OFFICE OF THE DIRECTOR
Kate Brown, Governor

Oregon Health Authority

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Dear Hospital Representative,

As you likely are aware, the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of remdesivir for the treatment of COVID-19.[1] The FDA has provided the state with an allotment of remdesivir and the state is distributing it to hospitals such as yours.

In order to receive an allocation of remdesivir, you must agree to the following:

- The hospital will review the EUA and comply with its terms.
- Remdesivir will only be used as authorized under its EUA.
    - All ordering clinicians will review a copy of the Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Remdesivir (GS-5734)
- The ordering clinician will review the Oregon Health Authority's document, Oregon's Federal Remdesivir Allocation: Patient Criteria and Hospital Distribution and comply with its terms.
- Doses requested are for patients that meet clinical criteria eligibility.
- Patients or their legally authorized health care representative will be given the opportunity to accept or refuse remdesivir treatment. The patient or legally authorized health care representative must be given all the information necessary to make an informed choice, including information about the potential risks and benefits of the treatment. If English is not the patient's primary language, a certified health care interpreter must be made available. Verbal consent must be documented in the patient's chart, reflecting that the associated potential risks and benefits were discussed with the patient or legally authorized health care representative.
- A patient must be provided with the following, translated into the patient's primary language:
    - FDA Fact Sheet for Patients and Parent/Caregivers – EUA of Remdesivir For Coronavirus Disease 2019 (COVID-19)
- Complete and submit information to the State of Oregon **for each patient** treated with remdesivir from the state's allocation. Hospitals should report this information to OHA *following each patient's completion of the remdesivir course* through the online OHA Confidential Oregon Morbidity Repor as instructed in the Oregon Health Authority's document, Oregon's Federal Remdesivir Allocation: Patient Criteria and Hospital Distribution (see instructions below).

[1] https://www.fda.gov/media/137564/download

- Adverse events related to the administration of remdesivir will be reported as specified in the Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Remdesivir (GS-5734).
- All necessary clinical care will be provided to a patient who is administered remdesivir.
- Notify and return to the Oregon Health Authority any medication not used within 48 hours of determining the hospital no longer has a need for the medication.

Required hospital reporting to OHA regarding patients who receive state-distributed remdesivir

As per the hospital agreement, hospitals that treat patients with remdesivir received from OHA must report basic information for each patient treated. Hospitals should report this information to OHA *following each patient's completion of the remdesivir course* through the online OHA Confidential Oregon Morbidity Report: https://www.oregon.gov/oha/PH/DISEASESCONDITIONS/COMMUNICABLEDISEASE/REPORTINGCOMMUNICABLEDISEASE/Pages/counties.aspx

This is the same system used to report COVID-19 hospitalizations and deaths and hospitals should be familiar with it.

The following basic steps should be followed to complete this remdesivir reporting:

1. Log-in to the OHA confidential Oregon Morbidity Report page
2. Fill out the patient's basic information (i.e., name, date of birth)
3. Click on the COVID-19 checkbox
4. Complete the remdesivir info page as displayed here:

The federal Public Readiness and Emergency Preparedness Act (PREP Act) immunity from liability (except for willful misconduct) applies to any claims of loss caused, arising out of, relating to, or resulting from the administration or use of covered countermeasures like remdesivir, for entities and individuals involved in the distribution, administration, and use of such countermeasures. The state assumes no liability related to the distribution or administration of remdesivir.

If you agree to the terms above, please sign and date this letter and return a signed copy to ORESF8.LogisticsChiefs@dhsoha.state.or.us. Once we receive the signed copy, the hospital will receive your requested allocation of remdesivir.

If you have clinical questions about remdesivir, please call 971.673.1111.

Signature

Printed Name and Title Date

You can get this document free of charge in other languages, large print, braille or a format you prefer. Contact Mavel Morales at 1-844-882-7889, 711 TTY or OHA.ADAModifications@dhsoha.state.or.us.