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Elective and Non-Essential Medical Procedures: States React to Federal Recommendations and the Opening Up America Again Guidelines

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On April 16, 2020, the Trump Administration issued its "Opening Up America Again Guidelines" (the "OUAA Guidelines") as a self-styled roadmap to the staged reopening of the American economy.

On Sunday, April 19, 2020, the Centers for Medicare & Medicaid Services ("CMS") followed suit by issuing new guidance (the "Reopening Guidance") designed to reintroduce the provision of non-essential surgeries and medical procedures by healthcare providers located in "Phase 1" states and/or regions. Such non-elective procedures were previously put on hold at the state and local levels in accordance with prior CMS guidance dated March 18, 2020 (the "March Guidance") in which CMS called for the delay of all elective surgeries, non-essential medical, surgical, and dental procedures during the COVID-19 state of emergency.

Since the issuance of the Reopening Guidance, various states – including California, New York, Ohio, and others discussed below – have announced their strategies to implement the Reopening Guidance's call for the reintroduction of elective procedures within their respective jurisdictions. As described below, the Reopening Guidance does not mandate specific state action but instead makes recommendations to the states as to those factors that they should consider when evaluating whether elective procedures should be allowed within their jurisdictions. Not surprisingly, without specific federal requirements, the implementation strategies being proposed and adopted by the states vary greatly both in timing and degree. Some states are opening the doors to all elective procedures immediately while others are delaying their start dates or rolling out the availability of elective procedures over time.

In this article, we will review the Reopening Guidance, consider previous state actions to cancel/delay/re-prioritize elective procedures in response to CMS's March Guidance, and highlight current state actions in response to the Reopening Guidance.

THE REOPENING GUIDANCE

Phase One States and Regions; The Gating Criteria

According to the Reopening Guidance, once a state or region satisfies certain gating criteria articulated in OUAA Guidelines, the state or region can proceed to OUAA Guidelines, Phase 1 and, in turn, the provision of elective procedures previously postponed pursuant to CMS's March Guidelines.

The gating criteria are organized into three categories – symptoms, cases, and hospitals – and include such requirements as: (1) a downward trajectory of COVID-like cases reported within a 14-day period; (2) a downward trajectory of documented cases within a 14-day period; (3) a downward trajectory of positive tests as a percent of total tests within a 14-day period; and (4) a robust testing program in place for at-risk healthcare workers, including emerging antibody testing.

The gating criteria as set forth in the OUAA Guidelines have come under criticism from some quarters. For example, in the area of testing, it has been noted that the criteria do not include any specific testing targets and goals. Instead, the criteria make it a state's responsibility to determine what constitutes a "robust testing program" with little guidance on how to make such a determination. Others have noted that the "14-day downward trajectory in positive cases" requirement misses the mark by not requiring that a state reduce its total number of cases to a predetermined threshold amount before, in this case, allowing the provision of elective healthcare procedures in the state's healthcare facilities.

State and Local Officials are Key Decisionmakers: Sufficient Resources and an On-the-Ground Assessment.

In CMS's April 19, 2020 Press Release (the "Press Release") announcing the new CMS elective surgery guidance, CMS makes it clear that the implementation of the Reopening Guidance makes state and local officials the key decisionmakers in determining when elective procedures can be reintroduced to a community. As set forth in the Press Release, "the CMS recommendations are not meant to be implemented by every state, county, or city at this time and Governors and local leaders ultimately need to make decisions on whether they are appropriate for their communities."

The role of state and local officials as key decisionmakers is reiterated in the Press Release by Seema Verma, the CMS Administrator, and her comments regarding two fundamental preconditions to the implementation of the Reopening Guidance at the state and local level. According to Administrator Verma, before elective procedures can be reintroduced to a community, state and local officials must (i) conduct an assessment of the "situation on the ground" to determine the best way to allow the provision of elective services, and (ii) determine whether there are **sufficient resources** to support the provision of elective services while maintaining "surge capacity" in the event that there is a resurgence of COVID-19 in the community. According to the new CMS elective surgery Guidelines, the term, "sufficient resources" includes the availability of, "personal protective equipment, healthy workforce, facilities, supplies, testing capacity, and post-acute care, without jeopardizing surge capacity."

By virtue of the above two preconditions, the Reopening Guidance, in some part, serves as a federal policy statement regarding the need to broaden the scope of available healthcare services as quickly as possible while leaving the responsibility for determining when this should happen to the states. Some commentators have stated that this aspect of the Reopening Guidance is the Administration's way to avoid the tough decisions that, if made prematurely, could result in the resurgence of COVID-19 in what was once a Phase 1 state.

General and Specific Guidance for Facilities Reopening to Patients Requiring Elective Services

For those facilities in a Phase 1 state or region that wish to reopen to patients requiring medically necessary elective procedures, the Reopening Guidance lists both general and specific recommendations regarding the services to be provided and how a facility should provide such services.

As recommended by CMS in the Reopening Guidance, facilities intending to provide elective procedures should prioritize the provision of "surgical/procedural care and high-complexity chronic disease management." The Reopening Guidance also acknowledges that certain "highly necessary" preventative services may also be worthy of prioritization.

In addition to above recommendations regarding the priority of elective procedures, the Reopening Guidance includes a myriad of other recommendations for those facilities intending to undertake the provision of elective procedures. According to CMS, facilities are recommended to:

1. establish "Non-COVID Care" (NCC) zones, including screening all patients for COVID-19 symptoms and temperature checks;

2. routinely screen healthcare and non-healthcare staff working in the NCC zone, quarantining any who test positive;

3. require healthcare providers and staff to wear surgical masks at all times and, when conducting procedures on the mucous membranes including the respiratory tract, with a higher risk of aerosol transmission, require staff to utilize appropriate respiratory protection such as N95 masks and face shields.

4. require patients to wear a cloth face covering that can be bought or made at home if they do not have surgical masks and such surgical masks are not available at the facility;

5. establish administrative and engineering controls to facilitate social distancing, such as minimizing time in waiting areas, spacing chairs at least 6 feet apart, and maintaining low patient volumes;

6. staff working in the NCC zones should not rotate into non-NCC zones;

7. NCC zones should be separated from other areas to the extent possible (e.g., in a separate building, designated floors or rooms with separate entrances and minimal crossover with COVID-19 areas);

8. prohibit visitors unless needed for an aspect of patient care, and visitors are pre-screening any such visitors;

9. utilize appropriate sanitation procedures;

10. maintain adequate supplies, while making sure volumes are available to respond to a COVID-19 surge; and

11. follow such other recommendations that are enumerated in the Reopening Guidance.

State Action on the Provision of Elective Surgical and Medical Procedures

According to an Ambulatory Surgery Center Association ("ASCA") article, "State Guidance on Elective Surgery," updated as of April 20, 2020, there have been thirty-six (36) states and the District of Columbia that have released official, or unofficial, statements (by state representatives through the media) addressing the issue of elective procedures during the ongoing COVID-19 state of emergency. Over the coming days, we anticipate that each of these thirty-six (36) states, and likely more, will be announcing how they intend to respond to the Reopening Guidance and, in turn, allow the provision of elective procedures within their respective jurisdictions.

The following are the most recent examples of how states are responding to the Reopening Guidance and easing previous restrictions on the performance of elective surgical procedures:

1. **Arkansas**. On April 22, 2020, Governor Asa Hutchinson announced that the state will allow hospitals and clinics to resume certain elective surgeries on Monday, April 27th. This marks a change of direction from the guidance letter that the Arkansas Department of Health ("ADH") sent on March 30, 2020, to all health facilities, including ambulatory surgery centers, recommending that elective surgeries be postponed statewide. In addition on April 3rd, the ADH issued a directive on elective surgeries mandating that "procedures, testing, and office visits that can be safely postponed shall be rescheduled to an appropriate future date."

2. **California**. On April 22, 2020, Governor Gavin Newsom announced the first significant effort to begin modifying the stay at home order by allowing hospitals to begin scheduling non-essential surgery. This easing applies to surgeries that are not an emergency, but if left neglected for months could become an emergency, such as procedures involving tumors and heart valves. Previously, on March 24, 2020, the California Department of Health Care Services ("DHCS") released guidance relating to non-urgent, non-essential, or elective procedures relative to COVID-19 that mirrored the March Elective Procedure Guidance released by CMS. DHCS affirmed that the framework established in the March Elective Procedure Guidance would help providers "focus on addressing more urgent cases and preserve critical resources, including PPE, needed for the COVID-19 response."

3. **Florida**. On April 21, 2020, the Florida Hospital Association shared its Open Plan with Governor Ron DeSantis. The Open Plan outlines a four (4) step approach to allow hospitals to resume elective surgeries. If followed, the Open Plan would mark a change in course from the executive order Governor DeSantis issued on March 20, 2020, directing that, "all hospitals, ambulatory surgical centers, office surgery centers, dental, orthodontic and endodontic offices, and other health care practitioners' offices…are prohibited from providing any medically unnecessary, non-urgent or non-emergency procedure or surgery which, if delayed, does not place a patient's immediate health, safety or wellbeing at risk, or will, if delayed, not contribute to the worsening of a serious or life-threatening medical condition."

4. **New York.** On April 21, 2020, Governor Andrew Cuomo announced "elective outpatient treatments can resume in counties and hospitals without significant risk of COVID-19 surge in the near term. Hospitals will be able to resume performing elective outpatient treatments on April 28, 2020 if the hospital capacity is over 25 percent for the county and if there have been fewer than 10 new hospitalizations of COVID-19 patients in the county over the past 10 days." Previously on March 22, 2020, Governor Andrew Cuomo held a press conference during which he announced that, "we're also canceling all elective, non-critical surgery for

hospitals as of Wednesday. Elective, non-critical – the critical surgery, fine. If it's not critical then postpone it." Following the press conference, on March 23, 2020, Governor Cuomo issued an executive order enacting many of the items he discussed during the March 22nd press conference, including requiring "…all general hospitals, ambulatory surgery centers, office-based surgery practices and diagnostic and treatment centers to increase the number of beds available to patients, including by canceling all elective surgeries and procedures, as the Commissioner of Health shall define."

5. **Ohio**. On April 22, 2020, Governor Mike DeWine, Lt. Governor Jon Husted, and Dr. Amy Acton, MD, MPH, announced "an order that directs healthcare providers in hospitals and outpatient surgery centers to reassess procedures and surgeries that were postponed" with the caution that "[r]esuming elective surgeries and procedures will take clinical judgment, and [they] will rely on our healthcare providers to make responsible decisions as we move forward." Previously, on March 17, 2020, the Ohio Department of Health issued an order for the management of non-essential surgeries and procedures. The directive ordered that, March 18th, all non-essential or elective surgeries and procedures utilizing PPE not be conducted. The order states that it will remain in force for the length of the state of emergency or until lifted by the Department of Health.

We will continue to provide updates as more developments occur.

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