

## Coppersmith Briefs

### ***UPDATE: ADHS ISSUES GUIDANCE ON RE-STARTING ELECTIVE SURGERIES***

Karen Owens, Coppersmith Brockelman PLC

April 29, 2020

**UPDATE TO LAST WEEK'S CLIENT BRIEF:** Since the publication of this client brief last week, the Arizona Department of Health Services (ADHS) has answered key outstanding questions about its implementation through an attestation form<sup>1</sup> and a set of frequently asked questions and answers (FAQs).<sup>2</sup>

#### Attestation Form

ADHS will not require providers to prove that they comply with the conditions for restarting elective surgeries. The attestation form requires individual providers (doing in-office surgery) and health care institutions (together, "providers") to attest to their compliance with the Governor's criteria for reinstating elective surgery. See summary of criteria, below. The provider submits a completed attestation form to ADHS, and ADHS approves the submission by acknowledging receipt of the form.

#### FAQs

Key FAQs include:

- Providers that receive an acknowledgement email from ADHS should retain the email and records related to the reinstatement of elective surgeries for a year.
  - For risk management purposes, we recommend that providers consider maintaining records documenting compliance with the criteria for reinstatement for at least two years from the date the moratorium ends.

<sup>1</sup> [https://docs.google.com/forms/d/e/1FAIpQLSdajNyyobE\\_tOUF66SQ\\_-8-0XmXP46MCCswGPfVCuvfPTHhaA/viewform](https://docs.google.com/forms/d/e/1FAIpQLSdajNyyobE_tOUF66SQ_-8-0XmXP46MCCswGPfVCuvfPTHhaA/viewform)

<sup>2</sup> <https://www.azdhs.gov/documents/preparedness/epidemiology-disease-control/infectious-disease-epidemiology/novel-coronavirus/healthcare-providers/waiver-faq.pdf>

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- Exemptions from the moratorium on elective surgery remain in effect until the moratorium is repealed or the provider can no longer meet the conditions for reinstatement of elective surgeries.
- ADHS states that it has not implemented any minimum criteria for reinstatement of elective surgeries other than the criteria set forth in the Governor’s executive order. *See* summary of criteria, below.
- One of the criteria for reinstatement of elective surgery is that a continuing supply of PPE be on hand that will support the provider or institutions for more than 14 days. ADHS says “continuing supply of PPE” means appropriate to the setting, and may include respirators, medical face masks, gowns, gloves, and eye protection.
  - For hospitals, ADHS points to the PPE items which hospitals are required to report to EMResource as demonstrating a sufficient continuing supply.
- ADHS explains that the requirement of having at least 20% bed capacity applies only to hospitals, and states that hospital can maintain 20% capacity by having a documented plan that includes triggers to maintain or increase capacity. The FAQ tells hospitals that exceed the bed capacity threshold to contact ADHS for guidance.
- The Governor’s order calls for a robust testing regimen that captures all at-risk health care workers, among others. The FAQ defines “at risk” to mean “any health care worker with significant exposures and those that are elderly or at risk for complications.”
  - The provider should have a policy in place on this point.
  - The policy should include staff who have provided care to COVID-19 patients, known or not, without minimum necessary PPE or source and engineering controls in place.
- If the supply of PPE drops below a continuous 14-day supply, the provider should stop doing elective surgeries for either least 14 days or reinstatement of the proper level of supplies, whichever is longer.
  - Providers other than hospitals should calculate the adequacy of their supply of PPE based on historical and anticipated use during the emergency.
  - Hospital are reporting on their supplies of PPE to EMResource.
- “Enhanced cleaning” means cleaning that is adjusted to the pandemic risk and documented in the provider’s policies and procedures.
- The FAQ clarifies that to prioritize elective, non-essential surgeries based on urgency, the provider should follow the CMS guidance “as much as practicable.” *See* discussion of CMS guidance, below.
- According to the FAQ, providers that have to suspend elective surgeries based on insufficient PPE supplies can become eligible to request PPE from state or county authorities starting 14 days after they relinquish their request for exemption.
  - It appears ADHS intends providers to formally relinquish their exemption from the moratorium, presumably by notifying ADHS. They then become eligible to apply for another exemption at least 14 days after requesting PPE from the state or county.

- Elective, non-essential **dental surgery** is a dental treatment or procedure that (1) involves removal or alteration of the hard or soft tissues of the patient’s oral cavity or surrounding structures, AND (2) is solely and only performed for a cosmetic purpose.

### **NEW EXECUTIVE ORDER SETS FORTH CONDITIONS FOR REINSTATEMENT OF ELECTIVE SURGERIES**

Karen Owens, Coppersmith Brockelman PLC

April 23, 2020

On April 22, 2020, Arizona’s Governor issued an executive order that very cautiously sets the stage for healthcare providers to begin to do elective surgeries again. Executive Order 2020-32 (Order)<sup>3</sup> allows providers to request exemption from an earlier Executive Order which in late March imposed a blanket prohibition on elective surgery by licensed facilities or licensed healthcare providers.<sup>4</sup>

The earlier Executive Order defined “elective surgery” as any surgery that can be delayed without undue risk to the current or future health of the patient.<sup>5</sup> State regulations define “surgery” as the “excision of or incision in a patient’s body for the: a. Correction of a deformity or defect; b. Repair of an injury; or c. Diagnosis, amelioration, or cure of disease.”<sup>6</sup>

**The new Order affects hospitals, outpatient and overnight surgery centers, other licensed healthcare institutions where surgeries are performed, and licensed providers and provider offices, including dental surgery offices.**

The Order acknowledges that social distancing and stay-at-home measures have made it possible to consider loosening the moratorium on elective surgeries. However, with patient and health care worker safety in mind, the Order sets stiff conditions for hospitals to ask the Arizona Department of Health Services (ADHS) for permission to reinstate some or all categories of elective surgeries as soon as May 1, 2020.

The Order instructs ADHS to establish minimum criteria that must include a list of conditions set forth in the Order. It is unclear so far whether ADHS may establish additional criteria, but that question should be answered soon. In the meantime, here are the conditions for exemption listed in the Order:

<sup>3</sup> <https://azgovernor.gov/executive-orders>

<sup>4</sup> *Id.*, Executive Order 2020-10.

<sup>5</sup> *Id.*

<sup>6</sup> Arizona Administrative Code R9-10-101(225).

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- The provider must have a continuing supply of personal protective equipment (PPE) that will support the provider for more than 14 days. The supply cannot depend on supplies from the state or a county health department. *Providers receiving an exemption to perform elective surgeries lose the right to request or receive PPE from the state or county health departments.*
- The provider must have adequate staffing, and hospitals must have bed availability with no greater than 80% of total bed capacity occupied.
- The provider must implement a “robust COVID-19 testing plan” that includes testing of all at-risk healthcare providers and each patient before surgery is scheduled, or at the latest during the preoperative time period. It is not clear whether this condition requires testing of all at-risk providers throughout a hospital or other large facility, even if they do not work in a high risk area. This provision does not preclude reliance on state and local governments to obtain tests, but the chronic insufficient availability of tests and test components may make this requirement a significant stumbling block.
- Providers must implement a process to identify, inventory and document both PPE and test kits, and must document the availability of a lab that can run COVID-19 diagnostic tests.
- Providers must implement a universal symptom screening process for all staff, patients and visitors before they enter the facility.
- The provider must implement an enhanced cleaning process both for patient areas and waiting areas.
- Providers must implement policies and procedures for appropriate patient discharge planning. Plans must include pre-discharge COVID19 diagnostic testing for patients going to a nursing care institution, residential care institution setting, or group home for developmentally disabled persons.
- Finally, providers must implement policies and procedures to prioritize elective, non-essential services based on urgency, compliant with CMS’s Adult Elective Surgery and Procedures Recommendations (CMS Recommendations).<sup>7</sup>

Published on April 7, 2020, the CMS Recommendations divide surgical services into 3 tiers, each with 2 sub-tiers. The Recommendations allow healthcare facilities to take into account a number of factors in deciding whether to do or postpone surgical cases:

- Current and projected COVID-19 cases in the facility and the region
- Supply of PPE to the facilities in the system
- Staffing availability
- Bed availability; in hospitals, especially ICU beds
- Ventilator availability
- Health and age of the patient, taking into account the risks of COVID-19 infection
- Urgency of the procedure.

<sup>7</sup> <https://www.cms.gov/files/document/covid-elective-surgery-recommendations.pdf>  
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On the other hand, the CMS Recommendations are perhaps not as helpful as they could be, as the 3-tiered approach recommends postponement, or consideration of postponement, for all cases except those which likely would not be postponed even under the moratorium on elective surgery. The original Order stated that surgeries would not be deemed elective if “it would threaten the patient’s life, threaten permanent dysfunction or impairment of any body part, risk metastasis or progression of staging, or require the patient to remain hospitalized if the surgery is delayed.”<sup>8</sup>

Here are the CMS Recommendations, by tier:

**Tier 1(a): Low acuity surgery on healthy patients.** Example include carpal tunnel release, EGD surgery, colonoscopies, and cataracts. CMS recommends postponement of this category of procedures.

**Tier 1(b): Low acuity surgery on unhealthy patients.** CMS gives endoscopies as an example and again recommends postponement.

**Tier 2(a): Intermediate acuity surgery on healthy patients.** Examples include low risk cancer surgeries; non-urgent spine & orthopedic surgery, including hip and knee replacement and elective spine surgery; stable ureteral colic, and elective angioplasty. CMS recommends consideration of postponement.

**Tier 2(b): Intermediate acuity surgery on unhealthy patients.** Same examples as in Tier 2(a). CMS recommends postponement if possible.

**Tier 3(a): High acuity surgery on healthy patients.** Examples are most cancers, neurosurgery, and surgery involving highly symptomatic patients. CMS recommends not postponing these surgeries, which may well be considered emergent under the standards set forth in Executive Order 2020-10. *See* note 2.

**Tier 3(b): High acuity surgery on unhealthy patients.** Examples are transplants, trauma surgery, cardiac surgery with symptoms, and limb-threatening vascular surgery. CMS recommends not postponing these cases. Again, such cases may well not be considered “elective” under the standard set in Executive Order 2020-10.

The Order will be considered every two weeks for repeal or revision. Thus, if the current conditions for exemption prove to be impossible to meet, an opportunity may exist for further discussion at two-week intervals. Of course, it will be critical in such discussions to be able to demonstrate that looser conditions will not cause risk to patients or health care workers.

<sup>8</sup> *See* Note 2, *supra*.  
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The logo for Coppersmith Brockelman Lawyers features the firm's name in a white, serif font against a dark blue background with a city skyline. The name is split across two lines: "COPPERSMITH" on the top line and "BROCKELMAN" on the bottom line, with a thin white horizontal line separating them. Below the name, the word "LAWYERS" is written in a smaller, all-caps, sans-serif font.

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The Order's success in allowing providers to perform at least some elective surgeries is likely to be very important to the survival of many health care providers in Arizona. The Arizona Hospital and Healthcare Association, which requested the change in an April 16 letter to the Governor, has stated, "[n]ot only will this decision allow patients to access needed procedures but also help decrease the financial strain Arizona hospitals are currently facing." The Association noted that its member hospitals reported revenues down 30-40% due to cancellation of elective procedures and a reduction in emergency department visits.<sup>9</sup> Presumably the data for physicians, dentists and other surgical providers are parallel. Whether the new Order will take the pressure off remains to be seen.

**Karen Owens'** practice focuses on health care administrative, regulatory, operations, and litigation matters. She regularly represents health care systems, hospitals, clinics, and other institutions in matters of quality management, medical staff peer review, practitioner credentialing, hospital and medical staff structure, and confidentiality. She also counsels hospitals and health care entities about Medicare certification, state licensure, EMTALA compliance, and many other regulatory matters touching clinical operations.

*By the way, you know the Coppersmith Briefs are not legal advice, right? Right!  
Check with your attorney for legal advice applicable to your situation.*

<sup>9</sup> <https://static1.squarespace.com/static/572a399a1bbee0add26af051/t/5ea0d5b31af0fc20e9657de4/1587598772218/NewsRelease-ElectiveSurgeriesToResume-4-22-2020+-+Final.pdf>

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