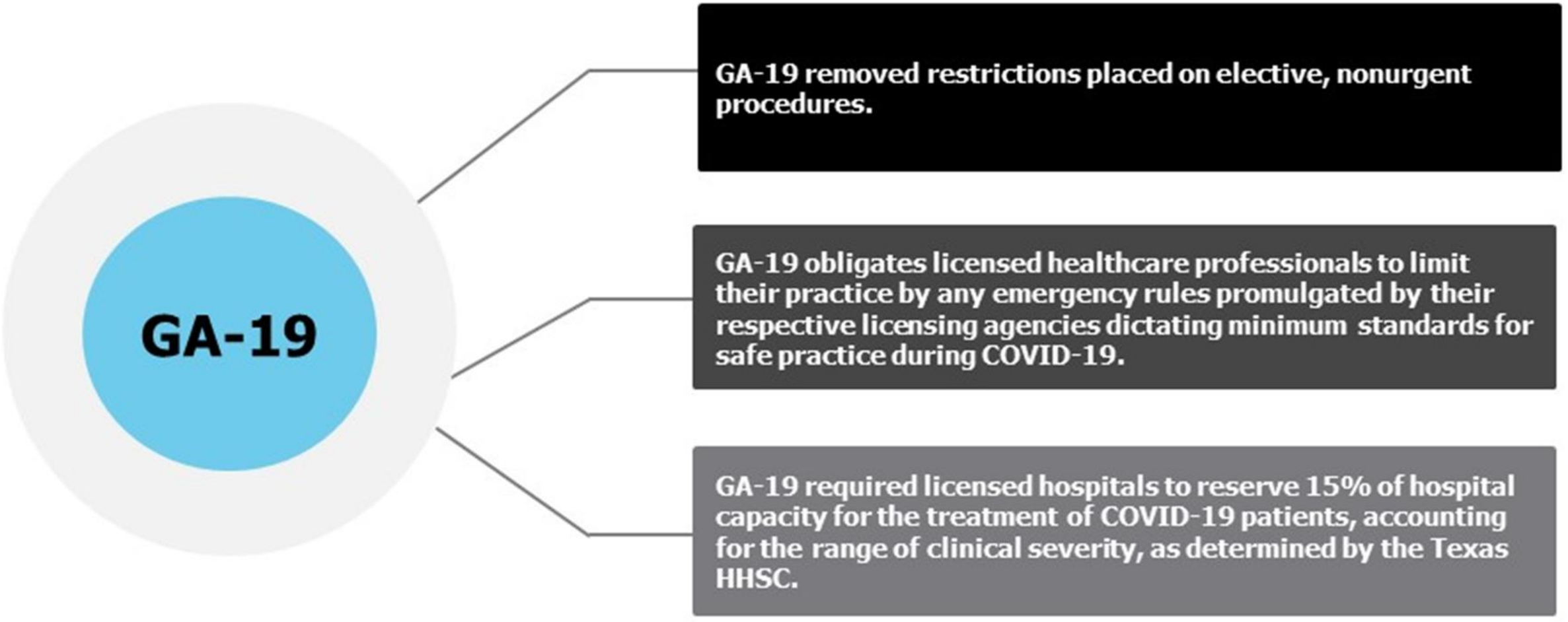
April 17
Executive Order GA-15 – loosening restrictions on elective, nonurgent procedures previously put in place.

April 27
Executive Order GA-19 – removing restrictions placed on elective, nonurgent procedures.

Texas Executive Orders Affecting Elective Procedures

- GA-15 required postponement of all surgeries and procedures not medically necessary to diagnose or correct a serious medical condition or to preserve the life of a patient.
- However, GA-15 provided two exceptions, allowing:
    1. Any procedure, which when performed consistently with standards of clinical practice, would not deplete the hospital capacity or the PPE needed to cope with COVID-19.
    2. Any surgery or procedure performed in a licensed healthcare facility that has certified in writing to the Texas Health and Human Services Commission (HHSC) both that it will reserve at least 25% of its hospital capacity for treatment of COVID-19 patients across the range of clinical severity, and that it will not request any PPE from any federal, state, or local public source for the duration of COVID-19.

Texas Executive Orders Affecting Elective Procedures



Texas Medical Board Emergency Rules and Guidance

- On April 30, the Texas Medical Board promulgated a new emergency rule that:
  - Repeals previous limitations on the provision of elective, nonurgent surgeries
  - Requires healthcare providers to follow certain social distancing protocols and minimal safety standards
- Guidance released by the Texas Medical Board on May 1 indicates that a violation of the new emergency rule could be considered unprofessional conduct that may result in the suspension or termination of a provider's license.

Massachusetts Executive Orders and Guidance Affecting Elective Procedures

In Massachusetts, the Department of Health issued a series of orders and guidance affecting elective, nonurgent procedures:

March 15
Order of the Commissioner and guidance directing all hospitals and ambulatory surgical centers to postpone or cancel any nonessential, elective invasive procedures.

May 18
Order of the Commissioner and guidance loosening restrictions on elective procedures and introducing attestation requirements.

June 6
Order of the Commissioner and guidance modifying restrictions on elective procedures and maintaining attestation requirements.

Massachusetts Department of Public Health Guidance

- Effective June 8, new guidance governs elective procedures in Massachusetts.
  - All healthcare providers should continue to use their clinical judgment on a case-by-case basis and perform invasive procedures that must be done to preserve a patient's life and health.
  - Subject to certain exceptions, the department defines nonessential, elective invasive procedures as procedures that are scheduled in advance because the procedure does not involve a medical emergency.
  - Providers, including acute care hospitals and ambulatory surgical centers, who attest to meeting specific criteria and public health and safety standards set by the Massachusetts Department of Health, may incrementally resume nonessential elective invasive procedures and services.

Massachusetts Department of Public Health Guidance

- The attestation requires providers to establish and monitor patient volume in each facility, clinic, or office setting where such procedures are performed and schedule patient visits to ensure compliance with:
  - The public health and safety guidelines set by the Massachusetts Department of Health, including standards related to PPE, restricting the number of healthcare workers in the treatment space, screening patients in advance of a service or procedure, and administrative and environmental controls that facilitate social distancing.
  - Ongoing compliance with CDC requirements and other public health guidance regarding environmental infection controls, including a suspension in the use of all examination, procedural, and surgical areas, between procedures, for sufficient air changes to remove airborne contaminants.

Florida Executive Orders Affecting Elective Procedures

In Florida, Governor Ron DeSantis issued executive orders affecting elective, nonurgent procedures.

March 20

Executive Order 20-72 – prohibiting any medically unnecessary, nonurgent or nonemergency procedure or surgery.

April 29

Executive Order 20-112 – authorizing the provision of nonemergency procedures and surgeries if certain conditions are met.

Florida Executive Orders Affecting Elective Procedures

- Effective May 4, a hospital, ambulatory surgical center, office surgery center, dental office, orthodontic office, endodontic office, or other healthcare practitioner's office may perform procedures *only if*:
  - The facility has the capacity to immediately convert additional facility-identified surgical and intensive care beds for treatment of COVID-19 patients in a surge capacity situation.
  - The facility has adequate PPE to complete all medical procedures and respond to COVID-19 treatment needs, without the facility seeking any additional federal or state assistance regarding PPE supplies.

Florida Executive Orders Affecting Elective Procedures

- The facility has not sought any additional federal, state, or local government assistance regarding PPE supplies since resuming elective procedures.
- The facility has not refused to provide support to and proactively engages with skilled nursing facilities, assisted living facilities, and other long-term care residential providers.

California Executive Orders and Guidance Affecting Elective Procedures

In California, Governor Gavin Newsom and the California the Department of Public Health issued a series of orders and guidance affecting elective, nonurgent procedures.

March 19
Executive Order N-33-20 – bars elective procedures in conjunction with the statewide stay-at-home orders.

April 27
Resuming California's Deferred and Preventive Health Care provides six considerations for resuming elective procedures.

May 7
Guidance for Resuming Deferred and Preventive Dental Care provides considerations specific to the provision of dental care.

California Department of Public Health Guidance

- The guidance provides general considerations to be reviewed and met before resuming services:
    1. When preparing to resume services, a variety of indicators should be considered for a service area, including:
        - COVID-19 infection rates
        - COVID-19 hospitalizations
        - COVID-19 emergency room admissions
        - COVID-19 Intensive Care Unit (ICU) utilization
        - Skilled Nursing Facilities COVID-19 outbreaks
        - Other COVID-19 factors that could increase the spread of COVID-19

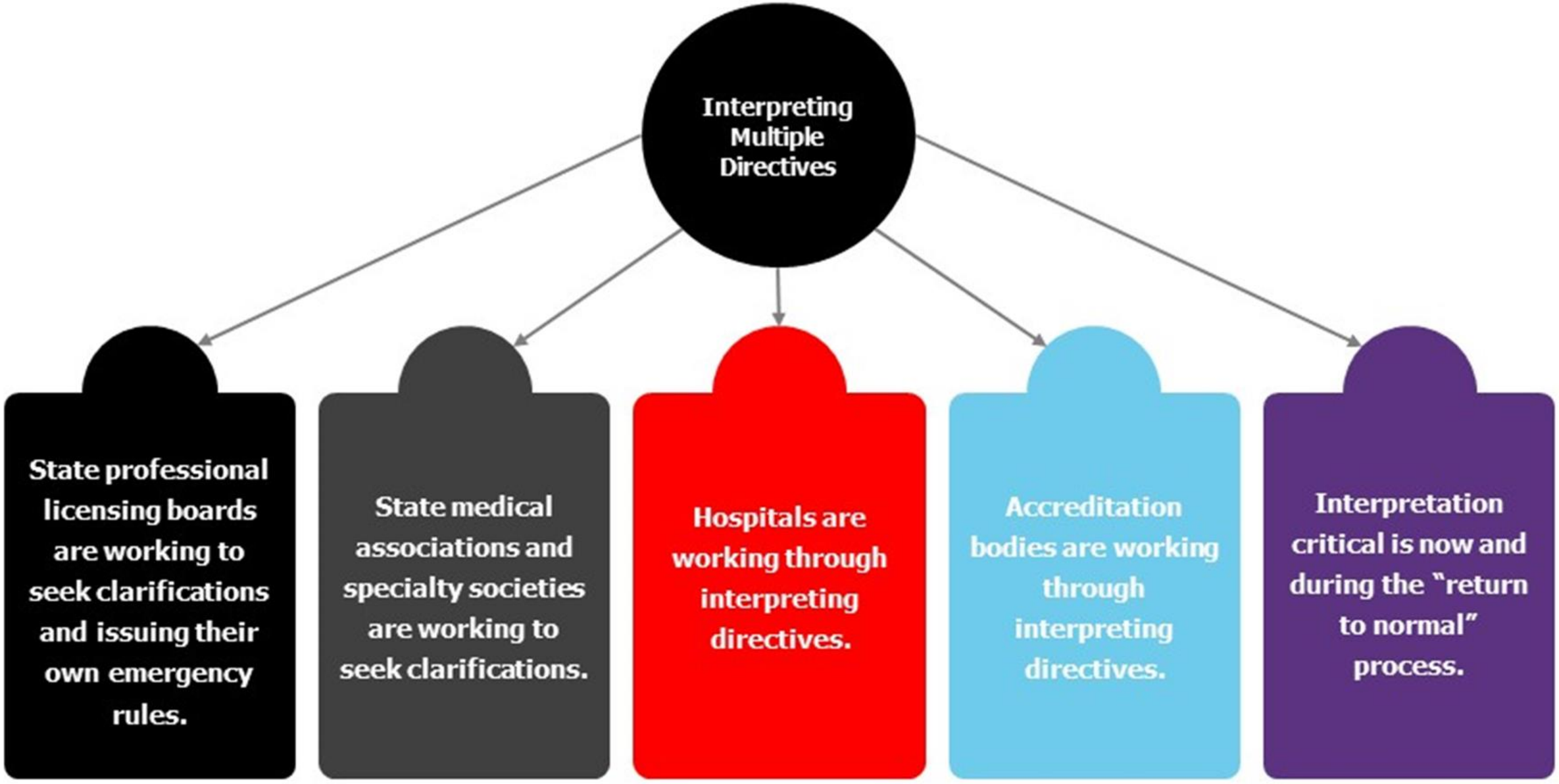
California Department of Public Health Guidance

2. Each facility, office, or any other place of healthcare services must have an adequate stock of PPE in supply for staff, based on the type of care provided, risk level of patients, number of staff required to use PPE, and daily usage demand. Consideration should be given for potential patient surges related to COVID-19 outbreaks.
3. Availability of testing with prompt results should be present for healthcare delivery situations when knowledge of the COVID-19 status of staff or patients served by the entity is important for clinical care and infection control.
4. Before resuming nonemergent and non-COVID-19 deferred services, offices and facilities should consult with local public health officers within applicable counties to determine if there are local COVID-19 patterns that could impact healthcare delivery.

California Department of Public Health Guidance

5. Availability of qualified staff to safely perform procedures and provide care and needed follow up.
6. Each facility and office should have patient flow systems and infection control precautions in place to minimize exposure and spread while caring for both COVID positive and non-COVID patients.

HOW THE INTERACTION OF FEDERAL AND STATE LAW AND GUIDANCE AFFECTS PROVIDERS IN PRACTICE


Interpreting Multiple Directives
State professional licensing boards are working to seek clarifications and issuing their own emergency rules.
State medical associations and specialty societies are working to seek clarifications.
Hospitals are working through interpreting directives.
Accreditation bodies are working through interpreting directives.
Interpretation critical is now and during the "return to normal" process.

QUESTIONS?

Join us next month!

Please join us for next month's webinar:

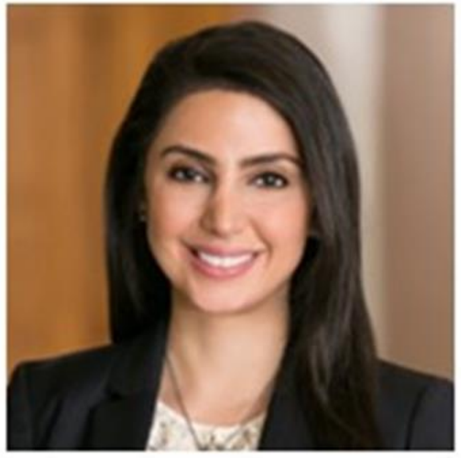
***Fast Break:* Global Healthcare Privacy during COVID-19**

Featuring

Jake Harper, Reece Hirsch, and Axel Spies

- Wednesday, July 22, 2020 3:00 PM (EST)

Thanks!



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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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Sydney K. Reed works with our team of healthcare lawyers to advise businesses and organizations navigating the complex healthcare industry. The team regularly represents clients in payment disputes; transactional, regulatory, and compliance matters; litigation involving federal and state False Claims Act (including qui tam claims), Anti-Kickback Statute, and physician self-referral (Stark Law) matters; and public policy advocacy.

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Jacob Harper advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. His practice focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, provider mergers and acquisitions, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.