

**STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
OFFICE OF PUBLIC HEALTH PREPAREDNESS**

**Guidelines for Ethical
Allocation of Scarce Medical
Resources and Services
During Public Health
Emergencies in Michigan**

Version 2.0

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Guidelines for Ethical Allocation of Scarce Medical Resources and Services During Public Health Emergencies in Michigan

Executive Summary

The Guidelines for Ethical Allocation of Scarce Medical Resources and Services during Public Health Emergencies in Michigan (Guidelines) presented in this report provide guidance to decision-makers throughout the state of Michigan to assist in making choices about resource and service allocation and prioritization during situations of scarcity that may arise during public health emergencies. These Guidelines do not present a formalized series of instructions but rather a set of criteria that can be employed by decision-makers in various circumstances during a public health emergency using their best professional discretion.

Assumptions

The Guidelines incorporate eight assumptions that help define their scope and purpose:

1. Public health emergencies give rise to unique public health challenges that can lead to, and be exacerbated by, scarcity of medical resources and services.
2. The likely conditions during public health emergencies may be anticipated even in emergency circumstances that arise from sudden, extraordinary, or temporary events.
3. Emergency planners have an ethical duty to provide guidance related to the ethical allocation of scarce medical resources and services during public health emergencies.
4. The Guidelines apply to public health emergencies, not everyday scarcity of medical resources and services.
5. The Guidelines apply to allocation decisions made by decision-makers at different levels of government and as well as the private and nonprofit sectors.
6. The Guidelines apply to allocation decisions affecting all medical resources and services that may become scarce during a public health emergency.
7. The Guidelines employ ethical principles that take into account both individual health and population health.
8. The Guidelines should be implemented in ways that comply with all relevant laws at the federal, state, and local levels.

Goals

The Guidelines recognize three salient goals in determining the allocation of scarce medical resources and services during public health emergencies. First, efforts should be made to protect and maintain the public's health through *minimizing morbidity and mortality*. Second, we should strive to *sustain a functioning society* through actions

to preserve the capacity to deliver health care, public health, public safety, and other social services and critical infrastructure. Efforts to promote trust, transparency, and understanding among the public regarding allocation decisions also support this goal. Third, decisions about how scarce medical resources and services are allocated should *ensure fairness* and endeavor to achieve equality. These goals are listed in no order of hierarchy – all are equally important to achieve.

Ethical Considerations

The committee identified numerous underlying ethical considerations that guide the structure, procedures, and recommendations outlined in these Guidelines. These ethical considerations include **beneficence** (preserving the welfare of others through affirmative acts to promote well-being and save lives); **utility** (achieving the greatest good for the greatest number); **fairness** (applying consistent, equitable, and non-discriminatory policies); **transparency** (providing open access to information and decision-making processes); **accountability** (holding decision-makers responsible for their actions); **veracity** (truth-telling); **respect for persons** (upholding individual autonomy, privacy, dignity, and bodily integrity); **proportionality** (demanding policies necessary and proportional to the scope and severity of the circumstances); **solidarity** (shared obligations and social cohesion); **reciprocity** (compensating someone for past actions or deeds); **stewardship** (preserve the effectiveness and impact of these resources and services as best as possible).

Allocation Criteria

Acceptable Allocation Criteria

The Committee identified two general criteria considered acceptable for guiding allocation decisions: *medical prognosis* and *essential social functions*. These criteria should be considered in conjunction with each other when evaluating allocation decisions.

1. Medical prognosis. Medical prognosis should be used to determine priority of access to scarce medical resources and services during public health emergencies. Decision-makers should consider the patient's medical condition, the likelihood of a positive medical response, the relative risk of harm posed by not treating the patient, and other indicia of survivability and favorable medical outcomes.
2. Essential social functions. Workers who perform essential social functions, i.e., those deemed critical for the ongoing functioning of society should receive priority access to scarce medical resources and services. Essential personnel may include:
 - health care workers who are directly treating patients affected by the public health emergency (doctors, nurses, etc.);

- personnel key to responding to the public health emergency (first responders, public health scientists, etc);
 - personnel key to public safety (police, fire, military, etc.); and
 - personnel key to critical infrastructure (energy grid, telecommunications etc.).
3. Applying the Acceptable Allocation Criteria. The acceptable allocation criteria of medical prognosis and essential social functions may apply to a number of different groups of people, requiring additional decisions to be made regarding the prioritization of scarce medical resources and services. The Committee reached the following conclusions regarding the ordering of priority among people who meet one or both of the two acceptable allocation criteria described above:

Tier 1 (highest priority):

- Essential personnel with high risk of severe morbidity or mortality and favorable medical prognosis
- Essential personnel that are irreplaceable with a favorable medical prognosis
- Essential personnel that have high occupational exposure with a favorable medical prognosis

Tier 2 (elevated priority):

- Essential personnel with a favorable medical prognosis
- Groups or individuals with elevated risk of severe morbidity and mortality with a favorable medical prognosis
- Groups or individuals with moderate risk of severe morbidity and mortality that have a high risk of exposing others (may not apply in some public health emergencies)

Tier 3 (lowest priority):

- All eligible groups and individuals

Some members of the Committee and external reviewers felt that the nature of the scarcity should be considered in determining priority for essential personnel compared with others at risk. These commenters felt priority access to resources for prevention, protection, and short-term treatment were ethically warranted, essential personnel who were not likely to be able to recuperate quickly and continue to assist others during the emergency should not have priority access to treatment resources needed for long-term recovery. Others on the Committee felt that essential personnel should receive priority to all types of scarce medical resources regardless of whether their recovery would be expeditious. The decision whether to differentiate between types of resources in granting priority to essential personnel relative to others should be assessed further by decision-makers implementing these Guidelines.

Situation-Dependent Allocation Criteria

The Committee identified three criteria—*age*, *lottery*, and *first-come, first-served*—that could be considered for medical resource and service allocation under limited circumstances due to their controversial nature. The Committee acknowledges that reasonable decision-makers may disagree on whether these criteria are appropriate to use. Yet, these criteria may be useful if scarcity requires prioritization between people who would be indistinguishable on the basis of the acceptable criteria of medical prognosis and essential social functions.

1. Age: Granting priority to access scarce medical resources or services based on numerical age, quality-adjusted life-years, disability-adjusted life-years, or some other measurement based upon longevity or functioning raises several difficult issues. It may be fair to allow a younger person to have the chance to live to an older age, given that older people have already had the opportunity to experience those phases of life. But this approach goes against equality in the sense that it is making an explicit differentiation between people on the basis of numerical age.
2. Lottery: A lottery approach gives each eligible person an equal random chance to be selected to receive scarce medical resources or services. Advantages include: truly random, and therefore fair, allocation across the population. But a lottery does not allow targeting of resources for maximum population health benefit and could be complicated to administer. The Committee considered the use of a lottery approach as a tie-breaker between potential recipients of scarce medical resources and services in the event that all other criteria are equivalent and scarcity persists.
3. First come/First served: This approach favors those with existing informational, social, and economic advantages. However, it is the easiest to administer and generally accepted in non-emergency situations.

Unacceptable Allocation Criteria

The Committee identified several criteria that are unacceptable to consider when making allocation decisions, due to their inherent lack of fairness, potential for abuse or discrimination, or irrelevance to achieving the goals set out in these Guidelines.

1. Social characteristics: Social characteristics, including but not limited to race, ethnicity, gender, national origin, sexual orientation, religious affiliation, and disability unrelated to immediate medical prognosis, should not be used as criteria in making resource or service allocation decisions during public health emergencies. These characteristics serve no meaningful purpose in differentiating between people in the context of allocation decisions. Moreover, categorization of people according to these types of characteristics is often used as pretext for favoritism, discrimination, and reduced access for minority groups. Therefore, use of social characteristics as allocation criteria is unacceptable.

2. Social worth: The discussion of acceptable allocation criteria recognizes that limited categories of people who provide specific social functions, namely groups of identified essential personnel, may be granted priority access to scarce resources and services during a public health emergency. However, beyond these limited categories, factors that take into account a person's social worth are not acceptable to consider for allocation decisions. Social worth criteria are generally unacceptable because they can lead to unfair decisions based on subjective determinations of a person's background or characteristics, which can in turn lead to stigma, bias, greed, or nepotism in allocation decisions. Unacceptable factors under this category would include but are not limited to job status, training or education, social standing, personal or familial relationships, belief systems, political affiliations, or any other measurement of a person's social value. In particular, the Committee found unacceptable any sort of decision-making process that considered a person's ability to pay for medical resources or services as relevant to prioritizing resources or services. Similarly, it would be inappropriate for providers of medical resources and services to take into account the financial or economic consequences of a person's ability to pay in making allocation decisions for scarce medical resources or services.

Implementation

1. Efforts should be made to eliminate scarcity prior to having to implement allocation guidelines. At all levels of planning, from the state government to individual health care institutions, efforts should be made to acquire sufficient levels of medical resources and services to alleviate the need for rationing these resources and services whenever possible through coordinated plans to share, stockpile, and estimate needed resources in advance of a predictable public health emergency scenario. The implementation of these Guidelines should only occur after all reasonable efforts to avoid scarcity have been explored.

2. The probability of scarcity occurring should be assessed and planning should occur to prepare for scarcity.

3. Criteria should be offered to determine when scarcity exists and when prioritization guidelines should be used. The Guidelines should only go into effect after conditions of scarcity have developed using the following factors:

- Nature of scarcity
- Duration of scarcity
- Severity of scarcity

4. Fair and transparent processes. Allocation decisions made under conditions of scarcity should adhere to clear and specific processes to ensure that these decisions are not being made in an unjust or discriminatory manner.

5. Prioritization guidelines and decisions should be reviewed continuously and periodically assessed. The policies and practices that emerge from these Guidelines should receive ongoing scrutiny to assure their relevance to the circumstances at hand. Periodic reassessment of an individual patient's qualifications to receive, or be excluded from receiving, scarce medical resources and services pursuant to these Guidelines also should be undertaken.

6. Prioritization guidelines should be used consistently across the state. Consistency in implementation of the Guidelines will promote fairness in access to scarce resources and services and will defuse allegations of favoritism and efforts to "venue-shop" for medical resources and services. However, local conditions may require allocation decisions to deviate from statewide guidance under some circumstances. Decision-makers who are departing from common guidance should only do so after careful deliberation and documentation.

7. Decisions to implement prioritization should be made by persons removed from the clinical context. To minimize conflicts of interest and difficult interactions at the clinical care level between health care providers and patients, decisions regarding when to apply these Guidelines should be made by decision-makers removed from the clinical context whenever possible. Health care professionals should not be required to determine which patients qualify as essential personnel. This determination should be made by decision-makers removed from the direct clinical relationship.

8. Palliative care resources should be provided consistently throughout a public health emergency. Access to palliative care resources and services should be provided to individuals who will not have access to some scarce medical resources and services based on allocation decisions.

I. Introduction

Effective public health emergency preparedness requires thoughtful planning and proactive anticipation of the likely needs of various sectors of the population during a public health emergency. Decision-makers must consider carefully the development and implementation of practical, logistical, and scientific methods that will be necessary for effective response and recovery initiatives. The state of Michigan, through the efforts of the Michigan Department of Community Health (MDCH) Office of Public Health Preparedness (OPHP), has made extensive progress in developing health-focused preparedness planning within the state. A number of ongoing initiatives around the state seek to supplement the planning process by examining key ethical issues that may arise during public health emergency preparedness and response.

Public health preparedness efforts raise numerous challenging questions. One set of particularly difficult questions asks what we should do when necessary medical resources and services are in short supply during a public health emergency? How can we ethically allocate scarce medical resources and services during emergencies? How can we ensure that our decisions about allocation are effective, humane, fair, and consistent with our ethical values and goals? Answering these questions presents a difficult task, which we undertake in this report.

The Guidelines for Ethical Allocation of Scarce Medical Resources and Services during Public Health Emergencies in Michigan (Guidelines) presented in this report seek to respond to these questions and to provide insight into how decision-makers throughout the state of Michigan can make tough choices about resource and service allocation and prioritization if such decisions become necessary. These Guidelines will provide a template from which health care practitioners, partners and institutions in the health sector, and local and state officials can plan for situations involving an acute scarcity of medical resources and services. The Guidelines also will serve as a tool that will assist decision-makers at all levels in making difficult decisions related to allocation of medical resources and services in times of emergency-induced scarcity.

The Guidelines build upon the already extensive emergency preparedness and planning efforts undertaken by the state of Michigan, and will complement the existing plans through addressing complex issues related to allocation.

The Guidelines have been developed as a part of an ongoing project to gain consensus on ethical issues relating to allocation of scarce medical resources and services during emergencies. The primary objectives of this project are: 1) to engage in a collaborative process to address ethical issues related to allocating scarce medical resources and services that may arise during public health emergencies; and 2) to develop ethical guidelines and other support materials that meet the needs of state, regional, and local partners who may be faced with making difficult decisions during an acute emergency or incident that leads to scarcity of needed medical resources and services.

The Guidelines and all other materials produced through this project are the result of a state level, multi-disciplinary committee.

The approach adopted by these Guidelines reflects similar concerns as other recent reports on the ethical and practical aspects of allocating scarce medical resources and services during public health emergencies. However, the Guidelines can be distinguished from similar guidance drafted by other jurisdictions in three notable ways.

1. The Guidelines take a broad approach to addressing scarcity of resources and services during public health emergencies. They are structured to be applicable to public health emergencies of varying types and to assist in allocation decisions affecting multiple types of resources. This approach contrasts with many similar efforts in other states and at the national and international levels addressing more targeted allocation questions.¹ For example, several other states have addressed the ethics of scarce resource allocation with regard to specific types of emergencies (e.g., pandemic flu)² or specific types of resources (e.g., ventilators or vaccines).³ While these other existing models provide useful frameworks in their respective contexts, the Guidelines outlined in this report will provide a model that can be applied in numerous different circumstances to address the ethical allocation of a wide range of potentially scarce resources.

¹ A notable exception are two recent report on crisis standards of care produced by the Institute of Medicine, which does take a more generalized approach to the ethics of scarce resources allocation in disaster situations. INSTITUTE OF MEDICINE, GUIDANCE FOR ESTABLISHING CRISIS STANDARDS OF CARE FOR USE IN DISASTER SITUATIONS: A LETTER REPORT (2009) and INSTITUTE OF MEDICINE, CRISIS STANDARDS OF CARE: A SYSTEMS FRAMEWORK FOR CATASTROPHIC DISASTER RESPONSE (2012). Further referred to as “IOM Report 2009” and “IOM Report 2012”.

² Ethics reports produced by authors in Canada as well as the states of Minnesota and Indiana, all of which focus on pandemic influenza. Dorothy W. Vawter et al., “For the Good of Us All: Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic” (2009). Available at: <http://www.ahc.umn.edu/mnpanflu/preliminary/rationing/home.html>. Indiana State Department of Health. 2008. *Confronting the Ethics of Pandemic Influenza Planning: Communique from the 2008 Summit of the States*. Available at:

http://www.bioethics.iu.edu/communique_2008_summit_of_the_states.pdf

University of Toronto Joint Centre for Bioethics. (2005). *Pandemic influenza and ethics – stand on guard for thee: Ethical considerations in preparedness planning for pandemic influenza*. Available at:

<http://www.utoronto.ca/jcb/home/documents/pandemic.pdf>

³ New York, for example, has produced an allocation planning document dealing specifically with ventilators. See New York State Workgroup on Ventilator Allocation in an Influenza Pandemic (2007). *Allocation of ventilators in an influenza pandemic: Planning document draft*. Available at;

http://www.health.state.ny.us/diseases/communicable/influenza/pandemic/ventilator/docs/ventilator_guidance.pdf

Creating an ethical allocation framework that can be applied to multiple emergency situations and varying types of medical resource and service scarcity presents a daunting challenge. To achieve this standard, the Guidelines must simultaneously be flexible enough to provide useful guidance in a variety of circumstances and also sufficiently concrete to provide meaningful support in specific situations. We have approached this quandary by providing both general goals and ethical criteria in the body of the Guidelines as well as more specific information in the appendices applying these ethical criteria in various situations.

2. The Guidelines focus on the state of Michigan and are designed to provide targeted guidance to practitioners and officials in the state. From its inception, this project has endeavored to ensure that ethical discussions reflect the values and decisions of the residents of Michigan. Consistent with this goal, these Guidelines have been developed with extensive input from representatives from a variety of constituencies across the state, reflecting a diversity of expertise, geography,⁴
3. The Guidelines consider the ethical implications of allocating scarce medical services as well as scarce medical resources. While the availability of medical resources (such as medication, medical equipment, ICU beds, health care personnel) and medical services (such as routine wellness care, elective surgery) is often closely connected, the factors in making these allocation decisions may raise different ethical and practical considerations.

These Guidelines are not envisioned as a formalized series of instructions but rather a set of criteria that can be employed by decision-makers in various circumstances during a public health emergency using their best professional discretion. It is expected that these Guidelines will be utilized to develop more detailed allocation plans at various levels throughout the state. Thus, the criteria offered within these Guidelines are meant to be malleable, adaptable, and functional. However, extreme or unforeseeable circumstances may challenge the foundations of the framework. In those situations, decision-makers will be expected to use their professional training and prudence to guide

⁴ There have been several other efforts to address the ethical issues that may arise during an influenza pandemic at the regional and hospital levels in Michigan. Three reports in particular have been helpful in our drafting of these Guidelines: 1) Spectrum Health, Caring for the Community: Preparing for an Influenza Pandemic, Ethics Committee Report (2009) further referred to as “Spectrum Ethics Report”; 2) University of Michigan Hospitals and Health Centers Pandemic Planning Committee Ethics Team, Guidelines for Allocating Life-Saving or Critical Resources During a Pandemic (working draft, August 28, 2009) further referred to as “University of Michigan Ethics Guidelines”; and 3) William Beaumont Hospital, Protocol for Allocation of Scarce Critical Care Resources During a Pandemic Influenza Emergency (draft December 16, 2009) further referred to as “Beaumont Ethics Protocol.”

allocation decisions. The criteria offered here may have to be amended to address unforeseen circumstances and should be periodically reviewed and updated to incorporate new information gained from practical experience. Successful implementation of the Guidelines will demand ongoing deliberation, transparency, public education and input, and careful evaluation and oversight.

II. Assumptions

There are many relevant ethical and practical considerations to be taken into account in developing appropriate guidelines for allocation of scarce medical resources and services during a public health emergency. The sections below outline some of the assumptions being used to inform our discussion of the Guidelines.

1. Public health emergencies give rise to unique public health challenges that can lead to, and be exacerbated by, scarcity of medical resources and services. During a public health emergency, health conditions could be dire and may require health workers and government officials to make difficult decisions regarding allocation and prioritization that differ from decisions made under normal conditions. Hospitals and other providers of health services may have to resort to triage techniques and supplies may have to be rationed due to scarcity. Emergency preparedness laws and policies recognize that the legal and operational environment changes during a public health emergency.⁵

2. The likely conditions during public health emergencies may be anticipated even in emergency circumstances that arise from sudden, extraordinary, or temporary events. Some types of public health emergencies present scenarios that are likely to give rise to predictable scarcity in medical resources and services. In other cases, public health emergencies may occur without advance warning, pose unanticipated and extraordinary threats to health, and last for a limited or uncertain duration. Regardless, many of the consequences that may arise during public health emergencies are foreseeable and therefore planning and preparedness efforts, along with proper implementation and response, can mitigate some of the negative impacts of the emergency.

3. Emergency planners have an ethical duty to provide guidance related to the ethical allocation of scarce medical resources and services during public health emergencies. Given that conditions of medical resource and service scarcity are often predictable during public health emergency situations; emergency planners have an obligation to provide guidance to aid decision-makers in navigating the difficult ethical issues that pertain to prioritizing scarce resources and services during public health emergencies. Since allocation decisions impact health across the population and may greatly affect the ability to achieve important public health goals, public health officials at the state level should take a leading role in promulgating this guidance to ensure consistency, visibility, and accountability for the Guidelines. Beyond the state-level guidelines provided in this document, other persons and organizations engaged in emergency planning also should prospectively consider providing targeted ethical

⁵ The Michigan Public Health Code (MCL §§ 333.1101 et seq.) and the Michigan Emergency Management Act (MCL §§ 30.401 et seq.) both have detailed provisions for authorizing legal powers during public health emergencies.

guidance to their respective constituencies regarding the ethical allocation of scarce medical resources and services during public health emergencies.

4. The Guidelines apply to public health emergencies, not everyday scarcity of medical resources and services. These Guidelines are drafted to deal with allocation decisions that may occur during the extraordinary circumstances created by a public health emergency, when these circumstances give rise to medical resource scarcity. In so doing, the Guidelines consider, and are based on, the atypical circumstances of public health emergencies and the heightened risks to morbidity and mortality that may arise in these situations. Therefore, the Guidelines should only apply to public health emergencies as defined in Appendix 1, which are severe events with the potential for widespread morbidity and mortality. The Guidelines are not meant to be applied to decision-making related to allocation of scarce medical resources in other situations. The seriousness scarcity will vary according to the circumstances. Public health emergencies may challenge conventional resource capacity and require contingency or crisis standards for addressing resource and service scarcity.⁶

5. The Guidelines apply to allocation decisions made by decision-makers at different levels of government and as well as the private and nonprofit sectors. One complexity of making ethical decisions regarding allocation of scarce medical resources and services during public health emergencies is that decisions will, by necessity, be made on multiple levels: 1) at the individual level between patients and health care practitioners in both clinical and non-clinical settings; 2) at an institutional level within a hospital, clinic, or other health care site; 3) at a local/regional level; 4) at the state level; and 5) at the national level. These Guidelines therefore consider who will be making the decisions at these respective levels and the effects of decisions from one level on the others. In addition, the Guidelines are designed to be useful to decision-makers at all levels. The Guidelines strive to complement and be consistent with other ethical guidance promulgated throughout the state of Michigan and nationally.

6. The Guidelines apply to allocation decisions affecting all medical resources and services that may become scarce during a public health emergency. During a public health emergency, a variety of medical resources and services may become scarce. The Guidelines view medical resources broadly to include medications, medical devices, medical supplies, and medical professionals. Medical services include the administration of medical care in a variety of settings by a variety of health care practitioners. While the ethical considerations relevant to allocating these various resources and services in differing situations may vary in application, the principles, goals, and strategies suggested by the Guidelines should apply to the full range of decisions. Therefore, the Guidelines should inform both public health-level resource and service allocation decisions and medical-level resource and service allocation decisions during public health emergencies.

⁶ See IOM Report 2012, pp. 1-37 – 1-41.

7. The Guidelines employ ethical principles that take into account both individual health and population health. Scarce medical resource and service allocation decisions have substantial population-level health effects as well as individual-level health effects. Therefore, decision-makers may need to consider the impact of their allocation decisions on population health. The Guidelines recognize this consideration by incorporating ethical principles derived from individual bioethics and public health ethics.⁷

8. The Guidelines should be implemented in ways that comply with all relevant laws at the federal, state, and local levels.

⁷ A detailed explanation of the relevant ethical considerations utilized in this Report is included in Section IV of this report.

III. Goals

The Guidelines recognize three salient goals in determining the allocation of scarce medical resources and services during public health emergencies.⁸ First, efforts should be made to protect and maintain the public's health through *minimizing morbidity and mortality*. Second, we should strive to *sustain a functioning society* through actions to preserve the capacity to deliver health care, public health, public safety, and other social services and critical infrastructure. Efforts to promote trust, transparency, and understanding among the public regarding allocation decisions also support this goal. Third, decisions about how scarce medical resources and services are allocated should *ensure fairness* and endeavor to achieve equality.

These goals are not listed in any particular order of priority and should be pursued concurrently. Several participants in the Committee discussions suggested that these three goals may have different priorities at the clinical level versus the state level and that guidance should be directed accordingly to help at both levels. For instance, the hospital level decision-makers are looking for guidance to help with situation management, while the state level may be focused on minimizing morbidity and mortality levels.

The specific ethical justifications underlying these goals and the principles designed to achieve them are outlined in more detail below.

Minimizing morbidity and mortality: The Ethics Advisory Committee had a general consensus that protecting the public's health was an important goal. Some committee members suggested that this goal should be the primary factor in making allocation decisions. However, a focus on reducing morbidity and mortality alone is not a sufficiently robust goal to direct allocation decision-making. First, achieving this goal faces some inherent difficulties related to the uncertainties of assessing risk and predicting patient outcomes at the population level. Moreover, public health emergencies create risks to population health that go beyond the direct health impacts of the emergency. If critical services become unavailable and there is a fraying of the social order, health consequences may be exacerbated.⁹

Suggestions to minimize morbidity and mortality include:

- employ evidence-based, scientific criteria for decision-making regarding resource and service allocation;
- make allocation decisions based on medical prognosis of a good health outcome rather than by which patient is worst off at the time.

⁸ These goals are adapted from the approach proposed by the state of Minnesota. See Dorothy W. Vawter et al., "For the Good of Us All: Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic" (2009). Available at: <http://www.ahc.umn.edu/mnpanflu/preliminary/rationing/home.html>.

⁹ See "For the Good of Us All" at 14.

Maintaining the social fabric: The Committee determined that several considerations supported the goal of maintaining the social fabric. Targeting scarce medical resources and services to support the ongoing functioning of important social institutions alleviates pressure on systems critical to societal functioning, including health care, public health, critical infrastructure, and public safety. These systems provide needed services to the community, protect against civil disorder, and facilitate efforts to respond effectively to the public health emergency. Committee members also pointed out that the complexity of maintaining a functioning society may be too much to ask of these Guidelines.

There was a robust debate on the issue of which categories of people with which vital skill sets to perform necessary societal functions should receive priority, particularly since granting prioritization based on profession was generally objected to by the Committee. Some groups identified as essential to societal functioning included health care workers, emergency responders, energy workers, police, military personnel, sanitation workers, supply distribution workers, and manufacturers of medical supplies. Maintenance of the health care infrastructure itself was deemed a particularly high priority to the Committee.

An additional consideration for maintaining the social fabric centers on public acceptance of allocation decisions and the ethical justifications for those decisions. Members of the public should have access to information about allocation priorities and the methods by which allocation decisions will be made in public health emergency circumstances. The public should also have an ample opportunity to comment on and provide input to emergency planners regarding these allocation priorities. Fostering transparency, accountability, and an informed populace will increase public support and confidence in the way that scarce medical resources and services will be allocated and will thereby enhance the stability of the social fabric during potentially difficult times.

Suggestions to maintain the social fabric include:

- identify specific groups that are essential to maintaining a functioning society and granting members of these groups some level of priority in accessing certain scarce medical resources and services;
- provide a process for members of essential groups to be quickly and clearly identified;
- provide a process for members of essential groups to receive access to medical resource and services that minimizes the need for individual health care professionals to have to make judgment calls about whether a person qualifies for priority access;
- solicit public feedback on allocation and prioritization plans;
- provide access to allocation guidance to members of the public through many forms of media;

- alert the public promptly to any changes to prioritization plans.

Ensuring fairness: The Committee included fairness as a core goal based upon the fundamental role that fairness plays in both ethical and legal discourse in our country. Fairness recognizes the moral equality of all people and the inappropriateness of treating people disparately in allocation decisions. The Committee recognized the difference between fair access and equal access. Adopting criteria and procedures that fairly allocate resources and services based on pre-determined decision criteria was favored strongly by the Committee, but many acknowledged that equal access (or some measures of equality) would not be feasible under the circumstances of a serious emergency. Moreover, it was noted that the public would understand that equal access is not always possible or appropriate. Many people will be willing to accept a fair process even if they are not fortunate to be at the top of the list for access and some will want to give up their right to access (choose a risk of illness or death) in order to save others. The Committee also acknowledged that tension may exist between what is fair and what is the best overall health outcome during an emergency situation.

Suggestions to ensure fairness include:

- outline fair procedures for decision-making related to allocation decisions;
- endeavor to reduce significant health outcome disparities across demographic categories in the population and across geographic regions of the jurisdiction;
- develop a fair process for allocating resources and services between individuals with equal priority;
- provide the highest level of medical care possible under the circumstances, including palliative care services.

IV. Ethical Considerations

The committee recognizes several underlying ethical considerations that guide the structure, procedures, and recommendations outlined in these Guidelines. These ethical considerations are not listed in any particular order of importance or priority. Rather, any or all of these considerations should be taken into account by those responsible for making allocation decisions during a public health emergency.

Beneficence is the duty to preserve the welfare of others through affirmative acts to promote well-being and save lives. In the context of public health emergencies, beneficence requires that decisions regarding the allocation of scarce medical resources and services strive to protect the welfare of individuals and the community as a whole. The duty of health care professionals and health institutions to provide the best possible care and services to patients is grounded in beneficence as well as notions of professional competence. The related ethical consideration of **utility** suggests that decisions should be made in order to achieve the greatest good for the greatest number.

Fairness demands that the process and the criteria used for allocation of scarce medical resources and services during public health emergencies be consistent, equitable, and non-discriminatory. In the event of a public health emergency, **procedural justice** requires that fair and clear processes be used to make allocation decisions, and that members of society are afforded a fair chance of access based on non-discriminatory criteria. **Distributive justice** in this setting requires that the scarce medical resources and services are fairly and equitably distributed across society. This may require making specific provisions to ensure that access to scarce resources and services is available to vulnerable populations and groups in society affected by disparities in access to health care. Allocation criteria based on fair and equitable factors will promote predictable and consistent decision-making. Fairness does not require that all people have equal access to scarce medical resources and services, but it does require that if certain groups receive priority access to these resources and services, this priority is granted according to appropriate factors such as increased medical risk or susceptibility.

Transparency, accountability, veracity, and trust are cornerstones to implementing a plan to allocate scarce medical resources and services during a public health emergency. **Transparency** refers to providing open access to information and decision-making processes. This allows the public to be aware of the content of and the rationale for allocation decisions and fosters both accountability and trust. In addition, transparency promotes understanding and the opportunity for comment and participation by interested members of the population. **Accountability** of those making allocation decisions also promotes thoughtful, fair, and consistent decisions. The ethical principle of **veracity**, or truth-telling, similarly bolsters trust and accountability. Transparency, accountability, veracity, and fairness are necessary to create **trust** in the allocation processes and criteria. Generating trust helps to encourage compliance with and understanding of allocation decisions.

Respect for persons, the ethical notion that encompasses individual autonomy, privacy, dignity, and bodily integrity, must be upheld during public health emergencies. The decision to provide palliative care resources throughout a public health crisis even if treatment resources and services are not available comports with the ideal of preserving dignity and promoting comfort and care even in the face of resource scarcity.

Proportionality demands that any allocation decisions made be necessary and proportional to the scope and severity of the circumstances.¹⁰ Allocation decisions made under conditions of resource or service scarcity will necessarily create burdens on those providing and receiving care. These burdens should be minimized as much as possible, and the level of health care provided should only be adjusted as little as necessary to address the immediacy of the situation.

Solidarity, the concept that we are all in this circumstance together, binds the community in a sense of shared sacrifice and social cohesion. Solidarity encourages members of the community to accept the validity of allocation decisions so long as they are made transparently and fairly. This notion supports community collaboration and cooperation. This sense of community also promotes the duty of health care workers to continue to provide care and services despite the difficulties created by the situation. As a result of such dedication, the community may reward health care workers for their efforts. The principle of **reciprocity**—compensating someone for past actions or deeds—sustains such actions. Providing priority access to specific essential workers may serve ethical goals of efficiency and utility, but also comports with reciprocity.

Finally, the principle of **stewardship** requires decision-makers at all levels to allocate scarce resources and services to preserve the effectiveness and impact of these resources and services as best as possible. This can be a challenge since it requires decision-makers to weigh competing duties to care for individual patients and to preserve adequate resources for the community and for future needs.¹¹

¹⁰ See IOM report (2009) p. 32.

¹¹ See IOM report (2009) p. 30.

V. Allocation Criteria

A. *Acceptable Allocation Criteria*

The Committee identified two general criteria considered acceptable for guiding allocation decisions: *medical prognosis* and *essential social functions*. These criteria should be considered in conjunction with each other when evaluating allocation decisions. The sections that follow explain the substance of these two criteria and delineate how prioritization decisions regarding the allocation of scarce medical resources and services should be made when people meet one or both of these criteria.

1. Medical prognosis. Medical prognosis should be used to determine priority of access to scarce medical resources and services during public health emergencies. Decision-makers should consider the patient's medical condition, the likelihood of a positive medical response, the relative risk of harm posed by not treating the patient, and other indicia of survivability and favorable medical outcomes. Treating patients according to their medical prognosis directly supports the goal of reducing morbidity and mortality. It is consistent with ethical principles of beneficence, utility, and stewardship.

2. Essential social functions. Workers who perform essential social functions, i.e., those deemed critical for the ongoing functioning of society, should receive priority access to scarce medical resources and services. The Committee agreed that workers who fall into these categories of people would be given priority because preserving their socially-useful functions will facilitate two of our overall goals: maintaining the social fabric and reducing morbidity and mortality. Essential personnel may include:

- health care workers who are directly treating patients affected by the public health emergency (doctors, nurses, behavioral and mental health professionals, etc.);
- personnel key to responding to the public health emergency (first responders, public health scientists, etc);
- personnel key to public safety (police, fire, military, etc.); and
- personnel key to critical infrastructure (energy grid, telecommunications etc.).

Giving priority to health care workers involved in treating and caring for the victims of a public health emergency serves the goals of maintaining social functioning and minimizing morbidity and mortality. With respect to this second goal, prioritizing health care workers has an aggregative effect on reducing morbidity and mortality: not only does providing health care workers priority access mitigate risks to the health and well-being of these critical workers; it allows them in many cases to continue to assist other sick individuals. Prioritization in this way is grounded on ethical notions of utility, reciprocity, beneficence, and efficiency. Many of these same justifications apply to the other categories of essential workers listed above. The Committee stressed however that the use of essential social functions as defined above is the only acceptable measure of

social worth to be used in allocation decision-making. Other considerations of social worth are inappropriate to use as decision-making criteria.

3. Applying the Acceptable Allocation Criteria. The acceptable allocation criteria of medical prognosis and essential social functions may apply to a number of different groups of people, requiring additional decisions to be made regarding the prioritization of scarce medical resources and services. The Committee reached the following conclusions regarding the ordering of priority among people who meet one or both of the two acceptable allocation criteria described above:¹²

Tier 1 (highest priority):

- Essential personnel with high risk of severe morbidity or mortality with a favorable medical prognosis
- Essential personnel that are irreplaceable with a favorable medical prognosis
- Essential personnel that have high occupational exposure with a favorable medical prognosis

Tier 2 (elevated priority):

- Essential personnel with a favorable medical prognosis
- Groups or individuals with elevated risk of severe morbidity and mortality with a favorable medical prognosis
- Groups or individuals with moderate risk of severe morbidity and mortality that have a high risk of exposing others (may not apply in some public health emergencies)¹³

Tier 3 (lowest priority):

- All eligible groups or individuals

B. Situation-Dependent Allocation Criteria

The Committee identified three criteria—*age*, *lottery*, and *first-come, first-served*—that could be considered for medical resource and service allocation under limited circumstances due to their controversial nature. The Committee acknowledges that reasonable decision-makers may disagree on whether these criteria are appropriate to

¹² These categories are adapted from models put forward by the state of Minnesota and the Department of Health and Human Services in their influenza pandemic allocation plans.

¹³ This category will only apply in situations where the causative agent of the public health emergency is an infectious disease or otherwise transmissible agent that can spread from affected persons to others with whom they come into contact. For example, if the scarce resource is medication to treat an infectious agent that can be transmitted respiratorily, then health workers likely to come into contact with this agent through their occupational exposure may receive priority access to the treatment. In some cases, this group may include the close family members of essential personnel as well, due to their heightened risk of exposure.

use. Yet, these criteria may be useful if scarcity requires prioritization between people who would be indistinguishable on the basis of the acceptable criteria of medical prognosis and essential social functions. Criteria based on longevity or functioning, such as age or quality-adjusted life years could provide additional stratification among the population to assist with allocation decision-making. Alternatively, a random sorting process such as a lottery or a first-come, first-served model could be used. These criteria should only be used as secondary allocation criteria to medical prognosis and essential social functions. Further, these criteria should only be used with appropriate procedural protections, including advanced notice to the public that they will be used, to ensure that they are implemented fairly and transparently. This guarantee of adequate process comports with ethical notions of fairness, transparency, accountability, veracity, and trust.

1. Age: Granting priority to access scarce medical resources or services based on numerical age, quality-adjusted life-years, disability-adjusted life-years, or some other measurement based upon longevity or functioning raises several difficult issues. The “fair innings” argument states that everyone should have the opportunity to live a full life, and those therefore younger individuals should receive preference over older individuals. This approach comports with notions of equality in one sense and cuts against equality in another sense. It may be fair to allow a younger person to have the chance to live to an older age, given that older people have already had the opportunity to experience those phases of life. But this approach goes against equality in the sense that it is making an explicit differentiation between people on the basis of numerical age. It also undermines attempts to achieve intergenerational equity in allocation decisions.

Other commentators have long tried to develop more sophisticated approaches and justifications for criteria based on longevity and functioning through the use of measurements such as quality-adjusted life years (QALYs) and disability-adjusted life years (DALYs). These measurements attempt to place a value on future life-years as opposed to just using numerical age as the relevant criteria. These approaches therefore adopt a different set of considerations, not just who will live the longest life, but also who will live the “best quality” life whether that is measured by health, self-satisfaction, or contributions to society. These approaches are problematic for some of the same reasons as the fair innings model, and in some ways they raise even more concern because they may introduce subjective evaluations of quality of life in the calculation.

2. Lottery: A lottery approach gives each eligible person an equal random chance to be selected to receive scarce medical resources or services. A lottery has two inherent advantages: 1) if conducted correctly it will lead to a truly random allocation across the population and 2) therefore it provides an allocation strategy that strongly upholds the goal of fairness. On the other hand, the random allocation approach advanced by a lottery is not conducive to minimizing

negative health consequences and resource stewardship since it does not allow for resources to be targeted. In addition, a lottery requires top-down coordination and consistent application for it to be equitable. The Committee considered the use of a lottery approach as a tie-breaker between potential recipients of scarce medical resources and services in the event that all other criteria are equivalent and scarcity persists. While the Committee generally supported the idea of using a lottery under these limited circumstances, the Committee did not come to a consensus on how such a lottery provision would be structured or implemented.

3. First come/First served: Another alternative allocation approach—first-come, first-served—presents several challenges from ethical and practical perspectives. This approach is potentially problematic as a sorting mechanism because it favors those with existing informational, social, and economic advantages. Nevertheless, it is the easiest to administer and generally accepted in non-emergency situations. Other states have endorsed the use of a first-come, first-served approach in their allocation plans for scarce medical resources during public health emergencies.

Table: Random sorting approaches – Pro and Con

	Pro	Con
Lottery	<ul style="list-style-type: none"> • Truly fair and completely random 	<ul style="list-style-type: none"> • Not conducive to minimizing morbidity and mortality or stewarding resources • Complex to administer
First come, first served	<ul style="list-style-type: none"> • Easy to administer • Widely accepted 	<ul style="list-style-type: none"> • Not truly fair since those with information and resource advantages will gain priority over those who do not

C. Unacceptable Allocation Criteria

The Committee identified several criteria that are unacceptable to consider when making allocation decisions. These criteria have been rejected due to their inherent lack of fairness, potential for abuse or discrimination, or irrelevance to achieving the goals set out in these Guidelines.

1. Social characteristics: Social characteristics, including but not limited to race, ethnicity, gender, national origin, sexual orientation, religious affiliation, and disability unrelated to immediate medical prognosis, should not be used as criteria in making resource or service allocation decisions during public health emergencies. These characteristics serve no meaningful purpose in differentiating between people in the context of allocation decisions. Moreover, categorization of people according to these types of characteristics is often used as pretext for favoritism, discrimination, and reduced access for minority groups. Therefore, use of social characteristics as allocation criteria is unacceptable.

2. Social worth: The discussion of acceptable allocation criteria (in section V.A. above) recognizes that limited categories of people who provide specific social functions, namely groups of identified essential personnel, may be granted priority access to scarce resources and services during a public health emergency. However, beyond these limited categories, factors that take into account a person's social worth are not acceptable to consider for allocation decisions. Social worth criteria are generally unacceptable because they can lead to unfair decisions based on subjective determinations of a person's background or characteristics, which can in turn lead to stigma, bias, greed, or nepotism in allocation decisions. Unacceptable factors under this category would include but are not limited to job status, training or education, social standing, personal or familial relationships, belief systems, political affiliations, or any other measurement of a person's social value. In particular, the Committee found unacceptable any sort of decision-making process that considered a person's ability to pay for medical resources or services as relevant to prioritizing resources or services. Similarly, it would be inappropriate for providers of medical resources and services to take into account the financial or economic consequences of a person's ability to pay in making allocation decisions for scarce medical resources or services.

VI. Implementation

1. Efforts should be made to eliminate scarcity prior to having to implement allocation guidelines. At all levels of planning, from the state government to individual health care institutions, efforts should be made to acquire sufficient levels of medical resources and services to alleviate the need for rationing these resources and services. Public health emergency preparedness planning can foster efforts to eliminate scarcity through the implementation of consistent and coordinated plans to share, stockpile, and estimate needed resources in advance of a predictable public health emergency scenario. Additional strategies may include sharing resources with other entities and possibly transferring patients to other settings that will have access to adequate resources.¹⁴

Despite the best efforts to avoid scarcity of medical resources and services during public health emergencies, it is inevitable that in some situations medical resources or services will become scarce, either due to unanticipated emergency circumstances, scientific limitations, or political and economic constraints on access to resources and services. The implementation of these Guidelines should only occur after all reasonable efforts to avoid scarcity have been explored. Additionally, as is further developed below, scarcity often occurs on a continuum and will vary over time as conventional capacity gives way to contingency strategies for conserving resources or the outright scarcity of a crisis situation.¹⁵

2. The probability of scarcity occurring should be assessed and planning should occur to prepare for scarcity. Scarcity of medical resource and services may emerge through various mechanisms during a public health emergency. The process of public health emergency preparedness planning should include assessing the likelihood of medical resource or service scarcity to materialize. Admittedly, in some situations this probability will be quite difficult to determine. Nevertheless, closely evaluating the potential for scarcity can assist with preparedness and allow for increased readiness should the Guidelines have to be put into place.

3. Criteria should be offered to determine when scarcity exists and when prioritization guidelines should be used. The Guidelines should only go into effect after conditions of scarcity have developed. What is scarcity and when is it sufficiently problematic to resort to prioritization approaches? Scarcity of medical resources and

¹⁴ The Task Force on Mass Critical Care agrees with this provision. See Devereaux et al., Definitive Care for the Critically Ill During a Disaster: A Framework for Allocation of Scarce Resources in Mass Critical Care 133 Chest 51-66 (2008). Suggestion 4.2 states: “All attempts should be made by the health-care facility to acquire scarce critical resources or infrastructure, or to transfer patients to other health care facilities that have the appropriate ability to provide care (state, national, and even international). Critical care will be rationed only after all efforts at augmentation have been exceeded.”

¹⁵ See IOM Report 2012, pp. 1-37 – 1-41.

services during a public health emergency may take many forms. Whether sufficient scarcity exists to merit the use of prioritization guidelines with respect to a specific medical resource or service can be evaluated using the following factors:

- Nature of scarcity
- Duration of scarcity
- Severity of scarcity

a. Nature of scarcity: What type of resource or service is in short supply? Is this a resource or service that can be adequately replaced by an alternative resource? In order to evaluate the intersection of complementary resources, decision-makers should weigh different allocation strategies to maximize all resources and services. Should, for example, staff forgo prophylaxis with oseltamivir during an influenza outbreak and use protective personal equipment instead in order to preserve the supply for sick patients?¹⁶

Some members of the Committee and external reviewers felt that the nature of the scarcity should be considered in determining priority for essential personnel compared with others at risk. These commenters felt that a distinction should be made between resources used for prevention, protection, and treatment where the patient is likely to have a rapid recuperation, and treatment resources necessary for long-term recovery. While priority access to resources for prevention, protection, and short-term treatment were ethically warranted in order to maintain health system capacity and the social fabric during an emergency, essential personnel who were not likely to be able to recuperate quickly and continue to assist others during the emergency should not have priority access to treatment resources needed for long-term recovery. Others on the Committee felt that essential personnel should receive priority to all types of scarce medical resources regardless of whether their recovery would be expeditious. These commenters based their support on notions of reciprocity and utility, as such prioritization would be a strong incentive for essential personnel to participate in emergency response efforts. The decision whether to differentiate between types of resources in granting priority to essential personnel relative to others should be assessed further by decision-makers implementing these Guidelines.

b. Duration of scarcity: What is the likely length of time that the scarcity will persist? If the scarcity is only likely to be of short duration (a few hours or days), then the use of prioritization strategies may not be appropriate. Scarcity of specific medical resources or services may rise and fall over time. For example, during an influenza pandemic vaccines may become more available over time as the production

¹⁶ See Harvard School of Public Health case study.

of a vaccine to combat a new flu strain is successfully produced, while antivirals may become more scarce as initial stockpiles are used up.¹⁷

c. Severity of scarcity: How significant is the shortage of the medical resource or service? How widespread is this shortfall? How significant are the consequences of not being able to provide access to that resource or service? The severity of scarcity of a particular resource or service not only informs decision-makers of the relative restrictions that may be imposed on their access to the scarce resource or service, it may also dictate the appropriate allocation strategy for the resource or service.

These criteria can be assessed on a continuum. The greater the duration and severity of scarcity, the more likely that using the prioritization criteria will be warranted.

4. Fair and transparent processes. Allocation decisions made under conditions of scarcity should adhere to clear and specific processes to ensure that these decisions are not being made in an unjust or discriminatory manner. Members of the public should be forewarned of the possibility of medical resource and service scarcity, the means by which decisions will be made in those eventualities, and who will be accountable for making such decisions. These defined processes should be followed by both public- and private-sector decision-makers. Appropriate procedural protections also include designated mechanisms to appeal allocation decisions. These and other process guarantees will foster fairness, transparency, accountability, trust, and consistency in the application of these Guidelines.

5. Prioritization guidelines and decisions should be reviewed continuously and periodically assessed. The policies and practices that emerge from these Guidelines should receive ongoing scrutiny to assure their relevance to the circumstances at hand. If scarcity abates, then measures to control access to medical resources and services pursuant to these Guidelines shall be discontinued. Once the Guidelines have been implemented, resource scarcity should be periodically reassessed (the timeline for which will be determined by the resource and the situation) to ensure continual allocation and reallocation in keeping with the tenants of these Guidelines.

6. Prioritization guidelines should be used consistently across the state. Consistency in implementation of the Guidelines will promote fairness in access to scarce resources and services and will defuse allegations of favoritism and efforts to “venue-shop” for medical resources and services. Also, consistent application of the Guidelines can promote the goal of minimizing morbidity and mortality by fostering a coordinated public health response. However, local conditions may require allocation decisions to deviate from statewide guidance under some circumstances. Decision-makers who are

¹⁷ Marcel Verweij, Moral Principles for Allocating Scarce Medical Resources in an Influenza Pandemic, 6 Journal of Bioethical Inquiry 159-169, at 161 (2009).

departing from common guidance should only do so after careful deliberation and documentation.¹⁸

7. Decisions to implement prioritization should be made by persons removed from the clinical context. To minimize conflicts of interest and difficult interactions at the clinical care level between health care providers and patients, decisions regarding when to apply these Guidelines should be made by decision-makers removed from the clinical context whenever possible. These decision-makers should take into account the broader systemic, community, and population-level resource needs in determining whether implementation of these Guidelines is necessary to address the medical resource and service shortages created by the specific public health emergency at hand. In addition, health care professionals should not be required to determine which patients qualify as essential personnel. This determination should be made by decision-makers removed from the direct clinical relationship. While health care professionals have a great deal of expertise in assessing a patient's medical prognosis, these professionals may be placed in a difficult position if they have to determine whether a patient requesting resources qualifies as a member of a prioritized essential personnel category.

8. Palliative care resources should be provided consistently throughout a public health emergency. When the guidelines are activated, it is possible that some individuals will not have access to some scarce medical resources and services based on allocation decisions. As a result, access to palliative care resources and services should be provided to these persons in order to minimize pain and suffering. It is critical that palliative care professionals be available to care for patients who may not receive scarce medical resources and services. The overall management of the public health emergency will be strengthened by providing persons in need with compassionate pain management and means to alleviate their symptoms, as well as offering emotional support and grief and bereavement services to patients, family members, and the community.¹⁹

¹⁸ IOM report (2009), p. 32.

¹⁹ IOM Report 2012, pp. 1-78 – 1-85.

ANNEX 1: SPECIFIC GUIDANCE FOR EMERGENCY MEDICAL SERVICES AND MEDICAL CONTROL AUTHORITIES

Introduction

The allocation of resources and services during emergency-induced situations of scarcity must be based on a sound ethical framework. This attachment provides specific guidance to actors and entities functioning in Emergency Medical Service (EMS) agencies and Medical Control Authorities (MCA), to assist these actor entities in planning for resource and service scarcity that may arise during public health emergencies. This attachment applies the general ethical guidance offered in the Ethical Guidelines for Allocation of Scarce Medical Resource and Services during Public Health Emergencies in Michigan (Guidelines) to the specific context of EMS and addresses in detail some considerations that may arise in this context. It also offers potential strategies for implementation of the Guidelines in the EMS setting.

EMS agencies and Medical Control Authorities should review the ethical framework presented in the Guidelines to ensure that their decision-making strategies for allocating scarce resources and services during public health emergencies comport with the principles and considerations outlined in the Guidelines.

These Guidelines are not envisioned as a formalized series of instructions but rather a set of criteria that can be employed by decision-makers in various circumstances during a public health emergency using their best professional discretion. Thus, the criteria offered within these Guidelines are meant to be malleable, adaptable, and functional. It is presumed that many hospitals and healthcare facilities will adapt the approaches and strategies contained in this document, tailored to fit the circumstances of their specific facility.

Extreme or unforeseeable circumstances may challenge the foundations of the framework. In those situations, decision-makers will be expected to use their professional training and prudence to guide allocation decisions. The criteria offered may have to be amended to address unforeseen circumstances and should be periodically reviewed and updated to incorporate new information. Successful implementation of the Guidelines will demand ongoing deliberation, transparency, public education and input, and careful evaluation and oversight.

Background

Public health emergencies have often led to scarcity of medical resources and services. The history of epidemic outbreaks, natural disasters, and other mass casualty events has demonstrated the need to prepare for medical surge planning across all medical disciplines and systems. These types of public health emergencies could

seriously impact the State of Michigan, its health care and public health systems, its transportation systems, its economy, and its social structure. Emergency medical services (EMS) will be faced with higher demands for services. EMS will experience problems similar to other health systems across the State, such as increased employee absenteeism, disruption of the supply chain and increased rates of illness and death. Public Safety Answering Points (PSAP) or 9-1-1 dispatch centers serve as the public's point of access to EMS, law enforcement, and fire services, as well as an avenue for requesting many other services. Ensuring both the dispatch centers and EMS are well-integrated into medical surge planning and response is essential to the health and safety of the citizens in a public health emergency.

The EMS and PSAP/9-1-1 Systems will be part of a group of medical providers that will have to decide how they will respond to a significant influx of patients during an incident. It is of the utmost importance that they have all of the tools necessary to make ethically sound and important decisions with regard to allocation of scarce medical resources and services. The objectives discussed in this attachment will assist local and regional responders in making important decisions that protect the lives and safety of both responders and patients alike.

Ethical Framework

The Guidelines developed for the State of Michigan discuss in detail the principles and methods used to develop the ethical framework. This attachment to that document endorses the same goals, ethical considerations, and allocation criteria. Several specific ethical considerations are highlighted below.

- Professional obligations to individual patients
- Professional and institutional obligations of competence
- Professional and institutional obligations of honesty and transparency
- Distributive justice, including equal treatment, utility
- Fair procedures, including in planning and implementation
- Accountability and legitimacy

Each of the above ethical considerations applies to the overarching aim of the document, which is the distribution of scarce medical resources and services in an ethical fashion within EMS and MCA settings. Planning and preparation of health care professionals working in EMS settings to respond ethically to situations of resource scarcity underlie both professional and systemic obligations to provide competent and just care to patients. Preparing the community for the types of difficult allocation decisions that may arise through public engagement and education supports obligations of honesty and transparency, and adds legitimacy to and accountability for these difficult decisions if they need to be made in the future. Distributive justice cautions against the possibility of applying different criteria to allocation schemes across different systems

and communities. Cooperation between Medical Control Authorities, EMS systems, and hospitals, and developing consistent allocation guidelines, by contrast, supports fairness and distributive justice. Prudent planning to increase stores of certain items proactively can avoid unnecessary shortages and is key to ethical planning. The protection of disabled and marginalized individuals in these circumstances is imperative. Therefore, criteria related to an individual's social utility and expected longevity to make allocation decisions should not occur.

The EMS Ethical Obligation

The National Association of Emergency Medical Services Physicians (NAEMSP) has outlined a number of important ethical obligations for EMS systems that hold themselves out to community as emergency response networks and those working within these systems. EMS systems assume the important ethical duty to respond “regardless of the patient’s income or social position. Care must not be limited to any specific group or class of people.” EMS responders have a duty to provide medically acceptable care to all, consistent with the standards of the EMS system.²⁰

EMS often determines priorities of care according to severity. During a public health emergency, EMS must adhere to set protocols and sound medical information, which may result in delaying or refusing transport for patients with minimal illnesses. In developing this triage system, EMS must take into account equitable considerations to ensure fairness and avoid arbitrariness in allocation decisions, while allowing for adequate response to the ill and injured. As noted by the NAEMSP, “when planned appropriately, EMS might be regarded as one of the most fair of health care institutions.”²¹

Beyond treatment, EMS personnel commonly deal with situations which require them to take on differing roles, which can create further ethical dilemmas. The EMS provider “must frequently interact and negotiate with reluctant patients, counsel those patients who ask for advice or refuse care, address requests for limitation of resuscitation, assume some degree of personal risk in the care of agitated, uncooperative, or infectious patients, deal with social and psychiatric challenges, and respond to a variety of unusual requests which may not be medical in nature.” NAEMSP has recognized three ethical principles that are meant to govern EMS personnel in their delivery of care. “The principle of justice implies that the system be fair and equitable. The principle of

²⁰ Ethics Committee, National Association of Emergency Medical Services Physicians, *Ethical Challenges in Emergency Medical Services Prehospital and Disaster Medicine*, April-June, 1993. <http://www.naemsp.org/documents/EthicalChallengesinEmergencyMedicalServices.pdf>

²¹ *Id.*

beneficence requires that actions and intentions are in the best interest of the patient. Respect for patient autonomy dictates that the requests of the patient are honored and nothing is done which is contrary to the wishes of the patient.”²²

Training alone does not prepare the EMS provider to deal with ethical situations. Many learn by experience; prehospital providers are guided by clearly defined protocols. Coupling the above principles with established EMS protocols and educating EMS providers about ethical conflicts that may arise should promote the appropriate ethical resolution of dilemmas encountered by those who provide and direct EMS care during public health emergencies.

Duty to Provide Care

EMS systems provide the community with important health care services, while presenting a unique and challenging environment for providers of these services. NAEMSP states that “[t]he primary mission of EMS is the reduction of patient morbidity and mortality through the delivery of fast and efficient highly specialized care.”²³ EMS systems have a duty to provide care to the community as they pursue this mission. This duty applies across the spectrum of EMS services and from the moment a patient contacts 9-1-1, through dispatch, treatment, transportation, and release.

In order to limit potential ethical conflicts, EMS systems must establish policies and protocols that outline the duties of their personnel. The more clear these policies and protocols, the greater the likelihood of ethically sound care. These policies should include, when appropriate, assurances that EMS personnel will have access to adequate equipment and training, offer timely and safe response, and provide patients with medically acceptable care, together, these policies outline the primary ethical duties of an EMS system. Additionally, the NAEMSP notes that an EMS system has an additional “duty to meet the commitments which it undertakes” for the safety of patients and providers.²⁴

EMS agencies should coordinate with other health care providers and public health authorities to ascertain the scope of their responsibility for providing services in the community, including their role in providing emergency situation mitigation measures. EMS agencies should develop contingency plans to account for situation in which community mitigation strategies have varying levels of effectiveness. Moreover, public health and EMS planners should be aware of ethical considerations surrounding

²² Id.

²³ [Id.](#)

²⁴ [Id.](#)

decisions that may affect public perceptions and response to community mitigation strategies.

Illness, absenteeism, increased workload, and death during a public health emergency may impact an EMS agency's ability to satisfy demand for services. Planned flexibility in staffing patterns, recruitment, and just-in-time training programs may help augment the EMS workforce. As the provider of emergency medical triage in the prehospital setting, along with treatment and transport, EMS plays an important role in every community's efforts to reduce morbidity and mortality from all sudden illness and injury.²⁵

The normal standard of care during an emergency response can be understood as requiring caregivers to provide "all appropriate health and medical resources" that may be available to benefit of each patient. However, according to the Agency for Healthcare Research and Quality (AHRQ); "should a mass casualty event occur, the demand for care provided in accordance with current standards would exceed system resources." The definition of "mass casualty" can change dramatically given the context of the event. What may be deemed a manageable incident in a large metropolitan area could be insurmountable number to treat in a small rural hospital. When an emergency causes injuries number far above what the system is capable of managing, altered standards of care may need to be implemented in order to preserve the system and mitigate morbidity and mortality. As the AHRQ goes on to note, "[i]t may also be necessary to create both pre-hospital operations and alternate care sites to supplement hospital care."²⁶

There is no generally accepted definition of "altered standards of care". However, this concept is typically interpreted to adjust the focus of care and allocation criteria from saving individuals to preserving the greatest number of patients possible under the circumstances. Meeting this goal could implicate a number of varying strategies, from the implementation of triage standards, to altering the criteria for who receives vaccinations, to using a school or other non-medical facility as a hospital alternative due to overflow.² Altered standards of care also may involve "changing who provides various kinds of care or changing privacy and confidentiality protections temporarily".²⁷

Efforts to develop ethically sound standards of care that allow EMS providers to deviate from their established, day-to-day treatment protocols support the evolving role of EMS while still providing for appropriate patient care. The State of Michigan will support regional and local EMS in establishing altered standards of care to legally deviate

²⁵ Id.

²⁶ <http://www.ahrq.gov/research/altstand/altstand2.htm>

²⁷ <http://www.ahrq.gov/research/altstand/altstand2.htm>

from everyday treatment protocols during response to a public health emergency and will support mitigation of and response to affected patients. EMS plans should identify sufficient State legislative authority, administrative rules/regulations, and liability protection to support the role of EMS providers during public health emergencies. The Medical Control Authority should provide for a system in which the treatment and protocols that EMS providers are authorized to use may be modified to reflect the evolving roles of EMS providers during an emergency incident that requires scarce medical resources. During this time the Medical Control Authority should assure medical direction, appropriate education, and quality assurance. EMS agencies and providers should, through protocol, coordinate with their EMS Medical Directors, and working with local healthcare facilities, provide just-in-time training for their responders during times of public health emergencies. The practice of EMS providers should be based on the most up-to-date clinical recommendations and treatment protocols/information from appropriate medical and public health authorities.

It is virtually impossible to create a scope of practice that takes into account every unique situation, extraordinary circumstance, and possible practice situation. This is further complicated by the fact that EMS personnel are an essential component of disaster preparedness and response. In many cases, EMS personnel are the only medically trained individuals at the scene of a disaster when other healthcare resources may be overwhelmed. If predictions about the surge of patients and the concomitant increase in absenteeism among EMS personnel become a reality, EMS providers' regular day-to-day practices may need to be modified during times of medical surge.²⁸

Ethical Resource and Service Allocation Decision Process

Public health emergencies may require EMS providers to prioritize access to services for those patients most likely to benefit from evaluation and treatment. Ensuring adherence to this strategy may require EMS systems to alter standards of care to reflect the circumstances of each incident, including in some cases the adoption of patient triage and service protocols. The Medical Control Authority will determine the EMS standard of care stage in response to the situation and any alterations in standards of care will apply to the EMS agencies in that Medical Control Authority. Section 20919 of the Public Health Code requires each Medical Control Authority in the State of Michigan to establish written protocols. The protocols, once adopted by the MCA and approved by MDCH have the force and effect of law. "Licensed life support agencies and individuals are accountable to the MCA in the provision of emergency medical services as defined in protocols. Each participating and non-participating hospital within a MCA region shall follow all standards, policies, procedures, and protocols established by the MCA as

²⁸ Id.

approved by the Department. Each MCA shall submit to the department current protocols for department review and approval.”²⁹

Table 1. EMS procedures will follow the schedule below:

EMS Standard of Care Staging ³⁰	Stage - Green 911 communications and/or pre-hospital response systems and/or hospitals at or near capacity	Stage - Yellow 911 communications and/or pre-hospital response systems and/or hospitals beyond capacity	Stage - Red 911 communications and/or pre-hospital response systems and/or hospitals and surge systems beyond capacity
Expansion of EMS personnel	Combining services or cross coverage	Use of Echo car or triage officer	Use of medical first responder or CERT volunteers
Implementation of alternate transport	See Response Triage Table 2	See Response Triage Table 2	See Response Triage Table 2
Implementation of treat and release protocols	See Response Triage Table 2	See Response Triage Table 2	See Response Triage Table 2
Single responder vehicles	No	Yes	Yes
Call Triage	Yes	Yes	Yes
Response Triage	No	Caller Notification	Emergent Calls Only

EMS PROTOCOLS: Scope and Applicability³¹

The protocols presented in this document apply to public health emergencies in which there is a sustained shortage of EMS services and personnel. Plans exist to identify resources available locally through the Medical Control Authorities (MCA), regionally through the Medical Coordination Centers (MCC), and statewide through the Community Health Emergency Coordination Center (CHECC) in coordination with the State Emergency Operations Center (SEOC). When all Michigan based resources are exhausted, the state may request Federal assistance through the SEOC. Mobilization of external resources through mutual aid from local and regional partners to supplement EMS services in localized areas of disaster is the preferred approach.

²⁹ http://michigan.gov/mdch/0,1607,7-132-2946_5093_28508-132260--,00.html

³⁰ Adapted from the “North Dakota EMS, Emergency Medical Service Pandemic Surge Protocols and Public Safety Answering Point Pandemic Surge Protocols”, 2010, <http://www.ndhealth.gov/EPR/Publications/EMS-PSAP-Stages-for-Standards-of-care2.pdf>

³¹ This section of the document is adapted from the document “Emergency Medical Service Pandemic Surge Protocols and Public Safety Answering Point Pandemic Surge Protocols,” published in 2010 by North Dakota’s EMS.

This document addresses a few specific protocols related to the delivery of care by EMS during a public health emergency. The first protocol addresses patient triage, which includes alternate forms of transport and the treatment and release of patients. The second protocol covers management of resources by standard of care staging, which includes personal protective equipment and antiviral distribution and use, the role of first responders, and the responsibilities of triage officers.

Assumptions Related to Pandemic Influenza or other Infectious Agents

During a pandemic influenza outbreak there will be some assumptions that must be taken into account in order for EMS personnel to prepare. First, a moderate to severe outbreak has the potential to overwhelm health care providers and available resources will be inadequate to serve the number of patients needing care, resulting in prioritization and rationing. Moreover, the number of calls being received by 911 dispatchers will greatly increase, which in turn will markedly increase the number of responses requested of EMS. These calls are likely to be primarily health related, although public safety calls may also increase depending on the situation. The number of workers available to staff EMS and 911 call centers will probably dwindle as a result of the spread of illness (whether due to infection of workers themselves or secondary reasons, such as school closures or responsibilities to care for ill family members). Workforce shortages may have an especially severe impact on service capacity in rural areas, since personnel fulfilling EMS and phone operations in these areas are often volunteers or very few in number to begin with. Emergency planning efforts must account for these anticipated staffing shortages.

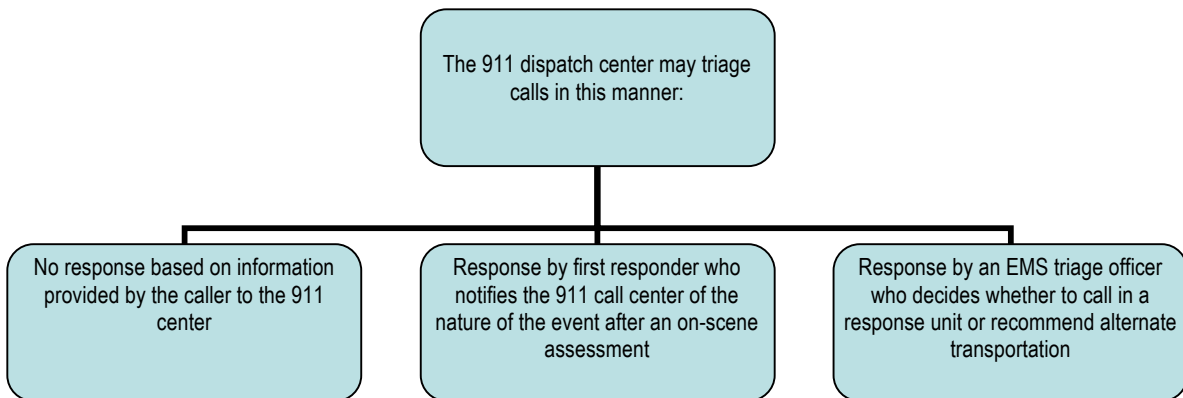
Assumptions Related to Other Public Health Emergencies

EMS Standard of Care

As discussed above, overloading of the EMS system is a significant risk during a public health emergency, resulting from an increase in patients and a potential decrease in available staff. Should this occur, the MCA may adopt altered standards of care to guide EMS systems in their response decisions. For example, an emergency protocol may implement a system of prioritization based on the condition reported to the operator of an emergency call, which determines whether EMS personnel should initiate an on-scene response. Another example would be a protocol that allows EMS personnel on-scene to determine the level of care required based on patient assessment. A third example would consider modifying the usual staffing requirements, recognizing the increased workload and limitations on response due to limited availability of personnel and other resources. Other emergency protocols not described here may be appropriate to implement as well. Several specific scenarios are described in the sections that follow.

Triage of On-Scene Response by Standard of Care Stage

The most effective way to reduce the workload on EMS systems during a moderate or severe public health emergency is to limit the number of calls that must be responded to by EMS personnel. As noted above, during a public health emergency, the altered standard of care allows for such decisions to be made ethically. The diagram below identifies three scenarios under which a 911 dispatcher may triage calls consistent with the standard of care.



The content of the call and the availability of resources at the time will dictate which of the above response methods are appropriate for the call center to use. Triage decisions should be made with a goal of ensuring the best possible resource allocation with the available information. Table 2, on the following page, outlines in detail a prioritization scheme to be applied to pre-scene information during public health emergencies. If the nature of the call is consistent with a response priority of zero, the PSAP/911 call center may choose not to send an EMS response. Although, the dispatcher's decision may have to be made with less than complete information obtained from the caller, the presence of a first responder or triage officer at the scene may improve the assessment of relevant circumstances to assist the dispatcher in making this decision. If the information comes into the PSAP/911 call center from an unreliable source, such as a child or intoxicated person, the decision to not send emergency responders would probably not be suitable. The distance between the responding unit and the response area also may be taken into consideration in making a response decision because of the extended time commitment of resources required when the response area is further from the responding unit. Additionally, in situations where an EMS system is faced with more severe emergencies requiring immediate assistance than it can handle, the system should request that the 911 call center identify additional EMS resources from existing mutual aid agreements that can respond immediately.

Table 2. Response Triage Based Information Available Pre-Scene to be Utilized by 911 Dispatch Centers³²

Response Triage by Standard of Care ³³ Patient Categories	Stage - Green	Stage - Yellow	Stage - Red
1 Cardiac Arrest	Priority 1 Current Standards of Care	Priority 1 Current Standards of Care	Priority 0 Adult - No response Pediatric- Priority 1 Priority 1 *
1 Life threatening event, threatening scene*	Priority 1 Current Standards of Care	Priority 1 Current Standards of Care	Alternate transport considerations if EMS is delayed anticipated Priority 2 *
2 Life threatening event, non-threatening scene	Priority 2 Current Standards of Care	Priority 2 Current Standards of Care	Alternate transport considerations if EMS is delayed anticipated Priority 3
2 Non-critical ALS assessment	Priority 2 Current Standards of Care	Priority 3 Alternate transport considerations	Priority 3 Alternate transport considerations
2 Inter-facility transport unstable patient	Priority 2 Current Standards of Care	Priority 2 Current Standards of Care	Priority 3 Current Standards of Care
3 BLS Assessment/unknown scene risk	Priority 3 Alternate transport considerations	Priority 3 Treat and Release considerations	Priority 4 Treat and release considerations
3 Inter-facility transport stable patient	Priority 3 Current Standards of Care	Priority 3 Alternate transport considerations	Priority 4 Alternate transport considerations
3 BLS Treatment	Priority 3 Alternate transport considerations	Priority 4 Treat and release considerations	Priority 4 Treat and release considerations
4 No acute illness or injury	Priority 3 Refer call, no on-scene response	Priority 4 Refer call, no on-scene response	Priority 4 Refer call, no on-scene response

*Threatening scene is a location in which the scene poses a potential danger to the health of the injured or ill person independent of the injury or illness itself (e.g., cold environment) or in which the person is trapped or pinned.

*Priority One - Serious Life Threat Priority Two – Life Threatening
Priority Three- Potential Life Threat Priority Four- Non life threatening³⁴

³² <http://www.ndhealth.gov/EPR/Publications/EMS-PSAP-Stages-for-Standards-of-care2.pdf>

³³ The responding unit may ascertain whether sufficient resources are available to permit a higher level of care than that authorized by the state-recognized disaster standard of care. Alternatively, the EMS provider may implement a policy adopting the state-recognized disaster standard of care thereby designating that sufficient resources are not available to provide a higher level of care.

³⁴ Clawson JJ: Emergency Medical Dispatching. In: Principles of EMS Systems. Rousch WR,

Treat and Release

In simplest term, treat and release, is just as it sounds. After assessment, or treatment of a patient on site, the EMS unit decides no further treatment is required and does not transport the patient to a hospital or care facility. While the patient is free to pursue further care on their own, the EMS unit is under no obligation to provide transportation, even if no alternative transportation is available. Treat and release provides the patient with an assessment and adequate treatment on-site, yet does not prevent EMS personnel from responding to other calls. Thus, treat and release may be utilized to preserve scarce resources for patients, and does not prevent the patient from pursuing further care independently.

There are several criteria that must be met before treat and release can be incorporated into EMS response. The Governor must declare a disaster, the protocols written by the MCA must include treat and release as an acceptable option, and EMS personnel must not identify any “illness or injury likely to result in patient harm” if not transported to a hospital (or other health care provider) immediately. If all of the above conditions occur, after thorough evaluation and treatment of the patient, EMS personnel may release the patient and move on to other responses.

Several alternative scenarios may challenge the straightforward treat and release criteria described above.

- If patient refuses treatment but other criteria are met for treat and release, patient may be released without treatment.
- If treat and release is not advisable, but resource constraints are severe, the next alternative is assessment for alternative transport.
- EMS personnel unit always have the option to transport assuming resources permit.
- If transport is not available on scene, EMS provider may conclude that the patient can be left pending arrival of the transport based if the conditions are sufficiently safe.

The utilization of the treat and release protocol also is subject to some limitations to ensure that no patient suffers as a result of over-use of this response protocol.

- Use of this protocol assumes that patients are provided the highest level of care available given resource scarcity.
- Application of the treat and release protocol is optional, not mandatory. Responding EMS personnel may employ this protocol under certain situations as defined by the MCA. However, the decision to employ this protocol comes within the judgment of the EMS personnel.

Alternate Transport

The alternate transport protocol is an option that may be available in some treat and release situations. This protocol is meant to cover patients in need of immediate assistance from a health care provider, as determined by EMS personnel on-site. Thus, these patients need a higher level of care than patients meeting the treat and release criteria. Under this protocol, an alternative vehicle—operated by a family member, friend, or first responder—can be used to transport the patient instead of an EMS vehicle. Use of alternate transport ensures that EMS vehicles are available to respond to more urgent emergencies, or patients with higher medical priority.

The criteria applied to the alternate transport protocol resemble those necessary to employ the treat and release protocol. The Governor must declare a disaster, the MCA protocols must specify alternate transport as an acceptable option, and the patient cannot have an illness or injury requiring treatment to prevent complications during the few hours after evaluation. Once these three criteria are met the EMS unit must identify the alternate vehicle. This can be any vehicle, operated by a person acceptable to the patient, and capable of safely transporting the patient in a medically sound manner given the patient’s condition. The action steps listed below (modified from the North Dakota “EMS – PSAP Stages for Standards of Care”) outline criteria for assessment of the appropriateness of alternate transport.

Assessment for Alternate Transport and Action Steps

- Patient evaluation suggests that alternate transport is available within a reasonable time frame;
- A person can be identified with a vehicle who is willing to transport the patient and can be reliably expected to do so;
- The transport vehicle has sufficient room for the patient
- If transport is not available on scene, the EMS provider may assess whether the patient can be left pending arrival of the transport based on the Safety of the scene
- Full expectation that the transportation will occur in a timely manner (reliability); and,
- No anticipated problem with patient loading into the transport vehicle.³⁵

³⁵<http://www.ndhealth.gov/EPR/Publications/EMS-PSAP-Stages-for-Standards-of-care2.pdf>

Single Responders and Triage Officers

Single Responder

During public health emergencies where a shortage of EMS personnel exists, EMS systems may opt to send only one responder per vehicle in order to maximize the available resources. These single responders should be professionals (not untrained volunteers). Indeed, any use of untrained volunteers is not considered EMS response. However, when using a single responder does become necessary, that responder may call in a second person to assist with certain actions (e.g., loading a patient, driving the truck if the EMS provider must remain with the patient). The second person assisting with patient care should use the same PPE (personal protective equipment) used by the EMS responder.

Triage Officer

A Medical Control Authority and 911 dispatch center may coordinate to use a triage officer as a single responder on-site. This responder is meant to function as a typically EMS responder in assessing for triage, treating and stabilizing, but not in transporting the patients. After assessment, and treatment, the triage officer can make a transport decision, either by calling in an EMS vehicle, releasing the patient, or finding alternate transport. Because a triage officer does not provide transport, use should be limited to situations where transport is not expected given the call, or to severe emergencies where their role will be assessment and treatment pending arrival of transporting units.

Personal Protective Equipment Use during a Pandemic, Infectious or Biological Event

911 Dispatch Center Screening

Because responding EMS units may be exposed to people with transmissible respiratory illnesses, the State of Michigan may recommend that all calls to 911 that are requesting EMS response include a single screening question for respiratory illness. For example, a screening question could inquire “***Does the patient have a cough or fever?***” (This question may be adjusted depending on the infectious agent involved). This screening question can provide EMS responders with information they need to reduce the threat of the infection.

EMS Notification

An affirmative answer to the screening questions should cue the dispatcher to notify the EMS responders of the potential exposure. EMS personnel should incorporate the appropriate PPE, if available, per their Medical Control Authority Protocols. Should the responders become aware of a possible acute respiratory illness on-scene, respiratory protection should be utilized. Further, if the Medical Control Authority notifies the 911 dispatcher that the prevalence of the respiratory illness in the community is sufficiently high to make the screening question unnecessary, EMS responders should wear respiratory protection consistently to every response.

Antivirals/Chemoprophylaxis

While treatment and post-exposure chemoprophylaxis with antivirals, antibiotics, or vaccines are feasible strategies for protecting our health care workers, pre-exposure prophylaxis an entire pre-hospital workforce may be prohibitive due to lack of resources. As a result the following protocol has been proposed for the use of antivirals for hospital staff:

Assumptions:

- Limited or no vaccine will be available to protect staff exposed to influenza patients.
- Personal Protective Equipment will provide adequate protection against influenza if used properly and is available.
- Antivirals have little effect if administered 48 hours after the onset of influenza symptoms (fever, myalgias, and cough)..
- Certain staff on flu wards (eg; ED and at the Alternate Care Centers) will be at a much higher risk of becoming infected.
- Staff might not present to work if they are not afforded adequate protection.

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ANNEX 2: SPECIFIC GUIDANCE FOR HOSPITALS AND OTHER HEALTH CARE FACILITIES

Introduction

The allocation of resources and services during emergency-induced situations of scarcity must be based on a sound ethical framework. This attachment provides specific guidance to hospitals and other healthcare facilities to assist these entities in planning for resource and service scarcity that may arise during public health emergencies. This attachment applies the general ethical guidance offered in the Guidelines for Ethical Allocation of Scarce Medical Resource and Services During Public Health Emergencies in Michigan (Guidelines) to the specific context of hospital and healthcare facility settings and addresses in detail some considerations that may arise in this context. It also offers potential strategies for implementation of the Guidelines in hospital and healthcare facility settings.

Healthcare facilities, whether individual hospitals, multi-site health systems, or other inpatient care delivery facilities, should review the ethical framework presented in the Guidelines to ensure that their decision-making strategies for allocating scarce resources and services during public health emergencies comport with the principles and considerations outlined in the Guidelines.

This attachment is meant to be a resource for hospitals and healthcare facilities. These Guidelines are not envisioned as a formalized series of instructions but rather a set of criteria that can be employed by decision-makers in various circumstances during a public health emergency using their best professional discretion. Thus, the criteria offered within these Guidelines are meant to be scalable, adaptable, and functional. Some facilities may not have the capacity to implement all of the suggestions offered in this document. Others will choose to adopt different strategies that are nonetheless consistent with the ethical framework presented in the Guidelines. However, it is presumed that many hospitals and healthcare facilities will adapt the approaches and strategies contained in this document, tailored to fit the circumstances of their specific facility.

Extreme or unforeseeable circumstances may challenge the foundations of the framework. In those situations, decision-makers will be expected to use their professional training and prudence to guide allocation decisions. The criteria offered may have to be amended to address unforeseen circumstances and should be periodically reviewed and updated to incorporate new information. Successful implementation of the Guidelines will demand ongoing deliberation, transparency, public education and input, and careful evaluation and oversight.

Background

Public health emergencies have often led to scarcity of medical resources and services. The history of epidemic outbreaks, natural disasters, and other mass casualty events has demonstrated the need to prepare for mass medical care planning across all medical disciplines and systems. These types of public health emergencies could seriously impact the State of Michigan, its health care and public health systems, its transportation systems, its economy, and its social structure. Hospitals and health care facilities will be faced with higher demands for services. These institutions and systems will experience problems similar to other health systems across the State of Michigan, including increased employee absenteeism, disruption of supply chains, and increased rates of illness and death.

Hospitals and other healthcare facilities will be part of a group of medical providers that will have to plan their response to a significant influx of patients in their respective areas. It is of the utmost importance that they have all of the tools necessary to make ethically sound and important decisions with regard to allocation of scarce medical resources and services. The objectives discussed in this attachment will assist health care professionals in making important decisions that protect the lives and safety of both health care professionals and patients.

Ethical Framework

The Allocation Guidelines developed for the State of Michigan discuss in detail the principles and methods used to develop the ethical framework. This is attachment to that document endorses the same goals, ethical considerations, and allocation criteria. Several specific ethical considerations are highlighted below.

- Professional obligations to individual patients
- Professional and institutional obligations of competence
- Professional and institutional obligations of honesty and transparency
- Distributive justice, including equal treatment, utility
- Fair procedures, including in planning and implementation
- Accountability and legitimacy

Each of the above ethical considerations applies to the overarching aim of the document, which is the distribution of scarce medical resources and services in an ethical fashion within hospitals and other healthcare facilities. Planning and preparation of

health care professionals and their institutions to respond ethically to situations of resource scarcity underlie both professional and institutional obligations to provide competent and just care to patients. Preparing the community for the types of difficult allocation decisions that may arise through public engagement and education supports obligations of honesty and transparency, and adds legitimacy to and accountability for these difficult decisions if they need to be made later. Distributive justice cautions against the possibility of applying different criteria to allocation schemes across different systems and communities. Cooperation between health systems and developing consistent allocation guidelines, by contrast, supports fairness and distributive justice. Prudent planning to increase stores of certain items proactively can avoid unnecessary shortages and is key to ethical planning. The protection of disabled and marginalized individuals in these circumstances is imperative. Therefore, criteria related to an individual's social utility and expected longevity to make allocation decisions should not occur.

Structuring guidance for hospitals and health systems presents obvious challenges. Each organization has its assets and areas of expertise, which can be vastly different from other organizations. Each organization must proactively examine its plans for continuing to deliver care to the public during a mass casualty incident (MCI), including how it would allocate scarce medical resources and services. The guidance discussed in this attachment is based primarily on a proposal developed by the University of Michigan Health System in collaboration with the Michigan Department of Community Health using the existing medical and ethics literature and ethical guidance documents available from some other states and from the federal agencies charged with health preparedness.³⁶ This attachment provides an effective example of how a hospital or other healthcare facility can accommodate the ethical considerations and allocation criteria outlined in the Guidelines.

Hospital/Health System Ethical Duty to Plan

Just as the state has a duty to prepare, so do hospitals and health systems. Most hospitals have an incident management team and must drill to fulfill regulatory agency mandates, but specific planning to care for patients in an atmosphere of scarce resources, for at least some period of time while awaiting assistance, must be undertaken. Hospital leadership must have a thorough understanding of the local, regional and state emergency plans, have active relationships with those organizations and exercise their plans. Planning for hospital surge, communications, public messaging, command and control, prevention of further casualties, business continuity, vulnerable population management

³⁶ Add citation to University of Michigan Health System Document; AHRQ, "Mass Medical Care with Scarce Resources: The Essentials" AHRQ Pub. 09-0016, September 2009, Phillips, Knebel and Johnson, editors

and security must take place in advance and be communicated to the members of the hospital organization. It is also extremely important for hospital organizations to have a detailed understanding of the regional prehospital capabilities and those Emergency Medical Services (EMS) entity's plans for care delivery in a Major Medical Emergency (MME). ED crowding and high hospital occupancy due to the MME may require an alteration of the normal patterns of EMS operation, including possible differences in activation and transport protocols under the prevailing standard of care. All efforts should be made to coordinate with partners providing prehospital services, including EMS services and Medical Control Authorities. The full guidance for prehospital settings can be found in Attachment #6.

In the normal course of care delivery, many hospitals do not care for certain populations and would transfer such patients out of their facility to a different level of care. During public health emergencies that affect a large region, specialty care facilities may not be able to accommodate these patients or adhere to their normal transfer relationships. "Sheltering in place," or caring for patients not normally kept at a particular facility, may be the most ethical solution, despite the high level of stress this would place on any system. Planning for potential situations where providers would have to practice outside their normal scope includes an assessment of hospital and staff capabilities and providing guidance for surge situations. Such guidance would include a robust plan of how, where and what a surge would entail and what would be expected of staff members AND some potential for augmenting their capabilities through "just in time" training assets. Examples of training modules for one type of mass casualty have been developed by the State Burn Coordinating Center at the University of Michigan:

<http://www.michiganburn.org/index.shtml>

Similar plans could be developed to care for other special populations, such as pediatric or obstetric patients.

Ethical Resource Allocation Decision Process Urban³⁷ Hospitals

Recognizing that each hospital organization is unique and planning for the allocation of resources should be proactive, this section proposes the composition and function of a Scarce Resource Allocation Committee (SRAC), Triage Officers Corps for hospital floors or units, and the Clinical Review Committee (CRC) which serves as a

³⁷ This section provides a model for hospitals that have access to larger number of resources and personnel, described here as "Urban Hospitals." Of course, some hospitals in urban locations may not have access to sufficient resources to enact all of these recommendations and some hospitals outside urban settings will have the requisite resources to do so.

decision making body and an appeals forum. Caregivers, physicians, and administrators will need clear guidance regarding how to distribute resources, and family members will need to know that a just and thoughtful process is in place.

Trigger Points

When a public health emergency is imminent, or has been declared by a relevant public health agency, the Medical Care Director, or his/her designee as predetermined in the Incident Management System, will direct the relevant emergency planning committees to:

- Identify resources which are likely to become scarce
- Develop a method (or implement a previously developed method) for tracking such resources
- Establish trigger points which indicate when conservation of a particular resource(s) is necessary

The trigger point(s) depends on the imminent depletion of a certain resource and will vary depending on the resource and the severity of the situation. The trigger point will be established based on the current and projected demand for a resource, and the current supply of this resource. As an example, during the 2009 novel influenza A pandemic outbreak, it became clear early on that N95 respirators and antiviral medication(s) would quickly become scarce and decisions on usage needed to occur immediately. On the other hand, given the low morbidity and mortality associated with this virus in most healthy persons, staffing resources, beds, and ventilators did not need to be considered as scarce resources during this early period.

Scarce Resource Allocation Committee (SRAC)

Once the trigger point is reached for a particular resource, the Incident Management Team must determine whether to activate the Scarce Resource Allocation Committee (SRAC) or a subset of the membership (dependent on the scarce resource) as shown in Figure 1.

FIGURE 1: Scarce Resource Allocation Committee (SRAC) Description

Statement of Purpose	SRAC should have the full authority to make necessary allocation decisions to assign or conserve resources for patient care.
Objectives	In the event of a shortage of services, supplies, or staffing, the SRAC should determine when and how these resources should be allocated or conserved. In addition, the SRAC will have responsibility for determining when Triage Protocols will be activated and deactivated.
Scope	All supplies, equipment, staffing (faculty and staff) and any other resource of the hospital or health system organization
Membership	<p>In the event of a disaster declaration and/or the establishment of the Incident Management System (IMS), the SRAC structure should be consistent with this system. At this point, the Incident Commander (or designee) will chair the SRAC.</p> <p>The SRAC composition should include appropriate adult and pediatric representation from each of the following groups:</p> <ul style="list-style-type: none"> • Medical Care Director, e.g. Chief of Staff or designee • Nursing Care Director, e.g. Director of Nursing or designee • Ambulatory Care Medical Director or designee • ICU Medical Director(s) or designees, e.g. Critical care Committee Chairs • Respiratory Therapy Medical Director and Technical Director or designees • Emergency Medicine Medical Director or designee • Admissions/Bed Capacity Manager or designee • Ethicist • Pharmacist <p>Each position on the SRAC should be filled by 3 people who will rotate shifts on the committee. Those members who are off shift should be available to rotate on an appeals committee (see below) if needed.</p>
Timeline	May be activated upon determination of one or more scarce resources.
Voting	In the event that consensus among members of SRAC cannot be reached regarding the assignment or conservation of a scarce resource, the Incident Commander will call for a vote. Voting consists of one vote for the incident commander and one vote for each of the eight groups for a total of nine votes. A simple majority vote will be required, the Incident Commander given the authority to decide in case of tie votes. The SRAC may implement additional procedures such as secret balloting to avoid undue pressure on members.
Progress Reports	SRAC should attempt to meet face-to-face, however, conference calls will suffice as long as minutes are documented. All decisions made by the SRAC should be documented in meeting minutes, including the rationale for those decisions.

These particular groups have been recommended because they represent the leadership in clinical care (Chief of Staff, Nursing Director), the leadership in areas most likely to be faced with scarce resources (ICU Directors, Respiratory Care, Emergency Medicine, Admissions/Bed Coordination Center, Ambulatory Care Directors), and experts in the ethics of health care delivery (ethicists). This is one proposed structure for a SRAC, but recognizing that some organizations would not have access to an ethicist, intensive care or ambulatory care leaders (because they do not normally deliver intensive care or ambulatory clinic services), such organizations should consider appropriate equivalent committee members.

In the event that consensus among members of SRAC cannot be reached regarding the assignment or conservation of a scarce resource, the Incident Commander will call for a vote. A voting scheme should be developed, with the Incident Commander given authority to decide in case of tie votes. Ad hoc advisors may be invited by SRAC members to provide expertise as needed. Ad hoc advisors may include representatives from the Office of the General Counsel, Pharmacy, Material Services, Epidemiology, Infection Control, Human Resources, etc. Ad hoc advisors will not be permitted to vote in matters to be decided by the SRAC.

During a mild or time limited MME, the SRAC may only need to meet intermittently and some decisions on specific resource allocation may be left to specialty groups. For example, during the 2009 novel influenza A (H1N1) outbreak, decisions regarding antiviral distribution for treatment and prophylaxis within some health systems were left to a small group including Infectious Diseases, Employee Health, and Infection Control. On the other hand, a severe pandemic or other MME, with more hospitalizations and a higher mortality rate might necessitate daily meetings of the SRAC to make recommendations for allocation of multiple scarce resources.

Triage Officers

During a severe MME, such as a pandemic that leads to multiple scarce resources, a Triage Officer will be assigned to oversee a patient care area, such as an inpatient floor or unit. Triage Officers will be selected from available personnel who normally care for patients on that unit, such as adult and/or pediatric Hospitalists, ICU specialists, Emergency Medicine physicians, Anesthesiologists, and others as assigned by the Medical Care Director. Triage Officers will be selected by SRAC in consultation with the Chairs and/or Service Chiefs. Potential Triage Officers will be identified by the hospital leadership based on the individual's leadership capabilities and clinical skills to meet the needs of the role. Pre-identification of Triage Officers is recommended. Selected Triage Officers will be responsible for thoroughly understanding their institution's allocation processes and triage protocols.

The Triage Officer will have the responsibility to assure that the clinicians caring for the patient perform an assessment, for triage purposes, at 48 and 120 hours (or a time deemed appropriate by leadership, given the type of pathology being seen with the particular mass illness) and attests that the assessments are accurate. Triage Protocols for use in such scenarios should be in place and well known to the Triage Officers and other clinicians to ensure transparency and facilitate rapid implementation. Day-to-day clinical care decisions for individual patients will continue to be made by the primary clinician caring for the patient with the supervision of the Triage Officer.

If Triage Protocols need to be implemented to manage a scarce resource (i.e. ICU care or ventilators), the Triage Officer will notify the clinicians within their assigned units to communicate regarding Triage Protocols and collect data about patient assessments as often as needed, but at least daily. The Triage Officers should communicate frequently with the Clinical Review Committee to assess the needs of all patients within the institution. Using the Triage Protocols, the Clinical Review Committee and the Triage Officers will determine which patients no longer meet criteria for the use of a scarce resource. When a patient no longer meets criteria for a particular resource, the Triage Officer will advise the primary clinician to discontinue its use. Decisions to discontinue *any* intervention based on resource conservation will only occur after the SRAC has determined that conservation of that particular resource is necessary.

Clinical Review Committee

While decisions to discontinue life sustaining interventions will be made in conjunction with the Triage Officers, in consultation with the primary clinician caring for the patient, any patient, family member or clinician (including the Triage Officer) can request consultation with the Clinical Review Committee (CRC). The makeup and purpose of the CRC is outlined in Figure 2. The CRC will have two functions:

- 1) The CRC will serve as a consultative body that will advise clinicians regarding clinical decision-making in complex patient care situations and identify principles that will serve as guidelines for triage officers.
- 2) The CRC will be involved in all decisions to discontinue a life-saving therapy. The CRC will have real-time information on all currently available life-saving scarce resources in the hospital system. The CRC will also have a list of all patients who, based on objective clinical parameters, have the lowest chance of survival. The CRC will discontinue a life-saving resource for a particular patient only when:

- The life-saving resource has been depleted throughout the organization and cannot be obtained from any outside source.
- Another person with a greater chance of survival, based on objective clinical parameters that have been selected for triage guidelines, requires the same life-saving resource.

Once a decision to discontinue a life-saving scarce resource has been made for a particular patient the CRC will instruct the Triage Officer responsible for the patient to withdraw the life-saving scarce resource.

3) The CRC will be the final decision making body for the appeal of Triage Officer clinical decisions. Decisions made by the CRC will be final, and will be determined based on a review of available medical information. Some institutions may feel it is appropriate to have an appeals process even after CRC has considered the case, but should consider whether, in an MME incident, they will have the depth of expertise to staff multiple committees.

FIGURE 2: Clinical Review Committee

Statement of Purpose	To act as an advisory body for requested consults from the Triage Officer and act as a final decision making body for all appealed Triage Officer decisions.
Objectives	<p>Consultation:</p> <ul style="list-style-type: none"> • Advise regarding clinical decision making in complex patient care situations • Identify principles that serve as a guide for the Triage Officer <p>Appeals:</p> <ul style="list-style-type: none"> • Resolve disputed cases of allocation of any scarce clinical resources
Scope	Any resource allocation decisions that require resolution.
Membership	<p>The CRC will consist of appropriate adult and pediatric providers including the following:</p> <ul style="list-style-type: none"> • Medical Care Director, e.g. Chief of Staff or designee • Triage Officer for that unit (non-voting) • Adult Triage Officer from another unit • Pediatric Triage Officer from another unit • Respiratory Therapy Medical Director or designee • Emergency Medicine Medical Director or designee • Nursing Director or designee (non-voting) • Social Work Director or designee (non-voting) • Ethicist, ad hoc advisor (non-voting) • Office of the General Counsel, ad hoc advisor (non-voting)
Timeline	Ad hoc activation
Progress Reports	<p>All decisions will be documented in the patient’s medical record. Additionally, the CRC will maintain a list of all patient names, registration</p>

These particular groups have been recommended because they represent those with expertise in relevant areas of medical care delivery and best equipped to make final clinical resource decisions. Some hospital organizations may not have staff who carry titles exactly the same as the proposed member titles in this guideline, but should make appropriate substitutions. In the event that consensus among members of CRC cannot be reached regarding life sustaining interventions, the Medical Care Director will call for a vote. A simple majority vote will be required. Voting abstentions are not permitted; anyone who feels they must recuse themselves will be replaced for that vote with a designee. All decisions will be reported to the Incident Commander and documented in the patient's medical record. Additionally, the committee shall maintain a record of all patient names, registration numbers, and the particular decision rendered by the CRC. Ad hoc advisors may be invited by CRC members to provide expertise as needed. Ad hoc advisors will not be permitted to vote in matters to be decided by the CRC.

Staffing Resources Personnel may be the most important scarce resource in an MME, especially if the emergency lasts for weeks or months. Equipment, medications, and vaccines cannot treat or prevent illness without trained personnel to prescribe, administer and oversee their use. Unlike material goods such as medicines, masks, and ventilators, personnel cannot be “stockpiled;” indeed, shortfalls in personnel could be exacerbated, for example, by communicable or infectious related absenteeism.

Most hospital organizations have mechanisms in place for planning human resource needs and strategies, the following ethical guidelines may be useful for allocating scarce human resources during an emergency:

1. As is the case for material resources, institutions should increase the “supply” of scarce human resources by prospectively training individuals whose current roles will be less urgently required during an MME to work in areas of likely shortfall, and consider training community members as well.
2. Professional ethics for clinicians generally discourage or prohibit practice outside the scope of one's expertise. Similarly, legal and ethical standards often prohibit laypersons from providing health services. During conditions of extreme scarcity of trained personnel, however, standards of competence may justifiably be lower than during normal conditions. Employing, for instance, a clinician who normally works in a specialty to instead work in primary care, or providing community volunteers with focused training to administer vaccine could expand capacity and alleviate some of the scarcity of personnel.
3. Individuals who assume the risks and burdens of working during a pandemic (e.g., extended hours and quarantine) should:
 - a. Receive appropriate protection (e.g., vaccine, protective gear) to minimize their risk of infection

- b. Receive priority for antivirals, antibiotics and other mid-level scarce resources, with the exception of life-sustaining interventions such as ventilators (for which they would not receive special priority). This priority is consistent with the acceptable allocation criteria detailed in the Guidelines.
- c. Individuals whose contracts or agreements clearly described expectations of continuing to work despite risk, but who failed to adhere to those agreements, should expect appropriate action. Institutions will vary greatly with respect to the ability to manage their workforce in the event of such an event.
- d. The allocation of scarce human resources should be done in a fashion consistent with the guidelines for other resources.

Ethical Resource Allocation Decision Process Rural³⁸ **Hospitals**

Smaller hospitals, especially those in rural areas, are faced with limited resources and support from other agencies, potentially smaller, more distant local public health departments, limited technology, a greater reliance on volunteers, limited medical transport units, and greater distances from potential lifesaving or supportive resources.³⁹

Advance planning may take a more critical role for medical surge and allocation of scarce resources within this setting. Furthermore, these facilities should recognize their role to also plan to care for populations they might not normally treat, such as pediatrics, obstetrics or critical care patients.

The members of the hospitals Emergency Management Planning Committee may also be called upon to be a part of a Scarce Resource Allocation Committee (SRAC). The SRAC should have the full authority to make necessary allocation decisions to assign or conserve resources for patient care in the event of a shortage of services, supplies, or staffing. The SRAC should be responsible for determining when and how these resources should be allocated or conserved.

It is understood that not all rural hospitals have the staffing capacity to fill all the recommended positions in the SRAC. Therefore, it would be reasonable that the hospital leadership looks to different entities from the healthcare services in the community to fill those vacancies. The hospital may look to private healthcare providers such as local

³⁸ As a contrast to the prior section, this section outlines guidelines for hospitals with less access to medical and personnel resource, here described as “Rural Hospitals.” These hospitals may have limited access to resources and personnel, thus requiring committees that are scalable according to availability.

³⁹ Manley et al., 2006, p. 80

pediatricians or internal medicine physicians to help guide decisions in their area of expertise. As well community religious leaders may fill some the roles that might normally be filled by hospital employed ethicists and pastoral care. It will really be up to each hospitals executive committees as well as risk management must decide the roles they would like represented in the SRAC.

Furthermore, it may be advantageous in regional areas that have a large numbers of rural hospitals to form a regional committee to include representation from all involved. This will help to ensure consistent decision making in all areas of the region as well as decrease the burden of dual functioning roles on the staff from the affected hospitals. This type of committee could consist of representation from regional Medical Control Authorities, Healthcare Coalitions and healthcare personnel from areas such as long term care, pediatrics. Integration into the regional emergency operational guidelines and would become active during times of scarce medical resources.

Jeff this would be the part where you insert the information concerning rural healthcare and having a SRAC formed from different entities from the healthcare services in the community vs each hospital having a SRAC.

FIGURE 1: Scarce Resource Allocation Committee (SRAC) Description

This is one proposed structure for a SRAC, recognizing that some organizations do not have access to an ethicist, intensive care or ambulatory care leaders (because they do not normally deliver these services), such organizations should consider appropriate equivalent committee members, such as consulting specialty physicians.

Statement of Purpose	SRAC should have the full authority to make necessary allocation decisions to assign or conserve resources for patient care within the institution.
Objectives	In the event of a shortage of services, supplies, or staffing, the SRAC should determine when and how these resources should be allocated or conserved. In addition, the SRAC will have responsibility for determining when Triage Protocols will be activated and deactivated.
Scope	All supplies, equipment, staffing (faculty and staff) and any other resource of the hospital or health system organization
Membership	In the event of a disaster declaration and/or the establishment of the Incident Management System (IMS), the SRAC structure should be consistent with this system. At this point, the Incident Commander (or designee) will chair the SRAC. The SRAC composition should include available patient group representation (e.g., adult, pediatric, geriatric, obstetric) from each of the following groups: <ul style="list-style-type: none"> • Medical Care Director, e.g. Chief of Staff or designee • Nursing Care Director, e.g. Director of Nursing or designee

	<ul style="list-style-type: none"> • Ambulatory Care Medical Director or designee • ICU/Internal Medicine Director(s) or designees • Respiratory Therapy Medical Director or designees • Emergency Medicine Medical Director or designee • Admissions/Bed Capacity Manager or designee • Ethicist or Pastoral Care Representative
Timeline	May be activated upon determination of one or more scarce resources.
Voting	In the event that consensus among members of SRAC cannot be reached regarding the assignment or conservation of a scarce resource, the Incident Commander will call for a vote. Voting consists of one vote for the incident commander and one vote for each of the eight groups for a total of nine votes. A simple majority vote will be required, the Incident Commander given the authority to decide in case of tie votes. The SRAC may implement additional procedures such as secret balloting to avoid undue pressure on members.
Progress Reports	SRAC should attempt to meet face-to-face, however, conference calls will suffice as long as minutes are documented. All decisions made by the SRAC should be documented in meeting minutes, including the rationale for those decisions.

These particular groups have been recommended because they represent the leadership in clinical care (Chief of Staff, Nursing Director), the leadership in areas most likely to be faced with scarce resources (ICU Directors, Respiratory Care, Emergency Medicine, Admissions/Bed Coordination Center, Ambulatory Care Directors), and experts in the ethics of health care delivery (ethicists).

In the event that consensus among members of SRAC cannot be reached regarding the assignment or conservation of a scarce resource, the Incident Commander will call for a vote. A voting scheme should be developed, with the Incident Commander given authority to decide in case of tie votes. Ad hoc advisors may be invited by SRAC members to provide expertise as needed. Ad hoc advisors may include representatives from the Office of the General Counsel, Pharmacy, Material Services, Epidemiology, Infection Control, Human Resources, etc. Ad hoc advisors will not be permitted to vote in matters to be decided by the SRAC.

Key issue planners should anticipate, to the degree possible, the types of health care needs and resource shortfalls that will occur and identify policy and operational adjustments that will be needed in response.

- Assess surge capacity (beds, ventilators, etc.) to meet expected increased needs.
- Develop plan to expand staff capacity. Determine how the hospital will meet staffing needs.
- Develop contingency plans for staff absences, particularly ED staff.

- Create procedures and policies for use of supplemental providers.
 - Consider volunteers
 - Ensure policies are in place to test and manage deployment of non-hospital personnel at both the community and hospital levels.
 - Ensure that a plan for managing volunteers is in place.
- Initiate discussions of allocation of hospital resources; hospital administrators meet with hospital ethics committee early in planning process:
 - Establish hospital process for scarce resource allocation.
 - Develop communication process so the community understands the rationale behind resource allocation policies.
 - Stockpile supplies and equipment including PPE equipment (e.g., gloves, masks).
 - Estimate increased need for medical equipment/supplies and develop strategy to acquire additional equipment/supplies if needed. Consult with local and State health departments about access to the Strategic National Stockpile.
 - Develop facility access guidelines
 - Define essential and non-essential visitors and develop policies for restricting visitors during a pandemic (and mechanisms for enforcing the policies).
 - Plan to limit hospital entry to a few key entrances.
 - Plan for increased security needs.
 - Develop a health care risk communication message, including criteria for seeking health care, such as postponement of elective procedures or surgeries. The hospital administration should work with the facility Public Information Officer, the Local Health Departments or the State Of Michigan Public information Officer to get this information out to the general public.

Ventilator/ICU Resources

During a severe MME such as a pandemic respiratory illness, we expect that the number of existing ventilators / ICU beds could be inadequate to meet the needs of patients. There have been several proposed mechanisms for initial triage of patients to critical care units, ventilator use or transport to ED / definitive care.

Hick⁴⁰ et al, proposed a triage system for ventilator assignment during an infectious disease disaster for adults. This system uses only clinical and not laboratory assessments and includes a reassessment of resource use for each patient with a

⁴⁰ Hick, J.L. and D.T. O'Laughlin, *Concept of operations for triage of mechanical ventilation in an epidemic*. Acad Emerg Med, 2006. **13**(2): p. 223-9.

requirement for improvement to continue use of the ventilator. Another proposal⁴¹ used the Sequential Organ Failure Assessment (SOFA) score for adult patients in a similar respiratory pandemic scenario to create triage criteria for critical care admission. The SOFA scores require both laboratory and radiology resources. Talmor⁴² suggested criteria for ICU admission during a pandemic respiratory disease disaster which used age and clinical criteria for adults over 18 years of age. Other triage criteria for acute mass casualty trauma such as START⁴³ & JumpStart⁴⁴ or SALT⁴⁵ do not completely address the circumstances covered in this section.

After the Severe Acute Respiratory Syndrome (SARS) epidemic in Toronto Canada, Christian⁴⁶ proposed a triage system for ventilator access based on pre-existing health status and SOFA scores. The New York Department of Health was the first U.S. governmental body to issue a proposed triage system for ventilator access during a pandemic influenza event⁴⁷. This system is similar to the Toronto proposal but has fewer exclusion criteria. None of the triage criteria designed for infectious disease disasters have included pediatric specific recommendations and this will be addressed in a subsequent section.

Clinical Evaluation:

When implementation of a scarce resource allocation plan is required, equipment such as ventilators and supplemental oxygen will require a consistent and predictable approach to utilization. Evaluation criteria to predict potential morbidity and mortality of severe cases of a pandemic respiratory illness should be discussed, vetted, and adopted prior to their needed utilization and should use simple and straightforward metrics that most clinicians recognize and can assess. As the physiology of adult and pediatric patients is often quite different, we have determined that separate triage tools are required to evaluate adults and pediatric patients. To comply with the need for equitable access to care, we have used the same expected mortality criteria for both groups.

⁴¹ Christian, M.D., et al., *Development of a triage protocol for critical care during an influenza pandemic*. CMAJ, 2006. **175**(11): p. 1377-81.

⁴² Talmor, D., et al., *Simple triage scoring system predicting death and the need for critical care resources for use during epidemics*. Crit Care Med, 2007. **35**(5): p. 1251-6.

⁴³ Benson, M., K.L. Koenig, and C.H. Schultz, *Disaster triage: START, then SAVE--a new method of dynamic triage for victims of a catastrophic earthquake*. Prehosp Disaster Med, 1996. **11**(2): p. 117-24

⁴⁴ Romig, L.E., *Pediatric triage. A system to JumpSTART your triage of young patients at MCIs*. JEMS, 2002. **27**(7): p. 52-8, 60-3.

⁴⁵ SALT reference

⁴⁶ Christian, M.D., et al., *Development of a triage protocol for critical care during an influenza pandemic*. CMAJ, 2006. **175**(11): p. 1377-81.

⁴⁷ Is this the New York reference? Powell, T., K.C. Christ, and G.S. Birkhead, *Allocation of Ventilators in a Public Health Disaster*. Disaster Med Public Health Preparedness, 2008. **2**(1): p. 20-26.

When a patient presents to the ED, or a decision is required for admission to ICU, or the patient is determined to need ventilator support, the appropriate triage tool will be used to determine whether the patient is allocated a ventilator. We have also included a requirement to systematically review the clinical progress of each patient who is currently receiving mechanical ventilation or ICU care with a requirement of improvement at 48 hours, 120 hours, and daily thereafter. This tool is meant to be a starting place for further clinical decision making tools as conditions evolve in any mass casualty or pandemic event.

In the event of a severe shortage of ventilators or ICU beds, not all patients will be eligible for mechanical ventilation or ICU care. The following inclusion and exclusion criteria are recommended (Table 3). These criteria have been informed by both the Toronto triage tool and the New York tool. Initiation of ventilatory support could be determined by the following inclusion and exclusion criteria, however it is understood that each institution may have their own policies and procedures for these types of determinations.

TABLE 3: Inclusion and Exclusion Criteria for Mechanical Ventilation

Inclusion Criteria	
The patient must have one of the following:	
A.	Requirement for invasive ventilatory support <ul style="list-style-type: none"> • Refractory hypoxemia (SpO₂ < 90% on non-rebreather mask or FIO₂ > 0.85) • Respiratory acidosis (pH < 7.20) • Clinical evidence of impending respiratory failure • Inability to protect or maintain airway
B.	ADULTS: Hypotension (systolic blood pressure < 90 mm Hg or relative hypotension) with clinical evidence of shock (altered level of consciousness, decreased urine output, or other evidence of end-organ failure) refractory to volume resuscitation requiring vasopressor or inotrope support that cannot be managed in ward setting PEDS: Hypotension (systolic BP < 70 + 2x age (years)) or clinical shock state (as evidenced by altered level of consciousness, decreased urine output, or other evidence of end-organ failure) refractory to volume resuscitation requiring vasopressor or inotrope support that cannot be managed in ward setting

Exclusion Criteria	
The patient is excluded from admission or transfer to critical care if <i>any</i> of the following is present:	
A.	Severe trauma
B.	Severe burns of patient with any 2 of the following: <ul style="list-style-type: none"> • Age > 60 yr • > 40% of total body surface area affected • Inhalation injury
C.	Cardiac arrest <ul style="list-style-type: none"> • Unwitnessed cardiac arrest • Witnessed cardiac arrest, not responsive to electrical therapy (defibrillation or pacing) • Recurrent cardiac arrest
D.	Metastatic malignant disease with poor prognosis
E.	Advanced and irreversible immunocompromise
F.	Severe and irreversible neurologic event or condition with highly expected mortality
G.	End-stage organ failure meeting the following criteria: <p><i>Heart</i></p> <ul style="list-style-type: none"> • New York Heart Association (NYHA) class III or IV heart failure <p><i>Lungs</i></p> <ul style="list-style-type: none"> • Severe chronic lung disease with FEV₁ < 25% predicted, baseline PaO₂ < 55 mm Hg, or secondary pulmonary hypertension • Previously diagnosed primary pulmonary hypertension with NYHA class III or IV heart failure, or mean pulmonary arterial pressure > 50 mm Hg <p><i>Liver</i></p> <ul style="list-style-type: none"> • Child–Pugh score ³ 7 or Meld scored of > 20

Institutions will need to develop clear initiation standards to determine when resource scarcity requires application of these allocation criteria. There also will need to be clear criteria in place to determine if patients currently using resources are obtaining the needed benefit to insure the lowest morbidity and mortality for the population at risk. When patients have improved in condition to the point that the resources are no longer necessary, or when patients are not progressing to the desired health outcomes, these resources may need to be reallocated to insure the stated goal.

Periodic reassessment of the patient's risk for mortality is recommended at specific time points during the course of care to determine if reallocation of resources is the most appropriate available option. Patients will be evaluated for improvement and for worsening potential for mortality at 48 hours and 120 hours by the following adult and pediatric criteria outlined below. This process is not a deviation from normal practices, as health care options for patients often are reassessed during a period of treatment. The difference here is simply that given the shortages of resources, reassessment of the patient's condition may be conducted more rapidly, more consistently, and through the application of different inclusion criteria.

These decisions will be both difficult and necessary, and to insure their fairness there will be a monitoring and appeals process along with these standardized criteria to best insure a cautious and moderated approach to these decisions.

Triage of eligible patients:

Once a patient is deemed eligible for triage by meeting the above inclusion criteria, the appropriate adult or pediatric triage tool will be used to determine initial and continuing use of mechanical ventilation and/or ICU care.

Adults:

It is recommended that for adult care the triage tools proposed by the Toronto and New York guidelines are used. These rely on the use of the Sequential Organ Failure Assessment Score (SOFA score) to determine likelihood of recovery if given adequate treatment. The SOFA score is determined by a multi-organ failure model and includes the measures of respiratory, hematologic, liver, cardiovascular, neurologic and renal function (see Figure 1).

FIGURE 3: Sequential Organ Failure Assessment (SOFA) Score

Variable	0	1	2	3	4
PaO ₂ /FiO ₂ mmHg	>400	< 400	< 300	< 200	< 100
Platelets, x 10 ³ /μL (x 10 ⁶ /L)	> 150 (>150)	≤ 150 (≤ 150)	≤ 100 (≤ 100)	≤ 50 (≤ 50)	≤ 20 (≤ 20)
Bilirubin, mg/dL (μmol/L)	<1.2 (<20)	1.2-1.9 (20 – 32)	2.0-5.9 (33 – 100)	6.0-11.9 (101 – 203)	>12 (> 203)
Hypotension	None	MABP < 70 mmHg	Dop ≤ 5	Dop > 5, Epi ≤ 0.1, Norepi < 0.1	Dop > 15, Epi > 0.1, Norepi > 0.1
Glasgow Coma Score	15	13 - 14	10 - 12	6 - 9	<6
Creatinine, mg/dL (μmol/L)	< 1.2 (<106)	1.2-1.9 (106 – 168)	2.0-3.4 (169 - 300)	3.5–4.9 (301 – 433)	>5 (> 434)

Dopamine [Dop], epinephrine [Epi], norepinephrine [Norepi] doses in ug/kg/min SI units in brackets

There is no scoring system for use in the pediatric population that is universally accepted. Some states have published a discussion of their planned method of ethical resource allocation (see UTAH state plan on the state preparedness web at:

http://extras.mnginteractive.com/live/media/site297/2010/0506/20100506_021026_04b_PEDIATRIC_PANDEMIC_TRIAGE_JANUARY1010.pdf

Also see Alaska’s plan on their state web page:

www.hss.state.ak.us/prepared/assets/conference/Scarce-Resources.pdf - 2009-02-13

Of critical care resources for children, the PELOD scoring method, discussed below, is felt to be more easily applied when data may be scarce, but decisions regarding allocation must be based on both clinical and laboratory data.

Table 3: The PELOD Scoring System

Organ system	Variable	SCORE				Max score
		0	1	10	20	
Neurologic						20
	Glascow coma score	12-15	7-11	4-6	3	
		AND		OR		
	Papillary reaction	Both reactive		Both fixed		
Cardiovascular						20
	Heart rate					
	< 12 yrs	≤ 195 bpm		> 195 bpm		
	> 12 yrs	≤ 150 bpm		>150 bpm		
		AND		OR		
	Systolic blood pressure					
	< 1 month	> 65 mmHg		35-65mmHg	< 35 mmHg	
	≥ 1month & < 1yr	> 75 mmHg		35-75mmHg	< 35 mmHg	
	≥ 1 yr & < 12 yr	>85 mmHg		45-85 mmHg	< 45 mmHg	
	≥ 12 yr	> 95 mmHg		55-95 mmHg	< 55 mmHg	
Renal						10
	Creatinine					
	< 7 days	< 1.59 mg/dl		≥1.59 mg/dl		
	≥ 7 days & < 1 yr	<0.62 mg/dl		≥ 0.62 mg/dl		
	≥ 1 yr & < 12 yrs	< 1.13 mg/dl		≥ 1.13 mg/dl		
	≥12 yrs	< 1.59 mg/dl		≥ 1.59 mg/dl		
Pulmonary						10
	PaO2/FiO2 ratio	> 70mmHg		≤ 70mmHg		
		AND		OR		
	PaCO2	≤ 90 mmHg		>90 mmHg		
		AND				
	Mechanical vent	No	Yes			
Hematologic						
	WBC	≥ 4.5K	1.5-4.4 K	<1.5		
		AND	OR			
	Platelets	≥ 35 K	< 35			
Hepatic						1
	AST	< 950 IU/L	≥ 950 IU/L			

		AND				
	Prothrombin time	> 60%	≤ 60%			

The calculation for determining predicted likelihood of mortality is shown in Table 4. Using this calculation if the PELOD score is > 33 the predicted mortality is 53%; in the validation study a PELOD score >33 had a mortality of 100%. Table 5 gives the predicted PELOD score associated with different mortality probability. To use the PELOD scoring system on a daily basis, the score is calculated as at presentation. If new data is not available (i.e. new laboratory values) the value can either be assumed to be unchanged or normal depending on the physician’s clinical judgment.

TABLE 4: Calculation for determining predicted likelihood of mortality

$$P = \frac{1}{1 + \exp(7.64 - 0.3 \times \text{PELOD score})}$$

TABLE 5: Predicted mortality levels for a given PELOD score

PELOD Score	Predicted Mortality probability	Predicted Mortality Rate
< 10	0.009	<1%
15	0.04	4%
20	0.1625	16%
22	0.26	26%
24	0.3917	40%
25	0.46	
26	0.53	53%
27	0.61	
28	0.68	68%
>30	0.98	98%

Using similar mortality levels for pediatric and adult patients leads to using a PELOD score of 33 as a reasonable proxy for a SOFA score of 11. The calculated probability of mortality with a score of 33 is 53%, however the validation study showed a 100% mortality at this score. This seems a reasonable compromise since to use a score of 29 (approximately 85% mortality) may prioritize some children who would receive futile allocation of scarce resources.

Critical Care Triage Tool – PEDIATRIC PATIENTS (<18 yrs)

	Initial Assessment		48 Hour Assessment		120 Hour Assessment	
Color Code	Criteria	Priority/Action	Criteria	Priority/Action	Criteria	Priority/Action
Blue	Exclusion Criteria* or PELOD \geq 33*	Medical Mgmt +/- Palliate & d/c	Exclusion Criteria or PELOD > 33 or PELOD 21-33 & no Δ	Palliate & d/c from CC	Exclusion Criteria ** or PELOD > 33 ** or PELOD 21-33 no Δ	Palliate & d/c from CC
Red	PELOD < 21 or Single Organ Failure	Highest	PELOD < 33 and decreasing	Highest	PELOD < 33 and decreasing progressively	Highest
Yellow	PELOD 21-33	Intermediate	PELOD < 21 no Δ	Intermediate	PELOD < 21 minimal decrease (< 3 point decrease in past 72 hrs)	Intermediate
Green	No significant organ failure	Defer or d/c, reassess as needed	No longer ventilator dependant	d/c from CC	No longer ventilator dependant	d/c from CC

*If exclusion criteria or PELOD > 33 occurs at any time from the initial assessment to 48 hours change triage code to Blue and palliate.

** If exclusion criteria or PELOD > 33 occurs at anytime from 48 – 120 hours change triage code to Blue and palliate.

Δ = change CC = critical care d/c = discharge

- **Blue:** High probability of mortality; should be discharged from critical care and should receive medical management and palliative care as appropriate
- **Red:** Highest priority for critical care
- **Yellow:** Intermediate priority for critical care
- **Green:** Low probability of mortality; defer admission/ discharge from critical care

ADULT Critical Care Triage Tool

	Initial Assessment		48 Hour Assessment		120 Hour Assessment	
Color Code	Criteria	Priority/Action	Criteria	Priority/Action	Criteria	Priority/Action
Blue (EXPECTANT)	Exclusion Criteria* or SOFA > 11*	Medical Mgmt +/- Palliate & d/c	Exclusion Criteria or SOFA > 11 or SOFA 8 – 11 no Δ	Palliate & d/c from CC	Exclusion Criteria ** or SOFA > 11 ** or SOFA 8 – 11 no Δ	Palliate & d/c from CC
Red	SOFA < 7 or Single Organ Failure	Highest	SOFA < 11 and decreasing	Highest	SOFA score < 11 and decreasing progressively	Highest
Yellow	SOFA 8 - 11	Intermediate	SOFA < 8 no Δ	Intermediate	SOFA < 8 minimal decrease (< 3 point decrease in past 72 hrs)	Intermediate
Green	No significant organ failure	Defer or d/c, reassess as needed	No longer ventilator dependant	d/c from CC	No longer ventilator dependant	d/c from CC

*If exclusion criteria or SOFA > 11 occurs at any time from the initial assessment to 48 hours change triage code to Blue and palliate.

** If exclusion criteria or SOFA > 11 occurs at anytime from 48 – 120 hours change triage code to Blue and palliate.

Δ = change CC = critical care d/c = discharge

- **Blue:** High probability of mortality; should be discharged from critical care and should receive medical management and palliative care as appropriate
- **Red:** Highest priority for critical care
- **Yellow:** Intermediate priority for critical care
- **Green:** Low probability of mortality; defer admission/ discharge from critical care

The initiation of other, more sophisticated methods of ventilatory support, such as ECMO or HFOV, will be evaluated and allocated using the same criteria as conventional ventilatory support. There is concern that these already scarce resources will become more frequently requested interventions, but their use strains the efficient and maximal use of all available resources and thus will be limited by established medical criteria. External transfers of patients into the hospital should be based on availability of resources and on medical necessity.

The above triage tools were designed to address a pandemic severe respiratory illness. As information about the illness is obtained, the criteria will need to be reviewed and refined. MMEs that are short lived and local or regional, where the expectation of material or other assistance is forthcoming, may not require implementation of such protocols.

Oxygen Therapy:

Given that in the worse case scenario, 15-20% of influenza patients may acquire pneumonia⁴⁸ during a pandemic, it is likely that oxygen therapy will be in great demand. In addition, the current needs for oxygen supplementation for COPD, heart failure, cystic fibrosis, and other respiratory diseases will remain the same. As such rationing decisions may need to be implemented. If rationing of oxygen therapy is required; oxygen will be administered based on the following guidelines:

- Ventilated patients
- Adult patients with oxygen saturation < 86% on room air
- Pediatric patients > 1 year with oxygen saturation <88% on room or respiratory rate of >40
- Pediatric patients with oxygen saturation <88% on room air or respiratory rate >60
- Hypoxic patients with pneumonia

It is unlikely that oxygen supplies will be depleted because of the storage capacity of hospitals and the ease of delivery by vendors. If oxygen supplies or personnel required to administer oxygen therapy become scarce, those patients categorized as Blue (expectant) who are not be eligible for ventilators will also not be eligible for oxygen therapy. Every effort will be made using other therapeutic means to keep these dying patients' comfortable (see Palliative Care Section).

Patients who are discharged requiring supplemental oxygen will go home with the oxygen masks or nasal cannulae used during their inpatient stay. Outpatients who

⁴⁸ Gupta RK, George R, Nguyen-Van-Tam JS. Bacterial pneumonia and pandemic influenza planning. *Emerg Infect Dis.* 2008 Aug;14(8):1187-92

currently receive home oxygen therapy will be resupplied based on oxygen availability and the guidelines listed above. If oxygen is only used during exertional activities, it should not be renewed.

No specific group should have priority for receiving oxygen therapy. Although direct care providers are a priority group for vaccines and antivirals, oxygen will not, by itself, improve survival and it is not likely to help staff return to work more quickly. As such, there will be no oxygen priority for patients on the basis of occupation.

Establishing the capability of providing oxygen delivery to the 250 bed Acute Care Center (ACC) will require the utilization of a mobile cryogenic bulk oxygen system. A micro-bulk cryogenic oxygen vessel with an 850 gallon capacity would support the 250 bed ACC for 4.06 days based on a utilization rate of 2-4 liters per minute per bed. Resupply would be coordinated with current vendor. Some equipment that would be very useful in maintaining the operation of this system may include:

Additional Equipment and Supplies

- GP45 Cryogenic O₂ vessels (backup to micro-bulk supply): 2 each on carts
- External Vaporizers: 2 – 4 each
- Various shutoff valves (~ 6 each)
- 1” Steel Braid transfer hoses (to be specified by bulk supplier)
- Pressure regulating manifold (1 ea)
- Pressure Adjustable regulators (2 each)
- ½” Steel Braid hoses (2 – 60 each)
- 70 each 12’ high pressure hoses
- 125 each TEE adapters
- 500 each ¼ check valves
- 120 each “Y” blocks with integrated Dial-A-Flow O₂ flowmeters
- Backup supply of size E O₂ cylinders – up to 1 cylinder per bed
- O₂ regulators for E O₂ cylinders
- Cylinder wrenches to connect and remove O₂ regulators onto O₂ cylinders
- 2-wheeled cylinder carriers to transport O₂ cylinders: ~100 + each
- 24 – 36 bank O₂ cylinder racks to store O₂ cylinders: ~ 5 – 8 racks

ANTIBIOTIC / ANTIVIRAL RESOURCES

Antibiotic Resources

During a pandemic or other infectious event, antibiotics will be necessary to treat secondary bacterial pneumonias. There is some evidence that many, if not most, of the deaths in the 1918 pandemic could be attributed to secondary bacterial pneumonias with *Streptococcus pneumoniae* and *Staphylococcus aureus*⁴⁹. These are still the most likely pathogens, however, the need to plan for infections with resistant strains of *S pneumoniae* and methicillin resistant *S aureus*. Antibiotics for bacterial pneumonia include: amoxicillin/clavulanate, fluoroquinolones (levofloxacin, gatifloxacin, moxifloxacin), doxycycline, third generation cephalosporins (ceftriaxone and cefotaxime) and macrolides (azithromycin, clarithromycin). In addition vancomycin, linezolid, rifampin, and tigecycline will be required for resistant bacteria⁵⁰.

There are currently no national guidelines on how to allocate antibiotics during a pandemic. It has been estimated that 15-20% of influenza patients developed pneumonia during the three pandemics of the 20th century⁵¹. Applying these estimates to the anticipated patient population of a large hospital system, a 1918-type pandemic might lead to tens of thousands of patients needing antibiotic treatment for pneumonia in a 12 week period. Many hospitals have stockpiled some antibiotics, particularly ciprofloxacin and doxycycline, for use during a bioterrorist attack. However, ciprofloxacin is not as active as other fluoroquinolones against *S pneumoniae* and, although doxycycline is useful for mild-moderate pneumonias, it is not a first-line agent for severe pneumonias. Other antibiotics would quickly run out during a pandemic. The Strategic National Stockpile (SNS) also contains antibiotics but this cache could not be relied upon as it would be needed in all parts of the country.

During a pandemic, antibiotics should only be used in patients who have suspected or proven bacterial pneumonia. There is no indication for prophylactic use of antibiotics to prevent bacterial pneumonia and this practice should be discouraged. Certain high risk patients (COPD, immunocompromised) might be given antibiotics to start immediately if antivirals fail to prevent worsening of respiratory symptoms. Generally, antibiotics should be allocated to those who are most ill and who have the

⁴⁹ Morens DM, Taubenberger JK, Fauci AS. Predominant role of bacterial pneumonia as a cause of death in pandemic influenza: Implications for pandemic influenza preparedness. *J Infect Dis* 2008;198:1-10

⁵⁰ Mandell LA, Wunderink RG, Azueto A, et al. Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults. *Clin Infect Dis* 2007;44:S27-72.

⁵¹ Gupta RK, George R, Nguyen-Van-Tam JS. Bacterial pneumonia and pandemic influenza planning. *Emerg Infect Dis*. 2008 Aug;14(8):1187-92

greatest likelihood for survival. For the sickest inpatients (ICU/Ventilated patients) it is suggested that antibiotics could be distributed based on SOFA scores. For example, patients with a SOFA > 11 (blue range) should not receive antibiotics if these are in short supply. Other hospitalized patients should only receive antibiotics when pneumonia is highly suspected or proven based on clinical symptoms, radiologic procedures, and laboratory data. Clinical case definitions based solely on symptoms and exam findings will be developed as needed in case radiology and laboratory services are overextended. Separate definitions will be required for adolescent/adult and pediatric patients. Outpatients will also only receive antibiotics for suspected or proven bacterial pneumonia or other bacterial complications of influenza. Clinical case definitions will be crucial in this population because limited resources and staffing will not allow for a full work-up with labs and X-rays. The use of more cost effective and more available oral antibiotics like doxycycline, ciprofloxacin, and amoxicillin will be necessary in the outpatient setting, even if these are less effective than intravenous antibiotics (ceftriaxone, vancomycin) and more expensive oral antibiotics (moxifloxacin, linezolid).

Beyond prioritizing antibiotics for patients who have a proven or suspected pneumonia and are likely to survive, it does not make sense to stratify people further. Patients with bacterial pneumonias who go untreated are very likely to have their condition worsen and will ultimately die. Denying antibiotics to anyone in this situation seems ethically unsound if that person is likely to survive with the treatment. This is in contrast to the use of antivirals. Antivirals, as treatment, would be used in patients with influenza symptoms regardless of the presence of pneumonia. Prioritizing can be justified because most people (97%) are expected to survive influenza with no treatment in a 1918-like scenario. Antiviral treatment is most likely to help high-risk groups.

Antiviral Resources

Antivirals including oseltamivir, zanamivir, rimantadine, and amantadine have been shown to decrease the duration of influenza symptoms, decrease hospitalization rates, decrease antibiotic use, and decrease mortality due to influenza^{52 53 54}. Furthermore, these drugs have been used as chemoprophylaxis to prevent acquisition of influenza either after exposure to a case or pre-exposure during the entire influenza season⁵⁵. The most effective antivirals for both treatment and chemoprophylaxis are the

⁵² Bowles SK, Lee W, Simor AE, et al. Use of oseltamivir during influenza outbreaks in Ontario nursing homes, 1999-2000. *J Am Geriatr Soc* 2002;50:608-16

⁵³ Kaiser L, Wat C, Mills T, Mahoney P, Ward P, Hayden F. Impact of oseltamivir treatment on influenza-related lower respiratory tract complications and hospitalizations. *Arch Intern Med* 2003;163:1667-72

⁵⁴ Whitley RJ, Hayden FG, Reisinger KS, et al. Oral oseltamivir treatment of influenza in children. *Pediatr Infect Dis J* 2001;20:127-33

⁵⁵ Ward P, Smith I, Small J, Suter P, Dutkowski R. Oseltamivir (Tamiflu®) and its potential for use in the event of an influenza pandemic. *J Antimicrob Chemother* 2005;55(Suppl S1):i5-i21

neuraminidase inhibitors, oseltamivir and zanamivir, and, as such, the CDC has recommended that these drugs be stockpiled for a potential pandemic and the agency has proposed priority groups that should receive these drugs in the event of an influenza pandemic⁵⁶.

While treatment and post-exposure chemoprophylaxis with antivirals are feasible strategies for protecting our health care workers, pre-exposure prophylaxis an entire hospital workforce may be challenging. As a result the following protocol has been proposed for the use of antivirals for hospital staff:

Assumptions:

- No vaccine will be available to protect staff exposed to influenza patients.
- Personal Protective Equipment will provide adequate protection against influenza if used properly.
- Antivirals have little effect if administered 48 hours after the onset of influenza symptoms (fever, myalgias, and cough)..
- Certain staff on flu wards, in the ED and at the Alternate Care Centers (ACCs) will be at a much higher risk of becoming infected.
- Staff might not present to work if they are not afforded adequate protection.

Antiviral Distribution Protocol:

Many hospitals intend to stockpile enough antivirals to treat and give chemoprophylaxis to at-risk workers. The Michigan Strategic National Stockpile (MISNS) has a limited cache of antivirals for distribution as indicated by the incident.

Any private stockpiling efforts are within the control of individual hospitals to manage and distribute as they see fit consistent with the ethical allocation criteria included in the Guidelines. The state stockpile will be distributed under the ethical allocation criteria included in the Guidelines.

PALLIATIVE CARE RESOURCES

Regardless of modeling or assumptions, a major pandemic event will require significant resources to care for dying patients and their families. Minimum expected case fatality rate up to 3% based on historical influenza pandemic data. The impact of pandemic death (Table 1) will stress all parts of the healthcare system and require clear, executable strategies for supporting very large numbers of patients and their families through the end of life.

⁵⁶ <http://www.hhs.gov/pandemicflu/plan/appendixd.html>

The ethical imperative to provide pandemic palliative care is well-supported under the framework used to create guidelines for ventilator allocation; specifically, obligations to individual patients, institutional competence and utility. Planning for palliative care resource allocation must also be guided by justice and fair distribution of resources, and administered honestly and transparently with specific processes for accountability to patients and families, institutional partners and state and community stakeholders.

In addition to the ethical imperative, palliative care is now recognized as a core institutional competency by multiple organizations including the Joint Commission (JCAHO) and the National Quality Forum (NQF). Palliative Medicine is also now a recognized American Board of Medical Specialties (ABMS) subspecialty and formal palliative care clinical services are now present in 70% of larger U.S. hospitals, creating not only an infrastructure for palliative care delivery, but also an expectation from patients, families and communities of available, responsive and competent care for patients through end of life.

Formal palliative care clinical guidelines have been developed and widely endorsed (*available at nationalconsensusproject.org*), and stress the importance of care in four key areas: physical symptom management (pain, dyspnea, nausea, etc); psychological symptom management (anxiety, depression, agitation, delirium); support for family and close persons; and spiritual care for patients and loved ones. Quality palliative care is also to be delivered by an interdisciplinary team skilled in integrating services across these domains, frequently consisting of physicians and advanced-practice nurses, social workers, and spiritual care providers.

As with all clinical resources mobilized for pandemic care, palliative care providers are limited and will need to be allocated based upon need and availability. Unlike some resources that can be concentrated geographically (i.e. ventilators, critical care providers), palliative care support will be needed across all care settings, including inpatient and intensive care, the alternative care center (ACC), and outpatient and community contact points. It should be assumed that patients with life-threatening illness could (and will) receive care in all parts of the system, which creates a formidable task to source palliative care throughout.

The broad need for palliative care during a pandemic does not dictate that resources be distributed evenly among settings, but that reasonable efforts be made to provide support likely to be most useful in each. For instance, it is expected that patients who require mechanical ventilation (whether or not they receive it) by definition have life-limiting illness, and thus a high mortality risk. In fact, those who require mechanical ventilation but do not receive it (per established protocols or CRC action) are most likely to require prompt, competent palliative care. The distribution of palliative care resources is thus closely connected to ventilator allocation, and should be integrated into the universal triage process for pandemic response.

Palliative Care Resource Allocation

Pandemic palliative care resources can broadly be divided into personnel and non-personnel categories. Non-personnel resources include oxygen, space (particularly private space) and medications for control of anticipated symptoms among those severely ill with influenza (e.g. opioids for breathlessness, benzodiazepines for anxiety/restlessness, anticholinergic medications for respiratory secretions, etc.). It is reasonable to assume that patients sufficiently ill to succumb to pandemic influenza may also have other substantive illness (advanced cancer, congestive heart failure, dementia, etc.) which expands the list of probable symptoms to include significant pain, nausea/vomiting, and agitation, as well as other significant clinical events such as non-respiratory infections, congestive heart failure exacerbations, myocardial infarctions, seizures, and others.

As many of these resources are finite, if not scarce, it is possible (and perhaps likely) that allocation for palliative care will compete with allocation for potentially curative care. Oxygen is a good candidate for such a conflict, if supplies become critically low. There is a fairly sound argument for allocating oxygen to those patients with the highest likelihood of survival, assuming that oxygen supplementation improves survival. Since alternative resources can ease the suffering of those who might benefit from palliation, prioritizing oxygen to probable survivors can be justified, if sufficient medications (e.g. opioids, benzodiazepines, anti-cholinergics, etc.) are available to manage the dying patients's distress acceptably. As with all potential scarce resources, distribution will be guided by SRAC.

Palliative Care Protocols

Given the personnel constraints described above, it will be necessary to develop written palliative care protocols to help unit providers care for patients and families through the end of life. These protocols would provide concise but complete descriptions of assessments and interventions for symptom management and support. Training and acclimation to these protocols will need to occur as part of routine pandemic preparedness training for staff.

Ethical Planning includes Assessment for the Use of Alternative Care Sites

The State of Michigan has a long established a regional healthcare coalition planning structure. Each hospital organization should understand the capabilities of their institution and their local or regional healthcare coordinators to set up an Alternative Care Site (ACS) in the event of an MME. Understandably, rural regions with small hospitals

may not have robust ACS planning in place, but their leaders should be familiar with the region's capabilities within the Michigan Emergency Medical System (MEMS) framework. An ACS could potentially relieve some of the burden on the hospital if the patient surge could be managed with resources that are easily delivered in such a venue, such as minor respiratory care, IV fluids and medications, some noninvasive oxygen delivery and even humane palliative care for the dying.

ANNEX 3: SPECIFIC GUIDANCE ON LEGAL ISSUES RELEVANT TO ALLOCATION OF SCARCE MEDICAL RESOURCES AND SERVICES DURING PUBLIC HEALTH EMERGENCIES

The Ethical Guidelines on Allocation of Scarce Medical Resources and Services During Public Health Emergencies in Michigan must be applied in accordance with federal, state, and local law. Such governing law draws on Constitutional provisions, statutes, regulations, and court decisions. This attachment addresses four key legal issues relevant to the allocation of scarce medical resources during public health emergencies: 1) the authority of the government to declare emergencies and/or disasters; 2) licensing of health care professionals and institutions; 3) applicable standards of care; and 4) liability of health care professionals and volunteers operating under emergencies.

The Committee provides this attachment only as a guide. Health care professionals and institutions should consult with their respective legal counsel on specific questions, situations, and concerns they may encounter during a public health emergency.

1. The ability to declare an emergency or disaster and the consequences of such a declaration.

A number of different legal provisions grant government officials at the federal and state levels the ability to declare an emergency, disaster, or public health emergency. Typically, state-level decisions drive emergency response activities, since many of these activities are governed by laws grounded in the state's police power. In Michigan, the Public Health Code⁵⁷ and the Emergency Management Act⁵⁸ address the management of emergencies and disasters. Both of these laws are construed broadly to allow state officials sufficient power to respond effectively to serious threats to the public's health and affect the ability to make allocation decisions about scarce resources during public health emergencies.

a. Michigan Emergency Management Act

The Emergency Management Act establishes the powers of the Governor to declare an emergency or disaster and to undertake the necessary actions to deal with the emergency or disaster.⁵⁹ The Governor, after a declaring a state of emergency or disaster for the entire state or a region of the state, may take any necessary and appropriate action under the circumstances, including suspension of regulatory statutes, orders, or rules related to the conduct of state business; seizure of property (with compensation); control

⁵⁷ Michigan Compiled Laws (MCL) §333.1101 et seq.

⁵⁸ Michigan Compiled Laws (MCL) §30.401, et seq.

⁵⁹ Michigan Compiled Laws (MCL) §30.403.

of access to and from affected areas; as well as a selection of other specified powers.⁶⁰ This Act also permits county and municipal governments to declare a local state of emergency.⁶¹ These powers could be used to control access to scarce medications in the possession of state or local agencies, or could be used to suspend normal regulations related to provision of medical resources.

b. Michigan Public Health Code

The Public Health Code grants the Michigan Department of Community Health (MDCH) and local health departments a wide range of public health powers that may be exercised in responding to a declared emergency or disaster, including powers to isolate and quarantine infected or exposed persons; to restrict movement and interaction of people through closure of roads, public venues, and schools, and suspension of public gatherings; and to coordinate medical interventions such as disease screening and mass vaccination efforts. The Public Health Code authorizes the issuance of emergency orders that can directly impact medical resource allocation.⁶² For example, the Director of MDCH issued an order limiting access to influenza vaccines to persons in high risk categories (including young children, pregnant women, adults over 65, people with underlying chronic medical conditions, and health care workers involved in direct patient care) during an influenza vaccine shortage in 2004. Health providers who violated this order during the two months it was in effect could have faced fines or sanctions imposed by the state.⁶³

c. Stafford Act

At the federal level, several laws permit emergency or disaster declarations and authorize response efforts. The Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1974⁶⁴ allows the President to declare an emergency or major disaster. A presidential declaration of emergency or major disaster under the Stafford Act usually occurs at the request of a state governor. A declaration allows for the federal government to provide assistance to state and local response efforts and to coordinate these response efforts if necessary. Under a Stafford Act emergency declaration, the response activities of all federal agencies are under the authority of the Federal Emergency Management Agency (FEMA) of the Department of Homeland Security (DHS). While the Stafford Act does not directly address issues of scarce resource allocation, the federal resources available through the Act and the federal coordination authorized by the Act may impact the availability of federally-controlled medical resources and personnel to members of the affected populations.

⁶⁰ Michigan Compiled Laws (MCL) §30.405.

⁶¹ Michigan Compiled Laws (MCL) § 30.410.

⁶² Michigan Compiled Laws (MCL) §333.2251.

⁶³ Michigan Compiled Laws (MCL) §333.2261.

⁶⁴ Public Law 93-288 and as codified as amended at 42 U.S.C. §§ 5121-5206 (2007).

d. Public Health Service Act

Pursuant to the Public Health Service Act (PHSA),⁶⁵ the Secretary of the Department of Health and Human Services (HHS) coordinates health and medical services during declared federal emergencies or major disasters. Additionally, the PHSA authorizes the HHS Secretary to declare a public health emergency, which permits the Secretary to take appropriate actions to respond through the provision of economic and logistical support, coordination, and expertise. By exercising these powers, HHS is able to expedite the availability of resources to alleviate a shortage. The PHSA gives HHS authority to coordinate activities related to vaccine development, stockpiling of medical resources, and immunization programs, as well as research and investigation into the cause, treatment, and prevention of the public health emergency. The PHSA allows the Secretary to initiate the process to use unapproved products or approved products for unapproved uses or to waive certain regulatory requirements.⁶⁶ The Public Health Security and Bioterrorism Preparedness and Response Act of 2002⁶⁷ amended the PHSA to establish the National Response Framework and the Strategic National Stockpile, as well as providing the HHS with the authority to suspend certain HIPAA (Health Insurance Portability and Accountability Act) and EMTALA (Emergency Medical Treatment and Labor Act) regulations during a public health emergency. On the national level, such powers authorize the HHS to effectively coordinate the appropriate federal resources to optimize response to the public health emergency when state and local resources may be diminished.

Formal declarations of a state of emergency, disaster, or public health emergency streamline access to potentially useful resources and may impact the required standards of care applicable to the response efforts (see section 3 below). Federal and state public health and emergency laws link a declaration of emergency to the provision of funds or specific aid to the area affected by the emergency, and in some instances provide the authority for directly imposing requirements on resource allocation decisions. Furthermore, these declarations may alter the legal environment in relevant ways that affect licensure and liability as described in the sections that follow.

2. Licensing of Personnel and Institutions in Emergency Situations, or Instances of Shortage.

Health care professionals must be licensed in the state of Michigan in their respective roles as physician, nurse, pharmacist, social worker, etc. to provide services. Such licensing requirements serve to protect the public from fraudulent practice as well as distinguish roles and competencies among health professionals. During a public health

⁶⁵ Public Health Service Act, 42 U.S.C. 201 et. seq. (2007) as amended.

⁶⁶ 42 U.S.C. 247d

⁶⁷ Public Law 107-188, 42 U.S.C. 201, The Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

emergency, scarcity may require efforts to expand staff capacity to deliver the necessary services across health care and public health systems.

Several state laws in Michigan relax the normal professional license requirements under certain circumstances during a public health emergency. As a means of coping with medical professional shortages during a time of crisis these laws may allow licensed out-of-state health professionals to practice without specific Michigan licensure or other persons with professional training to perform certain professional tasks without meeting the usual licensure requirements.

- A Michigan license is not required for an individual who by education, training, or experience substantially meets the state’s licensing requirements while rendering medical care in a time of disaster or while rendering medical care to an ill or injured individual at the scene of an emergency.⁶⁸
- A Michigan license is not required for an individual deployed under the Emergency Management Assistance Compact who is licensed in another state party to the compact.⁶⁹
- During a declared emergency or disaster, the Governor may suspend regulatory laws that impede the response to the emergency in an effort to expedite care, including licensure requirements.⁷⁰
- The Michigan Emergency Management Act provides that if an emergency or disaster has been declared, health professionals have an expanded scope of practice provided that they practice “under the supervision of a member of the medical staff of a licensed hospital.”⁷¹
- The Governor has the power to waive licensing requirements in the event that a health professional needs to provide services outside the normal scope of the license or a health care facility needs to expand space in excess of its existing license.⁷²
- The Public Health Service Act permits the waiver of some health professional and health facility requirements set by Medicare and Medicaid. The Department of Health and Human Services can issue a waiver under section 1135 of the Social Security Act to waive requirements that health care professionals be licensed in state where they are providing services if they have an equivalent license in another state (this only applies for purposes of Medicare, Medicaid, and CHIP reimbursement). Section 1135 waivers can also be issued to eliminate EMTALA sanctions for transferring patients to alternative locations for medical screening.

⁶⁸ Michigan Compiled Laws (MCL) § 333.16171.

⁶⁹ Michigan Compiled Laws (MCL) § 3.991.

⁷⁰ Michigan Compiled Laws (MCL) § 30.405.

⁷¹ Michigan Compiled Laws (MCL) § 30.411.

⁷² Michigan Compiled Laws (MCL) § 30.405.

These various provisions allow for the relaxation of licensing requirements for health professionals and health facilities during public health emergencies. Expansion of the availability of medical resources and services can be advanced by the use of these provisions, thereby reducing scarcity.

3. The Government and Altered Standards Of Care During A Public Health Emergency.

Professional standards of care are parameters established by law that outline the duty owed by a health professional to a patient. Professionals who violate the standard of care may be found liable for malpractice under state tort law. In the state of Michigan, all health professionals are expected to comport with the recognized standard of professional skill or care for those in their profession in the same or similar community in which they practice under the circumstances. If the professional is a specialist, he or she must uphold the recognized standard of practice within that specialty given the available facilities under the circumstances.⁷³ Since circumstances under situations of scarcity during public health emergencies differ from normal practice circumstances, what is expected of professionals under situations of scarcity will also differ. Regardless, the standard of care—acting consistently with the recognized professional skill or care under the circumstances—remains the same.

Since the level of care required to comply with the standard of care varies and changes according to relevant circumstances at the time and place of the act or omission in question, and it can be affected by resource availability. For example, during a public health emergency the standard of care may change because circumstances of scarcity may constrain the options available to a health professional as resources are allocated according to emergency protocols and the Ethical Guidelines. Formally recognized emergency protocols and guidance, while not legally determinative, may provide persuasive evidence for the applicable standard of care during a public health emergency featuring scarcity.

In addition, state and federal law authorizes the government to change the scope of the standard of care during a declared emergency or disaster. A public health emergency declared by the Governor of Michigan allows for the establishment of emergency centers and protocols, including altered levels of care if appropriate, under the Emergency Management Act,⁷⁴ or to issues orders for the protection of public health that have the effect of altering the scope of the standard of care.⁷⁵ The MDCH order limiting

⁷³ Michigan Compiled Laws (MCL) § 600.2912a.

⁷⁴ Michigan Compiled Laws (MCL) § 30.402, et seq.

⁷⁵ Michigan Compiled Laws (MCL) §333.2251.

access to influenza vaccines to persons in high risk categories in 2004 (described above) provides another example of this power in action.

Federal law provides for exceptions to EMTALA during public health emergencies, which effectively changes the standard of care for many hospital emergency departments. EMTALA requires that all Medicare-participating hospitals with emergency departments provide certain basic medical screening, treatment, and stabilization for all patients arriving at the emergency department, regardless of ability to pay.⁷⁶ Hospitals who fail to comply with these requirements can face fines or civil liability. However, HHS may waive EMTALA requirements during public health emergencies if there has been a Presidential declaration of emergency or major disaster under the Stafford Act, a declared public health emergency by the Secretary of HHS, and other procedural steps are followed.⁷⁷ Hospitals who qualify for the EMTALA waiver may direct or relocate patients to off-site locations or transfer patients who have not been stabilized.⁷⁸ Federal law is essentially recognizing that during public health emergencies, hospital emergency rooms may have difficulty in serving everyone. Taken together, these federal and state provisions greatly impact the expectation on health professionals as they make decisions related to the allocation of scarce medical resources during public health emergencies.

4. Available Liability Protection For Staff and Volunteers During A Public Health Emergency.

Tort liability can be a great concern of individuals and institutions responding during public health emergencies. A number of different legal provisions in state and federal law provide protection from liability for health professionals and volunteers during public health emergencies. The reason for these protections is to incentivize volunteers to participate during public health emergencies. Volunteers can help satisfy needs and fill shortages within the health system during conditions of scarcity. Without protection from liability volunteers may choose not participate.

a. Liability Protection Under Michigan Law.

Michigan law provides liability protection for individuals, institutions, and organizations providing services during a public health emergency if certain conditions are met. These state liability protections, however, do not protect in most cases against liability arising from acts of wanton or willful misconduct or gross negligence.

- Michigan law provides immunity from liability if a healthcare professional (defined to include physicians, physician assistants, nurses, dentists, interns and residents as well as selective allied health professionals)

⁷⁶ 42 U.S.C. § 1395dd et seq.

⁷⁷ 42 U.S.C. § 1320b-5.

⁷⁸ See HHS, *CMS Memo: Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Options for Hospitals in a Disaster*, Ref: S&C-09-52 (August 14, 2009).

- responds to a life-threatening emergency within a licensed medical facility when such a response is not part of his or her professional duties.⁷⁹
- Similarly, the Michigan Good Samaritan Act⁸⁰ extends liability protection to physicians, physician assistants, and nurses (both RNs and LPNs) who provide emergency care at an emergency scene, is uncompensated, and outside the hospital setting. The providers must have acted in good faith and have had no pre-existing patient relationship for the immunity to apply. If the Governor has declared an emergency or disaster, the director of the department of state police may issue a directive relieving persons or groups providing voluntary or private assistance from liability other than for gross negligence.⁸¹
 - The Michigan Emergency Management Act also establishes liability protection for “state and nongovernmental disaster relief force workers or private or volunteer personnel engaged in disaster relief activity.”⁸²
 - The Michigan Public Health Code carries many of the protections against liability for personnel dealing with emergencies within the state. While it does not provide protection against gross negligence, willful or wanton misconduct, or acts or omissions intended to injure the patient, the Code does provide liability protection for individuals serving in specified capacities. There are protections in place for first responders and EMS personnel⁸³, MDCH representatives or health department employees⁸⁴, those persons participating in mass immunization efforts⁸⁵, and volunteer health professionals serving the uninsured if certain conditions are satisfied.⁸⁶
 - The Emergency Management Assistance Compact (EMAC) provides the immunity from liability for good faith acts or omissions of officers or employees of the state party rendering aid. Therefore, responders sent to Michigan from other states pursuant to EMAC can claim immunity from liability from any acts or omissions that are not considered willful misconduct, gross negligence, or recklessness.⁸⁷

⁷⁹ See Michigan Compiled Laws (MCL) 691.1502

⁸⁰ Michigan Compiled Laws (MCL) § 691.1501

⁸¹ Michigan Compiled Laws (MCL) § 30.407(6)

⁸² Michigan Compiled Laws (MCL) § 30.411

⁸³ Michigan Compiled Laws (MCL) § 333.20965

⁸⁴ Michigan Compiled Laws (MCL) § 333.2228; MCL 333.2465

⁸⁵ Michigan Compiled Laws (MCL) § 333.9203

⁸⁶ Michigan Compiled Laws (MCL) § 333.16277

⁸⁷ Michigan Compiled Laws (MCL) § 3.991.

b. Federal Liability Protection.

The federal Volunteer Protection Act⁸⁸ (VPA) provides liability protection for the acts or omissions of volunteers working with non-profit and governmental agencies, provided that these volunteers are acting within the scope of their responsibilities, in compliance with state laws regarding the practice of such responsibilities, and not receiving compensation for their efforts other than reasonable reimbursement for incurred expenses. The VPA does not provide liability protection against willful, gross negligence, reckless or criminal misconduct. Taken together, the VPA, the Michigan Good Samaritan Act, and Michigan's Public Health Code, supply a great deal of liability protection for those who volunteer to respond to public health emergencies within Michigan.

Additionally, individuals and entities engaged in designing, manufacturing, labeling, distributing, selling, donating, administering, etc. pharmaceutical countermeasures during a public health emergency may find protection under the Public Readiness and Emergency Preparedness Act (PREP Act), which modified the PHSA.⁸⁹ The PREP Act allocates resources, encourages development of response plans by state and local agencies,⁹⁰ allows for strategic stockpiles,⁹¹ and includes provisions for the development of public health countermeasures.⁹² Because the law encourages rapid development of countermeasures, specifically vaccines and other response drugs, the law protects from liability those persons and organizations who develop, manufacture, distribute, sell, or otherwise have involvement with these products.⁹³ This liability protection, while extremely broad, is intended to provide an incentive for expedited development of these necessary countermeasures without the usual FDA procedural and quality control safeguards, which may be waived in times of emergency.⁹⁴ Without these protective provisions a company which produces a vaccine which may not be effective, or has unforeseen side effects could be held liable for all harm caused by the drug despite its being used in an unintended way, or before testing could be completed. The PREP component also preempts state law, meaning that no state can afford less protection to these entities protected by a PREP act declaration. The act does not, however, protect companies or other entities from liability for "willful misconduct" as outlined in 42 U.S.C. § 247d-6d, which primarily focuses on intended harm. The Secretary of HHS must designate a specific countermeasure before these strong liability protections apply.⁹⁵ Currently there are very few such countermeasures recognized.⁹⁶ In summary, the PREP

⁸⁸ 42 U.S.C. § 14501 et seq.

⁸⁹ Part of the Public Health Service Act, 42 U.S.C. §247d-6d.

⁹⁰ 42 U.S.C. §247d-3a

⁹¹ 42 U.S.C. §247d-6b

⁹² 42 U.S.C. §247d-6a

⁹³ 42 U.S.C. § 247d-6d

⁹⁴ 42 U.S.C. §247d-6b

⁹⁵ 42 U.S.C. § 247d-6d

⁹⁶ The HHS PREP Act website details PREP Act declarations. See <http://www.hhs.gov/disasters/discussion/planners/prepact/index.html>

act provides protection for virtually everyone involved in the provision of medical and public health countermeasures. This very broad protection incentivizes the production of new countermeasure, which may reduce scarcity of medical resources during public health emergencies.

APPENDIX 1: DEFINITIONS

The following definitions are used throughout this document:

Essential Personnel: those whose functions are critical to limiting deaths and degradation of health care, public health, public safety and other critical infrastructures, including volunteers.

Public Health Emergency: an occurrence or imminent threat of an illness or health condition that:

(1) is believed to be caused by any of the following: (i) bioterrorism; (ii) the appearance of a novel or previously controlled or eradicated etiological agent or toxin; (iii) a natural disaster; (iv) a chemical attack or accidental release; or (v) a nuclear attack or accident; and

(2) poses a high probability of any of the following harms: (i) a large number of deaths in the affected population; (ii) a large number of serious or long-term disabilities in the affected population, including disabilities that occur from physical, psychological, or emotional injuries; or (iii) widespread exposure to an infectious or toxic agent that poses a significant risk of substantial future harm to a large number of people in the affected population.⁹⁷

Scarce Medical Resource: a medical resource that is unavailable in sufficient quantity to provide to all patients who need the resource during a public health emergency. The specific resources identified as scarce medical resources will vary according to the type and scope of the public health emergency, but will include supplies (medicine, machines, other medical and support materials), space (available beds and treatment areas), and staff (adequately trained health care professionals). In the event of an influenza pandemic, for example, ventilators, masks, ICU beds, antivirals, and health care personnel are some of the types of medical resources that may be insufficient in quantity to treat all who are in need of them for the duration of the outbreak.

Scarce Medical Service: a medical service that is unavailable during a public health emergency due to insufficient quantity to provide to all patients who need the service or due to concerns that providing the services will impact the ability to adequately respond to the public health emergency. The scarcity of medical services will be closely linked to scarcity in medical resources. For example, in a public health emergency where ICU beds or health care personnel are scarce, the medical services provided in these beds or by these personnel may be similarly limited. Even if a resource is physically available, the exigencies of a public health emergency may cause a decision-maker to choose not to

⁹⁷ This definition is adapted from the Model State Emergency Health Powers Act (2001), which was drafted by the Center for Law and the Public's Health. The full text of this Model Act is available at: www.publichelathlaw.net/modelacts.

provide a service in order to steward resources for anticipated future needs, thus creating a scarcity of medical services. Protocols for use of ambulances or the availability of elective surgical procedures, for instance, may be limited during a public health emergency.

APPENDIX 2: ETHICS ADVISORY COMMITTEE PARTICIPANTS

Beginning in Fall 2008, Professor Lance Gable, Principal Investigator, began to develop these Guidelines along with expert guidance from the Ethics Advisory Committee (EAC). These Guidelines were drafted by Professor Gable along with substantial input from the EAC. Representing a wide range of subject matter expertise and professional training, the EAC met over the course of several years to debate and discuss the vital ethical and practical issues surrounding allocation of scarce medical resources and services during public health emergencies.

The following individuals served as members of the EAC and attended one or more advisory committee meetings: Lance Gable (Wayne State University, chair); Nancy Baum (University of Michigan); Julie Bulson (Spectrum Health); Denise Chrysler (MDCH); Don Edwards (District 1 Regional Medical Response Coalition); Leonard Fleck (Michigan State University); Sheri Greehoe (Michigan State Medical Society); Charles Guernsey (Michigan Osteopathic Association); Peter Hammer (Wayne State University); Gregory Holzman (MDCH); Theresa Jenkins (MDCH); Mark Kielhorn (MDCH); Marie Lozon (University of Michigan); Mary Macqueen (MDCH); Harry McGee (MDCH); Doris Neumeyer (Beaumont Hospital); Jeff Nigl (Region 3 Health Care Preparedness Network); Shelley Norris-Chapman (MDCH); Robert Piccinini (Michigan Osteopathic Association); Greg Roberts (Michigan Department of Human Services); Thomas Sands (Michigan State Police); Peter Schonfeld (Michigan Health and Hospital Association); Jacqueline Scott (MDCH); Linda Scott (MDCH); Dean Sienko (Ingham County Health Department); Matthew Rick (MDCH); Ashley Vandekopple (MDCH); Eden Wells (MDCH); John Wernet (Office of the Governor); Pamela Yager (Office of the Governor). Participation in the EAC does not necessarily represent the agreement or endorsement of all aspects of the Guidelines by these individuals or their organization.

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