The Ohio Senate
Senate Health Committee
Senator Steve Huffman, Chair

Senate Bill 21
Interested Party Written Testimony

Chairman Huffman, Vice Chairman Antani, Ranking Member Antonio, and Members of the Senate Health Committee, thank you for the opportunity to provide written testimony regarding Senate Bill 21. 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. We appreciate the efforts of Senator Antonio to improve the bill from its original version last General Assembly and ensure its broader and more inclusive of all stroke patients rather than updating training that would only benefit a small percentage of stroke patients.

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 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.

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*

[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

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

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 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 to know if a thrombectomy is the appropriate course of care. 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.

S.B. 21 would require the State Board of Emergency Medical, Fire, and Transportation Services to develop guidelines for the assessment, triage, and transport of stroke patients that must then be used to develop the written protocols for each EMS region. Multiple parties who provided proponent testimony this year and in the last General Assembly expressed their interest in seeing new guidelines and protocols that would transfer all stroke patients to comprehensive stroke centers. In fact, similar legislation that has passed in other states (e.g., Tennessee) have led to more patients suspected of large vessel occlusion being transferred to comprehensive stroke centers.

Our concern is that 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 under new guidelines, 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 comes

[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.

at a 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.

As the majority of patients with acute stroke can be rapidly and appropriately treated at a certified primary stroke center, at UH 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 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.

Time is brain when it comes to stroke, and intravenous tPA ("the clot buster") is the most important standard of care for patients with acute ischemic stroke due to a blocked artery. tPA works best when given as early as possible after the onset of stroke symptoms, but data from stroke registries indicate that less than a third of patients arrive to an emergency room within those key early hours of stroke symptoms and only half are eligible for tPA therapy. Thus, it is imperative that EMS time in-the-field is minimized and patients be transported right away to the nearest certified primary stroke center for a CT brain scan to optimize treatment with tPA therapy. Certified primary stroke centers have rapid stroke alert protocols, wheel patients directly to the CT scanner, and have goals of door-to-needle time for tPA administration of less than 30 minutes. This approach is the highest value care path and without delays could increase the use of tPA to 20-25% of patients – providing the best outcomes to the most patients with the lowest cost of care. If patients are transported even minutes later to a farther stroke center, they might not be able to receive tPA and may experience reduced quality outcomes.

Time is also critical in the 15% of patients with acute hemorrhagic stroke due to a ruptured brain artery as early expansion of the brain hemorrhage occurs in a third of patients within the first few hours. Here too, EMS time in-the-field needs to be minimized and patients need to be transported right away to the nearest certified primary stroke center for a CT scan for diagnosis and rapid control of blood pressure. Acute blood pressure lowering is critical in preventing worsening of an acute hemorrhagic stroke, yet this treatment can worsen acute ischemic stroke; thus, it simply cannot be done in the field without a CT scan to properly diagnose what kind of stroke a patient is having.

Many have compared stroke to trauma in describing the need for this legislation. However, the direct comparison to trauma is not appropriate because trauma can be much better diagnosed by visual inspection of the patient. Although major stroke signs can be assessed in the field, they are not specific enough. The diagnosis must be made through a medical evaluation at a hospital with a CT brain scan and a CT angiogram study. Furthermore, trauma certification is nationally standardized by the American College of Surgeons. There is no consensus or standard uniformity available for stroke "certification." There's always been a heavy reliance on meeting the needs of a local community rather than a one-size-fits all approach to stroke care.

Every community has its own unique needs and no two patients are alike, and we are concerned that this bill has the potential to interfere with local decision-making. Some rural communities rely on a single ambulance to cover 50-100 square miles. There is a great potential cost to that community if new guidelines dictate that they must transfer all stroke patients to a thrombectomy-capable 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. Importantly, it poses a risk to a stroke patient in a rural community who does not actually need to be a comprehensive stroke center, but loses precious minutes or hours taken to one out of an abundance of caution. Again, time is brain.

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 avoids the risk of costly, out-of-network duplicate or unnecessary tests and treatments.

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 Huffman, Vice Chairman Antani, Ranking Member Antonio, and members of the Senate Health Committee, for this opportunity to provide feedback on this important legislation. We greatly appreciate the ongoing discussion we continue to have with the S.B. 21 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