Navigating Crisis Standards and Scarce Resources During the COVID-19 Pandemic and Beyond

By Katherine M. Dru, Esq., Centura Health, Centennial, CO, Alicia W. Macklin, Esq., Hooper, Lundy & Bookman, P.C., Los Angeles, CA, and Andrea L. Frey Esq. and Maydha B. Vinson, Hooper, Lundy & Bookman, P.C., San Francisco, CA

As hospitals throughout the United States confronted a disastrous "third wave" of COVID-19 patients this past winter and into the early spring, the specter of rationing scarce medical resources — such as ventilators, medications, staff, and ICU beds — went from unthinkable to unavoidable. While hospital capabilities to fight COVID-19 have made significant strides since the early days of the pandemic, this winter's rapid increase in COVID-19 patients left many hospitals scrambling to figure out what to do when there simply were not enough medical resources to go around.

The concept of rationing scarce medical resources is not new, but in recent history has generally been inconceivable in countries with modern healthcare systems. COVID-19 upended this. In March 2020, physicians in Italy — unable to keep up with the sudden demands on limited resources created by the pandemic — reported agonizing over impossible decisions of "who must die and whom we shall keep alive."[1] Although the United States avoided similar worst-case scenarios at that time, and states took aggressive action to assist overloaded health systems,[2] the uncontrolled spike in infections throughout the country as the pandemic raged on once again brought the dilemma of limited critical supplies and massive influxes of patients to the forefront.

Resource allocation policies have broad support from medical ethicists as an effective means of ensuring consistent and ethical allocation of limited medical resources,[3] and crisis care guidelines recently have proliferated at both the state and health system levels.[4] Organizations including the American Medical Association (AMA) and the World Health Organization (WHO) have expressed support for resource allocation policies, and the WHO has published guidance for best adapting these policies to the current resource needs of the COVID-19 pandemic.[5] Thoughtful resource allocation policies can guide providers through the extremely difficult set of decisions involved in determining which patients should have access to high-demand resources when supply is limited. Additionally, effective implementation of a resource allocation policy can help shield providers from potential liability for withholding necessary care.

Resource Allocation Policies Overview

In general, resource allocation policies set forth levels of triage or decision-making processes that guide healthcare providers using a step-by-step framework to decide who should receive a scarce resource and who should not. Most policies are motivated by the ethical principle of maximizing the beneficial use of scarce resources for the greatest number of patients, though the actual framework for determining who receives care or resources varies. Maximizing benefits is usually understood to mean saving the most lives by giving priority to patients more likely to recover after treatment. With this principle at the forefront, many policies rely upon triage committees and priority scoring measurements and comorbid conditions to prioritize which patients should receive the resources identified as scarce based on both their short and long-term prognoses. (The Sequential Organ Failure Assessment (SOFA) score, for example, uses certain variables such as to predict a patient's outcome by assessing the degree of a patient's organ system dysfunction and provides a sort of predictive metric for the prognoses of adult patients requiring critical care). However, other ethical values may also drive how a policy is shaped; for example, a facility that prioritizes principles of fairness may adopt a random lottery or a first-come, first-serve allocation policy while others that

prioritize principles of health equity may, alternatively, introduce a correction factor into patients' priority scores to weight certain members of society higher in their criteria for eligibility, such as patients from vulnerable populations or "essential workers" on the front line providing services.[6] Additionally, the allocation process may vary depending on the type of resource in question and as more information becomes available. For instance, a policy may focus exclusively on one type of scarce resource (*e.g.*, a certain type of medication) or may broadly apply to any resource of which there is limited supply.

Some states have taken action to adopt guidelines for allocating scarce resources during the pandemic. For example, in July 2020, Arizona became the first state to adopt Crisis Standards of Care, which provide guidelines on triaging patients and reusing resources, including standards used to assess patients to see if the patient will "substantially benefit from the treatment that is available."[7] California, likewise, created Crisis Care Guidelines that take a triage approach similar to Arizona's plan. Where states have not taken action, a number of health systems and facilities have developed their own policies, such as in South Texas, where Starr County Memorial Hospital implemented an ethics and triage committee to review all COVID-19 patients to determine what type of life-saving equipment and treatment they require and whether they would likely survive. Those deemed too fragile, sick, or elderly are advised to go home to loved ones.[8] Another policy, developed by ethicists at the University of Pittsburgh Medical Center (UPMC), has been promoted as a model for health systems and facilities as a transparent and fair approach for allocating scarce critical care resources. Specifically, the model policy suggests the creation of allocation teams to ensure consistent decision-making and sets forth allocation criteria to prioritize patients who are most likely to benefit from access to critical care resources based on validated measures of acute physiology, rather than any sort of categorical exclusion criteria.[9]

As discussed below, regardless of the form a policy takes, it must be applied fairly and equally, and carefully structured to avoid creating categories of exclusion based on factors other than good clinical decisions supported by individualized patient assessments and empirical evidence.

Considerations and Practical Tips When Developing Resource Allocation Policies

Application of Federal and State Discrimination Laws to Resource Allocation Policies

A resource allocation policy that is not carefully crafted could potentially implicate laws prohibiting discrimination. In particular, at the

federal level, there are a number of laws including the Americans with Disabilities Act of 1990 (ADA),[10] Section 504 of the Rehabilitation Act of 1973,[11] and Section 1557 of the Patient Protection and Affordable Care Act[12] that prohibit disability-based discrimination by healthcare providers and/or health programs that receive federal financial assistance or are operated under a federal program or activity, depending on the particular law.[13] There is also a federal law, the Age Discrimination Act of 1975, which prohibits discrimination on the basis of age in programs or activities receiving federal financial assistance.[14]

At the state level, in particular, almost all states have adopted disability rights laws that complement the ADA. Where these state laws provide heightened nondiscrimination requirements or additional protection and remedies *beyond* the ADA requirements, a person with a disability may pursue both an ADA claim and the state law claim for any alleged violations. For example, in California, under the Unruh Civil Rights Act, any form of arbitrary discrimination on the basis of a wide variety of characteristics, including sex, disability, genetic information, race, religion, color, ancestry, and national origin, is prohibited. In addition to disability, section 51(e) of the Unruh Act lists "medical condition" (defined as "any health impairment related to or associated with a diagnosis of cancer or a record or history of cancer") as another characteristic protected under the law. Similarly, in Colorado, the Colorado Anti-Discrimination Act prohibits discriminatory actions against protected classes in "places of public accommodations," meaning "any place of business engaged in any sales to the public and any place offering services, facilities, privileges, advantages, or accommodations to the public," which includes hospitals.[15] The protected classes listed by the Colorado Anti-Discrimination Act include disability as well as race, creed, color, sex, sexual orientation, marital status, national origin, or ancestry.

The Department of Health and Human Services' Office for Civil Rights (OCR), the federal agency responsible for enforcing federal disability discrimination laws, has been actively investigating complaints related to state protocols to ration lifesaving medical care and has been providing technical assistance and guidance.[16] To date, OCR has conducted an investigation of four states'[17] allocation policies or protocols, and has offered technical assistance to several other states, as well as the Indian Health Service.[18] Throughout these efforts, OCR has made clear that "persons with disabilities should not be denied medical care on the basis of stereotypes, assessments of quality of life, or judgments about a person's relative 'worth' based on the presence or absence of disabilities. Decisions by covered entities concerning whether an individual is a candidate for treatment should be based on an individualized assessment of the patient based on the best available objective medical evidence."[19] While "states are free to and encouraged to adopt clear triage policies, ... they must do so within the guardrails of the law."[20] "Triage decisions must be based on objective and individualized evidence, not discriminatory assumptions about

the prognoses of persons with disabilities."[21]

OCR has also issued more recent guidance reminding healthcare providers who are recipients of federal financial assistance that, in addition to disability rights laws, providers must comply with applicable federal civil rights laws (such as Title VI of the Civil Rights Act of 1964), and regulations that prohibit discrimination on the basis of race, color, and national origin, even during COVID-19.[22] In particular, OCR noted that healthcare providers, including state and local agencies, must "[e]nsure that individuals from racial and ethnic minority groups are not subjected to excessive wait times, rejected for hospital admissions, or denied access to intensive care units compared to similarly situated non-minority individuals."[23]

In addition to OCR's work with state entities regarding their crisis standards of care guidelines, the agency also recently collaborated with the National Academy of Medicine (NAM) to advise on the development of a statement issued by the NAM and nine other national organizations reflecting key best practices for crisis standards care plans.[24] Released December 18, 2020, the statement calls upon governors, health departments, hospitals, and other healthcare sector partners to act immediately to be prepared to implement crisis standards of care and makes recommendations around addressing resource allocation decisions. For hospitals, the "best practices" highlighted in the joint statement include:

- "Socialize existing CSC plans with health care personnel and take steps to make the plans operational, including determining how staffing shortages will be addressed and what resources clinicians can draw upon for difficult triage or allocation decisions. Whenever possible, these decisions should be made according to best available evidence, consistent with crisis standards guidance, and supported by an incident management team, rather than left to bedside providers.

- . . . Plans should be focused on describing the incremental changes to the way health care – particularly critical care – will be delivered. They should define how staffing accommodations will be implemented to cover the demand for services as fairly as possible. Plans should define the role of an incident command team, how the facility should interact with the rest of the health care system in its region, and the clinical and resource support that is available to clinicians who have to make decisions that fall outside their usual practice standards.

- Provide instruction related to applicable civil rights law in the adoption and implementation of CSC plans including prohibitions on unlawful stereotyping.

- Make resource allocation decisions based on individualized assessments of each patient, using the best available objective medical evidence concerning likelihood of death prior to or imminently after hospital discharge, including clinical factors relevant and available to such determinations, which may include age under limited circumstances.

- However, such assessments should NOT use categorical exclusion criteria on the basis of disability or age; judgments as to long-term life expectancy; evaluations of the relative worth of life, including through quality of life judgments, and should NOT deprioritize persons on the basis of disability or age because they may consume more treatment resources or require auxiliary aids or supports.

- Plan for how to engage families and palliative care departments in end-of-life discussions and, crucially, ensure that end-of-life wishes are documented, including desire for multi-organ failure support and prolonged mechanical ventilation. Avoid steering or pressuring patients to agree to the withdrawal or withholding of life-sustaining care."[25]

While OCR investigations related to crisis standards of care and related guidelines thus far have focused on state-level policies, OCR has investigated at least one hospital for issues around reasonable access during COVID-19.[26] In light of the continuing possibility of another surge in COVID-19 cases, and already scarce resources in some states, OCR will likely continue to be proactive in investigating complaints related to both state CSC guidelines and facility-specific resource allocation policies.

Other Potential Liability Concerns and Immunities

In addition to potential liability for violating federal and state disability, discrimination, and civil rights laws, providers adopting and implementing resource allocation policies must be wary of potential malpractice lawsuits and quality of care concerns that may implicate their licensure. Malpractice generally is found when a healthcare provider negligently breaches a duty of care owed to a patient. Because the standard of care is based on what a reasonably prudent provider would do in the same circumstances, there is some level of protection built in for extraordinary circumstances like a pandemic. However, healthcare providers must be prepared to defend how their decisions in allocating scarce resources were made. A resource allocation policy that was thoughtfully developed and that is routinely followed will help

to evidence that the hospital and individual healthcare providers acted reasonably given the circumstances.

Individual providers who ration resources during the pandemic also may face quality of care concerns at the administrative level, *e.g.*, from the medical staff and from the state licensing boards. The medical staff of each hospital is responsible for the quality of care rendered to patients at the hospital.[27] To this end, medical staff leaders should be involved in the development of a hospital's scarce resource allocation policy as part of their obligation to ensure quality patient care. With a soundly-developed policy in place, individual practitioners who follow the policy in allocating scarce resources should be protected from action by the medical staff or by the state licensing boards when their actions, unfortunately, result in adverse patient outcomes. Similarly, a hospital with such policies in place will protect itself from violating state and federal licensing requirements. To the extent such policies result in medical staff review of a practitioner's actions those records may be protected from future discovery by state-level evidentiary privileges (*e.g.*, California Evidence Code section 1157).

In addition, states and the federal government have enacted laws specifically to shield healthcare providers from immunity during the pandemic. At the federal level, section 3215 of the CARES Act includes limitations on liability for *volunteer* healthcare workers during the COVID-19 pandemic.[28] However, this does not shield healthcare workers who are paid for their services. For that kind of protection, healthcare providers must rely on state law, to the extent it exists. Although many states had pre-existing "Good Samaritan" laws and laws protecting healthcare providers when a public health emergency has been declared, often those laws did not go so far as to completely shield healthcare providers faced with rationing resources during the pandemic.[29] In response, many states have enacted or amended their laws so that healthcare providers are immune from liability for any acts or omissions taken during the course of providing treatment as part of the pandemic response.[30] Notably, these laws do not provide immunity in the case of gross negligence; having a policy in place for the allocation of scarce resources, and following that policy in practice, should ensure that healthcare providers' actions in rationing care are not deemed "gross negligence."

Final Considerations

Over a year into this global pandemic, the need for having a well-developed allocation policy to address circumstances of scarce resources has become evident. With possible future surges on the horizon and future emergent situations, health systems and other facilities should be encouraged to build out such a policy – to the extent not already done – to create standards for both providers and patients in such

circumstances, and overall, to enhance patient care in times of crisis. For the reasons detailed above, however, these types of policies need to be carefully considered by providers to ensure they are clinically supportable and solidly grounded in underlying ethical principles, in addition to being based on individualized assessments of each patient using the best available objective medical evidence. Given the ever-evolving nature of the COVID-19 pandemic, it is also critical that developed policies be continually reviewed to ensure they stay up-to-date with current information and guidance from both federal and state regulatory agencies.

1 Rosenbaum, L., *Facing Covid-19 in Italy – Ethics, Logistics, and Therapeutics on the Epidemic's Front Line,* 382 N. Engl. J. Med. 1873 – 1875 (March 2020).

2 For example, the California Department of Public Health (CDPH) issued public health orders in January 2021 designed to "reduce pressure on strained hospital systems and redistribute the responsibility of medical care across the state so patients can continue to receive lifesaving care." Office of Communications, CDPH, *State Issues Public Health Order Ensuring Distribution of Health Care Resources across the State to Ensure Patients Get Life-Saving Care as ICU Capacity is Strained* (Jan. 5, 2021), https://www.cdph.ca.gov/Programs/OPA/Pages/NR21-006.aspx.

3 *See* Emanuel, E. *et al., Fair Allocation of Scarce Medical Resources in the Time of Covid-19,* 382 N. Engl. J. Med. 2049 – 2055 (May 2020): "The need to balance multiple ethical values for various interventions and in different circumstances is likely to lead to differing judgments about how much weight to give each value in particular cases. This highlights the need for fair and consistent allocation procedures that include the affected parties: clinicians, patients, public officials, and others. These procedures must be transparent to ensure public trust in their fairness."

4 For reference, crisis standards of care (CSC) exist when healthcare systems are so overwhelmed by a pervasive or catastrophic public health event that it is impossible for them to provide the normal, or standard, level of care to patients. In such situations, regulatory agencies may provide guidance in the form of CSC guidelines that facilities may follow and/or adopt to guide decision-making processes around achieving the best outcome for the community rather than focusing on an individual patient. Resource allocations policies are another term for CSC guidelines that are developed and implemented by a specific facility during such situations.

5 *See* World Health Organization Working Group on Ethics and COVID-19, *Ethics and COVID-19: resource allocation and priority-setting*, World Health Organization (2020), https://www.who.int/ethics/publications/ethics-covid-19-resource-allocation.pdf?ua=1; AMA Principles of Medical Ethics: I, VII, *Allocating Limited Health Care Resources*, American Medical Association (Nov. 14, 2016), https://www.ama-assn.org/delivering-care/ethics/allocating-limited-health-care-resources.

6 White, B. et al, *Mitigating Inequities and Saving Lives with ICU Triage during the COVID-19 Pandemic*, 203 Am. J. Respir. Crit. Care Med. 287 (Feb. 1, 2021).

7 Gurley, J., *Covid-19 Health Rationing: What You Need To Know*, Forbes (July 14, 2020), https://www.forbes.com/sites/nextavenue/2020/07/14/covid-19-health-rationing-what-you-need-to-know/#22037c853c74.

8 Sanchez, S., *Survival potential will determine whether South Texas county hospital takes in COVID-19 patients*, Border Report (July 21, 2020, updated July 23, 2020), https://www.borderreport.com/health/coronavirus/survival-potential-will-determine-whether-south-texas-county-hospital-takes-in-covid-19-patients/.

9 Department of Critical Care Medicine, School of Medicine, Univ. of Pittsburgh, *Allocation of Scarce Critical Care Resources During a Public Health Emergency*, Univ. of Pittsburgh (Apr. 15, 2020), https://ccm.pitt.edu/sites/default/files/UnivPittsburgh_ModelHospitalResourcePolicy_2020_04_15.pdf (*see also* https://ccm.pitt.edu/?q=content/model-hospital-policy-allocating-scarce-critical-care-resources-available-online-now). In collaboration with Harvard University, The University of Denver, Boston College and MIT, UPMC has also put together a "Model Hospital Policy for Fair Allocation of Scarce Medications to Treat COVID-19," available to download from https://ccm.pitt.edu/?q=content/model-hospital-policy-fair-allocation-medications-treat-covid-19 (draft last updated May 28, 2020).

10 Pub. L. No. 101-336, 104 Stat. 328 (1990), as amended by ADA Amendments Act of 2008, Pub. L. No. 110-325, 122 Stat. 3553 (2008), codified at 42 U.S.C. § 12101, *et seq.*

11 Pub. L. No. 93-112, title V, § 504, 87 Stat. 394 (1973), codified at 29 U.S.C. § 794.

Pub. L. No. 111-148, title I, § 1557, 124 Stat. 260 (2010), codified at 42 U.S.C. § 18116.

13 The Hill-Burton Act is another federal statute that prohibits discrimination on the basis of disability. The Act requires facilities to provide services "without discrimination on the ground of race, color, national origin, creed, or any other ground unrelated to an individual's need for the service or the availability of the needed service in the facility." However, the Hill-Burton Act only applies to certain facilities that are recipients of Hill-Burton Act funds. *See* 42 U.S.C. §§ 291, 300; 42 C.F.R. 124, Subpart G.

14 *See* 42 U.S.C. § 6101; *see also* 45 C.F.R. §§ 90, 91.

15 CO Rev. Stat. § 24-34-601 (2016).

16 *See* HHS.gov, *Civil Rights and COVID-19* (Jan. 21, 2021), https://www.hhs.gov/civil-rights/for-providers/civil-rights-covid19/index.html.

17 Alabama, Pennsylvania, Tennessee, and Utah.

18 HHS.gov, *OCR Provides Technical Assistance to Ensure Crisis Standards of Care Protect Against Age and Disability Discrimination* (Jan. 14, 2021), https://www.hhs.gov/about/news/2021/01/14/ocr-provides-technical-assistance-ensure-crisis-standards-of-care-protect-against-age-disability-discrimination.html. While OCR has not provided specifics on the technical assistance provided in each case, it notes that such assistance has been provided "through a collaborative process," resulting in issuance of revised crisis standard of care policies with protective language such as the "[p]rohibition on the use of a patient's long-term life expectancy as a factor in the allocation and re-allocation of scarce medical resources." *Id.*

19 HHS.gov, *OCR Issues Bulletin on Civil Rights Laws and HIPAA Flexibilities that Apply During the COVID-19 Emergency* (Mar. 28, 2020), https://www.hhs.gov/about/news/2020/03/28/ocr-issues-bulletin-on-civil-rights-laws-and-hipaa-flexibilities-that-apply-during-the-covid-19-emergency.html#:~:text=These%20laws%2C%20like%20other%20civil,absence%20of%20disabilities%20or%20age.

20 HHS.gov, *OCR Reaches Early Case Resolution With Alabama After It Removes Discriminatory Ventilator Triaging Guidelines* (Apr. 8, 2020), https://www.hhs.gov/about/news/2020/04/08/ocr-reaches-early-case-resolution-alabama-after-it-removes-discriminatory-ventilator-triaging.html.

21 HHS.gov, *OCR Resolves Civil Rights Complaint Against Pennsylvania After it Revises its Pandemic Health Care Triaging Policies to Protect Against Disability Discrimination* (Apr. 16, 2020), https://www.hhs.gov/about/news/2020/04/16/ocr-resolves-civil-rights-complaint-against-pennsylvania-after-it-revises-its-pandemic-health-care.html; *see also* HHS.gov, *OCR Resolves Complaint with Utah After it Revised Crisis Standards of Care to Protect Against Age and Disability Discrimination* (Aug. 20, 2020), https://www.hhs.gov/about/news/2020/08/20/ocr-resolves-complaint-with-utah-after-revised-crisis-standards-of-care-to-protect-against-age-disability-discrimination.html.

22 HHS.gov, *OCR Issues Guidance on Civil Rights Protections Prohibiting Race, Color, and National Origin Discrimination During COVID-19* (July 20, 2020), https://www.hhs.gov/about/news/2020/07/20/ocr-issues-guidance-on-civil-rights-protections-prohibiting-discrimination-during-covid-19.html.

23 HHS Office for Civil Rights in Action, *BULLETIN: Civil Rights Protections Prohibiting Race, Color and National Origin Discrimination during COVID*-19 (July 20, 2020), https://www.hhs.gov/sites/default/files/title-vi-bulletin.pdf.

24 National Academy of Medicine, *National Organizations Call for Action to Implement Crisis Standards of Care During COVID-19 Surge* (Dec. 18, 2020), https://nam.edu/national-organizations-call-for-action-to-implement-crisis-standards-of-care-during-covid-19-surge/.

25 *Id.*

26 HHS.gov, *OCR Resolves Complaints after State of Connecticut and Private Hospital Safeguard the Rights of Persons with Disabilities to Have Reasonable Access to Support Persons in Hospital Settings During COVID-19* (June 9, 2020), https://www.hhs.gov/about/news/2020/06/09/ocr-resolves-complaints-after-state-connecticut-private-hospital-safeguard-rights-persons.html.

27 22 C.C.R. § 70703; The Joint Commission Hospital Accreditation Standards LD 01.05.01, MS.01.01001.

28 *See* Coronavirus Aid, Relief, and Economic Security Act, H.R. 748, Pub. L. 116-136, 134 Stat. 281-615 (Mar. 27, 2020).

29 For example, California Business and Professions Code section 2395 shields healthcare providers from liability for "acts or omissions" that occur after a state of emergency has been declared, but does *not* shield providers "in the event of a willful act or omission." Similarly, California Government Code section 8659(a) shields practitioners who render services during a state of emergency from liability for injuries sustained as a result of those services, *except* in cases of "a willful act or omission." Because the decision to ration resources necessarily is a "willful act or omission," these laws do not protect healthcare providers who are charged with deciding which patients receive scarce life-saving resources, and which do not.

30 *See, e.g.*, New York Executive Order 202.10 (Mar. 7, 2020), https://www.governor.ny.gov/news/no-20210-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency.

About the Authors

Katherine M. Dru is Associate General Counsel for Centura Health in Centennial, Colorado. She previously was a Partner with Hooper, Lundy & Bookman, P.C., practicing in the firm's Los Angeles and Denver offices. Ms. Dru writes and speaks frequently on medical staff topics, and is a Vice-Chair of the ABA Health Law Section's Nursing and Allied Health Professionals Task Force.

Alicia Macklin is a partner in the Los Angeles office of Hooper Lundy & Bookman, P.C., with substantial experience in behavioral health law and EMTALA. She provides regulatory advice to hospitals, handling EMTALA investigations, compliance, training and counseling, and assists clients with a broad range of regulatory matters, including medical staff issues. Ms. Macklin also serves as co-chair of the firm's Health Equity Task Force. She may be reached at amacklin@HEALTH-LAW.com.

Andrea Frey is an associate in the San Francisco office of Hooper Lundy & Bookman, P.C. Her practice focuses on transactional and health care regulatory matters, with an emphasis on medical staff issues, scope of practice, health privacy, digital health, and licensure and certification. Ms. Frey is also the co-chair of the firm's Digital Health Task Force. She may be reached at afrey@HEALTH-LAW.COM.

Maydha Vinson is currently a third-year law student at the University of Michigan. She was a summer associate at Hooper, Lundy & Bookman in 2020 and will be joining the firm full-time after graduating. She is interested in transactional and healthcare regulatory matters.