

April 6, 2020

The Honorable Mandy K. Cohen  
Secretary of Health and Human Services  
North Carolina Department of Health and Human Services  
Adams Building, 101 Blair Drive  
Raleigh, NC 27603

Dear Secretary Cohen,

Attached please find a consensus document, the *North Carolina Protocol for Allocating Scarce Inpatient Critical Care Resources in a Pandemic* (2020 protocol). We would respectfully request that you present this document to the Governor for adoption, in its entirety, as an annex to the State's Emergency Management Plan.

### 2020 Protocol Summary

The primary purpose of the 2020 protocol is to provide recommendations for the triage of all inpatients in the event that a pandemic creates demand for critical care resources, such as ventilators, that outstrips the supply. The protocol would be in effect only when 1) the Governor has declared a State of Emergency due to a pandemic and 2) critical care resources are, or will shortly be, overwhelmed. Key recommendations to achieve the critical purposes of the 2020 protocol include:

- 1) the creation and utilization of triage teams and review committees to promote objectivity;
- 2) use of accepted criteria, methodologies, and processes for initial allocation of critical care resources;
- 3) periodic reassessment to determine whether ongoing provision of critical care treatment is likely to result in improvement for individual inpatients; and
- 4) effective communication with patients and their representatives regarding goals of care and treatment preferences, as well as allocation decision-making processes and results.

Thus, the protocol is not only grounded in ethical obligations (including the duty to care, the duty to steward resources to optimize public health, distributive and procedural justice, inclusivity, equity, and transparency), but it also specifically promotes objectivity in decision-making and endeavors to avoid conflicts of commitments and minimize moral distress. Additionally, the protocol is intended to establish a legal "safe harbor" for healthcare personnel, such that any action or inaction, as applicable, by health care facilities, health care professionals, and other personnel consistent with the recommendations in this protocol, as modified from time to time, are deemed to be in accordance with all applicable standards of practice and otherwise lawful.

We note that the 2020 protocol currently provides for the triage of *adult* inpatients (aged 18 or older). Given an already-identified need for supplemental guidance with respect to pediatric populations (currently in development), we anticipate that an additional recommendation will follow for the adoption of a pediatric appendix to this protocol, as part of the emergency response plan annex described above. Additional modifications may also be recommended from time to time to reflect advances in pandemic emergency medical care generally.

## 2020 Protocol Development Process

The 2020 protocol reflects broad stakeholder input obtained through immense efforts led by the North Carolina Institute of Medicine (NCIOM), the North Carolina Medical Society (NCMS), and the North Carolina Healthcare Association (NCHA).

On Thursday, March 26, 2020, NCIOM, NCMS, and NCHA convened a Scarce Critical Care Resource Allocation Advisory Group (advisory group), co-chaired by Joseph Govert, MD, Duke University Health System, and Karen Smith, MD, family physician, to raise awareness about, and obtain community input on, a revised protocol for allocating scarce inpatient critical care resources during the crisis stage of a pandemic. The advisory group included representatives from community and advocacy groups representing racial and ethnic minorities, vulnerable populations, people with disabilities, older adults, and faith communities, as well as representatives from several clinical specialties (including intensive care, pediatrics, palliative care, emergency medicine, family medicine, psychiatry, infectious disease, nephrology, and anesthesiology), nursing, spiritual care, ethics, law, and public health. The group initially focused on a recently-revised draft of a 2010 *North Carolina Triage Protocol for Allocation of Scarce Critical Care Resources During an Influenza Pandemic* (2010 protocol) developed at the request of then-State Health Director, Jeff Engel, MD. The first draft of the 2010 protocol was produced by the North Carolina Medical Society Ethical and Judicial Affairs Committee, in conjunction with invited bioethicists, intensivists, geriatricians, and representatives from the North Carolina Hospital Association, the Old North State Medical Society, the emergency management community, and NC Public Health.

At the March 26 advisory group meeting, Drs. Govert and Smith provided the charge to the group, presented background and context on the purpose and development of the protocols, and facilitated an extensive, detailed discussion of the newly-revised draft of the 2010 protocol. The advisory group acknowledged the need for urgency and a quick turnaround time due to steadily worsening pandemic conditions but that it was important for stakeholders to be informed and provide input on the draft.

Following the March 26 advisory group meeting, staff from NCIOM, NCMS and NCHA summarized feedback received on the revised North Carolina protocols. The primary areas of discussion included:

- need for statewide adoption of the protocol;
- need to eliminate proposed *a priori* clinical exclusions from the resource allocation process;
- need to remove functional status and activities of daily living (ADLs) as proposed priority scoring factors;
- concerns about age as a proposed factor in priority scoring;
- questions as to whether to include preferences for health care workers in priority scoring; and
- need to address pediatric populations.

Staff then identified and convened additional stakeholders from several major North Carolina health systems for additional input. On Tuesday, March 31, 2020, a health care stakeholder group comprised of clinical, legal, and ethics experts from several major health systems reviewed a newly-revised version of the draft 2010 protocol, key feedback from the March 26 advisory group, and a recently released model protocol published by the University of Pittsburgh School of Medicine (UPSM model) as a point of comparison.

At the March 31 meeting, the health system stakeholder group quickly achieved consensus that the UPSM model not only shared many common elements with the recently-revised draft 2010 protocol, but would, with some modest revisions, also be responsive to many of the concerns raised by the advisory group. Notable features of the UPSM model included:

- the model’s rapid adoption by other states as a statewide protocol;
- the absence of *a priori* clinical exclusions from resource allocation processes; and
- the omission of functional status/ADLs or age as priority scoring factors (rather, age has a far reduced role as a possible tie-breaker).

The health care stakeholder group then reviewed the UPSM model in detail and suggested revisions to suit North Carolina needs. A newly-revised draft protocol derived from the UPSM model was then sent out to the advisory group and the health system stakeholder group for final review and feedback, further informing the attached 2020 protocol.

Major modifications made to the UPSM model in developing the attached 2020 protocol include:

- eliminating elements that may have resulted in heightened priority for health care personnel due to definitional and equity concerns, including questions as to how best to determine which workers would receive heightened priority; and
- removing children ages 12-17 from the protocol, in lieu of a new 2020 protocol appendix, now under development, addressing pediatric populations.

Conclusion

Again, in light of the foregoing, we would respectfully request that you present this 2020 protocol to the Governor for adoption, in its entirety, as an annex to the State’s Emergency Management Plan. We also remain open to working with your team on a plan to more broadly inform the public and health care personnel regarding key protocol details.

In the meantime, please accept our sincere gratitude for your prompt attention to this matter. Please let us know if you have any questions regarding either our substantial efforts to date or the attached 2020 protocol.

Sincerely,



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