

BY ELECTRONIC MAIL

October 28, 2024

William Anderson

Office of the General Counsel

Department of Public Health

250 Washington Street

Boston, MA 02108

**Re: 105 CMR 130.000: Hospital Licensure and 105 CMR 140.000: Licensure of Clinics**

The Massachusetts Health & Hospital Association (MHA), on behalf of its member hospitals, health systems, physician organizations, and allied healthcare providers, appreciates the opportunity to submit these comments regarding the proposed changes to 105 CMR 130.000: *Hospital licensure* and 105 CMR 140.000: *Licensure of clinics*, as well as the proposed recission of 105 CMR 142.000 *Operation and maintenance of birth centers,* which were first presented at the Public Health Council meeting on October 9, 2024. MHA appreciates the Department of Public Health’s commitment to appropriate stroke care, and maternal, birthing persons, and newborn health outcomes in the state.

**Stroke Care**
*105 CMR 130.020 - 130.1405*
MHA and its members have serious concerns about the negative impact on timely patient access to stroke care posed by Section 90 of Chapter 28 of the Acts of 2023. While these draft implementing regulations address some potential negative effects within the confines of the legislation, DPH’s hands are tied by what is ultimately a short-sighted legislative directive that would result in a catastrophic outcome.

MHA appreciates DPH’s commitment to ensuring patients across the commonwealth receive appropriate and timely stroke care. However, the proposed regulation, 105 CMR 130.000, could lead to significant issues affecting patient care. MHA has long supported efforts to directly transport highly acute stroke patients to a Comprehensive Stroke Center instead of to the nearest Primary Stroke Service (PSS) emergency department (ED) if implemented in concert with other appropriate updates to the commonwealth’s stroke care system to bridge the data, reporting, and workforce education and public education gaps in the system. The measures in the draft regulation necessitated by the misdirected statute could ultimately redirect patients to specific facilities and away from closer, appropriate community hospital care. These measures, however, fail to address the core issue. A superior approach would instead concentrate on enhancing endovascular thrombectomy (EVT) capabilities in underserved areas and improving patient recognition of stroke symptoms.

Time is critical in stroke care; diverting care away from appropriate levels of care to an endovascular capable stroke service in many instances will inappropriately delay care. Currently, stroke patients in the commonwealth routinely present to EDs and, if determined to need EVT, are evaluated and stabilized at the facility, including through the use of intravenous tissue-type plasminogen activator (t-PA). Then, if needed, they are transported, often by air ambulance, to facilities with EVT. This process results in faster administration of treatment for patients. Because t-PA medications cannot be administered in ambulances, transporting directly to an endovascular capable stroke service would delay these life-saving medications.

Patients experiencing large vessel occlusions, which account for approximately 25-45% of serious strokes, benefit significantly from care provided by endovascular capable stroke service/Comprehensive Stroke Centers equipped to perform advanced EVT. To earn designation as a Comprehensive Stroke Center from the American Heart Association and the Joint Commission, a hospital must be able to offer EVT treatment around the clock. The requirement included in the proposed regulation, 130.1405, poses a considerable challenge for non-academic and teaching hospitals, especially in rural areas, due to the substantial costs involved and the intensive staff training needed for implementation. Current EMS stroke patient transport is typically delivered through a “hub and spoke” mechanism, with Emergency Medical Services (EMS) providers bringing patients directly to the nearest PSS facility in order to triage and transport to an endovascular capable stroke service, as needed. Additionally, prior to the proposed regulations, many community hospitals within the commonwealth already have established telestroke partnerships that provide clinically appropriate video-enabled stroke care consultations via telehealth with a physician with acute stroke expertise in real time, capitalizing on technical advancements and providing necessary, timely patient-centered care. We ask that DPH continue to honor these relationships when implementing the definition of acute stroke team in 105 CMR 130.1401 so that EMS point of entry (POEs) protocols allow ambulances to transport patients directly to any acute stroke ready facility that is part of a larger system that has endovascular capable stroke services or to any acute stroke ready facility that has a clinical relationship with endovascular capable stroke services. We urge that DPH consider these successful partnerships that have formed across the commonwealth. DPH should also be wary of the downstream impact on timely access to care posed by following rigid definitions and care procedures set by a national standardized accrediting body as opposed to the realities on the ground in Massachusetts.

MHA is increasingly concerned about the substantial strain on our emergency departments, ongoing workforce challenges, a shortage of EMS personnel, and the limited transportation options available for emergency medical services. Additionally, traffic conditions must be factored in for patients traveling long distances to these higher-tier designations, who could have received appropriate treatment closer to home, which is the best clinical decision for stabilizing patients. With this in mind, MHA respectfully requests that DPH prioritize time and distance when developing future POE protocols, including that a patient is transported to the nearest hospital if they are more than 20 minutes away, including any traffic, from any facility or if the nearest hospital is part of a system or has a clinical relationship with a hospital that has endovascular capable stroke services.

Additionally, MHA members express concerns that EMS providers routinely bypass hospitals appropriate for care. Before implementation of any new POE protocols can occur, additional education on, and increased implementation of the FAST-ED tool must occur across all EMS providers to ensure use of the FAST-ED tool while in route to hospitals.

MHA members have also asked for additional clarity to verify that primary stroke service requirements for “emergency diagnostic and therapeutic services” are met by the ability to administer thrombolytics.

Finally, we have significant concerns about the current timeline for these changes as these certifications for the different designation levels conservatively take 12-24 months to secure and implement. We urge DPH to extend the implementation timeframe by 18-24 months so facilities are able to obtain the needed certifications and to allow time to educate EMS and hospital ED providers. We fear community hospitals and emergency medical services providers will be plagued with unintended consequences, and most importantly, the commonwealth will miss the mark on fully addressing the intended goal of providing the best possible and most timely care for patients.

MHA and its members will continue to elevate concerns regarding the proposed stroke services regulations and remain hopeful that these concerns will be addressed in the additional guidance and point-of-entry plans from DPH.

**Hospital and Birthing Center Definition and Accreditation**

*105 CMR 130.020 Definitions*

While some Massachusetts hospitals opened and operated birth centers and midwifery units, many unfortunately closed due to historic under-reimbursement, which shifted a majority of low-risk pregnancy and birthing services back to hospital settings. Hospitals should continue to be able to establish birth centers under their license and have the option to provide birth center services to appropriate patients. The current definition of Birth Center Services in the hospital licensure proposed regulation reads “Birth center services are provided in a free-standing facility.” We believe that hospitals should be able to provide birth center services within their existing infrastructure, and that the birth center does not have to be freestanding. We believe the proposed definition precludes in-hospital birth centers and midwifery units that have operated under hospital licensure successfully in previous years at multiple hospitals in the state; therefore, we encourage DPH to remove this line from its proposed definition.

MHA also encourages DPH to consider the Commission for the Accreditation of Birth Centers (CABC) accreditation as evidence of meeting birth center regulation requirements. This would ensure that hospital and community birth centers do not have to go through two accreditation processes, which adds additional administrative burden and cost to these facilities. Additionally, to increase access to these services, MHA urges DPH to exempt birth centers on hospital licenses from the determination of need process, as is the case for birth centers licensed as clinics.

**Birth Center Staffing**

*105 CMR 130.810-812 & 105 CMR 140.902*

MHA and its members appreciate the updates to the proposed regulations to align with *An Act promoting access to midwifery care and out-of-hospital birth options* passed in August 2024. Healthcare facilities continue to struggle with staffing and workforce shortages. To ensure staffing and workforce sustainability, we propose birth attendants include the language designating “providers trained and licensed to provide birth care,” to allow for licensed midwives to meet this requirement in the future. Additionally, we propose expanding the requirements for licensed nurses functioning as a birth assistant. These nurses should have nursing experience with laboring and birthing patients, including but not limited to labor and delivery hospital nurses, nurses who have experience at a birth center, and nurses who have home birth experience.

**Patient Transfer**

*105 CMR 130.812 - 814 & 105 CMR 140.903 - 905*

MHA wants to ensure that birthing persons and newborns transferred from licensed birth centers to hospitals have seamless and optimal continuity of care. Under the proposed regulations, hospital and clinic licensed birth centers are required to have written policies and procedures for coordination of ongoing care to hospitals for treatment beyond that provided by the birth centers, including medical records at the time of transfer. We encourage DPH to provide an example of transfer policy requirements, and guidance to facilitate these partnerships between birth centers and hospitals. These policies and procedures for the care coordination and transfer agreements should ensure seamless patient transfers without disruption of life-saving care.

The proposed regulations removed the requirement for birth centers to have a transfer incubator. Some providers expressed concern with the removal of this requirement during the transfer of newborns from birth centers to hospitals. Is there a replacement standard that DPH suggests, such as skin-to-skin, that will replace the transfer incubator? Upon accreditation requirements from CABC, birth centers are required to have a plan for transport of an unstable neonate, including temperature maintenance. MHA appreciates that additional equipment such as a travel incubator can be costly to birth centers but want to ensure vulnerable newborns being transferred have the necessary equipment to ensure the best possible outcome if the receiving facility is a concerning distance from the birth center.

**Birth Center Operations**

*105 CMR 130.813-815 & 105 CMR 140.904 - 906*

MHA appreciates the additions to the patient records requirements. These regulations should align with tests that the American College of Obstetricians and Gynecologists (ACOG) recommends for prenatal laboratory screenings. MHA and its members are seeking clarification for 130.814 (D), to understand if a nurse is considered “professional staff” and is appropriate to perform examinations of birthing persons and newborns. Additionally, to eliminate unnecessary administrative tasks for birth center staff, within two weeks of the birth of a child, the staff should call the parent or guardian to verify the hearing screening was performed, if it is not documented in the available electronic medical record. Calls to the parent or guardian may not be necessary if the birth center staff have access to the newborn’s record and can see a completed newborn hearing screening.

The prohibited surgical procedures should also include assisted vaginal birth (also referred to as assisted vaginal delivery) as a prohibited practice. The regulation includes the term “forcep delivery,” but assisted deliveries can use other mechanisms or tools such as vacuum devices. We believe adding the term “assisted vaginal birth/delivery” is a more inclusive term to ensure this procedure does not occur in a birth center.

MHA is also seeking clarification on 130.815 (B)(4) prohibiting the provision of controlled substances for self-administration outside of the birth center. There are rare cases that providers, in compliance with MGL c.94C, may need to prescribe oxycodone or similar medications after birth. To provide optimal patient-centered care to birthing persons, the decision to administer and prescribe controlled substances should be available to DEA-licensed clinicians in these birth centers.

MHA looks forward to our continued work with the administration around advancing birthing person and newborn health equity. We respectfully urge DPH to consider amending the hospital licensure and birth center regulations to reflect the considerations above. Please do not hesitate to contact me at lsimons@mhalink.org with any questions or concerns.

Sincerely,



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Massachusetts Health & Hospital Association