Commissioner Robbie Goldstein, MD

c/o William Anderson,

Office of the General Counsel,

Department of Public Health,

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“Healthcare Facility Licensure Regulations” 105 CMR 130.000: *Hospital Licensure* regarding tiering of stroke services

Dear Commissioner Goldstein, MD

The American Heart Association is the nation’s oldest and largest voluntary organization dedicated to fighting heart disease and stroke, whose mission is to be a relentless force for a world of longer, healthier lives. The American Heart Association continues to advocate to update the Commonwealth’s stroke protocols and improve the systems of care for someone who suffers a stroke. The outcome of a stroke, in large part depends on how and when the patient is treated. Finalizing the stroke-related regulation will lead to an opportunity for every patient suffering a severe stroke to have equitable access to treatment that significantly reduces the chance of death or disability. We appreciate the opportunity to comment on the department’s update to 105 CMR 130.000: *Hospital Licensure*, in accordance with Section 90 of the Massachusetts FY24 budget, approved August 2023, which requires the Department to promulgate regulations that create statewide criteria for designating hospitals in a tiered system.

The impact of stroke is indisputable and widely recognized. Stroke is the nation's No. 51 killer and a leading cause of long-term disability. It is estimated that 9.4 million Americans 20 years of age and older have had a stroke.2 Someone in the U.S. dies from stroke every 3 minutes and 14 seconds.2 About 795,000 people have a stroke in the U.S. each year, including children, working-age adults, and people who are otherwise healthy and active contributors to society.2 Pivotal advances in the treatment of severe strokes necessitate modernization of the Commonwealth’s system for triage and transport of patients with strokes of different severities so that all residents can receive the right intensity of care as quickly as possible. Time is brain and different strokes need different emergency treatments. Advanced treatments for patients with the most severe ischemic stroke (large vessel occlusions, or LVO) and hemorrhagic strokes are not available or feasible at many hospitals in the Commonwealth or across the U.S., but the Commonwealth has seven advanced stroke centers that can provide these treatments. A tiered stroke system of care can significantly increase the proportion of patients who receive time-sensitive, right-sized stroke care while also encouraging continued improvement in the quality of care. Far too many people die or are disabled from stroke because they do not get available lifesaving treatment quickly enough. While many hospitals may be able to treat different types of strokes, we need a stroke system that prioritizes patients’ outcomes above all else. Going to a hospital that is not equipped to treat severe strokes wastes valuable time and puts a patient’s full recovery at risk.

The statute stated that the Department had to create (i) a statewide standard pre-hospital care protocol related to the assessment, treatment and transport of stroke patients by emergency medical services providers to a hospital designated by the department to care for stroke patients; provided, however, that the protocol shall be based on national evidence-based guidelines for transport of stroke patients, consider transport that crosses state lines and include plans for the triage and transport of suspected stroke patients, including, but not limited to, those who may have an emergent large vessel occlusion, to an appropriate facility within a specified timeframe following the onset of symptoms and additional criteria to determine which level of care is the most appropriate destination; (ii) statewide criteria for designating hospitals in a tiered system, featuring advanced designations in addition to primary stroke services, to treat stroke patients based on patient acuity; provided, however, that the tiers shall be based on criteria from at least 1 nationally-recognized program and shall not permit self-designation; provided further, that in developing such criteria, the department shall consider: (a) designation models and criteria developed by the Joint Commission, DNV GL Healthcare USA, Inc. or another national certifying body recognized by the Centers for Medicare and Medicaid Services; (b) designation models and criteria adopted by other states and the differences in geography and health care resources of such other states; (c) the clinical and operational capability of a facility to provide stroke services, including emergency and ancillary stroke services; (d) limiting the routing of stroke patients to thrombectomy-capable facilities whenever a comprehensive stroke center is within a recommended timeframe to maximize technical competency and patient outcomes; and (e) procedures to suspend or revoke a facility's designation if the department determines that the facility is not in compliance with designation requirements and procedures to notify emergency medical services providers of any such suspension or revocation; and (iii) recommended national evidence-based quality and utilization measure sets for stroke care for use by the center for health information and analysis pursuant to [**section 14 of chapter 12C**](https://malegislature.gov/Laws/GeneralLaws/PartI/TitleII/Chapter12c/Section14) of the General Laws; provided, however, that the department shall consider measures in current use in national quality improvement programs, including, but not limited to, the Centers for Medicare and Medicaid Services, the National Quality Forum, the Paul Coverdell National Acute Stroke Program or other nationally recognized data platforms.

We want to take this opportunity to highlight concerns and ask for some clarification to ensure that the regulations as promogulated are following the intent of the statute. As the draft regulations are written, we are concerned that only three levels of stroke care are addressed: Acute, Primary and Endovascular. The American Heart Association, The Joint Commission and DNV all recognize four tiers in the stroke system of care: Acute (to evaluate, stabilize and treat eligible patients with thrombolytic therapy), Primary (capabilities extending beyond Acute with stroke patients admitted to the facility), Thrombectomy-Capable (centers with the ability to provide endovascular procedures for LVO patients) and Comprehensive Stroke Centers (hospitals with the capability of treating LVO and Hemorrhagic stroke patients).

Secondly, it seems like a hospital would be defined as Acute Stroke Ready Service if it has not sought a higher level of certification from a nationally recognized body, and that it would meet guidelines set forth by the Department. This standard does not comply with the language in the statute which states that the tiers shall be based on criteria from at least one nationally recognized program and *shall not permit* self-designation from the department.

Third, the language around a transfer agreement for Acute Stroke Ready Service is weak. We want to ensure that if a patient needs to be transferred because they can’t be treated and/or they are a walk in and need a higher level of care that they will be transported to a facility that can provide the care they need. The transfer agreements are necessary. We request this language includes coordination, through agreement, within their service area to provide appropriate access to care for acute stroke patients. The coordinating stroke care agreements shall be in writing and include at a minimum: i. Transfer protocols for the transport and acceptance of stroke patients seen by the Acute Stroke Ready Hospitals for stroke treatment therapies which the remote treatment stroke center is not capable of providing; and ii. Communication criteria and protocols with one or more Acute Stroke Ready Hospitals, as needed. Such protocols could include tele-stroke systems.

We know that the Point of Entry (POE) Plan has not been released yet and we urge the department, and the Office of Emergency Services to include a list of recognized Comprehensive Stroke Centers, Thrombectomy-Capable Stroke Centers, Primary Stroke Centers and Acute Stroke Ready Hospitals to the medical director of each licensed emergency medical services provider in this state. The POE Plan should also adopt and distribute a nationally recognized standardized stroke triage assessment tool for use statewide which is designed to detect patients with suspected large vessel occlusions. FAST-ED is the pre-hospital stroke severity scale identified in the Emergency Medical Services Statewide Treatment Protocols.3 We recommend that a FAST-ED score ≥ 4 is set for bypass and EMS personnel should take a drive-time of ≤ 30 minutes into consideration when selecting a hospital destination.4.

Lastly the statute set forth that the Department of Public Health would utilize a national evidence-based quality and utilization measure sets for stroke care but in the current regulations as proposed the quality improvement data collection is very vague it just states that “facilityshall submit data, in a manner defined by the Department, and in accordance with protocols established by the Department in guidelines”, we are asking for some clarification on the collection of key data measures.

If you have any questions, please don’t hesitate to reach out to us, we appreciate your consideration of this lifesaving policy.

Sincerely,

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