March 25, 2020

Honorable Gavin Newsom
Governor, State of California
State Capitol
Sacramento, CA 95814

Dear Governor Newsom:

The California Ambulatory Surgery Association (CASA) applauds your outstanding leadership to address the COVID-19 pandemic crisis in California. Even with the decisive action your Administration has taken to curb the spread of the virus, concerns that hospitals will be overwhelmed have not been tempered. There is growing alarm how the state's health care infrastructure will meet the challenge as we work to meet the shortfall of 50,000 hospital beds. ASCs can and must play a role in ensuring that communities' health needs are met both during and following the cessation of the pandemic.

In order to best support our community hospitals that are at the center of care in this time of crisis, a list of ways that our ASC facilities, physicians, and team members are best equipped to serve the community and take the load off of hospitals has been compiled. In response to COVID-19, ASCs have already implemented a stringent protocol around urgent elective vs. elective procedures. Many CA ASCs have closed or are limiting operations to 1 to 2 days a week to respond to those urgent patients. A good number are also working closely with their hospitals and health systems to provide relief as hospitals are migrating their appropriate urgent elective procedures to the ASC environment. In order to implement fully these options as directed through community collaboration, we respectfully submit to you the following recommended actions:

1. **Waive enforcement of Health and Safety Code 1204.1, 1248.1 (a)(g) regarding length of stay restrictions in a surgical clinic, an ambulatory surgery center or outpatient surgery setting throughout the duration of this emergency.** Listed below are alternative services ASCs can provide to fully implement and provide the greatest resources and availability to the statewide response to COVID-19. However, to fully execute, they will need the ability to provide care for patients outside the current mandate of providing patient care up to 24 hours.

2. **Waive enforcement of Health and Safety Code 1248.15 (1)(2,C, i,ii) as pertaining to provider licensing and admitting privileges at a local accredited or licensed acute care hospital throughout the duration of this emergency.** This will align with other state waivers to allow physicians and health care personnel stepping out of retirement, crossing state lines or working between health facilities to provide patient care as these alternative patient care options and responses evolve in ASCs and outpatient surgery settings.

The options listed below are tiered in order of the ability to expedite their implementation and provide quicker service to the community and COVID-19 response.

Option 1: ASCs can take outpatient urgent elective procedures now as we are best positioned to do so based on our existing capabilities. *This is the quickest option as it is in line with our core competencies and business model and could be quickly implemented within 24 hours*.

Proposed Service	Requirements	Regulatory Engagement Required
Take on urgent surgeries for the community at an ASC	• Coordination with hospital system of urgent elective surgeries. • Common community adoption of urgent surgeries • Facility medical director involved in determining medical necessity and patient risk • Temporary privileges; accelerated credentialing • Consider increasing ASA Class to include "4s" • Consider expanded hours of operation, including weekends	• CMS defines ASC max ASA Class as 3 • CMS/AO notification • Eliminate length of stay restrictions- *waiver to H&S 1204.1, 1248.1 (a)(g)*
Take on emergency fracture surgeries **excluding hip fracture*	• Extend hours of operations and eliminate time limit of length of stay • Temporary privileges • If transferring from hospital, coordination with hospital system needed	• Eliminate length of stay restrictions- *waiver to H&S 1204.1, 1248.1 (a)(g)*Allow transfers from hospital to ASC

Option 2: ASCs can transition to accommodate complex surgical cases. *This option is in line with our core competencies and business model but could take additional time for implementation due to expanded equipment and surgical instrumentation needs. Time for implementation between 24-48 hours.*

Proposed Service	Requirements	Regulatory Engagement Required
Migrate overflow surgical case volume; inpatient and outpatient	• Temporary privileges • Consider expanded hours of operation including weekends • Fits within the centers current specialty offering • Expand our CPT list based on current specialties offered at the center • Hospital to potentially assist in providing necessary equipment, staff and supplies	• Expanded list of reimbursed codes -*In addition to CMS need waiver requiring health plans to accept payment of procedures at an ASC* • Eliminate length of stay restrictions- *waiver to H&S 1204.1, 1248.1 (a)(g)*

Option 3: ASCs can expand our services to meet the different needs you may have based on the assets we have in place across the country. *This option will take more time for implementation as there are extensive considerations to implement from physical plant limitations, provider and staff orientations and adequate equipment and supplies. Time for implementation 48 hours-1 week.*

Proposed Service	Requirements	Regulatory Engagement Required
Triage Center – diversion from Emergency Room	• Scope of service revision • Need on site MD or mid-level staffing • Consider expanded hours of operation including weekends • Rapid patient assessment and deployment to appropriate level of care • Isolation plan for suspected COVID cases	• Licensing – *waiver to H&S 1204.1 plus 1248* • Ability to transfer from hospital to ASC • Ability to provide non-surgical services in ASC
Serve as Infusion Center	• Scope of service revision—determine what type of infusions (fluids, chemo, immunotherapy, blood, globulins, IV hydration, etc.)	• Licensing • Ability to provide non-surgical services in ASC

	• Pharmaceutical procurement • Determine blood source • Teammate training or identify dedicated team • Cancer treatment (w disposal system) • Additional infusion pumps	
Provide inpatient overnight beds	• Focus on patients that just need 1-2-day length of stay before discharge home or rehab center • Acute care non-ICU/non-isolation	• Licensing • Eliminate length of stay restriction
Serve as an Urgent Care center – Non-COVID-19 patients	• Scope of service revision • Need on site MD or mid-level staffing • Determine hours of service • Colds/flu, bumps/bruises, stiches, burns, stings, allergic reactions, vaccines, minor infections, Fractures and sprains, lacerations, x-rays, dehydration	• Licensing • Ability to provide non-surgical services in ASC

Option 4: ASCs can further expand our services to meet the community's needs. Once these are employed, it would be difficult to go back to providing the services in Options 1-3. ***This option will take more time for implementation as there are extensive considerations to implement from physical plant limitations, provider and staff orientations and adequate equipment and supplies. Time for implementation 48 hours-1 week plus. Birthing Center and ICU- At least 1 week for implementation of ICU setting.***

Proposed Service	Requirements	Regulatory Engagement Required
COVID-19 Testing and Triage Center	• Scope of service revision • Need on site MD or mid-level staffing • Determine how to quarantine and isolate high risk • Determine hours of service • Need test kits—which I understand are limited county by county • Dependent upon current utilization of the ASC • Hospital would need to provide necessary supplies	• Licensing • Ability to provide non-surgical services in ASC
Birthing Suite	• Appropriate equipment • Hospital assist in providing necessary equipment, staff and supplies, including food service • Staffing—highly specialized nursing skill set • Explicit and early discussion and alignment of admission criteria • Nursery arrangement for high risk infants • Could do rooming in for healthy babies • OB medical staff call list	• Licensing • Ability to provide non-surgical services in ASC • Eliminate time limit on length of stay
ICU setting	• Appropriate equipment • Dependent on existing building's design and isolation requirements; air flow etc. • Trained Staff	• Licensing • Eliminate time limit on length of stay • Ability to provide non-surgical services in ASC

Option 5: Facility and/or resources used but not providing medical services within the facility. ***Time for implementation immediate.***

Proposed Service	Requirements	Regulatory Engagement Required
Sleep center for hospital call teams	• Can offer now during off hours • Expand if we cannot provide any services • Consider need for food services	TBD
Provide resources: staff and equipment only	• If we cannot provide any services	TBD

Thank you for your consideration.

Respectfully submitted,

Michelle George
President
California Ambulatory Surgery Association

ADDENDUM – CALIFORNIA LAW AS IT PERTAINS TO ASCS AND OUTPATIENT SURGERY SETTINGS

HEALTH AND SAFETY CODE - HSC

DIVISION 2. LICENSING PROVISIONS [1200 - 1797.8]

(Division 2 enacted by Stats. 1939, Ch. 60.)

H&S 1204.1

(1) A "surgical clinic" means a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. A surgical clinic does not include any place or establishment owned or leased and operated as a clinic or office by one or more physicians or dentists in individual or group practice, regardless of the name used publicly to identify the place or establishment, provided, however, that physicians or dentists may, at their option, apply for licensure.

CHAPTER 1.3. Outpatient Settings [1248 - 1248.85]

(Chapter 1.3 added by Stats. 1994, Ch. 1276, Sec. 2.)

1248.

For purposes of this chapter, the following definitions shall apply:
(a) "Division" means the Medical Board of California. All references in this chapter to the division, the Division of Licensing of the Medical Board of California, or the Division of Medical Quality shall be deemed to refer to the Medical Board of California pursuant to Section 2002 of the Business and Professions Code.
(b) (1) "Outpatient setting" means any facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care facility, as defined in Section 1250, and where anesthesia, except local anesthesia or peripheral nerve blocks, or both, is used in compliance with the community standard of practice, in doses that, when administered have the probability of placing a patient at risk for loss of the patient's life-preserving protective reflexes.
(2) "Outpatient setting" also means facilities that offer in vitro fertilization, as defined in subdivision (b) of Section 1374.55.
(3) "Outpatient setting" does not include, among other settings, any setting where anxiolytics and analgesics are administered, when done so in compliance with the community standard of practice, in doses that do not have the probability of placing the patient at risk for loss of the patient's life-preserving protective reflexes.
(c) "Accreditation agency" means a public or private organization that is approved to issue certificates of accreditation to outpatient settings by the board pursuant to Sections 1248.15 and 1248.4.
(Amended by Stats. 2011, Ch. 645, Sec. 2. (SB 100) Effective January 1, 2012.)

1248.1.

No association, corporation, firm, partnership, or person shall operate, manage, conduct, or maintain an outpatient setting in this state, unless the setting is one of the following:
(a) An ambulatory surgical center that is certified to participate in the Medicare program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act.
(b) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1601 of Title 25 of the United States Code, and located on land recognized as tribal land by the federal government.
(c) Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies.
(d) Any primary care clinic licensed under subdivision (a) and any surgical clinic licensed under subdivision (b) of Section 1204.
(e) Any health facility licensed as a general acute care hospital under Chapter 2 (commencing with Section 1250).

(f) Any outpatient setting to the extent that it is used by a dentist or physician and surgeon in compliance with Article 2.7 (commencing with Section 1646) or Article 2.8 (commencing with Section 1647) of Chapter 4 of Division 2 of the Business and Professions Code.
(g) An outpatient setting accredited by an accreditation agency approved by the division pursuant to this chapter.
(h) A setting, including, but not limited to, a mobile van, in which equipment is used to treat patients admitted to a facility described in subdivision (a), (d), or (e), and in which the procedures performed are staffed by the medical staff of, or other healthcare practitioners with clinical privileges at, the facility and are subject to the peer review process of the facility but which setting is not a part of a facility described in subdivision (a), (d), or (e).
Nothing in this section shall relieve an association, corporation, firm, partnership, or person from complying with all other provisions of law that are otherwise applicable.
(Added by Stats. 1994, Ch. 1276, Sec. 2. Effective January 1, 1995.)

1248.15.

(a) The board shall adopt standards for accreditation and, in approving accreditation agencies to perform accreditation of outpatient settings, shall ensure that the certification program shall, at a minimum, include standards for the following aspects of the settings' operations:
(1) Outpatient setting allied health staff shall be licensed or certified to the extent required by state or federal law.
(2) (A) Outpatient settings shall have a system for facility safety and emergency training requirements.
(B) There shall be onsite equipment, medication, and trained personnel to facilitate handling of services sought or provided and to facilitate handling of any medical emergency that may arise in connection with services sought or provided.
(C) In order for procedures to be performed in an outpatient setting as defined in Section 1248, the outpatient setting shall do one of the following:
(i) Have a written transfer agreement with a local accredited or licensed acute care hospital, approved by the facility's medical staff.
(ii) Permit surgery only by a licensee who has admitting privileges at a local accredited or licensed acute care hospital, with the exception that licensees who may be precluded from having admitting privileges by their professional classification or other administrative limitations, shall have a written transfer agreement with licensees who have admitting privileges at local accredited or licensed acute care hospitals.
(iii) Submit for approval by an accrediting agency a detailed procedural plan for handling medical emergencies that shall be reviewed at the time of accreditation. No reasonable plan shall be disapproved by the accrediting agency.
(D) The outpatient setting shall submit for approval by an accreditation agency at the time of accreditation a detailed plan, standardized procedures, and protocols to be followed in the event of serious complications or side effects from surgery that would place a patient at high risk for injury or harm or to govern emergency and urgent care situations. The plan shall include, at a minimum, that if a patient is being transferred to a local accredited or licensed acute care hospital, the outpatient setting shall do all of the following:
(i) Notify the individual designated by the patient to be notified in case of an emergency.
(ii) Ensure that the mode of transfer is consistent with the patient's medical condition.
(iii) Ensure that all relevant clinical information is documented and accompanies the patient at the time of transfer.
(iv) Continue to provide appropriate care to the patient until the transfer is effectuated.
(E) All physicians and surgeons transferring patients from an outpatient setting shall agree to cooperate with the medical staff peer review process on the transferred case, the results of which shall be referred back to the outpatient setting, if deemed appropriate by the medical staff peer review committee. If the medical staff of the acute care facility determines that inappropriate care was delivered at the outpatient setting, the acute care facility's peer review outcome shall be reported, as appropriate, to the accrediting body or in accordance with existing law.
(3) The outpatient setting shall permit surgery by a dentist acting within his or her scope of practice under Chapter 4 (commencing with Section 1600) of Division 2 of the Business and Professions Code or physician and surgeon, osteopathic physician and surgeon, or podiatrist acting within his or her scope of practice under Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code or the Osteopathic Initiative Act. The outpatient

setting may, in its discretion, permit anesthesia service by a certified registered nurse anesthetist acting within his or her scope of practice under Article 7 (commencing with Section 2825) of Chapter 6 of Division 2 of the Business and Professions Code.
(4) Outpatient settings shall have a system for maintaining clinical records.
(5) Outpatient settings shall have a system for patient care and monitoring procedures.
(6) (A) Outpatient settings shall have a system for quality assessment and improvement.
(B) (i) Members of the medical staff and other practitioners who are granted clinical privileges shall be professionally qualified and appropriately credentialed for the performance of privileges granted. The outpatient setting shall grant privileges in accordance with recommendations from qualified health professionals, and credentialing standards established by the outpatient setting.
(ii) Each licensee who performs procedures in an outpatient setting that requires the outpatient setting to be accredited shall be, at least every two years, peer reviewed, which shall be a process in which the basic qualifications, staff privileges, employment, medical outcomes, or professional conduct of a licensee is reviewed to make recommendations for quality improvement and education, if necessary, including when the outpatient setting has only one licensee. The peer review shall be performed by licensees who are qualified by education and experience to perform the same types of, or similar, procedures. The findings of the peer review shall be reported to the governing body, which shall determine if the licensee continues to meet the requirements described in clause (i). The process that resulted in the findings of the peer review shall be reviewed by the accrediting agency at the next survey to determine if the outpatient setting meets applicable accreditation standards pursuant to this section.
(C) Clinical privileges shall be periodically reappraised by the outpatient setting. The scope of procedures performed in the outpatient setting shall be periodically reviewed and amended as appropriate.
(7) Outpatient settings regulated by this chapter that have multiple service locations shall have all of the sites inspected.
(8) Outpatient settings shall post the certificate of accreditation in a location readily visible to patients and staff.
(9) Outpatient settings shall post the name and telephone number of the accrediting agency with instructions on the submission of complaints in a location readily visible to patients and staff.
(10) Outpatient settings shall have a written discharge criteria.
(b) Outpatient settings shall have a minimum of two staff persons on the premises, one of whom shall either be a licensed physician and surgeon or a licensed health care professional with current certification in advanced cardiac life support (ACLS), as long as a patient is present who has not been discharged from supervised care. Transfer to an unlicensed setting of a patient who does not meet the discharge criteria adopted pursuant to paragraph (10) of subdivision (a) shall constitute unprofessional conduct.
(c) An accreditation agency may include additional standards in its determination to accredit outpatient settings if these are approved by the board to protect the public health and safety.
(d) No accreditation standard adopted or approved by the board, and no standard included in any certification program of any accreditation agency approved by the board, shall serve to limit the ability of any allied health care practitioner to provide services within his or her full scope of practice. Notwithstanding this or any other provision of law, each outpatient setting may limit the privileges, or determine the privileges, within the appropriate scope of practice, that will be afforded to physicians and allied health care practitioners who practice at the facility, in accordance with credentialing standards established by the outpatient setting in compliance with this chapter. Privileges may not be arbitrarily restricted based on category of licensure.
(e) The board shall adopt standards that it deems necessary for outpatient settings that offer in vitro fertilization.
(f) The board may adopt regulations it deems necessary to specify procedures that should be performed in an accredited outpatient setting for facilities or clinics that are outside the definition of outpatient setting as specified in Section 1248.
(g) As part of the accreditation process, the accrediting agency shall conduct a reasonable investigation of the prior history of the outpatient setting, including all licensed physicians and surgeons who have an ownership interest therein, to determine whether there have been any adverse accreditation decisions rendered against them. For the purposes of this section, “conducting a reasonable investigation” means querying the Medical Board of California and the Osteopathic Medical Board of California to ascertain if either the outpatient setting has, or, if its owners are licensed physicians and surgeons, if those physicians and surgeons have, been subject to an adverse accreditation decision.
(Amended by Stats. 2015, Ch. 287, Sec. 3. (SB 396) Effective January 1, 2016.)