University Hospitals

The Ohio House of Representatives
House Health Committee
Representative Scott Lipps, Chair

Senate Bill 302
Interested Party Written Testimony

Chairman Lipps, Vice Chairman Manning, Ranking Member Boyd, and Members of the Committee, thank you for the opportunity to provide written testimony regarding Senate Bill 302 ("S.B. 302"), which would require the State Board of Emergency Medical, Fire, and Transportation Services ("State Board") to expand the requirement of H.B. 464 to use developed guidelines to fashion protocols for each EMS region. S.B. 302 also requires each EMS organization to provide training to its EMS personnel in the assessment of stroke severity. We appreciate that this language is broader and more inclusive of all stroke patients rather than updating training that would only benefit a small percentage of stroke patients. After several months of dialogue about the bill, we greatly appreciate the efforts taken by the bill sponsors to make this helpful improvement to the bill.

We appreciate the general aim of the bill and agree that Ohioans deserve the best stroke care that is available. We never stop looking for ways to improve patient care, but we want to avoid unintended consequences that could occur during the implementation of this bill. Specifically, we want to avoid any risk of negatively impacting the majority of patients with acute stroke in the pursuit of improving care for a markedly small percentage of stroke patients. All stroke patients deserve the highest quality and best value care. We also want to ensure that the process is balanced to avoid a one-size fits all solution in the development of guidelines and protocols. Accordingly, we greatly appreciate the amendment that the Senate unanimously supported that struck the language specific to large vessel occlusion (LVO). We appreciate the bill sponsors' intent to ensure the language in S.B. 302 is broad rather than focusing on one single type of stroke.

University Hospitals ("UH") is a Cleveland-based super-regional health system that serves more than 1.2 million patients in 15 Northeast Ohio counties. The hub of our 19-hospital system is UH Cleveland Medical Center, a 1,032-bed academic medical center. In September, UH Cleveland Medical Center became the first hospital in Ohio to attain all four of the American Heart Association/American Stroke Association's highest awards for stroke care[1]. These awards speak to the excellence of the stroke program at UH. We have worked diligently over the past 12 years to provide the highest levels of stroke care and education to the residents of Northeast Ohio. UH Cleveland Medical Center was also the first hospital in Northeast Ohio to achieve The Joint Commission's rigorous standards for Comprehensive Stroke Center

[1] The four 2020 awards are: "*Get with the Guidelines*-Stroke Gold Plus"; "Target: Stroke Honor Roll Elite Plus"; "Target: Stroke Honor Roll Advanced Therapy"; "Target: Type 2 Diabetes Honor Roll". See: https://www.uhhospitals.org/for-clinicians/articles-and-news/articles/2020/09/uh-cmc-first-hospital-in-oh-to-attain-ahas-all-four-highest-awards-for-stroke-care#:~:text=University%20Hospitals%20Cleveland%20Medical%20Center,The%20Guidelines%2DStroke%20Gold%20Plus

Certification[2]. We are proud to say that our stroke program has grown and expanded to a world-class program, truly one of a kind in the state. Importantly, UH's Stroke Program is a comprehensive system of stroke care across Ohio comprised of an additional nine certified Advanced Primary Stroke Centers across Northeast Ohio, whose high quality stroke care has also been recognized by American Heart Association/American Stroke Association "*Get with the Guidelines* – Stroke quality" awards.

As the majority of patients with acute stroke can be rapidly and appropriately treated at a certified primary stroke center, we have endeavored to develop system-wide protocols that prioritize transport to the closest certified stroke center, where the most rapid evaluation from stroke trained physicians and nurses and a CT brain scan foster the fastest access to tPA - clot buster therapy - and is also the most accurate way to determine whether the patient is in the small percentage of having a complex stroke condition that would constitute a medically necessary reason for them to be transferred out of their community to another facility to receive a higher level of care.

For awareness, the Ohio legislature passed House Bill 464 in the previous General Assembly, which has already enacted the following:

- Created a process for recognition by the Ohio Department of Health ("ODH") of hospitals as comprehensive stroke centers, primary stroke centers, or acute stroke ready hospitals.
- Prohibited hospitals from representing themselves as a comprehensive or primary stroke center or acute stroke ready hospital unless it is recognized as such by ODH.
- Required the establishment of written protocols for emergency medical service personnel when assessing, treating, and transporting stroke patients.

S.B. 302 builds on this prior legislation. However, we hope that the creation of future protocols and guidelines as a result of this bill would be approached cautiously. Every second matters when your loved one is having a stroke. Time equals brain. These are life and death situations that require a patient be properly assessed and stabilized at the *closest* hospital. [3] Accordingly, we want to ensure the legislation does not promote the creation of a protocol that would rely upon a pre-hospital provider, such as an EMT, to make a complex decision as to whether a patient should be transported to a thrombectomy-capable comprehensive stroke center. Such a protocol could have the unintended consequence of transporting numerous patients to a thrombectomy-capable comprehensive stroke center when it is medically unnecessary or even risky to do so. Rather, most stroke patients are able to receive best practice care at other stroke centers. The numbers speak for themselves. According to a 2017 study in the International Journal of Stroke, only 7.8% of stroke patients over 3 years would have been appropriate for transfer to a thrombectomy-capable comprehensive stroke center.[4]

The need to transfer a stroke patient to a thrombectomy-capable comprehensive stroke center is determined by a physician and baseline imaging using a CT brain scan. Thus, there is a potential risk of increasing the cost of care for the many stroke patients if this legislation were to result in the

[2] https://www.uhhospitals.org/services/neurology-and-neurosurgery-services/conditions-and-treatments/stroke-and-vascular/stroke

[3] See Section EMS 1.3 of the 2019 American Heart Association Stroke Guidelines Level 1 evidence: https://www.ahajournals.org/doi/pdf/10.1161/STR.0000000000000211

[4] Only 211 of 2,701, or 7.8%, of consecutive patients with acute ischemic stroke presenting to a certified Primary Stroke Center over 3 years, were actually clinically eligible for a mechanical thrombectomy treatment and had imaging evidence of a large vessel occlusion (LVO). Of these, nearly half were not transferred on to the thrombectomy center. One reason for not transferring is a response to the rapid administration of intravenous tPA therapy, whose efficacy in reversing stroke deficits is exquisitely time-dependent. In the study, only 1.9% of patients actually received the thrombectomy.

establishment of a protocol that would require pre-hospital providers (e.g., EMS personnel) to make a transport decision in the field where neuroimaging is unavailable. Rather, a patient needs to present at a hospital to get this necessary imaging. Given the real challenges faced by EMS personnel in the field who would have to rely on less accurate means to make transport decisions, there is an inherent risk that a large percentage of patients will be transported unnecessarily to a thrombectomy-capable comprehensive stroke center that is a farther distance. That decision could reduce the patient's quality of care by delaying their Emergency Room treatment with IV-tPA therapy, while potentially increasing their overall cost of care.

As you know, there is no one size fits all in medicine. Every community has its own unique needs and no two patients are alike, and we would caution that this bill could interfere with local decision-making. Patients in rural communities likely have the most to lose here. Some communities rely on a single ambulance to cover 50-100 square miles. There is a great potential cost to that community if they must transfer all stroke patients to a comprehensive stroke center nearly an hour away. It would pose an incredible risk to the community if there are any other emergencies that occur during that extended period of time and must wait an hour for the ambulance to return. Even in communities with several near-by hospitals, there are other factors to consider, such as the value of receiving in-network care through urgent access to the data in a patient's medical record and access to their community primary care providers that avoid the out-of-network risk of duplicate or unnecessary tests and treatments.

For the majority of stroke patients (*more than 90%*) who do not need to be at a comprehensive stroke center but may be forced to go to one, it could put them at risk of reduced quality of care traveling a farther distance, losing critical time. At the same time, it could put patients at risk of experiencing higher costs if they are transported to a large teaching hospital rather than their local community hospital. It also creates a greater likelihood of being out of network and increases the need for air ambulance, which often come at a very high cost and may carry a higher likelihood of being out-of-pocket for the patient. The longer distance also creates an inconvenience to family who will need to travel farther to see the patient in the hospital.

In sum, we want to avoid a one-size fits all model. One way to ensure there is greater transparency and public involvement in the establishment of new stroke guidelines and any subsequent amendments to such guidelines is the creation of a 60-day public notice and comment period, followed by a 30-day period for the State Board to consider such comments and finalize the guidelines or amendments.

Thank you Chairman Lipps, Vice Chairman Manning, Ranking Member Boyd, and members of the House Health Committee, for this opportunity to provide feedback on this important legislation. Again, we appreciate the Senate's amendment to strike LVO from the bill. We consider it to be an important step but it does not alleviate all of our concerns surrounding this bill. Thus, we greatly appreciate the ongoing discussion we continue to have with the S.B. 302 bill sponsors to ensure we are promoting what is in the best interest of all stroke patients in Ohio.

Cathy Sila, M.D.
Chair, Department of Neurology
Director, University Hospitals System Stroke Program

Nicholas Bambakidis, M.D.
Vice President and Director,
University Hospitals Neurological Institute

Daniel K. Ellenberger
Director, University Hospitals EMS Training & Disaster Preparedness, EMS Institute