

Alert | Health Care & FDA Practice



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New York Department of Health Previews Proposed PACE Regulations

*On Aug. 7, 2024, the New York State Register published a **notice of proposed rulemaking** regarding the proposed PACE regulations. The notice indicates that public comment will be received until 60 days after such publication date, which is Sunday, Oct. 6. As such, all comments will be due the next business day, Oct. 7, 2024. Based on its review of the public comments, the New York State Department of Health (DOH) will have the option either to finalize the regulations if DOH deems no changes or only minor changes required or, alternatively, to re-publish an updated revised version.*

Go-To Guide:

- New Unified PACE Application
- Rules Related to Ownership/Control of PACE
- Financial Requirements

In December 2022, New York Gov. Hochul signed legislation establishing a new streamlined licensure process for the Program of All-Inclusive Care for the Elderly (PACE) under Article 29-EE of the New York Public Health Law. The Department of Health (DOH) previewed the Commissioner of Health's **proposed implementing regulations** at a June 2024 meeting of the Public Health and Health Planning Council (PHHPC). The proposed regulations will be subject to the procedures of the State Administrative

Procedure Act, which requires that they be published in the State Register and that the public be given a comment period.

Background

The PACE program, overseen by the DOH and the Centers for Medicare and Medicaid Services (CMS), provides comprehensive medical and social services to elderly individuals and provides an alternative to those who prefer not to move into a nursing home but who need a higher level of specialized, coordinated care. The hallmark of PACE programs is comprehensive benefits, delivered via an interdisciplinary team approach to patient care, organized around a PACE center (usually a clinic). In New York, this approach implicates multiple areas of the Public Health Law (PHL): Article 44 (managed care), Article 28 (hospitals, clinics, and nursing homes), and Article 36 (home health agencies). As a result, the process to establish a PACE historically has been lengthy and complex, with entities completing multiple applications for multiple licenses. The new law and proposed regulations aim to streamline the application process in New York.

New PACE Application Process

The proposed regulations would establish a new unified licensure process to address the requirements of PHL Articles 44, 28 and 36 such that a new applicant would submit a single application but would be licensed separately as an Article 44 and an Article 28 in accordance with the new regulatory framework. Under the proposed regulations, DOH would develop a unified PACE license application and unified applications must eventually be approved by PHHPC.

At the same time, the proposed regulations indicate that the program requirements of Article 29-EE of the PHL, as well as the provisions of Articles 28, 36 and 44, would apply to the new process. This presents questions as to how the new law would apply these requirements to a new applicant and sets up a potential conflict between the new application process and existing limitations on PACE entities.

Who Can Apply to Establish a PACE Program

Previously, to apply to operate a PACE program, an applicant needed to be an “Eligible Applicant,” which is defined in the PHL as an entity controlled or wholly owned by a clinic (Article 28), a home health agency (Article 36), a managed care organization (Article 44), or a not-for-profit organization with a history of providing or coordinating health care services and long-term care services to the elderly and disabled.

The proposed regulations do not contain these limitations on applicants, allowing not-for-profit corporations, business corporations, partnerships, and limited liability companies to apply for the program.

For-Profit Applicants and Holding Company Structure

Since 2015, CMS has permitted for-profit organizations to operate as PACE organizations and, under New York’s proposed regulations, an applicant also can be a for-profit entity. DOH staff confirmed during its preview of the proposed regulations at PHHPC that PACE applicants can be for-profit entities under the proposed regulations. While PACE entities in New York have traditionally been not-for-profit, the capital requirements discussed below may result in new applicants using a for-profit structure.

- Holding Company Issues – DOH historically has required that a single entity hold both the Article 44 (managed care organization) license and Article 28 (clinic) license to operate a PACE program in New York. In addition, New York has required clinic owners to be ‘natural persons’ or business entities owned or controlled by natural persons. Effectively, this policy made it difficult to use a holding company structure for clinics and, by extension, PACE programs in New York state.

Capital Requirements

The proposed regulations would continue to require that a PACE organization meet financial solvency requirements under PHL Section 4403(1)(c) and Part 98 of the DOH regulations, including a contingent reserve that must be funded with a cash deposit. These financial solvency standards require a significant financial commitment from the applicant, which typically amount to millions of dollars based on the expected premium that will be paid to the PACE applicant.

Service Area

The proposed regulations expressly empower DOH to exclude from designation any geographic service area that is already covered by a PACE program to “avoid unnecessary duplication of services” and to “avoid impairing the financial and service viability of an existing PACE program.” Adding the impact of PACE competition into the application process expands the issues involved in an application beyond the applicant to potential competitors. And, as PHHPC is now the ultimate decision maker, the council’s public approval process invites participation of a wider set of stakeholders, potentially expanding the grounds for objection and complicating (and perhaps lengthening) the PACE approval process.

Conclusion

The proposed regulations would create a unified application path but also indicate that existing substantive provisions of the PHL would continue to apply. Because those substantive rules are sometimes difficult to reconcile, the proposed regulations may require careful analysis and interaction with DOH to address questions the proposed regulation raises. Interested parties, including existing PACE organizations and entities considering PACE licensure, should take advantage of the public comment process to seek clarification of the new PACE licensing process.

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