California Department of Public Health
Weekly Facility COVID-19 Update Call
July 7, 2020
8:00 am – 9:00 am

I. **Welcome / Introduction:** **Heidi Steinecker**
None provided.

II. **Overview:** **Ngoc Ly Le**
None provided.

III. **Laboratory Update:** **Dr. Jill Hacker**

Testing for Skilled Nursing Facilities (SNFs) or Other Occupational Health Testing:

The California public health laboratory system is working hard to address the public health testing needs for COVID. However, as cases and the need for testing increases, many jurisdictions are struggling to keep up with the burgeoning demand. We have mentioned previously the list of CLIA-certified commercial laboratories that is maintained by the CA Testing Task Force (TTF). This is not an exhaustive list of all of the available laboratories that can provide COVID testing in California. The CDPH Laboratory Field Services (LFS) maintains a more comprehensive list that is continually updated and is shared monthly with the local public health laboratory directors. If you need overflow testing help, please reach out to your local public health laboratory or health jurisdiction. If testing is not available at your local PHL, they may be able to help you find outside testing resources. Several of the larger health jurisdictions have tried to capture additional details such as testing capacity, pricing, and expected turnaround times for laboratories that serve their jurisdiction.

You may find it beneficial to establish accounts with more than one laboratory to ensure you will have access to quick testing when you need it most.

The link to the TTF list is provided in the call notes and is available on the TTF webpage under "COVID-19 Lab Resources." Efforts are underway on the TTF to survey and include additional details that may help you identify viable resources. If you have suggestions on useful information that should be collected, please send them to the TTF at testing.taskforce@state.ca.gov .

Laboratory Testing Updates from the FDA:

False Positive Results with BD SARS-CoV-2 Reagents for the BD Max System
The FDA is alerting clinical laboratory staff and health care providers of an increased risk of a false positive result with BD SARS-CoV-2 Reagents for the BD Max System PCR test. In one study, the manufacturer found approximately 3% of results were false positive results. The FDA recommends that any positive result from this test be considered "presumptive positive" and that you consider confirming the result with an alternate authorized test. Please report any issues with using COVID-19

tests to the manufacturer or the FDA. Additional information can be found in the False Positive Results with BD SARS-CoV-2 Reagents for the BD Max System - Letter to Clinical Laboratory Staff and Health Care Providers.

FDA continues to work with Abbott on the ID NOW post-market studies. These studies are ongoing and negative test results on the platform should continue to be treated as presumptive.

Select Guidance Links:
APHL Considerations for the Use of Antigen Tests
https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARSCov2-Antigen-Testing-Considerations.pdf

Specimen collection: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

The California COVID-19 Testing Task Force: https://testing.covid19.ca.gov

CA TTF Laboratory list for SNF testing:
https://testing.covid19.ca.gov/wpcontent/uploads/sites/332/2020/07/COVID-19-Testing-Task-Force-Lab-List-updated-07_2_20.pdf

IV. Healthcare-Associated Infections — Dr. Erin Epson

CDC recently updated their interim infection control guidance by incorporating some of the guidance included in their FAQ. This includes considerations around universal use of personal protective equipment (PPE) for healthcare personnel (HCP) working in facilities located in areas with moderate to substantial community transmission. The rationale is that these HCP are more likely to encounter asymptomatic or pre-symptomatic patients with SARS-CoV-2 infection. So even for patients presenting with no signs or symptoms concerning for COVID-19 infection in these settings, CDC is recommending HCP wear eye protection in addition to their source-control facemask to ensure the eyes, nose, and mouth are all protected from splashes and sprays of infectious material from others; and that HCP wear an N95 or equivalent or higher-level respirator, instead of a facemask, for aerosol generating procedures or surgical procedures that might pose higher risk for transmission if the patient has COVID-19 (e.g., that generate potentially infectious aerosols or involving anatomic regions where viral loads might be higher, such as the nose and throat, oropharynx, respiratory tract).

We recognize the addition of eye protection for all patient encounters likely represents a substantial operational challenge, and have reached out to CDC for clarifications on whether this reasonably extends to all healthcare settings (including skilled nursing facilities, outpatient clinics) and settings where patients may remain source controlled throughout the encounter, or where admission or pre-operative/procedural testing has been performed. We will provide updates as we get clarifications; in the meantime, we would be interested in feedback from facilities that are implementing this practice.

V. Remdesivir Update — Dr. Philip Peters

Remdesivir Distribution Update for all Healthcare Facility Call

California received its sixth and final shipment of donated Remdesivir in the amount 464 cases (18,560 doses) on July 3rd and this shipment is being distributed based on June 29th data for hospitalized patients with confirmed COVID-19. The excel spreadsheet that details Remdesivir the distribution to each county for this last shipment of donated Remdesivir should be posted to the web today on the CDPH website on the guidance page (https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Guidance.aspx) under Remdesivir.

Please note that given the recent increase in hospitalizations, the demand for Remdesivir is likely to outstrip supply. It is critical that hospitals have a transparent and fair method for allocation if multiple patients have similar indications for treatment. CDPH has posted guidance for hospitals regarding the allocation of scarce medications for COVID-19 that is posted to the web and a link is provided in the notes: https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/GuidanceForHospitalsRegardingAllocationOfScarceMedicationsForCOVID19.aspx

Now that Remdesivir is moving from a donated to a commercial product, there will be a change in the distribution process starting next week. As Remdesivir is still authorized under an EUA, the federal government will continue to direct its distribution from July to September. California will still be allotted a percentage of the national supply next week based on the number of patients hospitalized with COVID-19 in our state. CDPH will then use hospital data on volume of hospitalized COVID-19 patients to determine how much Remdesivir each hospital may purchase based on the state allocation. This process will be discussed with the MHOACs and the California Hospital Association.

The information on allocation by hospital will be communicated to the distributor AmerisourceBergen. Hospitals will be contacted by AmerisourceBergen to coordinate shipments. AmerisourceBergen will generate invoices to hospitals upon shipping. The drug will be billed per the standard relationship between AmerisourceBergen and the receiving hospital. Hospitals that do not have an account with AmerisourceBergen should email sales@asdhealthcare.com to complete this process. A number of private insurers have committed to waive cost-sharing payments for COVID-19 treatment and the CARES Act Provider Relief Fund can reimburse hospitals for COVID-related treatment costs for uninsured people.

VI. Question and Answer

Q: As the situation is changing, we should change our policy? I will follow CDPH recommendation, but if there is something that we can adopt, can we proceed? Are Respiratory Care Program recommendation or requirements?
A: Within your own policy, you can change but adhere to CDPH and CDC. Respiratory Care Program refer to CalOSHA for requirement specifics.

Q: In the hospital admissions and negative, do we still need eye protection for healthcare workers? In terms of testing asymptomatic workers who are furloughed, why do we need to test them?
A: A negative test upon admission, doesn't rule out possibly of exposure during incubation period. It doesn't exclude them to become positive and infectious later. I do not see a need to test worker at home if they are not returning to work. But you might consider if you are going to allow them back to work and be able to quickly exclude them.

Q: Related to June 19th CDC guidance, what is CDPH's expectation for this screening practice? Trying to operationalize what the screening practice requires. Can they physician self-screen? Can them clocking in attest to no symptoms, etc.
A: The CDC guidance is to screen everyone which includes documenting absence of symptoms. Documentation is best practice especially for healthcare personnel.

Q: So, you expect someone standing there to screen?
A: Whichever way you have it set up, inside or outside, at the point of entrance, elevator, stair well, as it all depends on the best way to screen due to the map of your facility.

Q: How long is documentation retained?
A: It is not necessary a documentation of marking patient, but policy and procedure for clinic. It is best practice to maintain documentation and records to evaluation potential exposure.

Q: How are COVID-19 results being maintained to employees while complying with HIPPA, and other confidentially measure.
A: Don't have any information about the HIPPA consideration, but that is something we can clarify to get the regulatory info. Was told that employer cannot ask for results but can get it voluntarily. As an occupational health and safety, we have been getting the results at the SNF.

Q: Last week, a CalOSHA representative was going to provide clarification on procedural mask with N95. What to know if it's REQUIRED as it's an urgent matter. Following up on this.
A: Valve respirators do not provide adequate or ideal source control. They are protective but the concern is that they do not provide source control. In general, a non-valve respirator is always preferred. We will do a follow up on the exact requirements.

Q: For entry screening, for employees it becomes more challenging. What does "screening everyone" mean? It is unclear if employees can do self-screening prior to entry because the last call made it sound like someone had to be at entry. There needs to be clarification about employee screening. Specifics about best practices for employees.
A: Again, just as they enter, would be best practice before you get into facility because you limit exposure. An employee entrance that is separate for the main entrance. An electronic process that doesn't require a physical person but allow documentation would be preferable.

COVID-19 Testing Task Force Lab List

The Testing Task Force is working to ensure that Californians who need COVID-19 testing have access to tests. As part of this effort, the Testing Task Force is maintaining and publishing a list of labs that have met all criteria for readiness and can receive samples for RT-PCR COVID testing.

The objective of this list is to provide information on available capacity across the state. Lab capabilities are listed as a reference to help identify labs providing services in need.

4 criteria are used to **screen for readiness**:

- Lab has obtained a California clinical laboratory license and a CLIA certificate for high or moderate complexity testing (depending on test categorization)
- Lab is running FDA EUA RT-PCR, other molecular, or antigen-based tests approved for clinical diagnostic use
- Lab is registered with LFS for COVID-19 testing (https://arcg.is/1qOWjb)
- Lab is submitting data to CalREDIE (either via ELR or .csv)

Please contact your local health department for public health laboratory testing for any of the following use cases:

- Hospitalized patients with symptoms consistent with COVID-19
- Persons identified for testing by public health contact investigations and disease control activities in high risk settings
- Screening of asymptomatic residents or employees of congregate living facilities (e.g., after positive cases have been identified in a facility)
- Other individuals with symptoms consistent with COVID-19

Contact information for each local health department can be found on the CDPH website (https://www.cdph.ca.gov/Programs/CCLHO/Pages/LHD-Communicable-Disease-Contact-List.aspx).

A list of labs for **other testing needs** (e.g., routine healthcare facility testing, occupational health testing, etc.) are provided below. Please note, your local hospital or health system may also be able to process COVID tests.

Labs can provide a variety of test-related services. Capabilities associated with each lab are defined as follow:

- **Full service**: Lab can provide onsite/offsite sample collection (including supplies like PPE and sample collection kits), facilitates logistics to collect and process specimens, and conduct diagnostic testing
- **Enhanced service**: Lab can provide sample collection kits, manage inbound logistics (e.g. preprinted shipping labels), and conduct diagnostic testing
- **Testing only service**: Lab can conduct diagnostic testing. Submitter must supply their own collection kits

This list is being refreshed on an ongoing basis. If your lab would like to be represented on this list or if you would like to update your lab's information, please complete this form (https://arcg.is/1qOWjb).

Please reach out to CA Testing Task Force (testing.taskforce@state.ca.gov) if you have any questions.

Additional COVID-19 Testing Laboratories

For COVID testing not covered by your local health department (e.g., routine healthcare facility testing, occupational health testing, etc.), below are additional labs available.

Updated as of 7/2

Lab Name	Contact	Location	Type of specimen collected*	COVID testing service capabilities		
				Full service: Lab can provide onsite/offsite sample collection (including supplies like PPE and sample collection kits), facilitates logistics to collect and process specimens, and conduct diagnostic testing	**Enhanced service:** Lab can provide sample collection kits, manage inbound logistics (e.g. preprinted shipping labels), and conduct diagnostic testing	**Testing only service:** Lab can conduct diagnostic testing. Submitter must supply their own collection kits
Neoanalytics Laboratory	rona@neoanalyticslab.com	Alhambra, CA	N/A	YES		
Bio Genetisys	(714) 257-9348; fax (714) 257-9348 covid19@bgilaboratory.com https://biogenetisysinc.com/	Brea, CA	NP swab Nasal swab		YES	YES
Physicians Immunodiagnostic laboratory	(800) 363-6562 https://www.pil-lab.com/index.php info@pil-lab.com	Burbank, CA	N/A		YES	YES
Color Genomics	(844) 352-6567 covid-response@color.com https://www.color.com	Burlingame, CA	NP swab Nasal swab		YES	YES
Navigate Biopharma Services Inc	jelveh.lameh@navigatebp.com	Carlsbad, CA	N/A			YES
Pathology Sciences Medical Group	(530) 891-6244 https://www.pathologysciences.com/	Chico, CA	NP swab OP Swab		YES	YES

Lab Name	Contact	Location	Type of specimen collected*	COVID testing service capabilities		
				Full service: Lab can provide onsite/offsite sample collection (including supplies like PPE and sample collection kits), facilitates logistics to collect and process specimens, and conduct diagnostic testing	**Enhanced service:** Lab can provide sample collection kits, manage inbound logistics (e.g. preprinted shipping labels), and conduct diagnostic testing	**Testing only service:** Lab can conduct diagnostic testing. Submitter must supply their own collection kits
US Lab Inc	626-385-6560 erik@taskforcelab.com; http://www.taskforcelab.com	Costa Mesa, CA	NP SWAB; OP SWAB; NASAL SWAB; MT SWAB	YES	YES	YES
Innovative Bioanalysis	(949) 338-8325 http://www.innovativebioanalysis.com/	Cypress, CA	N/A	YES	YES	YES
North East Medical Service Laboratory	yulong.ji@nems.org	Daly City, CA	N/A			YES
Sun Clinical Lab	Frances Sun (626) 234-2355 https://sunclinicallab.azurewebsites.net	El Monte, CA	Nasal swab Oral swab		YES	YES
StemExpress	(530) 303-3828 https://www.stemexpress.com/covid-19-testing/	Folsom, CA	NP swab OP swab	YES	YES	YES
Exceltox Laboratories	Jonathan Pittman (216) 373-1360 jonathan@exceltox.com	Irvine, CA	NP swab OP swab	YES	YES	YES
Global Discovery Biosciences	info@gdbiosciences.com	Irvine, CA	Serum Antibody IGG	YES		
Cedars-Sinai Hospital	(800) 233-2771 https://www.cedars-sinai.org/covid-19-your-health.html	Los Angeles, CA	N/A			YES

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Keck Medicine of USC Clinical Laboratories	(800) 872-2273 https://www.keckmedicine.org/coronavirus/	Los Angeles, CA	N/A			YES
MiraDx	(424) 387-8100 info@miradx.com https://miradx.com/covid-19-testing/	Los Angeles, CA	OP swab	YES	YES	YES
UCLA Health	310-267-8000 https://www.uclahealth.org/coronavirus	Los Angeles, CA	NP swab OP Swab Sputum			YES
UltimateDx	(800) 799-7248 https://ultimatedx.com/	Los Angeles, CA	NP swab OP swab	YES	YES	YES
Avellino Lab	(650) 396-3741 https://www.avellinocoronatest.com/ tom@avellino.com	Menlo Park, CA	NP swab OP swab	YES	YES	YES
IGeneX	(800) 832-3200 customerservice@igenex.com https://igenex.com/webinars/covid-19-tests/	Milpitas, CA	NP swab OP Swab Nasal swab MT swab Saliva Sputum	YES	YES	YES
Yosemite Pathology Medical Group	(209) 577-1200 https://www.ypmg.com/	Modesto, CA	N/A		YES	YES

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Let's Get Checked – Priva Path Diagnostics	(626) 479-8460 info@lgclabs.com	Monrovia, CA	NP swab Nasal swab		YES	YES
Sunrise Diagnostic Laboratories, Inc	Maya Chakhlayan; 818-696-8575; sunriselab8@gmail.com	Montrose, CA	NP SWAB	YES		
El Camino Hospital	www.elcaminohealth.org/covid19testing	Mountain View, CA	N/A			YES
Stanford Hospital and Clinics	https://stanfordhealthcare.org/health-care-professionals/covid-19-test/lab-intake-form-covid-19.html	Palo Alto, CA	NP swab			YES
Transplant Genomics	(508) 337-6200 info@trugraf.com http://transplantgenomics.com	Pleasanton, CA	NP swab OP Swab Nasal swab MT swab		YES	YES
Alcala Testing & Analysis Services	peteramdin@alcalalabs.com; davidhogan@alcalalabs.com; (619) 450-5870; http://www.alcalalabs.com/	San Diego, CA	NP swab Nasal swab	YES	YES	YES

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Biocept	(888) 332-7729 customerservice@biocept.com https://biocept.com/covid-19/	San Diego, CA	NP swab Nasal swab BAL		YES	YES
Laboratory for Personalized Molecular	Phone: +1 858.224.6650, Fax: +1 858.224.6655; Email: support@labpmm.com; Web: www.invivoscribe.com	San Diego, CA	NP Swab; OP Swab	YES	YES	
US Specialty Labs	(833) 705-0136 info@usspecialtylabs.com ;https://usspecialtylabs.com/	San Diego, CA	N/A	YES	YES	YES
Curative KorvaLabs	(650) 713-8928	San Dimas, CA	NP swab OP swab Nasal swab Saliva Sputum MT swab Oral Fluid		YES	YES
UCSF Clinical Laboratories	COVID19Outreach@ucsf.edu ;https://clinlab.ucsf.edu/covid-19	San Francisco, CA	NP swab OP Swab Nasal swab MT swab			YES

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Zuckerberg San Francisco General Hospital Clinical Laboratory	mary.eugenio-allen@ucsf.edu	San Francisco, CA	N/A	YES		
Pacific Diagnostic Lab	(805) 879-8100; https://www.pdllabs.com	Santa Barbara, CA	NP swab		YES	YES
Westpac Labs	(562) 906-5227 https://www.westpaclab.com/covid-19/	Santa Clara, CA	NP swab OP swab		YES	YES
Fulgent Genetics	(626) 350-0537 covid19@fulgentgenetics.com ;https://www.fulgentgenetics.com/covid19	Temple City, CA	NP swab OP swab Nasal swab		YES	YES
PrimeX Clinical Lab	(800) 961-7870 https://primexlab.com/test-announcement-for-the-2019-novel-coronavirus/	Van Nuys, CA	NP swab OP Swab Nasal swab MT swab		YES	YES
Prime Lab Inc	818-485-1004; primelab@yahoo.com	Westlake Village, CA	N/A	YES	YES	

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ARUP Laboratories	(800) 522-2787 https://www.aruplab.com/infectious-disease/coronavirus	Salt Lake City, UT	NP swab OP swab Nasal swab BAL		YES	YES
BioReference Laboratories	(833) 684-0508 https://www.bioreference.com/coronavirus/	Elmwood Park, NJ	NP swab OP Swab Nasal swab MT swab	YES	YES	YES
Quest Diagnostics	(866) 697-8378 https://www.questdiagnostics.com/home/Covid-19/	Secaucus, NJ	NP swab OP swab Nasal swab Sputum MT swab		YES	YES
Boston Heart Diagnostics	Kathy McGuire, KMcGuire@bostonheartdx.com	Framingham, MA	NP SWAB		YES	
CQuentia NGS, LLC	682-200-3028; alan@cquentia.com; www.cquentia.com	Memphis, TN	NP SWAB NASAL SWAB SALIVA MT SWAB		YES	
Poplar Healthcare	(901) 526-1912 covid19@poplarhealthcare.com ;https://www.micropathid.info/micropathid-tests/covid-19-test/	Memphis, TN	NP swab OP Swab Nasal/oral swab BAL		YES	YES
Molecular Pathology Laboratory Network, Inc.	www.mplnet.com (865) 380-9746	Maryville, TN	NP SWAB; OP SWAB		YES	

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LabCorp	https://www.labcorp.com/coronavirus-disease-covid-19	Burlington, NC	NP swab OP swab Nasal swab MT swab BAL		YES	YES
Viracor Eurofins Clinical Diagnostics	800-305-5198 Info@Viracor-Eurofins.com hectorcarrasco@viracor-eurofins.com ;www.Viracor-Eurofins.com	Lee's Summit, MO	NP swab OP Swab Nasal swab MT swab BAL	YES	YES	YES

** based on a combination of lab response to TTF and specimen types listed on lab websites.*
NP swab = Nasopharyngeal swab
OP swab = Oropharyngeal Swab
MT swab = Mid-turbinate swab
BAL = Bronchoalveolar Lavage

What You Need to Know: Remdesivir for the Commercial Marketplace

On Sunday, June 28, 2020, the U.S. Department of Health and Human Services (HHS) signed a Memorandum of Agreement with Gilead Sciences, Inc. (the manufacturer of remdesivir) and AmerisourceBergen (the distributor of remdesivir) to secure approximately 500,000 treatment courses of remdesivir for use in American hospitals. This represents 100 percent of Gilead's projected production for July (94,200 treatment courses), 90 percent of production for August (174,900 treatment courses), and 90 percent of production in September (232,800 treatment courses), in addition to an allocation for clinical trials. At the end of this three-month period, the federal government will assess the COVID-19 environment to determine the best path forward relative to future distributions.

In alignment with the current terms of the Emergency Use Authorization (EUA) for remdesivir, HHS will oversee the drug's allocation and distribution process.

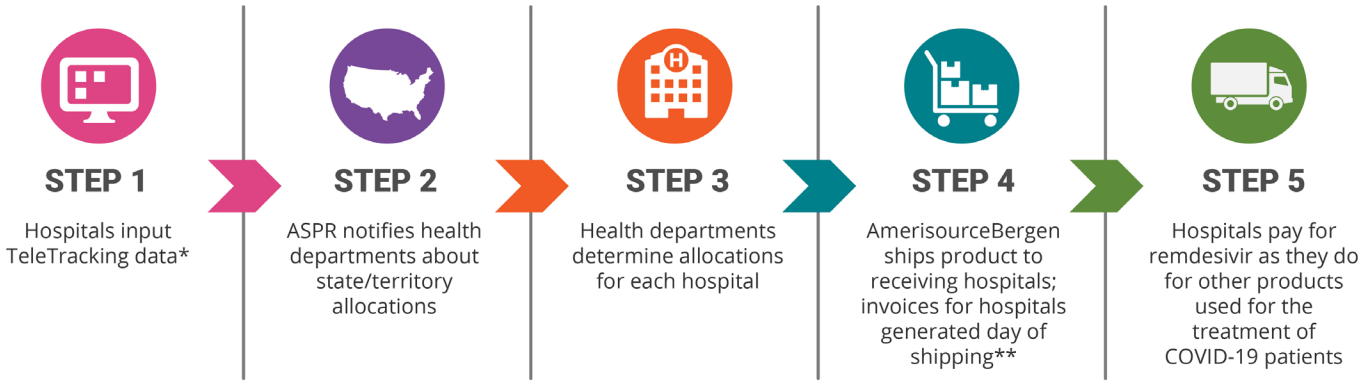
Allocation and Distribution Strategy

To achieve the federal government's priority of distributing the limited doses of available remdesivir in a fair and equitable manner, the HHS Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR) will oversee the allocation of the commercially available drug using the same process employed for the donated lots of remdesivir. States and territories should continue providing any remaining donated remdesivir to hospitals in their jurisdictions at no cost.

Step 1: Beginning Monday, July 6 and every two weeks thereafter through September, hospitals will input TeleTracking data by 8:00 pm ET regarding their COVID-19 confirmed and suspected positive patients.

Step 2: HHS/ASPR will notify state/territorial health departments about their allocated amounts of remdesivir based on their respective COVID-19 hospital

Allocation & Distribution of Remdesivir: A Five-step Process



**Data input likely to occur every other Monday, beginning Monday, July 6*
***Shipments likely to occur every other Monday, beginning the week of Monday, July 13*

burden. Just as the donated remdesivir was calculated, a state/territory's percentage of the country's COVID-19 hospitalized patients will equal that state's allotted percentage of commercially available remdesivir for a given distribution week.

Step 3: Health departments will determine how much remdesivir hospitals within their respective jurisdictions may purchase based on the state/territory's allocation. Health departments will communicate information regarding receiving hospitals and drug amounts to AmerisourceBergen. Neither AmerisourceBergen nor Gilead are involved in allocation decisions for the remdesivir.

Step 4: Hospitals identified by their state/territorial health department to receive an allocation of remdesivir will be contacted by AmerisourceBergen to coordinate shipments. AmerisourceBergen will generate invoices to hospitals upon shipping. Receiving hospitals will be responsible for payment of the drug, as they are for other products used for the treatment of their COVID-19 patients.

Step 5: Beginning the week of Monday, July 13 and every two weeks thereafter through September, AmerisourceBergen will ship remdesivir directly to receiving hospitals.

Payment and Reimbursement

Hospitals will pay no more than the wholesale acquisition cost (WAC) set by Gilead, which amounts to approximately $3,200 per treatment course. A treatment course of remdesivir is, on average, 6.25 vials.

The drug will be billed per the standard relationship between AmerisourceBergen and the receiving hospital. Hospitals that do not have an account with AmerisourceBergen should email sales@asdhealthcare.com to complete this process.

Generally, patients do not pay directly for hospital-administered drugs like remdesivir; rather, for Medicare and most private insurers, the drug's cost is incorporated into payments made by the insurer.

HHS is using a portion of the $100 billion CARES Act Provider Relief Fund to reimburse healthcare providers, at Medicare rates, for COVID-related treatment of the uninsured. Hospitals can apply for reimbursement of hospitalization costs through this program. Private insurers (including Humana, Cigna, UnitedHealth Group, and the Blue Cross Blue Shield system) have committed to waive cost-sharing payments for treatment related to COVID-19 for plan members.

About Remdesivir

Under the EUA, the investigational drug remdesivir is approved for distribution and use by licensed health care providers to treat adults and children hospitalized with severe COVID-19. Severe COVID-19 is defined as patients with an oxygen saturation (SpO2) ≤ 94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO), a heart-lung bypass machine.

Remdesivir as a treatment for COVID-19 continues to be evaluated in clinical trials and is available through expanded access and compassionate use mechanisms for certain patient populations. Preliminary results of a clinical trial supported by the National Institutes of Health suggest that the drug may be associated with faster recovery compared with patients in the study who did not receive the drug.

For more information about remdesivir and the EUA, visit www.phe.gov. This site will be updated regularly to reflect the current state-by-state dashboard of allocations.

March 2020

COVID-19 & HIPAA Bulletin
Limited Waiver of HIPAA Sanctions and Penalties During a Nationwide Public Health Emergency

The Novel Coronavirus Disease (COVID-19) outbreak imposes additional challenges on health care providers. Often questions arise about the ability of entities covered by the HIPAA regulations to share information, including with friends and family, public health officials, and emergency personnel. As summarized in more detail below, the HIPAA Privacy Rule allows patient information to be shared to assist in nationwide public health emergencies, and to assist patients in receiving the care they need. In addition, while the HIPAA Privacy Rule is not suspended during a public health or other emergency, the Secretary of HHS may waive certain provisions of the Privacy Rule under the Project Bioshield Act of 2004 (PL 108-276) and section 1135(b)(7) of the Social Security Act.

In response to President Donald J. Trump's declaration of a nationwide emergency concerning COVID-19, and Secretary of the U.S. Department of Health and Human Services (HHS) Alex M. Azar's earlier declaration of a public health emergency on January 31, 2020, Secretary Azar has exercised the authority to waive sanctions and penalties against a covered hospital that does not comply with the following provisions of the HIPAA Privacy Rule:

- the requirements to obtain a patient's agreement to speak with family members or friends involved in the patient's care. See 45 CFR 164.510(b).
- the requirement to honor a request to opt out of the facility directory. See 45 CFR 164.510(a).
- the requirement to distribute a notice of privacy practices. See 45 CFR 164.520.
- the patient's right to request privacy restrictions. See 45 CFR 164.522(a).
- the patient's right to request confidential communications. See 45 CFR 164.522(b).

The waiver became effective on March 15, 2020. When the Secretary issues such a waiver, it only applies: (1) in the emergency area identified in the public health emergency declaration; (2) to hospitals that have instituted a disaster protocol; and (3) for up to 72 hours from the time the hospital implements its disaster protocol. When the Presidential or Secretarial declaration terminates, a hospital must then comply with all the requirements of the Privacy Rule for any patient still under its care, even if 72 hours have not elapsed since implementation of its disaster protocol.

More on HIPAA Privacy and Disclosures in Emergency Situations

Even without a waiver, the HIPAA Privacy Rule always allows patient information to be shared for the following purposes and under the following conditions.

Treatment Under the Privacy Rule, covered entities may disclose, without a patient's authorization, protected health information about the patient as necessary to treat the patient or to treat a different patient. Treatment includes the coordination or management of health care and related services by one or more health care providers and others, consultation between providers, and the referral of patients for treatment. See 45 CFR §§ 164.502(a)(1)(ii), 164.506(c), and the definition of "treatment" at 164.501.

Public Health Activities The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to protected health information that is necessary to carry out their public health mission. Therefore, the Privacy Rule permits covered entities to disclose needed protected health information without individual authorization:

- ***To a public health authority***, such as the CDC or a state or local health department, that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability. This would include, for example, the reporting of disease or injury; reporting vital events, such as births or deaths; and conducting public health surveillance, investigations, or interventions. A "public health authority" is an agency or authority of the United States government, a State, a territory, a political subdivision of a State or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency. See 45 CFR §§ 164.501 and 164.512(b)(1)(i). For example, a covered entity may disclose to the CDC protected health information on an ongoing basis as needed to report all prior and prospective cases of patients exposed to or suspected or confirmed to have COVID-19.

- ***At the direction of a public health authority, to a foreign government agency*** that is acting in collaboration with the public health authority. See 45 CFR 164.512(b)(1)(i).

- ***To persons at risk*** of contracting or spreading a disease or condition if other law, such as state law, authorizes the covered entity to notify such persons as necessary to prevent or control the spread of the disease or otherwise to carry out public health interventions or investigations. See 45 CFR 164.512(b)(1)(iv).

Disclosures to Family, Friends, and Others Involved in an Individual's Care and for Notification A covered entity may share protected health information with a patient's family members, relatives, friends, or other persons identified by the patient as involved in the patient's care. A covered entity also may share information about a patient as necessary to identify, locate, and notify family members, guardians, or anyone else responsible for the patient's care, of the patient's location, general condition, or death. This may include, where necessary to notify family members and others, the police, the press, or the public at large. See 45 CFR 164.510(b).

- The covered entity should get verbal permission from individuals or otherwise be able to reasonably infer that the patient does not object, when possible; if the individual is

incapacitated or not available, covered entities may share information for these purposes if, in their professional judgment, doing so is in the patient's best interest.

- For patients who are unconscious or incapacitated: A health care provider may share relevant information about the patient with family, friends, or others involved in the patient's care or payment for care, if the health care provider determines, based on professional judgment, that doing so is in the best interests of the patient. For example, a provider may determine that it is in the best interests of an elderly patient to share relevant information with the patient's adult child, but generally could not share unrelated information about the patient's medical history without permission.
- In addition, a covered entity may share protected health information with disaster relief organizations that, like the American Red Cross, are authorized by law or by their charters to assist in disaster relief efforts, for the purpose of coordinating the notification of family members or other persons involved in the patient's care, of the patient's location, general condition, or death. It is unnecessary to obtain a patient's permission to share the information in this situation if doing so would interfere with the organization's ability to respond to the emergency.

Disclosures to Prevent or Lessen a Serious and Imminent Threat Health care providers may share patient information with anyone as necessary to prevent or lessen a serious and imminent threat to the health and safety of a person or the public – consistent with applicable law (such as state statutes, regulations, or case law) and the provider's standards of ethical conduct. See 45 CFR 164.512(j). Thus, providers may disclose a patient's health information to anyone who is in a position to prevent or lesson the serious and imminent threat, including family, friends, caregivers, and law enforcement without a patient's permission. HIPAA expressly defers to the professional judgment of health professionals in making determinations about the nature and severity of the threat to health and safety. See 45 CFR 164.512(j).

Disclosures to the Media or Others Not Involved in the Care of the Patient/Notification In general, except in the limited circumstances described elsewhere in this Bulletin, affirmative reporting to the media or the public at large about an identifiable patient, or the disclosure to the public or media of specific information about treatment of an identifiable patient, such as specific tests, test results or details of a patient's illness, may not be done without the patient's written authorization (or the written authorization of a personal representative who is a person legally authorized to make health care decisions for the patient). See 45 CFR 164.508 for the requirements for a HIPAA authorization. Where a patient has not objected to or restricted the release of protected health information, a covered hospital or other health care facility may, upon a request to disclose information about a particular patient asked for by name, release limited facility directory information to acknowledge an individual is a patient at the facility, and may provide basic information about the patient's condition in general terms (e.g., critical or stable, deceased, or treated and released). Covered entities may also disclose information when the patient is incapacitated, if the disclosure is believed to be in the best interest of the patient and is consistent with any prior expressed preferences of the patient. See 45 CFR 164.510(a).

Minimum Necessary For most disclosures, a covered entity must make reasonable efforts to limit the information disclosed to that which is the "minimum necessary" to accomplish the

purpose. (Minimum necessary requirements do not apply to disclosures to health care providers for treatment purposes.) Covered entities may rely on representations from a public health authority or other public official that the requested information is the minimum necessary for the purpose, when that reliance is reasonable under the circumstances. For example, a covered entity may rely on representations from the CDC that the protected health information requested by the CDC about all patients exposed to or suspected or confirmed to have COVID-19 is the minimum necessary for the public health purpose. In addition, internally, covered entities should continue to apply their role-based access policies to limit access to protected health information to only those workforce members who need it to carry out their duties. See 45 CFR §§ 164.502(b), 164.514(d).

Safeguarding Patient Information

In an emergency situation, covered entities must continue to implement reasonable safeguards to protect patient information against intentional or unintentional impermissible uses and disclosures. Further, covered entities (and their business associates) must apply the administrative, physical, and technical safeguards of the HIPAA Security Rule to electronic protected health information.

HIPAA Applies Only to Covered Entities and Business Associates

The HIPAA Privacy Rule applies to disclosures made by employees, volunteers, and other members of a covered entity's or business associate's workforce. Covered entities are health plans, health care clearinghouses, and those health care providers that conduct one or more covered health care transactions electronically, such as transmitting health care claims to a health plan. Business associates generally are persons or entities (other than members of the workforce of a covered entity) that perform functions or activities on behalf of, or provide certain services to, a covered entity that involve creating, receiving, maintaining, or transmitting protected health information. Business associates also include subcontractors that create, receive, maintain, or transmit protected health information on behalf of another business associate. The Privacy Rule does not apply to disclosures made by entities or other persons who are not covered entities or business associates (although such persons or entities are free to follow the standards on a voluntary basis if desired). There may be other state or federal rules that apply.

Business Associates

A business associate of a covered entity (including a business associate that is a subcontractor) may make disclosures permitted by the Privacy Rule, such as to a public health authority, on behalf of a covered entity or another business associate to the extent authorized by its business associate agreement.

Other Resources

The COVID-19 Public Health Emergency declaration is available at:
https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx

For more information on COVID-19, please visit: https://www.coronavirus.gov

For more information on HIPAA and Public Health, please visit: https://www.hhs.gov/hipaa/for-professionals/special-topics/public-health/index.html

For more information on HIPAA and Emergency Preparedness, Planning, and Response, please https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/index.html

General information on understanding the HIPAA Privacy Rule may be found at: https://www.hhs.gov/hipaa/for-professionals/privacy/index.html

For information regarding how Federal civil rights laws apply in an emergency, please visit: https://www.hhs.gov/civil-rights/for-individuals/special-topics/emergency-preparedness/index.html