

October 27, 2016

Monica Bharel, M.D., MPH

Commissioner

Department of Public Health

250 Washington St.

Boston, MA 02108-4619

Re: Proposed Regulations Amending the Licensure of Clinics (105 CMR 140.000)

Dear Commissioner Bharel:

The Massachusetts Health & Hospital Association (MHA), on behalf of our member hospitals and health systems, appreciates the opportunity to submit comments on the proposed amendments to the Department of Public Health (DPH) regulations for licensure of clinics.

While many of the changes that are proposed in the regulations are based on the overall goal of reducing duplicative and outdated language, we are very concerned with a few provisions that we believe go against the goal of healthcare planning and patient safety. It is important to note that many clinics spend a considerable amount of staff time and resources ensuring quality improvement within their services. However, the proposed changes relating to planning for emergency level services and the definition of urgent care services would actually create major confusion and negatively affect these quality improvement efforts. Therefore, we would request the following changes to the proposed regulations.

First, we are concerned that the new definition of urgent care within 105 CMR 140.020, is in direct conflict with other federal and state regulations and therefore creates two different standards for provider groups. Specifically hospitals and health centers are required to develop services that are defined as primary, urgent, and emergent based on the definitions that the Health Safety Net Office uses (101 CMR 613.02) in following federal EMTALA guidance. In addition, urgent care is a service and not a general healthcare delivery model, which has specific coding and billing standards. At a time when the state is requesting providers to develop integrated care organizations and develop regional health planning, creating two standards by agencies within EOHHS creates numerous operational, clinical, and financial problems that should not occur. Therefore we strongly urge DPH to revise the proposed definition as follows:

* *Urgent Care means medically necessary services provided after the sudden onset of a medical condition, whether physical or mental, manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson would believe that the absence of medical attention within 24 hours could reasonably expect to result in placing a Patient’s health in jeopardy, impairment to bodily function, or dysfunction of any bodily organ or part. Urgent Care Services are provided for conditions that are not life threatening and do not pose a high risk of serious damage to an individual’s health. Urgent Care shall not mean surgical services, dental services, physical rehabilitation services, mental health services, substance abuse services, birth center services or limited services as defined in 105 CMR 140.020: Specific Service (1) through (9), which require a separate licensure designation; or Emergency Service or Satellite Emergency Facility as defined in 105 CMR 130.020 Hospital Licensure.*

Second, we request that within 105 CMR 140.103, the state consider adding in a new subpart (H). There continues to be growing concern among many providers in the New England region about the development of freestanding Emergency Departments under the state’s applicable clinic licensure requirements. Many sites are being developed without coordination with existing providers and are often established in a manner that only cares for certain patient populations, including those covered by Medicare and private insurance. From the perspective of healthcare planning and to ensure that such sites are developed based on the satellite emergency facility requirements in the hospital licensure regulations, we would urge DPH to amend the clinic licensure regulations. Currently the only DPH licensure requirements on satellite emergency facilities are those developed by a hospital, but there are not standards or requirements for those that are developed by a clinic. To that end, we would request that DPH consider the adoption of criteria that ensure strong patient safety and quality assurance for any such facilities, as follows:

*(H) an applicant seeking licensure to provide services as a free standing emergency center shall provide documentation showing that it is affiliated with an existing Acute Care Hospital licensed pursuant to M.G.L. c. 111, § 51 or is a joint venture with an existing Acute Care Hospital licensed pursuant to M.G.L. c. 111, § 51, that also meets the clinical and staffing requirements of a satellite emergency facility under 105 CMR 130.821 through 130.836, is recognized as a designated emergency department under the federal Emergency Medical Treatment and labor Act (EMTALA), is accredited by an approved national accreditation organization, and provides integration and communication of patient health records between the joint entities.*

Third, we are also very concerned with the proposed changes in 105 CMR 140.305 that would remove the strong patient protection and healthcare planning requirements for emergency transfer of patients. Specifically, DPH is planning to remove in subparts (A) and (D) the current requirements that a clinic must have a written plan and procedure as well as written agreement with a nearby hospital for the transport of patients with an emergency condition or for those seeking emergency treatment. Instead the state is solely allowing a clinic to just call 911 if such an occasion arises. It is not clear from the DPH Public Health Council memorandum as to the reasons that this specific change was made in the proposed regulations. In talking to various providers, we feel that the proposed changes would take a large step backwards in terms of emergency care planning and coordination in the state. If a clinic is publicly advertising to a prudent layperson that it can provide urgent or other care services, but it is not able to care for certain patients when they walk to the clinic, then it is not clear why DPH would remove an important healthcare planning requirement. Clinics should continue to have arrangements with other care providers (such as a hospital emergency department) for transfer protocols for patients, which may also include routing the notification through the state’s 911 system. Removing this requirement, we believe, is a bad precedent for patient care and safety in the state.

MHA again appreciates the opportunity to provide these comments. MHA and our members are committed to working with DPH to provide any necessary background on the reasons for our requested changes as well as meeting to review these items. Should you have any questions about our comments, please do not hesitate to contact me at (781) 262-6034 or agoel@mhalink.org.

Sincerely,

Anuj K. Goel, Esq.

Vice President, Legal and Regulatory Affairs