

COVID-19 Pandemic

Federal Licensing and Certification Waivers

April 12, 2020

The need to respond to COVID-19 in California and nationally poses substantial and complex legal questions and concerns. Below are federal legal resources compiled by CHA related to licensing and certification waivers, survey activity, enforcement discretion, and the like. **Hospitals should consult legal counsel with specific questions.**

Note: Federal waivers apply only to federal law and do not change state law — even if the state and federal requirements are the same. CHA has also compiled a [list of state waivers](#).

National Emergency Declarations

Presidential Emergency Declaration. On March 13, 2020, President Trump declared a state of emergency under the [National Emergencies Act](#) and the [Stafford Act](#).

U.S. Health and Human Services (HHS) Determination of Public Health Emergency.

On January 31, 2020, HHS Secretary Azar declared a [nationwide public health emergency](#).

Centers for Medicare & Medicaid Services (CMS)

CMS Survey Activity

- CMS [announced general enforcement discretion](#) until at least April 13. This applies to hospitals, long-term care facilities, home health agencies, hospices, and laboratories.
- No surveys will be conducted except: (1) In response to complaints and facility-reported incidents that may constitute an immediate jeopardy — a streamlined infection control review tool will be used during these surveys, regardless of the allegation; (2) Targeted infection control surveys of providers identified through collaboration with the Centers for Disease Control and Prevention (CDC) and HHS Assistant Secretary for Preparedness and Response (ASPR) — the streamlined infection control review tool will be used; and (3) Initial certification surveys.
- The infection control tool is included with the CMS announcement and may be used for self-assessment.
- The CMS announcement also includes voluntary guidance on visitor restrictions for hospitals.

CMS Waivers

CMS has issued waivers on various dates; all are effective March 1, 2020, through the end of the emergency declaration. CMS has combined them [into one document](#).

A single asterisk preceding a waiver below indicates that the state has waived a similar state requirement. Waivers followed by a double asterisk apply only so long as the hospital's action is not inconsistent with the state's emergency preparedness or pandemic plan.

- ***EMTALA**: Allows hospitals to redirect patients to offsite locations for a medical screening exam in accordance with the state emergency preparedness or pandemic plan. CMS [issued an updated memo](#) on March 30 with detailed information about COVID-19 and EMTALA requirements.
- ***Physician/practitioner orders**: Waives the requirement to date/time/authenticate orders promptly; to use pre-printed and electronic orders, order sets, and protocols only if approved by medical staff, nursing, and pharmacy leadership in accordance with national standards; to use verbal orders only infrequently; and allows critical access hospitals to use verbal medication orders.
- **Death in restraints**: Waives the requirement to report to CMS an ICU patient whose death was caused by their disease process but who required soft wrist restraints to prevent pulling tubes/IVs; however, if the restraint may have contributed to the death, must report as usual.
- **Patient rights**: Waives the CMS time frame for providing patient access to their record (however, state law still applies; *see Health and Safety Code Section 123110*); waives visitation requirements, including requirement to have written policies and procedures regarding isolated/quarantined COVID-19 patients; and deletes the requirement that seclusion be considered a restraint.
- ***Sterile compounding**: Allows used face masks to be removed and retained in the compounding area to be re-donned and re-used during the same work shift. (*See also "Food and Drug Administration" below for flexibility for personal protective equipment use by compounding pharmacies.*)
- **Discharge planning**: Waives: (1) the requirement to tell patients of their freedom to choose among participating post-acute providers and suppliers, and to provide data on quality measures and resource use measures; (2) the requirement to include in the discharge plan a list of available post-acute providers; and (3) the requirement that the discharge plan identify any disclosable financial interest between the hospital and the home health agency or skilled-nursing facility.
- ***Medical staff**: Allows physicians whose privileges will expire to continue practicing, and for new physicians to practice at the hospital before full medical staff/governing body review and approval.
- ***Medical records**: Waives the time frame for completion of medical records.
- **Advance directives**: Waives the requirement to provide patients information about advance directives policies.

- ***Physical environment:** Permits non-hospital buildings/space to be used for patient care if the location is approved by the state.
- ***Telehealth:** Allows hospitals to provide telehealth without credentialing agreements with off-site hospitals (*See additional information under “CMS Telehealth Waivers,” below.*)
- ***Physician services**:** Allows Medicare patients to be under the care of other practitioners, not just a physician.
- **Anesthesia services**:** Certified registered nurse anesthetists (CRNAs) need not be supervised by a physician to the extent consistent with state law and hospital policies (California does not require physician supervision of CRNAs).
- **Utilization review**:** Waives the entire utilization review Condition of Participation that provides for a review of services furnished to Medicare/Medi-Cal beneficiaries to evaluate medical necessity of the admission, duration of stay, and services provided.
- **Off-campus hospital departments**:** For surge facilities only - Off-campus hospital departments do not need to have written policies and procedures for appraisal of emergencies
- ***Emergency preparedness policies and procedures:** Waives requirements for surge sites at hospitals and CAHs to develop and implement emergency preparedness policies and procedures.
- **Quality Assessment and Performance Improvement Program (QAPI)**:** Waives many requirements related to hospital and CAH QAPI programs; however, hospitals and CAHs must maintain their QAPI program – CMS expects that any improvements to the plan focus on the public health emergency.
- ***Nursing care plan and nursing policies**:** Waives the requirements for: (1) a nursing care plan for each patient and (2) a policy and procedure establishing which outpatient departments need not have an RN present.
- ***Therapeutic diet manuals**:** Therapeutic diet manuals need not be readily available at surge capacity sites.
- **Respiratory care personnel**:** Hospitals need not designate in writing the personnel qualified to perform specific respiratory care procedures and the amount of supervision required for specific procedures.
- **Critical access hospital (CAH):** Waives the 25-bed limit and the 96-hour length of stay limit.
- **CAH personnel qualifications**:** Waives minimum personnel qualifications for clinical nurse specialists, nurse practitioners, and physician assistants at CAHs.
- **CAH status and location**:** CAH surge sites need not be located in a rural area or area being treated as rural, and off-campus and co-location requirements for CAHs are waived.
- **Physicians in CAHs:** Waives the requirement that a physician must be physically present to provide medical direction and supervision for CAH patients; instead, they can be available by radio, telephone, or online communication.

- **Temporary expansion locations:** In addition to waiving physical environment requirements, provider-based department requirements are waived to allow hospitals and CAHs to operate any location as part of the hospital, and change the status of their current provider-based departments so long as the location meets Conditions of Participation and other requirements not waived. This also extends to an ambulatory surgical center (ASC) enrolling as a hospital during the pandemic under a streamlined process. Further information for such ASCs is [available here](#).
- ***Patient location:** Allows hospitals to put acute care inpatients in excluded distinct-part units, and excluded distinct-part unit patients (psychiatric, rehabilitation) in acute care units.
- **Inpatient Rehabilitation Facility (IRF) 60 percent rule:** Allows IRFs to exclude certain patients from the calculation to determine whether the facility can receive payment as an IRF.
- **Extension for inpatient prospective payment system (IPPS) wage index occupational mix survey submission:** Deadline extended from July 1, 2020, until August 3, 2020. Hospitals with difficulty meeting the extended deadline should contact their Medicare administrative contractor.
- **Long-term acute care hospital (LTACH):** Allows LTACHs to exclude certain patient stays for 25-day length of stay requirement.
- **Extended neoplastic disease care hospitals:** Allows these hospitals to exclude inpatient stays where the hospital admits or discharges patients due to the pandemic from the greater than 20-day average length of stay requirement, so they can receive an adjusted payment for Medicare inpatient operating and capital-related costs under the reasonable cost-based reimbursement rules, rather than IPPS.
- **Skilled-nursing facility (SNF) three-day prior hospitalization:** Waives the three-day prior hospitalization for Medicare SNF coverage; provides renewed SNF coverage without having to start a new benefit period, for Medicare beneficiaries who recently exhausted their SNF benefits.
- **Minimum Data Set reporting:** Waives Minimum Data Set assessment and transmission time frames.
- **Staffing data submission:** Waives the requirement for long-term care facilities to submit staffing data through the Payroll-Based Journal system.
- **Pre-Admission Screening and Annual Resident Review (PASARR):** Suspends these requirements for new residents for 30 days. After 30 days, new residents admitted with a mental illness or intellectual disability should be assessed as soon as resources become available.
- **SNF physical environment:** Allows non-SNF buildings to be temporarily certified; CMS will waive certain Conditions of Participation and revise processes to facilitate certification of these sites. Also ** allows rooms in a long-term care facility not normally used as a resident's room to be used to accommodate beds and residents.
- **SNF resident groups:** Waives resident rights to participate in resident groups.

- ***SNF nurse aides:** Waives certain training and certification requirements for nurse aides.
- **SNF practitioner visits:** Allows physician and other practitioner required in-person visits to be conducted via telehealth.
- **SNF roommates and groupings:** Waives resident roommate and grouping requirements
- **SNF transfer and discharge:** Allows facilities to transfer or discharge residents to another facility in order to cohort COVID-19+ and non-COVID-19+ patients so long as the receiving facilities agrees to accept the resident (*See waiver for additional guidance and limitations*).
- **SNF scope of practice:** Allows physicians to delegate tasks/visits to nurse practitioners, physician assistants, and clinical nurse specialists where federal regulation would otherwise require that the physician perform the task or provide the visit personally, if the activity is within the delegate's scope of practice under state law.
- **Home health deadlines:** Suspends OASIS transmission timelines (five-day completion and 30-day submission); allows Medicare administrative contractors to extend the auto-cancellation date of requests for anticipated payment.
- **Home health initial assessments:** Allows initial assessment and determination of homebound status to be performed remotely or by record review.
- **Home health scope of practice:** Allows occupational therapists to perform initial and comprehensive assessments for all home health patients, regardless of whether occupational therapy is the service that establishes eligibility for the patient to receive home health care.
- **Home health and hospice:** Waives the requirement for nurses to conduct onsite visits every two weeks; virtual visits are encouraged, but not required.
- **Hospice:** Waives the requirement to use volunteers; waives the requirement to provide non-core services (PT, OT, speech-language pathology); extends the time frame for completing comprehensive assessments from 15 to 21 days.
- **Hospice in-service training:** Waives the requirement that hospices provide 12 hours of in-service training during a 12-month period for each hospice aide.
- **ESRD facilities:** Waives several requirements for ESRD facilities, including audits of operators of water/dialysate equipment, on-time preventive maintenance of dialysis machines and ancillary dialysis equipment, on-time fire inspections, staff certifications, physician credentialing, on-time requirements for initial and follow-up comprehensive patient assessments, modifying time period for initiation of care planning and monthly physician visits (*See waiver for additional ESRD-related waivers.*)
- **Durable medical equipment, prosthetics, orthotics and supplies (DMEPOS):** Allows replacement of lost, damaged or destroyed DME without meeting the face-to-face, physician order, and new medical necessity documentation requirements. See waiver for information about billing and documentation.
- **Out-of-state personnel:** Waives requirements for out-of-state practitioners to be licensed in the state where they are working, if they are licensed in another state. CMS will waive the licensing requirements when the following four conditions are met: (1)

provider is enrolled in Medicare, (2) provider has a valid license to practice in the state that relates to his/her Medicare enrollment, (3) provider is furnishing services (in person or telehealth) in a state in which the emergency is occurring in order to contribute to relief efforts and (4) the provider is not affirmatively excluded from practice in the state or any other state that is part of the 1135 emergency area. This applies to billing for services rendered to Medicare and Medicaid patients. (The California Emergency Medical Services Authority has the ability to quickly authorize out-of-state medical personnel to practice in California. (See <https://emsa.ca.gov/covid19/> for details.)

- **Provider enrollment:** Establishes a hotline for providers and suppliers to enroll and receive temporary Medicare billing privileges; waives application fee, background checks, and site visits; postpones revalidations; allows practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location; and allows opted-out practitioners to terminate their opt-out status early and enroll in Medicare.

CMS Beneficiary Notice Delivery Guidance

CMS [is allowing](#) various beneficiary notices to be provided in alternative manners.

CMS Guidance on Elective Surgeries

CMS [issued recommendations](#) on elective surgeries/procedures, stating that decisions will be made at the local level by the clinician, patient, hospital, and state and local health departments. The recommendations include suggested factors and framework for consideration.

CMS Telehealth Waivers

CMS [exercised its waiver authority](#) to expand Medicare telehealth benefits, allowing Medicare fee for service reimbursement for office, hospital, and other visits furnished via telehealth, including in a patient's home and in non-rural locations, starting March 6, 2020. CMS waived certain originating site, communication device and prior relationship requirements. CMS also [issued an FAQ](#) and has encouraged Medicare Advantage plans and Medicaid programs to expand telehealth as well. The Office of Inspector General is [providing flexibility](#) for health care providers to reduce or waive cost-sharing for telehealth visits paid by federal health care programs. In addition, the Office for Civil Rights will [exercise enforcement discretion](#) and waive penalties for HIPAA violations against health care providers that serve patients in good faith through everyday communications technologies, such as FaceTime or Skype, during the COVID-19 emergency. An FAQ on the enforcement discretion [can be found here](#). The Drug Enforcement Administration has [issued guidance](#) for prescribing based on telehealth.

CMS Quality Reporting Exceptions and Extensions

CMS [announced exceptions and extensions](#) for upcoming measure reporting and data submission for Medicare quality reporting and value-based purchasing programs.

Laboratories — Clinical Laboratory Improvement Amendments (CLIA)

CMS [issued guidance](#) and [FAQs](#) related to CLIA flexibilities, including the remote review and reporting by pathologists, clarification of proficiency testing requirements, alternate specimen collection – and responding to other questions about COVID-19 testing requirements.

Health and Human Services

[Waivers – Dated March 13, 2020 \(but released on March 15, 2020\)](#)

This document seems to grant broad waivers; however, it states that most of these waivers will be granted “only to the extent necessary, as determined by the Centers for Medicare & Medicaid Services, to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in ... Medicare...” The only waiver that appears self-executing in this document relates to HIPAA; however, this waiver lasts only for the first 72 hours that the hospital implements its disaster protocol:

- Waives the requirement to obtain a patient’s agreement to speak with family members or friends or to honor a patient’s request to opt out of the facility directory – however, California has a similar state law provision that has not been waived (*See Civil Code sections 56.1007 and 56.16.*).
- Waives the requirement to distribute a Notice of Privacy Practices
- Waives the patient’s right to request special privacy restrictions
- Waives the patient’s right to request to receive confidential communications in an alternative manner or location (such as at a different address or by text)

Additional information about this waiver may be [found here](#). The Office for Civil Rights has been urged to expand this waiver beyond 72 hours.

[Hoarding/Price Gouging](#)

HHS announced a list of health and medical resources subject to hoarding and price-gouging prevention measures. This action prevents accumulation in excess of reasonable demands of business or home consumption, or for the purpose of resale at prices in excess of prevailing market prices. The list includes ventilators, personal protective equipment (PPE), and similar items. Penalties for violation include a fine of up to \$10,000 or imprisonment for up to one year, or both. (*See also “Price Gouging/Hoarding” below for information on making a complaint to the government about price gouging or hoarding.*)

[Pharmacists Ordering/Administering COVID-19 tests](#)

The Department of Health and Human Services [issued guidance](#) authorizing pharmacists to order and administer COVID-19 tests, including serology tests. The authorization qualifies them for immunity from any related claims under the Public Readiness and Emergency Preparedness Act.

Office for Civil Rights (OCR)

- Discrimination: [OCR guidance](#) that civil rights laws are not set aside during emergency
- HIPAA general waiver: Certain HIPAA requirements [are waived](#) for the first 72 hours that

the hospital implements its disaster protocol:

- Waives the requirement to obtain a patient’s agreement to speak with family members or friends or to honor a patient’s request to opt out of the facility directory – however, California has a similar state law provision that has not been waived (*See Civil Code sections 56.1007 and 56.16.*).
- Waives the requirement to distribute a Notice of Privacy Practices
- Waives the patient’s right to request special privacy restrictions
- Waives the patient’s right to request to receive confidential communications in an alternative manner or location (such as at a different address or by text)

Additional information about this waiver may be [found here](#). CHA and the American Hospital Association have urged the Office for Civil Rights to expand this waiver beyond 72 hours.

- [HIPAA guidance](#) for disclosures to first responders: Note that California has stricter privacy laws that are not described in the OCR document; California covered entities must comply with the stricter state laws. In addition, there are longstanding state and federal laws requiring hospitals to notify first responders about exposure to infectious disease; see chapter 18 (starting on page 18.10) of CHA’s *Consent Manual*.
- HIPAA [enforcement discretion](#) for community-based testing sites, which are mobile, drive-through, or walk-up sites that provide only COVID19 specimen collection or testing services
- HIPAA [enforcement discretion](#) for a business associate (BA) who discloses protected health information to a health oversight agency for public health or health oversight activities, even if the disclosure is not permitted under the BA agreement. The BA must notify the covered entity within 10 days.
- HIPAA telehealth information: *See “CMS Telehealth Waivers” above for information about telehealth-related waivers and enforcement discretion.*

Office for Human Research Protections

- COVID-19 [guidance related to research](#)

[Physician Self-Referral \(Stark\) Law Waiver](#) (effective March 1, 2020; issued March 30, 2020)

- Identifies 18 financial relationships and referrals where Stark Law requirements are waived so that providers may still be reimbursed by Medicare, Medi-Cal, and CHIP, and exempt from sanctions if acting in good faith and absent the government’s determination of fraud or abuse (see list below)
- **For COVID-19 purposes only:** The waivers apply only to financial relationships and referrals that are “solely related to COVID-19 purposes.” COVID-19 purposes are defined as:
 - Diagnosis or treatment of COVID-19 (whether or not the patient is diagnosed with a confirmed case of COVID-19)
 - Securing physicians and other practitioners to furnish medically necessary services in response to the pandemic (including services not related to the

diagnosis and treatment of COVID-19 patients)

- Ensuring the ability, or expanding the capacity, of health care providers to address patient and community needs due to the pandemic
 - Shifting patient care to alternative settings due to the pandemic, or
 - Addressing medical practice or business interruption due to the pandemic to maintain the availability of medical care and related services for patients and the community.
1. **Fair Market Value (FMV) for Physician Services.** Remuneration from an entity to a physician (or immediate family member) that is above or below the FMV for services personally performed by the physician (or immediate family member) to the entity.
 2. **Office Space Rented from a Physician Below FMV.** Rental charges paid by an entity to a physician (or immediate family member) that are below FMV for the entity's lease of office space from the physician (or immediate family member).
 3. **Equipment Rented from a Physician Below FMV.** Rental charges paid by an entity to a physician (or immediate family member) that are below FMV for the entity's lease of equipment from the physician (or immediate family member).
 4. **Purchase of Items or Services from a Physician Below FMV.** Remuneration from an entity to a physician (or immediate family member) that is below FMV for items or services purchased by the entity from the physician (or immediate family member).
 5. **Office Space Rented to a Physician Below FMV.** Rental charges paid by a physician (or immediate family member) to an entity that are below FMV for the physician's (or immediate family member's) lease of office space from the entity.
 6. **Equipment Rented to a Physician Below FMV.** Rental charges paid by physician (or immediate family member) to an entity that are below FMV for the physician's (or immediate family member's) lease of equipment from the entity.
 7. **Purchase of Items or Services by a Physician Below FMV.** Remuneration from a physician (or immediate family member) to an entity that is below FMV for the use of the entity's premises or for items or services purchased by the physician (or immediate family member) from the entity.
 8. **Medical Staff Incidental Benefits.** Remuneration from a hospital to a physician in the form of medical staff incidental benefits that exceeds \$36 per occurrence in calendar year 2020.
 9. **Non-Monetary Compensation.** Remuneration from an entity to a physician (or immediate family member) in the form of nonmonetary compensation that exceeds \$423 in calendar year 2020.
 10. **Loans to a Physician Below FMV or More Favorable Terms.** A loan to a physician (or immediate family member): (1) with an interest rate below FMV; or (2) on terms that are unavailable from a lender that is not a recipient of the physician's referrals or business generated by the physician.
 11. **Loans from a Physician Below FMV or More Favorable Terms.** A loan from a physician: (1) with an interest rate below FMV; or (2) on terms that are unavailable from a lender

that is not in a position to generate business for the physician (or immediate family member).

12. **Expansion of Physician-Owned Hospitals.** The referral by a physician owner of a hospital that temporarily expands its facility capacity above the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement on that date, but did have a provider agreement in effect on December 31, 2010, the effective date of the provider agreement) without prior application and approval of the expansion.
13. **Physician Ownership in Hospitals Converted from an ASC.** Referrals by a physician owner of a hospital that converted from a physician-owned ambulatory surgical center to a hospital on or after March 1, 2020, provided that: (1) the hospital does not satisfy one or more of the requirements of section 1877(i)(1)(A) through (E) of the Act; (2) the hospital enrolled in Medicare as a hospital during the public health emergency; (3) the hospital meets the Medicare Conditions of Participation and other non-waived requirements; and (4) the hospital's Medicare enrollment is not inconsistent with the state's emergency preparedness or pandemic plan.
14. **Physician Ownership in a Home Health Agency.** The referral by a physician of a Medicare beneficiary to a home health agency: (1) that does not qualify as a rural provider; and (2) in which the physician (or immediate family member) has an ownership or investment interest.
15. **Practice Location of In-Office Ancillary Services.** The referral by a group practice physician for medically necessary services furnished by the group practice in a location that does not qualify as a "same building" or "centralized building" for purposes of 42 C.F.R. section 411.355(b)(2).
16. **In Home, In-Office Ancillary Services.** The referral by a group practice physician for services furnished by the group practice in a patient's private home, assisted living facility, or independent living facility where the referring physician's principal medical practice does not consist of treating patients in their private homes.
17. **Rural Area Referrals.** The referral by a physician to an entity with which the physician's immediate family member has a financial relationship if the patient who is referred resides in a rural area.
18. **Writing/Signature Requirements.** Referrals by a physician to an entity with whom the physician (or immediate family member) has a compensation arrangement that does not satisfy the writing or signature requirement(s) of an applicable exception but satisfies all other non-waived requirements of the exception.

The Stark waiver document includes 19 examples of permissible arrangements under the waiver, including:

- A hospital pays physicians above their previously-contracted rate for furnishing professional services for COVID-19 patients in particularly hazardous or challenging environments.
- A hospital provides free use of medical office space to allow physicians to provide timely

and convenient services to patients who come to the hospital but do not need inpatient care.

- An entity provides free telehealth equipment to a physician practice to facilitate telehealth visits.
- An entity gives free personal protective equipment to a physician, or sells it for less than FMV.
- A hospital sends an employee to an independent physician practice to help train staff on COVID-19 or to help with patient intake, treatment, and care coordination between the hospital and the practice.
- A hospital provides meals, comfort items (for example, a change of clothing), or onsite child care with a value greater than \$36 per instance to medical staff physicians who spend long hours at the hospital during the COVID-19 outbreak in the United States.
- An entity provides nonmonetary compensation to a physician or immediate family member in excess of the \$423 per year limit (per physician or immediate family member), such as food or other grocery items, isolation-related needs (for example, hotel rooms, and meals), child care, or transportation.
- A hospital lends money to a physician practice that provides exclusive anesthesia services at the hospital to offset lost income resulting from the cancellation of elective surgeries to ensure capacity for COVID-19 needs or covers a physician's 15% contribution for electronic health records items and services in order to continue the physician's access to patient records and ongoing electronic health record technology support services.

Under California's similar statute, there is a broad exception for referrals to hospitals and other health facilities if the recipient of the referral does not compensate the physician for the referral. An equipment lease arrangement between the licensee and the referral recipient must meet certain requirements. (*See Business and Professions Code section 650 et seq.*)

The Department of Health and Human Services' [Office of the Inspector General announced](#) that it will exercise enforcement discretion not to impose penalties under the federal anti-kickback statute for payments related to first 11 waivers listed above, effective April 3, 2020 through the emergency period. To use one of the other seven waivers, OIG suggests providers consult them beforehand.

Department of Homeland Security

- [I-9 documents](#): Employers are not required to review an employee's identity and employment authorization documents in the employee's physical presence. They may do so remotely.

Department of Justice and Federal Trade Commission

- [Antitrust statement](#)

Drug Enforcement Administration (DEA)

- DEA has [issued guidance](#) for prescribing based on telehealth

Federal Non-Discrimination Laws

- [OCR guidance](#) that civil rights laws are not set aside during the emergency
- [EEOC guidance](#): “What You Should Know About the Americans with Disabilities Act, the Rehabilitation Act, and COVID-19”

Food and Drug Administration (FDA)

- [Certain controlled medicines](#) may now be prescribed without patients undergoing lab tests (e.g., liver enzyme testing) or imaging studies (e.g., magnetic resonance imaging) to ensure the medicine is safe for the patient. Providers who are “prescribing and/or dispensing these drugs should consider whether there are compelling reasons not to complete these tests or studies during the [public health emergency], and use their best medical judgment in weighing the benefits and risks of continuing treatment in the absence of laboratory testing and imaging studies.”
- Enforcement policy for [ventilators and other respiratory devices](#) and [infusion pumps and accessories](#).
- FDA [provides flexibility](#) for personal protective equipment use by sterile compounding pharmacies.
- [Draft guidance](#) issued for hospital and health system compounding pharmacies, including on the not-yet-implemented "one mile radius" provision; and a [draft Memorandum of Understanding](#) for interstate distribution. These clarifications, taken together, suggest that hospitals' 503A compounding pharmacies should be able to compound many drugs that are in short supply during the pandemic.
- [Coronavirus-related guidance](#), including guidance related to portable cryogenic oxygen, manufacturing alcohol, and preparing alcohol-based hand sanitizer.

U.S Citizenship and Naturalization Services (USCIS)

Public Charge Rule

USCIS [issued an alert](#) clarifying that treatment or preventive services related to COVID-19 will not negatively affect an immigrant’s future public charge determination, even if the treatment is paid for by public benefits (Medicaid, for example). In addition, the USCIS will consider circumstances — such as social distancing and quarantine — that prevent an immigrant from working or attending school, resulting in the immigrant relying on public benefits for the duration of the COVID-19 outbreak and recovery phase.

Other

Statistics

- **U.S. count:** The current count of COVID-19 cases in the United States is available on the [CDC’s website](#).

- **California count:** The current count of COVID-19 cases in California is available on [CDPH's website](#).
- **Local count:** Check with your local public health department. A list of public health departments is [available here](#).

The Joint Commission (TJC)

- All regular, on-site surveys of hospitals and other health care organizations are suspended, effective March 16 until the end of May. If an organization goes beyond its accreditation due date, accreditation status is extended, and Medicare payment status is not affected. See [TJC's customer letter](#) from April 1.
- Data submission for accreditation (ORYX) and certification (with standardized measures) **will be optional** for Q4 of 2019 and Q1 and Q2 of 2020 .

Price Gouging/Hoarding

Price gouging is illegal, and the California Attorney General is conducting surveillance on potential price gouging in the health care marketplace. If you have information or leads that you would like to share, use the Attorney General's complaint intake portal at <https://oag.ca.gov/contact/consumer-complaint-against-business-or-company>.

In addition, the U.S. Department of Justice and the U.S. Department of Health and Human Services are aggressively pursuing cases to prevent the hoarding or price gouging of medical supplies and drugs essential to combat COVID-19, as well as other fraud related to the pandemic. If you have been the target or victim of price gouging, or are aware of the hoarding of essential medical supplies or drugs necessary to fight the virus, please report it to the National Center for Disaster Fraud Hotline at 866-720-5721 or via email at disaster@leo.gov. For more information, visit www.justice.gov/coronavirus.

Additional CHA Resources

CHA maintains a coronavirus resource web page featuring content and FAQs specific to human resources, wage and hour laws, employee health and safety, clinical concerns, Medi-Cal waivers, and more – go to www.calhospital.org/coronavirus. CHA has also created a daily newsletter for hospitals, called Coronavirus Response, that notifies hospitals of important developments, including newly issued waivers, flexes, enforcement discretion, and a wide range of other topics. To be added to the distribution list, contact Christina Devi at cdevi@calhospital.org.

Questions about waivers? Email Lois Richardson at lrichardson@calhospital.org.