CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

COVID-19 Pandemic
Federal Licensing and Certification Waivers

October 28, 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 that relate to hospital 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 (retroactive to March 1) 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 (retroactive to January 27). This has been renewed and is still in effect.

Congress

Coronavirus Aid, Relief, and Economic Security (CARES) Act. Signed March 27, 2020
Note: CMS has issued regulations to carry out some provisions of this Act. *See "CMS Interim Final Rule with Comment Period [85 Fed.Reg. 27550 (May 8, 2020)]" below.*

- Requires providers to post on their website their cash price for COVID-19 testing; includes $300 per day penalty for failure to post – see FAQ here.
- Revises law on confidentiality of substance use disorder information (effective March 27, 2021)
- Expands the types of professionals that can be reimbursed by Medicare for providing telehealth services and home health certification
- Expands care locations for telehealth
- Allows Medicare reimbursement for certain services provided by phone
- Increases Medicare reimbursement for certain services and suspends sequestration
- Allows marketing of certain lab-developed COVID-19 tests
- Requires certain plans/insurers to reimburse providers for COVID-19 testing, preventive services

Centers for Medicare & Medicaid Services (CMS)

CMS Survey Activity

On March 20, CMS announced general regulatory enforcement discretion (updated on 9/28/20) for at least three weeks – later extended indefinitely. The enforcement discretion applied to hospitals, long-term care facilities, home health agencies, hospices, and laboratories. No surveys were conducted except:

- In response to complaints and facility-reported incidents that CMS believes may constitute an immediate jeopardy. A streamlined infection control review tool will be used during these surveys, regardless of the allegation. Hospitals are, therefore, able to prioritize infection control and responding to the COVID-19 pandemic over less important regulatory requirements.
- Targeted infection control surveys of acute and long-term care providers. The streamlined infection control review tool included with the CMS announcement will be used. The California Department of Public Health (CDPH), as the CMS contractor, may use this entrance checklist as it conducts infection control surveys of both skilled-nursing facilities (SNFs) and hospitals. While the checklist is labeled for SNFs and references "residents," it is being used for both SNFs and hospitals. CHA has received clarification that CDPH surveyors may use the hospital-specific information on the attachment to the March 20 CMS announcement labeled "COVID-19 Focused Infection Control Survey: Acute and Continuing Care."

On June 1, 2020, CMS issued a memo allowing states, at their discretion, to also perform the following hospital surveys:

- Complaint investigations that are triaged as Non-Immediate Jeopardy-High
- Revisit surveys of any facility with removed Immediate Jeopardy (but still out of compliance).

On August 17, CMS encouraged state survey agencies (CDPH in California) to resume normal survey activities, while also addressing the backlog of surveys that were postponed during the pandemic. During the COVID-19 Public Health Emergency (PHE), CMS urges surveyors to continue to use the COVID-19 Focused Infection Control Survey: Acute and Continuing Care tool as part of any survey that is conducted. CMS recognizes that resumption of surveys will depend on state reopening plans, staffing, and resources. See CHA's list of state waivers for more information about CDPH state survey activity (as opposed to CDPH survey activity on behalf of CMS).

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. The list below summarizes waivers pertaining to acute and skilled-nursing facilities, home health and hospice. See the waiver document for waivers related to ambulatory surgery centers, clinics, end-stage renal disease facilities, and intermediate care facilities.

A single asterisk preceding a waiver below indicates that a similar state requirement is waived. 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.

Hospitals, Critical Access Hospitals (CAHs), Skilled-Nursing Facilities, and Others

- **Inspection, testing and maintenance***:* Waives many inspection, testing, and maintenance frequencies and activities for facilities and medical equipment. See waiver for details – some Life Safety Code and Health Care Facilities Code requirements are considered critical and therefore have not been waived.
- **Outside window/door:** waived to allow alternate space usage.
- **Alcohol-based hand rub dispensers**: Waiving prescriptive requirements about placement of dispensers.
- **Fire drills:** Due to the inadvisability of drills that move and mass staff together, CMS is waiving fire drill requirements to instead allow a documented orientation training program related to the current fire plan. The training must instruct new, existing, and temporary employees about their duties, life safety procedures, and fire protection devices in their assigned area.
- **Temporary construction:** Waives requirements that would otherwise not permit temporary walls and barriers between patients.

Hospitals and CAHs

- **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 has issued a memo and Frequently Asked Questions on EMTALA and COVID-19.

- **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 CAHs to use verbal orders for medication administration.

- **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. This waiver only applies if the state has 51 or more confirmed COVID-19 patients.

- ***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 requirements for organization and staffing of the medical records department; form and content of medical records; record retention period; and 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 information about additional telehealth waivers under "CMS Interim Final Rule with Comment Period" and "CMS Telehealth Waivers" below, and "Coronavirus Aid, Relief, and Economic Security (CARES) Act" above*.)
- **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****: <u>For surge facilities only</u> - 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.
- **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. See waiver for information about billing and documentation.
- **Swing Beds****: Waives many swing bed requirements so that acute care hospitals can be reimbursed for providing SNF-level care when a SNF placement is not available. Hospitals must call the CMS Medicare Administrative Contractor enrollment hotline to add swing bed services. CMS has released guidance on requesting approval for swing beds from the Medicare Administrative Contractor, and information on requirements of the waiver, billing and payment.
- **Extension for inpatient prospective payment system (IPPS) wage index occupational mix survey submission**: Deadline extended until September 3, 2020. Hospitals with difficulty meeting the extended deadline should contact their Medicare administrative contractor.
- **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.
- **CAH length of stay**: 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.
- **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.
- **Inpatient Rehabilitation Facility (IRF) 60 percent rule and 3-hour rule:** Allows IRFs to exclude certain patients from the calculation to determine whether the facility can receive payment as an IRF. Waives the requirement to provide 15 hours of therapy per week.

- **Long term care hospital (LTCH) site neutral payments**: Waives payment adjustment for LTCHs that do not have a discharge payment percentage of at least 50%; waives site neutral payment provisions for certain admissions. See waiver for details and billing/re-billing instructions.
- **Long-term acute care hospital (LTACH)**: Allows LTACHs to exclude certain patient stays for 25-day length of stay requirement.
- **Sole Community Hospitals:** Waives distance requirements, market share, and bed requirements for sole community hospitals.
- **Medicare-Dependent, Small Rural Hospitals**: Certain eligibility requirement are waived. See waiver for details.
- **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 Facilities (SNFs)

- **SNF and swing bed 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. See important information and billing instructions here.
- **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. This waiver has ended; facilities must submit the requisite staffing data for Calendar Quarter 2 (April – June) 2020 by August 14, 2020. See CMS announcement for details.
- **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 long term care nurse aides. In addition, the deadline for completing the annual 12-hour in-service training is postponed until the end of the first full quarter after the public health emergency ends.

- **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 (S*ee waiver for additional information and limitations*). CMS also issued guidance on these transfers.
- **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. Permits telehealth.
- **Quality Assurance and Performance Improvement (QAPI):** A long term care facility's QAPI program may be narrowed to focus on adverse events and infection control.
- **Long term care facility discharge planning**: Waives the requirement help patients choose a post-acute provider using data, such as standardized patient assessment data, quality measures and resource use.
- **Long term care facility medical records**. Allows long term care facilities to provide patients a copy of their record within ten days, rather than two days.
- **Paid feeding assistants**: Reduces the training requirement from 8 hours to one hour.

Home Health Agencies

- **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.
- **Requests for Anticipated Payment (RAPs):** CMS is allowing Medicare Administrative Contractors (MACs) to extend the auto-cancellation date of Requests for Anticipated Payment (RAPs) during emergencies.
- **Home health initial assessments:** Allows initial assessment and determination of homebound status to be performed remotely or by record review.
- **Home health occupational therapy assessments**: Allows occupational and physical therapists, as well as speech language pathologists, to perform initial and comprehensive assessments for home health patients (except nursing-only patients), regardless of whether occupational/physical/speech therapy is the service that establishes eligibility for the patient to receive home health care. All providers must act within their scope of practice.
- **Home health discharge planning**: Waives the requirement help patients choose a post-acute provider using quality and resource use data.
- **Home health medical records**. Allows home health agencies to provide patients a copy of their record within ten business days instead of four.

- **Home health aide training:** The deadline for completing the annual 12-hour in-service training for home health aides is postponed until the end of the first full quarter after the public health emergency ends.

Home Health Agencies and Hospices

- **Home health and hospice nurse visits**: Waives the requirement for nurses to conduct onsite visits every two weeks, including requirement to visit every two weeks to evaluate aides' care is consistent with care plan. For hospice patients, virtual visits are encouraged (although not required).
- **Home health and hospice nurse aid training and assessment:** Waives the requirement for a registered nurse or other professional to make an onsite annual visit to directly supervise a nurse aide. Postponed visits must be completed within 60 days of the end of the public health emergency.
- **Home health and hospice Quality Assurance and Performance Improvement (QAPI):** Home health and hospice QAPI programs should be narrowed to focus on infection control and adverse events.

Hospices

- **Hospice miscellaneous**: 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 aide in-service training and competency testing**: Waives the requirement that hospices provide 12 hours of in-service training during a 12-month period for each hospice aide. Allows competency testing to be performed on pseudo-patients, such as a trained person or a mannequin.
- **Hospice competency assessment and in-service training**: May be postponed until the end of the first full quarter after the public health emergency ends.

Other providers/suppliers

- **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 can 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; allows opted-out practitioners to terminate their opt-out status early and enroll in Medicare; and modifies the 60-day locum tenens limit.

CMS Area Wage Index Reclassification

Deadline to apply for area wage index reclassification extended from Sept. 1 until 15 days after CMS releases its inpatient prospective payment system final rule for FY 2021. The rule was released on Sept. 2; therefore, the deadline was Sept. 16, 2020.

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 postponing non-essential surgeries/procedures, stating that decisions will be made at the local level by the clinician, patient, hospital, and state and local health departments. CMS has also issued guidance on resuming non-emergency care (see also CDPH guidelines for resuming services and joint guidance from the American College of Surgeons, American Society of Anesthesiologists, Association of perioperative Registered Nurses, and American Hospital Association).

CMS Guidance on Visitors

CMS has issued two documents on visitor limitations: QSO-20-13-Hospitals-CAHs and QSO-20-20-All (these supersede CMS FAQ dated June 28, 2020). Sample hospital visitor policies are found here. (See also All Facilities Letter AFL 20-38.5 for CDPH visitor guidelines.)

CMS Interim Final Rule with Comment Period [85 Fed.Reg. 19230 (Apr. 6, 2020)]

- Allows telehealth in place of many services that ordinarily must be provided in-person or face-to-face (allows some audio-only phone services)
- Relaxes some telehealth “established patient” requirements, frequency limitations
- Allows physician supervision by telehealth, including teaching physician supervision (with exceptions)
- Expands allowable billing for resident moonlighting
- Adjusts NCD and LCD policies regarding respirators, home anticoagulation therapy, and infusion pumps
- Relaxes the definition of “homebound” for purposes of Medicare’s home health benefit

- Removes inpatient rehabilitation facility (IRF) post-admission physician evaluation requirement; removes the 3-hour intensive therapy rule if the facility is impacted by COVID-19 – however, the requirement that the facility be impacted by COVID-19 was rescinded in the interim final rule published on May 8 – see below.
- Establishes a clinical lab specimen collection fee for COVID-19 testing
- Changes the Medicare Diabetes Prevention Program, Comprehensive Care for Joint Replacement model, the Alternative Payment Model under the Quality Payment Program, and the Medicare Shared Savings Program
- Relaxes data submission requirements for MA and Part D star ratings
- Expands list of ambulance destinations
- Expands permissible Inpatient hospital services furnished under arrangements outside the hospital

CMS has published FAQs about this rule.

CMS Interim Final Rule with Comment Period [85 Fed.Reg. 27550 (May 8, 2020)]
Note: Some provisions of this rule carry out provisions in the CARES Act, described above.

- Waives limits on types of providers that can furnish Medicare telehealth services (allows physical/occupational therapists, speech language pathologists, and others)
- Expands list of Medicare audio-only (telephone) services to include certain evaluation and management services, many behavioral health and patient education services; increases Medicare reimbursement for telephone services
- Allows any healthcare professional authorized under state law to bill Medicare for ordering and supervising COVID-19 lab tests (including serological and antibody tests) as well as flu and respiratory syncytial virus testing if needed to rule out COVID-19
- Authorizes Medicare reimbursement for antibody testing; specimen collection for COVID-19 testing; testing only (for self-collected specimens)
- Establishes a relocation exception policy for on-campus and excepted off-campus provider-based departments of hospitals that relocate in response to the public health emergency (hospital can be paid at full OPPS rate, rather than site-neutral rate)
- Describes the hospital outpatient services that can be furnished in temporary expansion locations (including the patient's home) – includes wound care, drug administration, behavioral health services, and more
- Allows payment for partial hospitalization services provided in temporary expansion locations, including the patient's home
- Allows various teaching hospital waivers related to residents sent to/hosted by other hospitals; supervision by telehealth; additional payments to teaching physicians for resident services; hold harmless for increased bed counts; teaching status adjustments; and other direct and indirect graduate medical education requirement waivers
- Allows physical or occupational therapists to delegate outpatient maintenance therapy to assistants
- Allows pharmacists to provide services 'incident to" physician services

- Grants extensions/exceptions for data reporting under various hospital and home health value-based purchasing programs, including Merit-based Incentive System data (expired 7-1-20; however, hospitals can submit an extraordinary circumstance exception request to CMS within 90 calendar days of the extraordinary circumstance.)
- Makes adjustments to Medicare Shared Savings Program Accountable Care Organizations
- Adjusts NCD and LCD policies regarding continuous blood glucose monitors
- Clarifies that the waiver of the IRF "3-hour rule" applies to all IRFs
- Waives certain requirements for patients admitted to a freestanding IRF solely to relieve acute care hospital capacity in a surge area – includes patients that don't need rehabilitation care
- Allows IRFs and IPFs to increase beds without impacting reimbursement
- Revises Medicare reimbursement for certain durable medical equipment and enteral nutrients, supplies, and equipment
- Allows physician assistants, nurse practitioners, clinical nurse specialists and other practitioners to supervise diagnostic testing, certify home health, and order home health equipment, supplies and services
- Requires skilled-nursing facilities to report COVID-19 cases among residents and staff, to implement specified infection control policy. CMS has issued a detailed memo about these requirements.
- Allows long term acute care hospitals to accept any Medicare acute patient and be paid at a higher Medicare rate, as mandated by the CARES Act.
- Delays for one year the compliance date for IRFs, LTCHs, and HHAs to report data on two Transfer of Health (TOH) Information quality measures and certain Standardized Patient Assessment Data Elements (SPADEs)

Additional information is available here.

<u>CMS Telehealth Waivers</u>
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. Subsequently, CMS issued two interim final rules with comment period that also include various telehealth waivers (described above). The Drug Enforcement Administration has issued guidance for prescribing

based on telehealth. See additional telehealth changes under "Coronavirus Aid, Relief, and Economic Security (CARES) Act" above.

CMS Innovation Center Models

CMS has published flexibilities and adjustments for COVID-19 to various innovation models — such as Bundled Payments for Care Improvement Advanced, Comprehensive Care for Joint Replacement, and Medicare Accountable Care Organization model — including methodology changes, quality reporting changes, and model timeline changes.

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. See also "Food and Drug Administration" below.

Provider Reimbursement Review Board (PRRB)

PRRB and CMS Issued Alert 19, adjusting some processes and suspending some (not all) deadlines

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 extend 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 and Vaccines

The Department of Health and Human Services (HHS) 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. This authorization preempts state licensing laws. (The California Board of Pharmacy has issued a similar waiver – see CHA's list of state waivers. HHS has allowed pharmacists, pharmacy interns and technicians to administer COVID-19 vaccines; these guidance documents preempt state law.

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 extend 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 infections 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.*
- Guidance on how health care providers can contact former COVID-19 patients about blood and plasma donation

Office for Human Research Protections

- COVID-19 guidance related to research (*See also FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 under "Food and Drug Administration" below.*)

Internal Revenue Service

- Deadline extended for 990s (Forms 990, 990-EZ, 990-PF, 990-T and Schedule H) in Notice 2020-23.
- Deadline for a community health needs assessment/implementation strategy is postponed to December 31, 2020 in Notice 2020-56. The IRS also provided guidance on how hospitals should document their reliance on the postponement.

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). CMS has issued Explanatory Guidance on the scope and application of these Stark law blanket waivers.
- **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. OIG has also posted FAQs, which include an email address to get quick answers to questions related to COVID-19 arrangements that may implicate federal fraud and abuse laws.

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 regarding procompetitive collaboration and COVID-19
- Antitrust statement regarding potential labor collusion that could harm healthcare workers by suppressing wages, benefits, and other terms of employment

Drug Enforcement Administration (DEA)

- DEA has issued guidance for prescribing based on telehealth
- Oral prescriptions for schedule II controlled substances are permitted
- DEA-registered hospital/clinics can use satellite locations under their current registrations; distributors can ship controlled substances directly to these satellite hospitals/clinics, even though they are nonregistered locations
- DEA-registered dispensers can distribute controlled substances to other dispensers
- Out-of-state prescribers authorized to practice in California do not need a separate DEA registration in California if they have a DEA registration in another state

Federal Communications Commission

- Clarified that COVID-19 related informational calls fall under the emergency provision of the Telephone Consumer Protection Act – see July 28 public notice

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. FDA updated this guidance here. (The California Board of Pharmacy has issued similar waivers – see CHA's list of state waivers.)
- 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. FDA also issued a temporary policy for compounding certain drugs used to treat COVID-19 patients.
- Coronavirus-related guidance, including guidance related to portable cryogenic oxygen, manufacturing alcohol, preparing alcohol-based hand sanitizer, repackaging and compounding.

- Guidance allowing the use of certain non-invasive fetal and maternal monitoring devices in the home.
- Guidance to expand mobile and portable imaging options to diagnose and monitor treatment of lung disease patients with COVID-19.
- Guidance on remote review of pathology slides – digital pathology devices have not been cleared for home use; instead, they have been limited to clinical laboratories, hospitals, and other healthcare settings. FDA has issued guidance on its enforcement policy to expand the availability of devices for remote reviewing and reporting of scanned digital images of pathology slides, to reduce healthcare personnel exposure to COVID-19. CMS previously issued a notice of enforcement discretion to ensure pathologists may review pathology slides from remote locations, subject to certain criteria.
- Guidance on the Conduct of Clinical Trials of Medical Products during the COVID-19 Public Health Emergency

U.S Citizenship and Naturalization Services (USCIS)

Public Charge Rule

A nationwide injunction has been issued preventing the Department of Homeland Security from enforcing, during the COVID-19 pandemic, the "public charge" federal regulations that became effective last August. See the USCIS policy for details.

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.

Free Crisis Counseling

Available to all U.S. residents through the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration's Disaster Distress Helpline. Call 1-800-985-5990 or text TalkWithUs to 66746.

Supplier Vetting - Project N95: The National COVID-19 Medical Equipment Clearinghouse

The Joint Commission

- All regular, on-site surveys of hospitals and other health care organizations were suspended from March 16 until June 3. Limited surveys resumed in June; see The Joint Commission (TJC) announcement and further clarification. 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 dated April 1. Listen to CHA's June 30 webinar with TJC describing its survey process during the pandemic.

- Data submission for accreditation (ORYX) and certification (with standardized measures) was optional for Q4 of 2019 and Q1 and Q2 of 2020.

DNV GL Healthcare

See Healthcare Advisory Notice Nos. 2020-HC17, HC 18, HC 19, and HC-10 regarding current survey activity

National Practitioner Data Bank

- Waived one-time query and continuous query fees from March 1, 2020 through May 31, 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 https://www.calhospital.org/coronavirus. CHA has also created a 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 Matt Bryant at mbryant@calhospital.org.

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