

SUBJECT: ALLOCATION OF SCARCE RESOURCES DURING A PUBLIC HEALTH EMERGENCY- PHARMACEUTICALS

CHAPTER: RIGHTS & RESPONSIBILITIES OF THE INDIVIDUAL

AUTHOR: ETHICS COMMITTEE

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PURPOSE:

The purpose of this document is to provide ethical guidance for the allocation of medications to treat patients during a public health emergency (such as COVID-19); in the event, that need outstrips supply during the pandemic. The framework was designed to be broadly applicable to any medication that may become available for treatment. Because medication shortages may change and evolve quickly, this policy allows for feedback and amendment as needed. This policy should be used with [San Mateo Medical Center’s \(SMMC\) Infection Control \(IC\) Chapter Policy “Outbreak and Surge”](#).

POLICY:

- A. Implementation: Before implementation of the allocation plan for scarce medications, hospitals must have exhausted every resource to increase available pharmaceuticals, including, but not limited to health system resources, healthcare coalition partners, and state resources through the Medical Health Operational Area Coordinator (MHOAC). Hence, this allocation process will be implemented only if: 1) the supply of pharmaceuticals is, or will shortly be insufficient to treat all patients, despite taking all appropriate steps to increase the supply of medications; and 2) a regional authority has declared a public health emergency. Pursuant to guidelines published by the State of California, any impending need to implement this directive regarding allocation of scarce resources must include notification of San Mateo County Health (SMCH) system leadership and the California Department of Public Health (CDPH).
  
- B. Ethics: This allocation framework is grounded in ethical obligations that include the Duty to Care, Duty to Steward Resources to Promote Population Health, Duty to Lessen the Impact on Health Disparities in Health Outcomes, Distributive and Procedural justice, and Transparency. It is consistent with existing recommendations of allocation of scarce resources during a public health emergency. It has also been informed by extensive consultation with citizens, disaster medicine experts, and ethicists. Our SMMC workgroup tasked with the development of this guideline was comprised of legal, ethical, clinical experts, diversity and inclusion experts, as well as patient volunteers.

- C. Non-Discrimination: SMMC will provide emergency services and care without regard to an individual’s race, ethnicity, national origin, citizenship, age, sex, sexual orientation, gender identification, preexisting medical condition, physical or mental disability, insurance status, economic status, ability to pay for medical services, or any other characteristic listed in the Unruh Civil Rights Act, except to the extent that a circumstance such as age, preexisting medical condition, or physical or mental disability is medically significant to the provision of appropriate medical care to the patient.
- D. Enforcement: The Chief Executive Officers of SMMC shall ensure compliance with this policy. All staff members of SMMC must comply with this policy.

I. ETHICAL CONSIDERATIONS:

A. Ethical Goals of the Allocation Framework:

The purpose of this document is to provide ethical guidance for the allocation of medications to treat patients during a public health emergency, in the event that need outstrips supply. The framework was designed to be broadly applicable to any medication that become available to treat a novel infection or disease syndrome. Therefore, this document does not contain medical instructions that will be part of detailed treatment protocols for specific medications.

Consistent with accepted standards during public health emergencies, a goal of the allocation framework is to achieve the most good for populations of patients.<sup>1,2</sup> This is different from the traditional focus of medical ethics, which is centered on promoting the wellbeing of individual patients. This document is designed to protect and maintain the public’s health through *minimizing morbidity and mortality*, to promote trust, transparency, and understanding among the public regarding allocation decisions, and to ensure fairness and equality in the allocation of scarce medical resources. The framework is designed to achieve the following:

1. To create meaningful access for all patients. All patients who require pharmacotherapy during ordinary circumstances remain eligible, and there are no exclusion criteria based on age, disabilities, or other factors.
2. To ensure that all patients receive individualized assessments by clinicians, based on the best available objective medical evidence.
3. To ensure that no one is denied care based on stereotypes, assessments of quality of life, or judgments about a person’s “worth” based on the presence or absence of disabilities or other factors.
4. To diminish the impact of social inequalities that negatively impact patients’ long-term life expectancy.

B. Ethical Principles These Guidelines are Built Upon:

The allocation framework described in this document is grounded heavily in two public health ethical obligations: the *duty to steward scarce resources to promote the public's health*, and the *duty to lessen the impact of social inequities during a public health emergency on health outcomes in disadvantaged communities*. In addition, the document draws on the *duty to care*, *duty to plan*, *duty to implement distributive justice*, and *duty to provide transparency*.

***Duty to Steward Scarce Resources to Promote the Public's Health:*** An established principle of public health ethics is the importance of improving the outcomes of populations of patients. This orientation is distinct from clinical ethics, which generally focuses on the well-being of individual patients. Balancing an obligation to the community of patients against the primary duty to care for each patient generates ethical tension in devising a rationing system. Clinicians need to save the greatest possible number of lives while continuing to care for each individual patient. As the number of affected patients multiplies, accommodating these two goals will require making increasingly difficult decisions.

To maximize community benefit, access to the scarce medications shall be restricted to patients who meet the clinical eligibility criteria recommended in peer-reviewed Randomized Controlled Trials that demonstrate efficacy for each medication. For example, if the medication only has established efficacy for *severe* COVID-19 disease, the medication should be reserved for patients with *severe* disease. Exclusion criteria based on research considerations, such as the lack of a surrogate decision maker or inability to speak English, should not be used as exclusion criteria for access to the drug during clinical care. *If clear evidence emerges that certain clinical subgroups derive larger benefits from the treatment than others (e.g., a lower number needed to treat to save a life), these groups should receive priority.*

Patients who are essential workers should be given heightened priority, not because they are intrinsically more worthy, but because of their instrumental value to save others and ensure the continuity of critical societal infrastructure. This heightened priority may also be justified by a reciprocal obligation to provide treatment to individuals who are at heightened risk in occupations needed to safeguard society during a public health emergency. It is important to note that the category of essential workers includes not only health care workers, but also lower-paid workers who may be socially and economically vulnerable, such as grocery store clerks, bus drivers, agricultural workers, and custodial workers. Therefore, giving essential workers heightened access to treatment may also mitigate the disproportionate impact of a public health emergency on disadvantaged communities.

Individuals expected to die within 6 months from an end-stage condition should not be excluded from access but should receive lower priority than individuals who do not have a poor 6-month survival prognosis. The rationale is that doing so will achieve greater improvements in population outcomes by prioritizing individuals with greater ability to benefit from treatment.

***Duty to Lessen the Impact on Health Disparities in Health Outcomes:*** Any distribution plan must take into consideration long standing healthcare disparities and the particular subgroups most vulnerable to the disease. As in COVID-19, epidemiological data reveal that the burdens of COVID-19 have been unequally borne, with higher burden in economically disadvantaged groups and certain racial/ethnic minorities. For example, individuals from low-income areas are more likely to be hospitalized with COVID-19 than individuals from higher income areas.<sup>4</sup> The death rates from COVID-19 infection are more than twice as high in very high-poverty populations compared to low-poverty populations (242 per 100,000 vs 104 per 100,000, respectively).

The distribution of confirmed COVID-19 cases reveals significant disparities within California's overall racial and ethnic demographics, with Latino and Native Hawaiian / Pacific Islander groups having a disproportionate share of cases relative to their share of the population. California adults who are Black, Latino, or Native Hawaiian / Pacific Islander have disproportionately more deaths for their share of the population. Structural racism, poverty and the increased likelihood of having underlying conditions, such as diabetes mellitus, heart disease and asthma, are likely to contribute to this disparity.

Public health interventions are commonly used to mitigate disparate outcomes across groups within a community, especially when the disproportionate burden is borne by disadvantaged groups. The rationale is that a core goal of public health is to redress social injustices that make health and safety less accessible to disadvantaged groups. Providing heightened access to treatment for patients who are from disadvantaged groups is one way to mitigate the unequal effects of a pandemic.

SMMC is a public safety net hospital dedicated to providing healthcare to the underserved population in San Mateo County regardless of their insurance status, immigration status, or ability to pay. By legal mandate and SMMC's mission, we serve the uninsured, underinsured, low-income, and other vulnerable residents. Hence, vast majority of our patients meet the socially disadvantaged criteria.

***Duty to Care:*** An ethically sound rationing system must sustain the fundamental obligation of providers to care for patients. Physicians must not abandon, and patients should not fear abandonment. Patients who are not eligible to receive scarce medications, will receive available forms of curative and/or palliative treatment.

Patient preference is not and cannot be the primary factor in devising a rationing system for scarce pharmaceuticals because more patients will want these resources than can be accommodated. A public health disaster, by virtue of severe resource scarcity, will impose harsh limits on decision-making autonomy for both patients and providers.

***Duty to Plan:*** A failure to produce acceptable guidelines for a foreseeable crisis amounts to a failure of responsibility toward both patients and providers. Although planning is obligatory, any guidelines devised will be imperfect, both ethically and medically. Ethically, access to healthcare is unequal, and no rationing system for a crisis can resolve inequities in preexisting health status that result from unequal access. However, our responses to disaster must not exacerbate such disparities. Medically, the clinical parameters of a pandemic are uncertain, increasing the difficulty of predicting benefit or survival. Despite the difficulties inherent in planning, public health entities must accept this responsibility.

***Duty to Implement Distributive Justice:*** To be fair, an allocation system must be applied broadly and consistently to everyone. The use of a reproducible scoring combined with the lottery system is an attempt to eliminate any implicit or explicit bias in the criteria we apply. Applying this allocation system, uniformly helps the public recognize and accept that the allocation procedures are fair and ensures that vulnerable groups are not affected inequitably.

***Duty to Provide Transparency:*** A just system of allocating scarce resources requires transparency. To limit bias, triage allocation decisions are made, as much as possible based on objective data, and evidence-based research on predicting clinical outcomes.

## II. TRIAGE DECISION MAKING OUTLINE:

Below we describe A) the creation of pharmaceutical shortage team, B) process of approving alternative therapies, C) the creation of Allocation Teams to ensure consistent decision making, and D) allocation guidelines for scarce medications.

- A. Creation of Pharmaceutical Shortage Team: The pharmacy shall manage the drug shortage by ensuring that designated staff members have access to real time information and are empowered to make recommendations to the Allocation Officer/Team based on this information. When a shortage is identified, the team will conduct an operational and therapeutic assessment to evaluate its potential impact and will inform the SMMC Chief Medical Officer (CMO).
- B. Process for Approving Alternative Therapies: SMMC will follow our currently established [“MM Chapter Policy – Alternative Therapies”](#); the decision-making process about alternative agents will involve timely collaboration among representatives of medicine, nursing, pharmacy, administration, and other affected disciplines, and those decisions will be approved by the Pharmacy and Therapeutic Committee as promptly as possible.
- C. Creation of Allocation Teams and Communication Channels: Patient treating clinicians will not make triage decisions. Instead, the CMO will designate an Infectious Disease Specialist and another Licensed Provider as Allocation Co-O; supported by the following key stakeholders and experts to include: hospitalist medicine specialists, critical care providers (if available), nurses, pharmacists, Ethics Committee Members, diversity and inclusion representatives, and an administrator (collectively, “The Allocation Team”), who will apply the allocation framework described in this document. The Allocation Team will determine the appropriate patient characteristics and clinical evidence for prioritization and rationing of all scarce medications, based on information provided by the Pharmaceutical Shortage Team. The Allocation Team should not have access to information that is not relevant to fairly applying the allocation framework, such as patients’ names, age, gender, race, ethnicity, or presence of disabilities. The separation of the allocation role from the clinical role is intended to promote objectivity, avoid conflicts of commitments, and minimize moral distress. The Allocation Co-Officers will also be involved in patient or family appeals of allocation decisions, and in collaborating with the attending physician to disclose allocation decisions to patients and families. *(See below Section III/Procedures A for further detail.)*
- D. Allocation Framework for Scarce Medications: Patients shall be eligible to receive the scarce medication only if they meet the clinical eligibility criteria based on scientific evidence that demonstrate the medication’s safety and efficacy. For example, if the medication only has established efficacy for severe COVID-19 disease, the medication should be reserved for patients with severe disease. *If clear evidence emerges that certain clinical subgroups derive larger benefits from the treatment than others (e.g., a lower number needed to treat to save a life), these groups should receive priority.* If there is insufficient supply to treat all eligible patients, priority groups will be

established daily, and weighted lottery system shall be used to fairly allocate the drug supply within each priority group (*see Section III/Procedures B below for further detail*).

E. The Following Groups Will Receive Heightened Priority:

1. The Allocation Team shall carefully determine appropriate patient characteristics and clinical evidence for prioritization and rationing of each medication. If clear evidence emerges that certain clinical subgroups derive larger benefits from the treatment than others (e.g., a lower number needed to treat to save a life), these groups should receive priority for the particular medication, and those medications should be reserved for these patients only. Subsequently, each scarce medication will have its own priority group.
2. Essential workers: work, in person, in essential businesses that are required to continue physical operations during the pandemic, as defined by the State. Only persons required to report physically to perform their jobs are considered essential workers under this category. It is important to note that the category of essential workers includes not only health care workers, but also lower-paid workers who may be socially and economically vulnerable, such as grocery store clerks, bus drivers, agricultural workers, and custodial workers. Although, essential workers receive priority, they shall still be subject to the limitations set below for individuals expected to die within 6 months.
3. The following group will receive lowered priority: Individuals expected to die within 6 months from an end-stage condition (see Table 1) shall not be excluded from access to the medication, but shall receive lower priority than individuals who do not have an end-stage condition. The rationale is that doing so will achieve greater improvements in population outcomes by prioritizing individuals with greater ability to benefit from treatment.

III. PROCEDURES:

A. Creation of Pharmaceutical Shortage Teams:

The pharmacy manager and a designated individual will be responsible for completing an operational and therapeutic assessment, which include: data gathering and monitoring drug shortages; change storage, preparation, and dispensing procedures as needed; provide indications and clinical evidence for prioritization for each rationed drug to the Allocation Team; report daily on scarce medication status; search for alternative medications and sourcing, etc.

The team shall work closely and communicate directly with Allocation Team Officers.

1. Operational Assessment:

- a. *Details and Duration of Shortage:* The pharmacy team will contact product manufacturers, distributors, FDA, the Centers for Disease Control and Prevention (CDC), and other sources to determine the cause of the shortage and *its expected timing and duration*. This information may already be available on the [ASHP Drug Shortage Resource Center website](#) or the [FDA Drug Shortages website](#). If it is not, visitors to the sites should report the shortage online. Predictions of when the product will be available will help SMMC develop its short and long-term strategies. Because the status of a shortage may change quickly, follow-up communications with manufacturers may be required to obtain updates on previous estimates of product availability.
- b. *Inventory on Hand:* Once a shortage is identified, pharmaceutical shortage team should assess the inventory on hand and estimate the time period it will cover. Available inventory includes all supplies of the drug product within SMMC, including the pharmacies, inpatient units, ambulatory care clinics, automated medication storage and distribution devices, floor stock, code carts, prepared trays, etc. The pharmacy will estimate how long this supply will last based on available quantities and historical usage, converting inventory counts of alternative drug products into common measurement units (e.g., common dose, days of therapy) to augment estimates of use.

2. Therapeutic Assessment to Identify the Patient Population Affected and Therapeutic Alternatives:

- a. *Prioritization:* When a limited supply of a drug remains available and alternatives are unavailable, SMMC will prioritize use of the drug for specific patient groups. This prioritization will always rely on evidence-based decision making, and we shall adhere to the indications authorized by the FDA, with supplemental indications guided by new developments in the literature. For instance, national organizations (e.g., CDC or an organization of healthcare specialists) may provide guidance on patient prioritization. Medication-use evaluation data on prescribing and utilization trends, if available for the drug in question, may be useful in developing prioritization criteria to guide appropriate drug use. Additional criteria, such as therapeutic use (curative versus palliative), may also be helpful in guiding appropriate use of the drug. Such criteria are particularly helpful in dealing with long-term shortages. Each scarce medication will have its own indication and recommendations, and this information will be provided by the

Pharmacy Shortage Team to the Allocation Leads/Team to establish the priority groups for each rationed medication.

- B. Therapeutic Alternatives: Therapeutic alternatives should be inventoried, and availability assessed to ensure adequate supplies to meet new demand. In many cases, supplies of the best alternative agent may be affected by the response to the shortage. If therapeutic alternatives are not on the formulary or not currently stocked in the system, there should be a process to expedite adding the new product to all systems (e.g., the electronic health record [EHR], smart pump libraries, automated dispensing cabinets [ADCs]). If a compounded medication is an appropriate alternative, the team must decide whether resources are available to compound inhouse or if the best solution is to purchase the compounded medication from an FDA-registered outsourcing facility.
  
- C. Process for Approving Alternative Therapies: SMMC will follow the established [“MM Chapter Policy Alternative Therapies”](#). All alternative pharmaceutical treatment will be approved by the Pharmacy and Therapeutics Committee as promptly as possible.
  
- D. Creation of Allocation Teams, Communicating Decisions, Appeals Process:
  - 1. **Allocation Co-Officers**: shall be appointed by the CMO. This team shall have two Allocation Officers, 1) shall be a physician with established expertise in the management of infectious disease (generally, Infectious Disease Specialist) and 2) another provider with an active medical license. Both providers shall have strong leadership ability, effective communication and conflict resolution skills.

Allocation Co-Officers will serve on the Allocation Teams and shall oversee the allocation process, assess all patients (in person or via chart review), determine if patient is eligible to receive the scarce medication based on recommended clinical criteria from evidence, and communicate with treating physicians. Allocation Co-Officers have the responsibility and authority to apply the principles and processes of this document to make decisions about which patients will receive priority for receiving scarce medications. Allocation Co-Officers will make decisions according to the allocation framework described below in this policy, which is designed to benefit the greatest number of patients, even though these decisions may not necessarily equally benefit individual patients. The Allocation Co-Officers will review the indications and clinical evidence for prioritization

for each scarce drug provided by the Pharmaceutical Shortage Team. The Allocation Co-Officer/Team shall carefully determine appropriate patient characteristics for prioritization and rationing of medications based on this clinical evidence and communicate the outcome to the patient's attending.

To optimize effective functioning in a crisis, the Allocation Officer should ideally be well prepared and trained in advance by means of disaster drills or exercises and SMMC will endeavor to provide such training opportunities for Allocation Officers.

So that the burden is fairly distributed, Triage Officers will be nominated by the chairs/directors of the clinical departments. The CMO and the individual responsible for emergency management should approve all nominees. A roster of approved Allocation Officers shall be maintained by SMMC Administration that is large enough to ensure that Allocation Officers will be available in person, via phone or other media within a short notice to the ED, 2AB, ICU and other patient care areas at all times during a public health crisis. Administration must also ensure that Allocation Officers will have sufficient rest periods between shifts.

The Allocation Co-Officers/Team should ONLY be provided clinically relevant data required by the allocation protocol.

2. Allocation Team:

In addition to the Allocation Officer, the team shall also consist:

- a. Hospitalist medicine specialists or critical care provider (if available);
- b. Nurse (e.g., if available, with critical care or emergency medicine experience);
- c. Pharmacist;
- d. Ethics Committee member appointed by the Ethics Committee Chair to ensure that ethical values are an integral part of the decision-making process;
- e. Diversity and inclusion representatives;
- f. Operations representative from SMMC administration with real-time knowledge of logistics related to availability, acquisitions, and distribution of medication supplies responsible to provide information regarding available supplies and assistance liaising with the SMMC Command Center/Administration;
- g. And one administrative staff member who will conduct data-gathering activities, documentation and record keeping.

The Allocation Team must be provided with appropriate Information Technology support to maintain updated databases of patient priority levels and scarce resource usage (total numbers, location, and type). The role of Allocation Team members is to provide information to the Allocation Co-Officers and to help facilitate and support the Allocation Co-Officers' decision-making process.

3. **Allocation Team members should receive advanced training to prepare them for the role, including training in the following:**
  - a. Applying the allocation framework;
  - b. Communicating with clinicians and families, including the need to call on professional interpreters to facilitate communication in the preferred spoken language of patients and/or their families;
  - c. Recognizing and avoiding implicit bias;
  - d. Respecting disability rights; and
  - e. Diminishing the impact of social inequalities on health outcomes.

The Allocation Teams should work in shifts lasting no longer than 13 hours (i.e., twelve hour shifts with 30 minutes of overlap and handoffs on each end of the shifts). Therefore, there should be at least two shifts per day to fully staff the allocation function. Team decisions and supporting documentation should be reported daily to appropriate SMMC leadership and incident command.

4. Allocation Mechanism: From the time a medication shortage that affects patient care is identified by Pharmacy, the Allocation Team will convene as soon as able, but within two hours.

The Allocation Teams will use the allocation framework, detailed in Section B, to determine the weighted treatment score of all patients eligible to receive scarce medication(s). The Allocation Co-Officers will review the comprehensive list of weighted treatment scores daily for all patients and will communicate with the clinical teams immediately after a decision is made regarding allocation of the scarce medication.

5. Communication of Allocation Decisions to Patients and Families: Although the *authority* for allocation decisions rests with the Allocation Co-Officers, there are several potential strategies to *disclose* triage decisions to patients and families. Communicating allocation decisions to patients and/or their next of kin is a required component of a fair process that manifests respect for persons.

The Allocation Co-Officers should first inform the affected patient's attending physician about the decision. Those physicians should

collaboratively determine the best approach to inform the individual patient and family. The best approach will depend on a variety of case-specific factors, including the dynamics of the individual doctor-patient-family relationship and the preferences of the attending physician. If the attending physician is comfortable with undertaking the disclosure, this approach is useful because the communication regarding triage will bridge naturally to a conveyance of prognosis, which is a responsibility of bedside physicians, and because it may limit the number of clinicians exposed to a circulating pathogen.

A more collaborative approach may also be useful because it may lessen moral distress for individual clinicians and may augment trust in the process, but these benefits must be balanced against the risk of greater clinician exposure. Under this approach, the attending physician would first explain the severity of the patient's condition in an emotionally supportive way, and then the Allocation Co-Officer(s) would explain the implications of those facts in terms of the allocation decision. The Allocation Co-Officer(s) would also emphasize that the decision was not made by the attending physician but is instead one that arose from the extraordinary emergency circumstances and reflects a public health decision.

Regardless of who communicates the decision, it may be useful to explain the medical factors that informed the decision, as well as the factors that were not relevant (e.g., race, ethnicity, gender, insurance status, perceptions of social worth, immigration status, among others). If resources permit, palliative care clinicians, social workers, or chaplain should be present or available to provide ongoing emotional support to the patient and family. All approaches to inform the individual patient and family should take into consideration the family's spoken language needs and involve professional interpreters as necessary.

6. Appeals Process for Individual Allocation Decisions:

Patients, families, or clinicians may challenge individual allocation decisions. Procedural fairness requires the availability of an appeals mechanism to resolve such disputes. Appeals based on an objection to the overall allocation framework should *not* be granted.

Appeals should be allowed when they are based on a claim that an error was made by the Allocation Team in determining the characteristics of the patient relevant to the weighted treatment score (i.e., whether the patient is an essential worker, or has a poor 6-month survival prognosis). The process of evaluating the appeal should include the Allocation Team verifying the accuracy of each determination. For example, if there is an

appeal regarding the accuracy of whether the patient is a healthcare worker, it would be appropriate to verify the patient's status. If there is an appeal of a determination that a patient is expected to die within 6 months from an end-stage condition despite successful treatment of the acute medical condition, it may be appropriate to obtain a second medical opinion from an appropriately trained physician. The treating clinician or Triage Officer should be prepared to explain the calculation to the patient or family on request.

Elements of this appeals process includes:

- a. The individuals appealing the allocation decision should explain to the Allocation Co-Officer(s) the grounds for their appeal. Appeals based in an objection to the overall allocation framework should not be granted.
- b. The Allocation Team should explain the grounds for the allocation decision that was made.
- c. If the issue is not resolved based on above, appeals based in considerations other than disagreement with the allocation framework should immediately be brought to the Allocation Review Committee that is independent of the Allocation Co-Officer(s)/Team and of the patient's care team (see below for recommended composition of this body).
- d. The appeals process must occur within two hours or sooner, so that the appeals process does not harm patients who are in the queue for scarce medications.
- e. The decision of the Allocation Review Committee will be final.
- f. Periodically, the Allocation Review Committee should retrospectively evaluate whether the review process is consistent with effective, fair, and timely application of the allocation framework.

7. The Allocation Review Committee:

The committee should be made up of at least three individuals, recruited from the following groups or offices: CMO or designee, Chief Nursing Officer (CNO) or designee, Legal Counsel, SMMC's Ethics Committee, and/or an off-duty Allocation Officer. The Allocation Review Committee shall consist of at least three members and at least three members are needed to constitute a quorum. The Committee shall render a decision using a simple majority vote. The Allocation Review Committee may meet in person or remotely using appropriate technology, and the outcome will be promptly communicated to the party bringing the appeal. Regardless of how the outcome is communicated (e.g., in writing, telephonically, in person, etc.), the Committee will prepare and keep a written record of its deliberations and decisions. In addition, the

Allocation Review Committee shall provide oversight of the Allocation Teams. This oversight shall consist of periodic reviews of Allocation Teams' processes and documentation, with a particular focus on discovering implicit bias or inappropriate use of assessment/reassessment tools.

E. Allocation framework for scarce medications

1. General:

- a. Eligible patients: We will adhere to the indications authorized by the FDA, with supplemental indications guided by new developments in the literature. If clear evidence emerges that certain clinical subgroups derive larger benefits from the treatment than others (e.g., a lower number needed to treat to save a life), this group shall receive heightened priority and the scarce medication should be reserved for this patient population.
- b. When the patient arrives to SMMC in the middle of a prescribed course of a scarce medication, the home medication will be relabeled in the pharmacy and reserved for the patient to finish the entire course. Once the patient finishes the course of the home medication, if further treatment is needed, the patient will enter the general population and the weighted lottery system.
- c. Once a patient is started, via the weighted lottery system, on a course of scarce medication at SMMC, the patient will be allowed to finish the course of medication, unless, continuing the medication becomes clinically contraindicated or the patient no longer benefits from the treatment.

2. Weighted treatment score system shall be used to fairly allocate the scarce medication supply within the eligible group for each medication.

The following group will receive heightened priority:

- Essential workers, working in person in essential businesses that are required to continue physical operations during the pandemic.

The following group will receive lower priority:

- Individuals who are expected to die within 6 months from an end-stage condition should not be excluded from access but should receive lower priority than individuals who do not have an end-stage condition (Table 1).

3. Procedures to Conduct Weighted Lottery for the Allocation of Scarce Medication: This section provides step-by-step instructions for how to conduct the weighted lottery for each patient who is eligible to receive the scarce medication.

- d. Preliminary steps. The following three steps should be completed at the time that a shipment of drugs is allocated to the hospital that is insufficient to meet the expected need.

Step 1. Determine the number of available courses of the scarce therapy.

- This information will be provided by the Pharmaceutical Shortage Team to Allocation Co-Officers/Team. For instance, Remdesivir is allocated to our hospital once a week, hence we may calculate the number of doses we will have available for the upcoming week.

Step 2. Estimate the number of eligible patients over the time period in question, for which the drug is allotted.

- First, determine the average number of patients admitted daily over the past week who met eligibility criteria for the scarce medication.
- Second, determine the number of days the supply of drug is expected to last (based on information from Step 1).

Step 3. Determine the chances for each eligible “general population” patient to receive the drug.

- Divide the number of available courses of scarce drug by the projected number of eligible patients.
  - For example, if there are 25 courses of Remdesivir available for the upcoming week and 100 patients are expected to be eligible over the upcoming week (based on last week’s patient flow), the “general population” chances for each patient to receive Remdesivir are 25 out of 100 (25%). This number will be used in step 4 below to calculate the chances for other populations.

Step 4. Conduct the weighted lottery, see details below.

STEP 5. Reassess patients daily:

Patients should generally be given the full duration of a medication trial, unless continuing the scarce medication will no longer benefit the patient.

For instance, if patients experience a precipitous decline (e.g., refractory shock and DIC) or a highly morbid complication (e.g., massive stroke) which portends a poor prognosis for survival, the triage team or the physician actively directing the patient's care (if the triage team is not available) may make a decision before the completion of the specified trial length that the patient is no longer eligible for the medication treatment (see Life-Sustaining Treatment, Code Status Decisions-Making and Futile care Guidelines Policy). Another example, if a patient's condition on Remdesivir deteriorates so that he/she is placed on a ventilator, the clinician may consider discontinuing the Remdesivir if clinically appropriate.

The remaining scarce medication will be re-entered into the pool of available medications and shall be re-allocated to another patient.

NOTE: There may be uncertainty or changes in the number of treatment courses available, the time period that the supply of medication needs to last, or the average number of eligible patients per day. *It is appropriate to recalculate the lottery chances as new information becomes available about these parameters.*

e. Daily Steps to Allocate Scarce Medications Using Weighted Lottery.

Step 1. Proactively identify eligible patients.

- Daily, the Allocation Co-Officer(s)/Team shall take proactive steps to identify eligible patients by screening each novel condition patient in the hospital, either in person or via chart review. This approach increases the chances that all eligible patients will be offered the opportunity to be in the lottery for the drug.

Step 2. Confirm each affected patient's eligibility with the attending physician.

- The Allocation Team should contact the attending physician of each patient with novel condition who is potentially eligible in order to

- confirm eligibility. This conversation should ascertain that the patient indeed meets the clinical eligibility criteria to receive the scarce pharmacotherapy as per peer-reviewed evidence.

Step 3. Determine patient's characteristics relevant to the weighted lottery.

- The Allocation Team should engage with the patient's attending physician to assess the two characteristics relevant to the weighted lottery:
  - *Is the patient an essential worker?* In conjunction with the patient's attending physician, the Allocation Team should determine whether the patient meets the criteria defined by the State Public Health Officer (Attachment 1).
  - *Is the patient expected to die within 6 months of a chronic, end-stage condition?* In conjunction with the patient's attending physician, the allocation should determine whether the patient is likely to die within 6 months from underlying end-stage condition(s) despite successful treatment of the acute medical condition (Table 1). The objective medical evidence supporting this determination should be documented. If needed, specialist consultation should be sought (e.g. oncology, geriatrics, palliative care) to ensure the prognostication is an objective medical determination.

<b>Table 1. Death expected within 6 months in the following chronic conditions:</b>
<ul style="list-style-type: none"> <li>• <b>Known severe dementia</b> medically treated and requiring assistance with activities of daily living. (Functional Assessment Staging (FAST) grade 6e and above: doubly incontinent and speaks only a few words, unable to walk, loss of intelligible speech, unable to smile, unable to hold their head up).</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Advanced untreatable neuromuscular disease</b> (such as ALS or end-stage MS) requiring assistance with activities of daily living or requiring chronic ventilatory support.</li> </ul>
<ul style="list-style-type: none"> <li>• <b>Incurable metastatic malignant disease</b></li> </ul>
<ul style="list-style-type: none"> <li>• <b>End-stage organ failure</b> meeting the following criteria: <ul style="list-style-type: none"> <li>○ <b>Heart:</b> New York Heart Association (NYHA) Functional Classification System Class IV (Unable to carry out physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.)</li> <li>○ <b>Lung:</b> (any of the following): <ul style="list-style-type: none"> <li>▪ (COPD) with Forced Expiratory Volume in one second (FEV1) &lt; 15% predicted baseline, PaO2 &lt;55 mm Hg, or severe secondary pulmonary hypertension.</li> <li>▪ Pulmonary fibrosis with VC or TLC &lt; 50 % predicted, baseline PaO2 &lt;55 mm Hg, or severe secondary pulmonary hypertension.</li> <li>▪ Primary pulmonary hypertension with NYHA class IV heart failure.</li> </ul> </li> <li>○ <b>Liver:</b> Meld score indicative of &lt;50% chance of 6-month survival.</li> </ul> </li> </ul>

Step 4. Conduct the lottery for each eligible patient.

- *The first step is to determine the lottery threshold for each eligible patient.* Table 2 contains a summary of the adjusted chances for each patient group, which are based on the chances of a “general community” member, with adjustments for priority considerations. Table 3 provides an example of this when there are only enough courses of treatment to treat 25 out of 100 (i.e., 0.25) of general community members over the upcoming week.

**Table 2. Weighted chances to receive treatment for each patient group**

Group	Chances to receive treatment
General community chances	Number of available treatment course/Number of eligible patients in the determined time period
Essential worker (if yes: add 0.25)	$(1+0.25) \times$ (general community chances)
Death likely within 6 months (if yes: subtract 0.75)	$(1-0.75) \times$ (general community chances)
Essential worker + death likely within 6 months	$(1 + 0.25 - 0.75) \times$ (general community chances)

**Table 3. Example when the chances for treatment for the general community are 25 out of 100**

Group- Individuals who are...	Chances to receive treatment
General community members	0.25 (25 out of 100)
Essential workers	$1.25 \times 0.25 = 0.31$ (31 out of 100)
Expected to die within 6 months from an end-stage condition	$0.25 \times 0.25 = 0.06$ (6 out of 100)
Essential worker AND Expected to die within 6 months from an end-stage condition	$0.5 \times 0.25 = 0.13$ (13out of 100)

*The second step is to randomly select a lottery number for each eligible patient.* This can be done with a random number generator such as found at random.org; the range of the lottery should be set to “1 to 100”. The drawing of each patient’s lottery number should be witnessed by two individuals and recorded. Unless a parameter changes, each patient is entered into the lottery only once, not every day that they are eligible to receive the scarce medication. If some of the parameters change, for instance, medication supplies increase unexpectedly, or the number of expected eligible patients decrease, etc, it is appropriate to recalculate the lottery chances. In this case, the Allocation Team may decide to re-enter eligible patients into the lottery more than once.

- *Determine whether each patient’s lottery number is within the range to offer the scarce therapy.* For example, if the lottery chances for the patient is 31 out of 100 and the patient’s randomly drawn lottery number is  $\leq 31$ , she should be offered the scarce therapy. If her lottery number is  $>31$ , then she should not be offered the scarce therapy.

Step 5. Inform the patient’s attending physician of the lottery result.

- Immediately after the weighted lottery is conducted, the Allocation Team should contact the patient’s attending physician to inform him/her of the lottery results (i.e., whether the patient will be offered the scarce therapy). The treating team or the Allocation Team should also inform the patient or their surrogate about the lottery result.

Step 6. If patient is to receive the drug, contact the pharmacy to provide the patient-specific medication order and authorize release of drug.

Step 7. Documentation.

- For each eligible patient, the Allocation Team should document that each of the steps above was performed. Two members of the Allocation Team should witness and attest to the correct conduct of the lottery, and should record each patient’s lottery number, as well as each patient’s lottery threshold to receive the scarce therapy.

## REFERENCES:

*Note: [This guideline is based on the guideline and work done at the University of Pittsburg and published at: White DB, et al. Model hospital policy for fair allocation of scarce medications to treat COVID-19. Version May 28, 2020.](#)*

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SMMC Policy Review & Approval Grid	
Origination Date: 2020-09	Last Review Date: New
Reviewed and approved by:	Date:
Chapter Chair	07/20
Ethics Committee	07/20
Critical Care Committee	06/20
Department of Medicine	10/20
Emergency Medicine	10/20
Medical Executive Committee	10/20, FINAL
Date & Submission By: 2020-09	

## **Attachment 1.**

The following sectors are designated as essential by the State Public Health Officer;

1. Health and Public Health Sector
2. Emergency Services Sector
3. Food and Agriculture Sector
4. Energy Sector
5. Water and Wastewater Sector
6. Transportation and Logistics Sector
7. Communications and Information Technology Sector
8. Government Operations and Other Community-Based Essential Functions
9. Critical Manufacturing Sector
10. Financial Services Sector
11. Chemical Sector
12. Defense Industrial Base Sector
13. Industrial, Commercial, Residential and Sheltering Facilities and Services

## Attachment 2.

