Plan for Remdesivir Distribution
Presented to the Kansas Department of Health and Environment
June 5, 2020

The Kansas Remdesivir Distribution Task Force (KS RDTF) was charged with developing an allocation plan to distribute remdesivir across the State of Kansas. This plan will apply to the shipment of remdesivir received from the Federal government by the Kansas Department of Health and Environment (KDHE) on 6/2/2020. Future shipments will be allocated according to this plan unless otherwise determined by the KS RDTF to allow for adaptation based on disease burden, disease understanding, and data available at the time of the shipment.

The KS RDTF was formed on Thursday, May 14, 2020 in response to a request by the Secretary of KDHE, Dr. Lee Norman (see Appendix A for list of members). The Task Force met on Friday, May 15, to develop an interim allocation plan to be executed immediately for state distribution of an impending remdesivir shipment (see Appendix B). The Task Force reconvened on Wednesday, May 20, 2020, to develop the allocation plan used for the 5/20/2020 shipment (see Appendix C). Further changes to the allocation plan were based on the TF meeting held on 6/2/2020.

Members of the KS RDTF include representatives from Wichita, Kansas City, Dodge City, and Liberal. In addition to an expert pharmacist in the area of Critical Care and Emergency Medicine, the KS RDTF consisted of physicians specializing in Infectious Disease, Hospital Medicine, and Pulmonary/Critical Care. A separate group of data experts worked to develop the data process and guidelines that would be used to apply the allocation formula created by the medical team.

Allocation of Remdesivir
The KS RDTF made the following recommendations to KDHE for remdesivir distribution:

- Allocation will be based on number of current inpatients diagnosed with COVID-19.
- The unit of allocation will be 0.5 cases. This is equivalent to 20 vials, enough to treat 3 patients for a 5-day course.
- To align with the minimum allocation of 0.5 cases, hospitals with ≥ 3 admitted patients are eligible for allocation. Hospitals with fewer than 3 inpatients can request remdesivir from KDHE using the process outlined below.
- When medication is shipped to hospitals, the following items should be addressed:
    - Remdesivir use should meet EUA specifications and guidance.
    - Remdesivir shipped to hospitals is available for immediate use; however, KDHE retains ownership of unused medication. If a hospital has unused doses, KDHE may ship the remaining vials to another location to address clinical needs. A letter to this effect will be included with the remdesivir shipments. This letter applies retrospectively to prior shipments of remdesivir sent to hospitals from KDHE.

After the creation of the allocation formula, the data team will apply the calculations to a dataset created using the following procedures:

- The most current data from all hospitals in the state of Kansas will be identified, looking across multiple data sources to ensure the best representation of data. Data from the National

Healthcare Safety Network (NHSN), EMResource (reported by hospitals to the State of Kansas), and TeleTracking will be evaluated. Data more than 7 days old will not be included.

Guidelines for Use

The KS RDTF will not institute specific requirements for patient qualification within a facility that has remdesivir available at the time of patient evaluation, but will provide the following guidelines for usage:

- Usage should be in concordance with the EUA.
- Remdesivir is intended to treat patients who have been diagnosed with COVID-19 and require inpatient care.
- Remdesivir is intended to treat patients who have an oxygen saturation (SaO2) ≤ 94% on room air or require supplemental oxygen.
- We suggest that remdesivir should be used for patients admitted for fewer than 5 days and who have had symptoms for fewer than 12 days.
- Patients should have liver enzymes less than 5 times the upper limit of normal.
- Pediatric and pregnant patients can currently apply for compassionate use access to remdesivir and may not need to access the supply from KDHE.

KDHE Reserve Remdesivir Supply

KDHE will hold back at least 20% of each total shipment. This will ensure remdesivir access for patients diagnosed with COVID-19 who are inpatients at facilities with fewer than 3 total inpatient cases. These facilities do not meet minimum census requirements to be eligible for receiving remdesivir from KDHE per the distribution plan. The KDHE reserve supply may also be used to re-stock hospitals whose existing remdesivir supplies have been exhausted.

Procedure for Requesting Remdesivir from KDHE

Hospitals or medical providers may send requests to KDHE for direct delivery of medication doses to treat appropriate patients if the facility does not have any remdesivir in stock.

Requests should be sent from the hospital to their County Emergency Manager (list is available here). The County Emergency Manager will then send the request to the State Emergency Operations Center (SEOC) for processing and review. Requests should include the following information about the patient:

- Number of days the patient has been admitted to the facility (must be 5 days or fewer)
- Number of days since symptom onset for the patient generating the request (must be 12 days or fewer)
- Affirmation that the patient has an SaO2 ≤ 94% on room air or requires supplemental oxygen
- Liver enzyme values (ALT, AST and alkaline phosphatase) are within 5 times the upper limit of normal

If the patient meets these criteria, and KDHE has supply to be able to meet the request, KDHE will send a shipment of 6 vials of remdesivir (to complete a 5-day course).

High-volume hospitals (hospitals with >10 COVID-19 inpatients) or hospitals responding to localized outbreaks that anticipate an increase in cases (such as outbreaks occurring in local high-risk settings like

long-term care facilities, food processing plants, or other defined settings) may also send requests for additional anticipatory remdesivir supply. Requests for anticipatory supply should be sent to the County Emergency Manager and include the following information:

- Number of remdesivir doses in stock (must be 20 vials or fewer)
- Reason for anticipated need

Criteria for KDHE to Recall Distributed Remdesivir from Hospitals

As stated above, KDHE retains ownership of unused medication stored at any hospital. If a clinical need arises, KDHE may re-direct unused medication from one facility to either the KDHE warehouse or directly to another health care facility. If a healthcare facility has demonstrable need for medication and KDHE is unable to supply the medication from the KDHE reserve supply, KDHE will re-direct unused medication from one facility to another using the following process:

- A ratio comparing the total number of doses in stock to the total number of doses administered in that preceding 7 days will be calculated for all hospitals with any remaining remdesivir supply.
- The hospital with the highest ratio will be asked to send a specified quantity of remdesivir to the location indicated by KDHE (KDHE warehouse or hospital with immediate need or remdesivir as determined by KDHE).

Data Collection

Hospitals will be asked to report the number of remdesivir vials on hand to KDHE weekly.

Hospitals will be asked to report the following information for each patient given remdesivir, using the process outlined by KDHE:

- Patient last name
- Patient first name
- Patient date of birth
- Date of positive SARS-CoV-2 test
- Date of first dose
- First dose (mg)
- Date of last dose
- Last dose (mg)
- Total number of doses
- Date of admission
- Date of discharge
- Discharge disposition
- ICU admission
- Date of ICU admission
- Date of ICU discharge
- RRT required
- Mechanical ventilation required
- Ventilation LOS
- Vasopressor duration (hours)
- Co-mordibity list
- Gender
- Race
- Ethnicity
- BMI

Guiding Principles

Allocation decisions should not consider or be based upon:

- Race, ethnicity, gender, gender identity, sexual orientation or preference, religion,
- citizenship or immigration status, or socioeconomic status;
- Ability to pay;
- Age as a criterion in and of itself (this does not limit consideration of a patient's age in
- clinical prognostication of likelihood to survive to hospital discharge);
- Disability status or comorbid condition(s) as a criterion in and of itself (this does not limit

- consideration of a patient's physical condition in clinical prognostication of likelihood to
- survive to hospital discharge);
- Predictions about baseline life expectancy beyond the current episode of care (i.e., life
- expectancy if the patient were not facing the current crisis), unless the patient is imminently
- and irreversibly dying or terminally ill with life expectancy under 6 months (e.g., eligible for
- admission to hospice);
- First-come, first-served (should not distinguish between patients when treatment has not
- yet been started on equivalent patients);
- Judgments that some people have greater "quality of life" than others;
- Judgments that some people have greater "social value" than others.

(from Minnesota Department of Health, *Ethical Framework for May 2020 Allocation of Remdesivir in the COVI-19 Pandemic*, https://www.health.state.mn.us/diseases/coronavirus/hcp/remdesivir.pdf)

Appendix A: Members of the Kansas Remdesivir Distribution Task Force

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Michael McNulty
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Catherine Satterwhite, PhD, MSPH, MPH
Regional Health Administrator, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

Appendix B: Interim Plan for Allocation of 5/15/2020 Shipment

The Kansas Remdesivir Distribution Task Force (KS RDTF) met on Friday, May 15, to develop an interim allocation plan to be executed for state distribution of remdesivir (received by KDHE from the federal government). Members of the KS RDTF present included representatives from Wichita and Kansas City. Future meetings will include additional representation from SW Kansas. The KS RDTF consisted of physicians specializing in Infectious Disease, Hospital Medicine, and Pulmonary/Critical Care in addition to a pharmacist. A separate group of data experts worked to support decisions made by the KS RDTF.

The KS RDTF made the following recommendations to KDHE as the interim allocation plan for remdesivir distribution:

- Allocation will be based on number of current COVID-19 inpatients.
- The unit of allocation will be 0.5 cases. This is equivalent to 20 vials, enough to treat 3 patients for a 5-day course.
- To align with the minimum allocation of 0.5 cases, hospitals with ≥3 admitted patients are eligible for allocation.
- When medication is shipped to hospitals, the following items should be addressed:
    - Remdesivir use should meet EUA specifications and guidance.
    - Remdesivir shipped to hospitals is available for immediate use; however, KDHE retains ownership of unused medication. If a hospital has unused doses, KDHE may ship the remaining vials to another location to address clinical needs.

The decisions about allocation formulas were communicated to the data team, who applied the strategy and submitted the results to KDHE. KDHE accepted the results, withholding one case of remdesivir to retain at KDHE.

The KS RDTF made recommendations about the allocation formula without reviewing any data on actual case burden by hospital. This data-blind approach was undertaken to emphasize neutrality to the degree possible. When executing the allocation formula, the data team used the most recent data available from all hospitals in the state of Kansas, looking across multiple data sources to ensure the best representation of data.

Appendix C: Plan for Allocation of 5/20/2020 Shipment

The Kansas Remdesivir Distribution Task Force (KS RDTF) revised the interim plan described in Appendix A to inform the shipment of remdesivir received from the Federal government by the Kansas Department of Health and Environment (KDHE) on 5/20/2020. Key components of the 5/20/2020 plan are described below.

Allocation of Remdesivir

The KS RDTF made the following recommendations to KDHE for remdesivir distribution:

- Allocation will be based on number of current inpatients diagnosed with COVID-19.
- The unit of allocation will be 0.5 cases. This is equivalent to 20 vials, enough to treat 3 patients for a 5-day course.
- To align with the minimum allocation of 0.5 cases, hospitals with ≥3 admitted patients are eligible for allocation. Hospitals with fewer <3 inpatients can request remdesivir from KDHE using the process outlined below.
- When medication is shipped to hospitals, the following items should be addressed:
    - Remdesivir use should meet EUA specifications and guidance.
    - Remdesivir shipped to hospitals is available for immediate use; however, KDHE retains ownership of unused medication. If a hospital has unused doses, KDHE may ship the remaining vials to another location to address clinical needs. A letter to this effect will be included with the remdesivir shipments. This letter applies retrospectively to prior shipments of remdesivir sent to hospitals from KDHE.

After the creation of the allocation formula, the data team will apply the calculations to a data set created using the following procedures:

- Current data (reported within ≤3 days) from all hospitals in the state of Kansas will be identified, looking across multiple data sources to ensure the best representation of data. If current data are not available in any of the data sources, the most recently reported data will be used. Data more than 7 days old will not be included.
- The primary data source will be data reported into the National Healthcare Safety Network (NHSN, COVID-19 Module, https://www.cdc.gov/nhsn/acute-care-hospital/covid19/index.html).
- If current NHSN data are not available, data from EMResource will be evaluated (secondary source). This is the state system used as part of the hospital preparedness program.
- The final data source considered will be TeleTracker, an alternate system for providing Federally-requested hospital capacity and patient impact data (tertiary source).

Guidelines for Use

The KS RDTF will not institute specific requirements for patient qualification within a facility that has remdesivir available at the time of patient evaluation, but will provide the following guidelines for usage:

- Usage should be in concordance with the EUA.
- Remdesivir is intended to treat patients who have been diagnosed with COVID-19 and require inpatient care.

- Remdesivir is intended to treat patients who have an oxygen saturation (SaO2) < 94% on room air.
- We suggest that remdesivir should be used for patients admitted for fewer than 5 days and who have had symptoms for fewer than 12 days.
- Patients should have liver enzymes less than 5 times the upper limit of normal.
- Pediatric and pregnant patients can currently apply for compassionate use access to remdesivir and may not need to access the supply from KDHE.

KDHE Reserve Remdesivir Supply

KDHE will hold back and store 6 cases from the 5/20/2020 shipment. This quantity represents slightly greater than 20% of the total shipment. This accounts for the approximately 20% of patients diagnosed with COVID-19 who are inpatients at facilities with fewer than 3 total inpatient cases. These facilities did not meet minimum census requirements to be eligible for receiving remdesivir from KDHE per the distribution plan.

Hospitals or medical providers may send requests to KDHE for direct delivery of medication doses to treat appropriate patients if the facility does not have any remdesivir in stock. KDHE will evaluate patient clinical characteristics and ship medication if available and appropriate.

Criteria for KDHE to Recall Distributed Remdesivir

As stated above, KDHE retains ownership of unused medication stored at any hospital. If a clinical need arises, KDHE may re-direct unused medication from one facility to either the KDHE warehouse or directly to another health care facility. If a healthcare facility has demonstrable need for medication and KDHE is unable to supply the medication from the KDHE reserve supply, KDHE will re-direct unused medication from one facility to another using the following process:

- A ratio comparing the total number of doses in stock to the total number of doses administered in that preceding 7 days will be calculated for all hospitals with any remaining remdesivir supply.
- The hospital with the highest ratio will be asked to send a specified quantity of remdesivir to the location indicated by KDHE (KDHE warehouse or hospital with immediate need or remdesivir as determined by KDHE).