

# KROKIDAS & BLUESTEIN

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## ATTORNEYS

### HEALTH LAW CLIENT ALERT

#### IMMUNIZATION BY CERTIFIED MEDICAL ASSISTANTS

Earlier this month, the Massachusetts Department of Public Health (“DPH”) finalized amendments to its controlled substances regulations, [105 CMR 700.000](#). Among the changes to these regulations is a section which implements provisions in [M.G.L. c. 112, Section 265](#) (“Section 265”) which allow certified medical assistants (“CMAs”) to administer immunizations if they are directly supervised by a primary care provider. Previously, administration of immunizations by a CMA was prohibited.

The newly amended regulations implement, but do not modify, Section 265’s standards for CMA immunization administration. Therefore, it remains important to be knowledgeable about the requirements of Section 265 itself. Importantly, Section 265 contains the following three definitions which pertain specifically to the administration of immunizations:

- “CMA” means an individual who: (i) has graduated from a post-secondary medical assisting education program accredited by the committee on allied health education and accreditation of the American Medical Association or its successor, the Accrediting Bureau of Health Education Schools or its successor, or another certificate program that DPH may approve; (ii) is employed in the medical practice of a licensed primary care provider; and (iii) performs basic administrative, clerical, and clinical duties upon the specific authorization and under the direct supervision of a licensed primary care provider.
- “Direct supervision” means oversight of a CMA exercised by a primary care provider who is present in the facility and immediately available to furnish assistance and direction throughout the course of the performance of a delegated procedure; provided, however that the primary care provider shall not be required to be present in the room when the procedure is performed. *(Note that this definition is substantially the same as the Medicare “incident-to” billing supervision standard.)*
- “Primary care provider” means a health care professional qualified to provide general medical care for common health care problems who: (i) supervises, coordinates, prescribes, or otherwise provides or proposes health care services; (ii) initiates

referrals for specialist care; and (iii) maintains continuity of care within the health care professional's scope of practice. *(There is no indication that a "primary care provider" could not be a nurse practitioner or physician assistant, as opposed to a primary care physician. We have not confirmed this with DPH, however.)*

Although they do not modify Section 265, the amended regulations open the door for DPH to promulgate additional sub-regulatory guidance. To date, DPH has released two Circular Letters fleshing out the CMA immunization requirements. Circular Letter DCP-16-12-664, released in 2016, generally sets out the statutory standard and clarifies that other primary care and immunization requirements still apply (e.g., reporting of immunization administration data to the Massachusetts Immunization Information System). Circular Letter DCP-17-8-102, released last year, provides guidance on the adequacy of CMAs' training and/or certifications for the purposes of administering immunizations. It remains to be seen to what extent DPH will release additional sub-regulatory guidance on this topic and how aggressive they would be in imposing further standards on CMA immunization.

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