

SUMMARY OF EXPRESS TERMS

This regulation amends Title 10 of the Codes, Rules, and Regulations of the State of New York by adding a new Subpart 98-5 and will be effective upon publication of a Notice for Adoption in the New York State Register.

The proposed regulations implement a new licensure requirement for the Program of All-Inclusive Care for the Elderly (PACE) program under Article 29-EE of the Public Health Law requiring the Commissioner of Health to develop regulations for a unified licensure process for PACE organizations that includes the applicable program requirements of this article and Articles 28, 36 and 44 of the Public Health Law.

The regulations specifically provide the criteria for the establishment application process for the newly developed Article 29-EE PACE program including: the criteria needed to submit or make amendments or modifications to PACE applications, the criteria for an applicant withdrawing and abandoning a PACE application, the criteria for revocation, limitation or annulment of approvals of establishment and decision-making process, the criteria for determining if a PACE program is operating a Diagnostic and Treatment Center, and the responsibilities of the governing authority of a PACE program.

The following is a summary of the amendments to the Department's regulations which creates a new Subpart: 98.5 – Programs of All Inclusive Care for the Elderly (PACE):

- **Section 98-5.1** establishes the new PACE program. A PACE organization lawfully operating at the time this Subpart takes effect may continue to operate while the PACE organization transitions into full compliance with Articles 29-EE and this Subpart. All pending applications for PACE-related programs currently under review by the

Department under Article 29-EE, Article 28, Article 36 and Article 44 shall automatically be reviewed for compliance with this section at the time this Subpart is adopted.

Further, this section lists the criteria that PACE programs must comply with and provides the Commissioner of Health the authority to establish a uniform licensure process for the newly formed PACE organizations and that any license granted requires the approval of the Public Health and Health Planning Council (PHHPC).

- **Section 98-5.2** defines certain terms in the Subpart.
- **Section 98-5.3** outlines the criteria for the application process for Article 29-EE PACE licenses.
- **Section 98-5.4** outlines the requirements for approval of a PACE license.
- **Section 98-5.5** outlines the requirements to revise, amend, or modify a PACE licensure application.
- **Section 98-5.6** outlines the requirements to withdraw or abandon a PACE licensure application and what processes will be taken if an applicant fails to satisfy contingencies.
- **Section 98-5.7** outlines the procedures for the revocation, limitation, or annulment of approvals for establishment of PACE licenses.
- **Section 98-5.8** outlines the procedures for necessary hearings conducted by PHHPC, a committee of the Council, a person designated by the Council, or the Department related to PACE licenses.
- **Section 95-5.9** outlines how decisions of PHHPC on PACE licensure applications will be disseminated.
- **Section 98-5.10** outlines the criteria for determining the operation of a diagnostic and treatment center for PACE programs.

- **Section 98-5.11** outlines the criteria for the governing authority or operator of a PACE program licensed under Article 29 EE.
- **Section 98-5.12** outlines the procedures for agents, nominees, and fiduciaries for the new PACE program.
- **Section 98-5.13** outlines the procedures for name-of-purpose changes of operators and medical facilities related to PACE programs.

Pursuant to the authority vested in the Commissioner of Health by Section 2999-u of the Public Health Law, and the authority vested in PHHPC, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by adding a new Subpart 98-5 within Subchapter R, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

A new Subpart 98-5 is added to read as follows:

SUBPART 98-5. Program of All-Inclusive Care for the Elderly (PACE)

Section 98-5.1 PACE Program Established.

(a) The program of all-inclusive care for the elderly (PACE) is established in the department to provide community-based, risk-based, and capitated long-term care services as optional services under Medicaid and, where applicable, under Medicare, as well as under contracts among Centers for Medicare and Medicaid Services (CMS), the department, and PACE organizations.

(b) A PACE organization lawfully operating at the time this Subpart takes effect may continue to operate while the organization transitions into full compliance with this section under a process and requirements established by the department. Such requirements will take effect 180 days after the effective date of this Subpart.

(c) For purposes of existing contractual obligations of PACE organizations currently established under articles 28, article 36 and article 44 of the Public Health Law, a PACE program may continue to be established if the organization notifies the department of its intention to do so in writing within 30 days following the effective date of this section. Such approval is at the discretion of the department based on criteria set forth by the commissioner. Any material change (such as, but not limited to, change in current PACE-related services, current location, or change in any of the established operators) to the makeup and composition of the PACE program

under this section will automatically trigger requirements for licensure of the PACE organization under article 29-ee of the Public Health Law.

(d) All pending applications for PACE-related programs currently under review under article 28, article 36 and article 44 of the Public Health Law shall automatically be reviewed for compliance with this section at the time this Subpart is adopted for licensure under article 29-ee of the Public Health Law.

(e) Any new PACE program pursuant to article 29-ee of the Public Health Law or a PACE program currently established (prior to enactment of article 29-ee of the Public Health Law) shall comply with this section except for those PACE programs that qualify under section 98-5.1(c) of this Subpart.

(f) A PACE organization under this section must:

(1) Comply with applicable federal law and regulations, 42 USC §1396u-4 and 42 CFR part 460, respectively. The statute at 42 USC §1396u-4 is contained Title 42 of Supplement 4 of the United States Code, the 2006 Edition. The regulations at 42 CFR part 460 are contained in volume 42 of the Code of Federal Regulations, Public Health, at part 460 (42 CFR part 460), 1984 edition. Both are published by the Office of the Federal Register National Archives and Records Service, General Services Administration. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office Washington, DC 20402. Both 42 USC §1396u-4 and 42 CFR part 460 are available for public inspection and copying at the Records Access Office, New York State Department of Health, Corning Tower Building, Empire State Plaza, Albany, NY 12237.

(2) Provide a PACE program or facilities at which primary care and other services are furnished to enrollees.

(3) Provide an interdisciplinary team approach to care management, care delivery, and care planning.

(4) Unless specifically enumerated in this section, comply with this section and the applicable provisions of articles 29-ee, and if relevant, articles 28, 36 (if not already contracted with an article 36 licensed entity for home care services), and 44 of the Public Health Law.

(5) Enter into a PACE organization contract and agreement with the department and CMS.

(g) (1) A PACE organization shall serve an approved geographic service area as determined by the department.

(2) (i) A PACE organization and its incorporators, directors, sponsors, stockholders, members, and operators shall have the experience, competence, and standing in the community as to give reasonable assurance of their ability to operate the organization to provide a consistently high level of care for enrollees and comply with this section.

(ii) A PACE organization shall demonstrate that where any incorporator, director, sponsor, stockholder, member, or operator of the organization holds, or within the past 10 years has held, a controlling interest or been a controlling person in a PACE program licensed under this Chapter or outside the State of New York, a consistently high level of care has been rendered in each such organization.

(iii) A PACE organization shall demonstrate that where any incorporator, director, sponsor, stockholder, member, or operator of the organization facility holds, or within the

past 10 years has held, a controlling interest in any other entity providing health-related or senior services inside or outside the State of New York, a consistently high level of care has been rendered in each such organization or facility.

(3) A PACE organization shall meet requirements for financial solvency under paragraph (c) of subdivision 1 of section 4403 of the Public Health Law, including a contingent reserve requirement as developed by the commissioner.

(4) A PACE organization shall be deemed to be a health maintenance organization under article 44 of the Public Health Law for purposes of subdivision 1 of section 6527 of the Education Law.

(h) (1) A unified licensure process for PACE organizations is hereby established that includes the applicable program requirements of article 29-ee of the Public Health Law, and, if not noted in this section, the provisions found in articles 28, 36 and 44 of the Public Health Law shall apply.

(2) A license under this Subpart shall require approval of the Public Health and Health Planning Council (PHHPC) and CMS.

(3) Any part of the PACE application that is approved by PHHPC is considered contingently approved until such time as all components of the PACE application are finally approved in writing by CMS which confers the final approval to become a PACE organization.

(4) A PACE application can be submitted at any time to the department during a calendar year. The separately required CMS application may only be submitted based on the quarterly submission schedule, or any other scheduled timeframes, issued by CMS and only after the department has officially issued the *State Attestation and Assurances*. An

applicant that has received an executed *State Attestation and Assurances* document must notify the department within 10 business days upon filing their CMS application.

Section 98-5.2 Definitions.

- (a) *Application* shall mean all or a part of the application for PACE licensure as defined in section 29-ee of the Public Health Law.
- (b) *Council* shall mean the New York State Public Health and Health Planning Council or PHHPC, the body set forth in section 225 of the Public Health Law.
- (c) *CMS* shall mean the federal Centers for Medicare and Medicaid Services
- (d) *Department* shall mean the New York State Department of Health.
- (e) *Health maintenance organization* or *HMO* shall have the same meaning as defined in article 44 of the Public Health Law unless otherwise noted in this section.
- (f) *Hospital* shall have the same meaning as defined in article 28 of the Public Health Law unless otherwise noted in this section.
- (g) *Interdisciplinary team* shall have the same meaning as found in section 42 CFR 460.102 unless otherwise noted.
- (h) *Medicaid* shall mean the program established pursuant to title 11 of article 5 of the Social Services Law and the program thereunder.
- (i) *Medicare* shall mean the program established by the federal government pursuant to title XVIII of the Federal Social Security Act and the programs thereunder.
- (j) *PACE services* shall mean those services defined by CMS as all Medicare Part A, Part B, and Part D services along with all Medicaid state plan covered services as determined appropriate by the Interdisciplinary Team.

Section 98-5.3 Applications for uniform licensure to the PACE program.

(a) The department will develop a unified PACE license application which will consist of three parts:

- (1) health maintenance organization, newly licensed under this Subpart;
- (2) hospital, newly licensed under this section; and
- (3) proof that a home care agency licensed or certified pursuant with defined criteria under article 36 of the Public Health Law is either newly licensed under this Subpart for the proposed PACE program, or the proposed PACE program plans to contract with an already existing home care provider currently licensed under article 36 of the Public Health Law.

(b) An application to CMS must be accompanied by a fully executed *State Attestation and Assurances* document indicating that the council considers the entity qualified to be a PACE organization and is willing to enter into a three-way agreement with the PACE program upon final approval of the application by both the council and CMS. This document will also clearly define the applicant's proposed geographic service area, consistent with both the applicant's State and CMS applications.

(c) (1) An application shall be in writing on forms provided by the department and subscribed by the chief executive officer (or other officer duly authorized by the applicant) of the proposed PACE program or, where an application is to be submitted by a local governmental applicant, the president or chairperson of the board of the proposed PACE program or the chief executive officer if there is no board; and accompanied by a certified copy of a resolution of the board of a corporate applicant authorizing the undertaking which is the subject of the application, and the subscribing and submission thereof by an appropriate designated individual. In the event that an

application is to be submitted by an entity which necessarily remains to be legally incorporated it shall be subscribed and submitted by one of the proposed stockholders or directors. If a local governmental applicant submitting an application has not designated a president, chairperson or chief executive officer for the proposed facility, the application shall be subscribed by the chairperson or president of the local legislature or board of supervisors having jurisdiction, or other appropriate executive officer. An original application and two copies thereof shall be prepared. The original shall be filed with the council through submission to the PACE project management unit in the department's Office of Aging and Long Term Care in Albany, New York, or by such means as determined by the commissioner.

(2) Applications shall contain information and data with reference to:

(i) the justification for the existence of the proposed PACE program at the time and place and under the circumstances proposed for use in a specific PACE program;

(ii) the character, experience, competency, and standing in the community of the proposed incorporators, directors, stockholders, sponsors, individual operators, or partners;

(iii) the financial resources and sources of future revenue of the proposed PACE program to be operated by the applicant as defined in article 29-ee of the Public Health Law;

(iv) the fitness and adequacy of the premises and equipment to be used by the applicant for the proposed facility;

(v) the following documents shall be filed:

(a) a certified copy of the applicant's certificate of doing business;

(b) where the applicant is a partnership, full and true copies of all partnership agreements, which shall include the following language:

"By signing this agreement, each member of the partnership created by the terms of this agreement acknowledges that the partnership and each member thereof has a duty to report to the New York State Department of Health any proposed change in the membership of the partnership. The partners also acknowledge that the prior written approval of the Public Health and Health Planning Council and the New York State Department of Health is necessary for such change before such change is made, except that a change resulting from an emergency caused by the severe illness, incompetency or death of a member of the partnership shall require immediate notification to the New York State Department of Health of such fact and application shall be made for the approval by both the Public Health and Health Planning Council and the New York State Department of Health of such change within 30 days of the commencement of such emergency. The partners also acknowledge that they shall be individually and severally liable for failure to make the aforementioned reports and/or applications."; and

(c) any additional information or documents which may be requested by the council.

(3) Each application shall include an application fee of \$2,000 in addition to the fee described in section 2802 of the Public Health Law due upon submission of application. All fees pursuant to this paragraph shall be payable to the Department of Health for deposit into the Special Revenue Funds - Other, Miscellaneous Special Revenue Fund - 339, Certificate of Need Account.

(4) Any person filing a proposed certificate of incorporation or an application for licensure shall file with the commissioner information regarding the property interests in such facility, including the following:

(i) the name, address, and a description of the interest held, or proposed to be held, by each of the following persons:

(a) any person who, directly or indirectly, beneficially owns an interest in the land on which the proposed PACE program premises is located;

(b) any person who, directly or indirectly, beneficially owns any interest in the building in which the proposed PACE program is located;

(c) any person who, directly or indirectly, beneficially owns any interest in any mortgage, note, deed of trust or other obligation secured in whole or in part by the equipment used in the facility, or by the land on which or the building in which the proposed PACE program is located;

(d) any person who, directly or indirectly, has any interest as lessor or lessee in any lease or sublease of the land on which or the building in which the proposed PACE program is located; and

(e) any person who, directly or indirectly has any interest as a lessor or lessee in any lease or sublease of the equipment used in the building in which the proposed PACE program is located;

(ii) if any person named in response to subparagraph (i) of this paragraph is a partnership, then the name and address of each partner;

(iii) if any person named in response to subparagraph (i) of this paragraph is a corporation, other than a corporation whose shares are traded on a national securities

exchange or are regularly quoted in an over-the-counter market or which is a commercial bank, savings bank or savings and loan association, then the name and address of each officer, director, stockholder and, if known, each principal stockholder and controlling person of such corporation;

(iv) any additional information and documents which may be requested by the council.

Section 98-5.4 Requirements for Approval.

(a) The application must be complete and in proper form. It shall provide all the scope and organization of services defined by CMS for a PACE plan and all information essential for the council's and the department's consideration.

(b) The applicant must satisfactorily demonstrate to the council:

(1) that there is a justification for the proposed PACE program. All applicants must demonstrate in their application that the PACE services provided by the proposed PACE program will be an organized and comprehensive program. The department may exclude from designation an application's proposed geographic service area that is already covered under another PACE program agreement to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing PACE program;

(2) (i) if a nonprofit corporation, that the members of the board of directors and the officers of the corporation are of such character, experience, competence, and standing as to give reasonable assurance of their ability to conduct the affairs of the corporation in its best interests and in the public interest and so as to provide proper care for the patients or residents to be served by the proposed PACE program;

(ii) if a proprietary business, that the owner, or all the partners, if a partnership, are persons of good moral character with the experience, competence and standing as to give reasonable assurance of their ability to operate the business so as to provide proper care for the patients or residents to be served by the proposed PACE program;

(iii) if a business corporation, that the members of the board of directors, the officers and the stockholders of the corporation are of such character, experience, competence, and standing as to give reasonable assurance of their ability to conduct the affairs of the corporation so as to provide proper care for the patients or residents to be served by the proposed PACE program;

(iv) if a limited liability company, that the members, managers, and officers of the company, are of such character, experience, competence, and standing as to give reasonable assurance of their ability to conduct the affairs of the company so as to provide proper care for the patient or residents to be served by the proposed PACE program;

(3) that there are adequate finances to properly establish and conduct the proposed PACE program for purposes of this section, including:

(i) all sources of capital;

(ii) all audited financial statements of all holding companies, related parties, and principals;

(iii) financial projections that identify the medical loss ratio and administrative overhead in line with industry standards;

(iv) the ability of the applicant to project financial viability;

(v) the ability of the applicant to meet reserved requirements defined in Part 98 of this Title; and

(vi) templates or contracts to meet all administrative and management services requirements;

(4) that with respect to an applicant who is already, or within the past 10 years has been, an incorporator, director, sponsor, stockholder, member, controlling person, principal stockholder, principal member, or operator of any PACE program or other entity providing health-related or senior services in New York as specified in paragraph (b) of subdivision (3) of section 2801-a of the Public Health Law or any other jurisdiction outside the State of New York, a substantially consistent high level of care has been rendered in each such PACE program or other entity providing health-related or senior services, with which the applicant is or has been affiliated.

(i) In reaching this determination, the council shall consider findings of PACE program or any other health facility related inspections, including but not limited to title XVIII and XIX of the Social Security Act and any relevant article 28, article 36, or article 29-ee survey findings that pertain to violations of this Chapter, routine and patient abuse complaint investigation results, and other available information. The council's determination that a substantially consistent high level of care has been rendered shall be made after evaluating such information, with the following criteria: the gravity of any violation, the manner in which the applicant/operator exercised supervisory responsibility over the proposed PACE program operation, or other entity providing health-related or senior services, and the remedial action, if any, taken after the violation was discovered.

(a) In evaluating the gravity of the violation, the council shall consider whether the violation threatened, or resulted in direct, significant harm to the health, safety or welfare of patients/residents.

(b) In evaluating the manner in which the applicant/operator exercised supervisory responsibility over the proposed PACE program operation, or other entity providing health-related or senior services, the council shall consider whether a reasonably prudent individual of the applicant/operator should have been aware of the conditions which resulted in the violation and/or was notified about the conditions which resulted in the violation.

(c) In evaluating any remedial action taken, the council shall consider whether the applicant/operator investigated the circumstances surrounding the violation and took steps which a reasonably prudent applicant/operator would take to prevent the reoccurrence of the violation.

(ii) When violations were found which either threatened to directly affect patient/resident health, safety, or welfare, or resulted in direct, significant harm to the health, safety or welfare of patients/residents, there shall not be a determination of a substantially consistent high level of care if the violations were recurrent or were not promptly corrected.

(a) A violation is recurrent if it has the same root cause as a violation previously cited within the last 10 years.

(b) A violation is not promptly corrected if a plan of correction has not been submitted to the department within 10 calendar days of the issuance of the *Statement of Deficiencies (Form CMS-2567)*, and the PACE program, or other entity providing

health-related or senior services has failed to provide an acceptable date of compliance based on the violation(s) requiring correction.

(c)(1) The applicant must supply any additional documentation or information requested by the council or the department within 30 days of such request, or must obtain from the council or the department, an extension of the time to provide such documentation or information which is requested during the review of the application. Any request for an extension of time shall set forth reasons why such documentation or information could not be obtained within the prescribed time. The granting of a request for an extension shall be at the discretion of the council or the department. Failure to provide such documentation or information within the time prescribed or as extended by the council or the department, shall constitute an abandonment or withdrawal of the application without any further action by the council or department.

(2) The applicant must supply any authorization the council or the department requests in order to verify any documentation or information contained in the application or to obtain any additional documentation or information which the council or department finds is pertinent to the application. Failure to provide such authorization shall constitute an abandonment or withdrawal of the application without any further action by the council or department.

(d) Whenever any applicant proposes to lease premises in which the operation of a hospital as defined in section 2801 of the Public Health Law is to be conducted, the lease agreement shall include the following language:

"The landlord acknowledges that their rights of reentry into the premises set forth in this lease do not confer on them the authority to select or install an operator or to operate a hospital as defined in article twenty-eight or article twenty-nine-ee of the Public Health Law on the premises and agrees that they will give the New York State Department of Health, Center for Long Term Care

Licensure, Planning and Finance, Office of Aging and Long Term Care, New York State Department of Health, Empire State Plaza, Albany, N.Y. 12237, notification by certified mail of their intent to reenter the premises or to initiate dispossess proceedings or that the lease is due to expire, at least 30 days prior to the date on which the landlord intends to exercise a right of reentry or to initiate such proceedings or at least 60 days before expiration of the lease.

Upon receipt of notice from the landlord of their intent to exercise his right of reentry or upon the service of process in dispossess proceedings and 60 days prior to the expiration of the lease, the tenant shall immediately notify by certified mail to the Center for Long Term Care Licensure, Planning and Finance, New York State Department of Health, Office of Aging and Long Term Care, Empire State Plaza, Albany, NY 12237, of the receipt of such notice or service of such process or that the lease is due to expire."

(e) No lease covering the premises in which the operation of a hospital as defined in article 29-ee or, if relevant, 28 of the Public Health Law may contain any provision whereby rent, or any increase therein, is based upon the Consumer Price Index, or any other cost-of-living index, except:

(1) Leases for outpatient facilities and premises leased solely for administrative purposes may contain cost-of-living index rent determination or adjustment provisions, provided the following conditions are met:

(i) the lease is reviewed and approved by the department;

(ii) the space rented is in a multi-purpose, multi-use building not constructed specifically for the purpose of housing an outpatient proposed PACE program;

(iii) the rental, if the lease is a sublease, is the same or less than the rental in the overlease;

(iv) the applicant has no interest, direct or indirect, beneficial or of record, in the ownership of the building or any overlease; and

(v) the rental per square foot, in the judgement of the department, is the same as or is comparable to other rentals in the building in which the outpatient service or administrative space is to be located, and the rental per square foot is comparable to the rental of similar space in other comparable buildings in the area when such comparisons can be made.

(2) In addition to the exception set forth in paragraph (1) of this subdivision, in the event the lease covering hospital premises contains provisions whereby it is the lessor's responsibility to pay necessary expenses associated with such premises, such as real estate taxes, utilities, heat, insurance, maintenance and operating supplies, such lease may contain provisions which allow adjustments to the rent only to the extent necessary to compensate for changes in such expenses.

Section 98-5.5 Revisions, Amendments, and Modifications to Applications.

(a) For purposes of this section, the following terms shall have the following meanings:

(1) *Amendment* shall mean a change to an application which has been approved or contingently approved by the council but for which an operating certificate has not been issued, and meets the criteria contained in subdivision (c) of this section.

(2) *Modification* shall mean a change to an application which has been approved or contingently approved by the council for which an operating certificate has not been issued and does not meet the criteria contained in subdivision (c) and is approvable pursuant to subdivision (e) or meets the criteria in subdivision (d) of this section.

(3) *Revision* shall mean a change to an application which has not been approved or contingently approved before the council.

(4) *Total basic cost of construction* means total project costs less the capitalized amount of construction loan interest and financing fees.

(5) *Total project cost* means total costs for construction, including but not limited to costs for demolition work, site preparation, design and construction contingencies, total costs for real property, for fixed and movable equipment, architectural and/or engineering fees, legal fees, construction manager and/or cost consultant fees, construction loan interest costs, and other financing, professional and ancillary fees and charges. If any asset is to be acquired through a leasing arrangement, the relevant cost shall be the cost of the asset as if purchased for cash, not the lease amount.

(b) Revisions: changes prior to council approval. An application made to the council pursuant to this Subpart, may be changed before the council has approved or contingently approved the application, which shall constitute a revision as defined in this section. Such revisions shall be made on appropriate forms supplied by the department and submitted to the council through the PACE project management unit in the department's Office of Aging and Long Term Care in Albany and shall be governed by the following:

(1) any change in the information contained in the original application must be accompanied by a satisfactory written explanation as to the reason such information was not contained in the original application;

(2) when reviewing a competitive batch of applications, the department, acting on behalf of the council, may establish deadlines pursuant to written notification for the submission of any change to an application; and

(3) if a change is submitted after any such deadline(s), the application shall be removed from consideration within the competitive batch being reviewed.

(c) Amendments. An application made to the council pursuant to this Subpart may be changed after the council has approved or contingently approved an application but prior to the issuance of an operating certificate. For any amendment which changes the information set forth in paragraphs (1) through (3) of this subdivision, the applicant shall submit the proposed amendment, to the council, with appropriate documentation explaining the reason(s) for the amendment and such additional documentation as may be required in support of such amendment to the council for their reevaluation and recommendations. The approval of the council must be obtained for any such amendment including the following:

- (1) a change in the number and/or type of services, other than a reduction in service which would be subject to an administrative review;
- (2) a change in the location of the site of the construction if outside the facility's service area or adjacent service areas; and
- (3) any change in the applicant.

(d)(1) If the commissioner, acting on behalf of the council determines that increases in total project costs or total basic costs of construction are due to factors of an emergency nature such as labor strikes, fires, floods, or other natural disasters or factors beyond the control of the applicant, or modifications to the architectural aspects of the application which are made on the recommendation of the department, the applicant may proceed without the need for the application to be referred back to the council and the department.

- (2) If the applicant can document by evidence acceptable to the commissioner, acting on behalf of the council, that increases in total project cost or total basic cost of construction were caused by delays in obtaining zoning or planning approvals which were beyond its control, the commissioner may permit review of the application to proceed without the need

for the application to be referred back to the council and the department pursuant to this Subpart. The evidence shall demonstrate clearly that the applicant had timely pursued the zoning or planning permits, has now obtained all such required permits and approvals, and is prepared to proceed with the project.

(3) If the applicant can document by evidence acceptable to the commissioner, acting on behalf of the council, that increases in the total basic cost of construction were caused by inflation in excess of that estimated and approved in the application and that such inflation has affected the total basic cost of construction as a result of delays which were beyond the applicant's control, the commissioner may permit review of the application to proceed without the need for the application to be referred back to the council and the department, pursuant to this Subpart. The evidence shall demonstrate clearly that the increase in inflation exceeds that estimated and approved in the application, and that any delays resulting in such inflationary cost increases were beyond the applicant's control.

(e) Any modification submitted subsequent to the issuance of any approval by the council, which does not constitute an amendment pursuant to subdivision (c) of this section shall require only the prior approval of the commissioner.

(f) Failure to disclose an amendment as described in subdivision (c) of this section prior to the issuance of an operating certificate shall constitute sufficient grounds for the revocation, limitation, or annulment of the approval of licensure.

Section 98-5.6 Withdrawals or abandonment of applications and failure to satisfy contingencies.

(a) An application made to the council and the department in accordance with this Subpart may, on written request of the applicant, be withdrawn prior to decision by the council at any time without prejudice to resubmission. Such resubmission shall be considered a new application.

(b) The failure, neglect, or refusal of an applicant to submit documentation or information, within the stated time frame, to satisfy a contingency imposed by the council and the department in conjunction with the council's or the department's proposal to approve an application shall constitute and be deemed an abandonment or withdrawal of the application by the applicant without the need for further action by the council and the department.

(c) When an applicant submits documentation or information, within the stated time frame, in an attempt to satisfy a contingency imposed by the council but the department, on behalf of the council, does not consider the documentation or information sufficient to satisfy the contingency, the application may be returned to the council for whatever action the council deems appropriate.

Section 98-5.7 Revocation, limitation, or annulment of approvals of licensure.

(a) An approval of licensure may be revoked, limited, or annulled by the council or the department if the council or the department finds:

(1) that the licensed operator employed fraud or deceit, as determined by the department (such as, but not limited to, information from a conviction, civil suit, or an investigation by a government agency), in procuring such approval of licensure or has made statements or furnished information in support of the application which were not true, accurate, or complete in any material respect;

(2) that the operating certificate of a hospital or PACE program has been revoked, limited, or annulled pursuant to the applicable provisions of law;

- (3) that a PACE program or hospital caused or allowed a patient to be subjected to violence or abuse by an employee, consultant, volunteer, or other person serving in any capacity in the hospital or that a hospital has failed to comply with the relevant provisions of article 29-ee, article 28, article 36, or article 44 of the Public Health Law or the rules and regulations promulgated thereunder;
- (4) that the licensed operator has had such a change in his financial condition or in the fiscal aspects of the proposed institution since the approval of licensure as to render the project economically unfeasible or render unsatisfactory the financial resources of the proposed institution and its sources of future revenue;
- (5) that the licensed operator has been convicted in a court of competent jurisdiction, of a relevant crime, as determined by the commissioner. Such crimes may entail fraud, theft, falsifying an instrument, or any crime that affects patient safety;
- (6) that the licensed operator has transferred his ownership interest in the operation of the PACE program without council approval and department approval, and that such person has terminated his participation in the operation of the PACE program;
- (7) that there has been a violation of section 610.4(a) of this Title;
- (8) that the licensed operator has granted any person convicted of a crime relating to PACE program, hospital, Medicaid, Medicare, or HMO activities the authority to direct or cause the direction of the operations, management, or policies of the PACE program;
- (9) that the licensed operator has failed to comply fully with any condition, limitation, or other requirement imposed as part of, or in conjunction with, the approval of licensure; or
- (10) that the applicant has failed to commence and complete construction within the time period determined under Part 710 of this Title.

(b) For purposes of this section, licensed operator shall include any person, partnership, or partner thereof, company and its members, and any corporation or stockholder, officer or director thereof, actual or proposed, whose application for licensure has been approved, regardless of whether an operating certificate has been issued.

Section 98-5.8 Decisions.

Copies of the resolution of the council approving or disapproving an application shall be transmitted to the commissioner.

Section 98-5.9 Governing authority or operator.

(a) The governing authority or operator is the party responsible for the operation of a medical facility.

(b) The governing authority or operator shall mean:

- (1) the policy making body of a government agency;
- (2) the board of directors or trustees of a not-for-profit corporation;
- (3) the officers, directors and stockholders of a business corporation;
- (4) the proprietor or proprietors of a proprietary medical facility; and
- (5) the members of a limited liability company.

(c) An individual, partnership or corporation which has not received establishment approval pursuant to articles 28, 36, and 44 of the Public Health Law or licensure pursuant to article 29-ee of the Public Health Law, may not participate in the total gross income or net revenue of a medical facility.

(d)(1) Except as provided in section 405.3 of this Title, the governing authority or operator may not contract for management services with a party which has not received establishment or licensure approval.

(2) The criteria set forth in this paragraph shall be used in determining whether there has been an improper delegation to a contracting entity or individual by the governing authority or operator of its responsibilities. The governing authority shall not delegate the following elements of management authority:

- (i) authority to hire or fire the administrator or other key management employees;
- (ii) maintenance and control of the books and records;
- (iii) authority over the disposition of assets and the incurring of liabilities on behalf of the PACE program;
- (iv) the adoption and enforcement of policies regarding the operation of the facility; or
- (v) regular review and oversight of the contracting entity or individual activities.

(3) The criteria set forth in paragraph (2) of this subdivision shall not be the sole determining factors of an improper delegation, but indicators to be considered with such other factors that may be pertinent in particular instances.

(4) Professional expertise shall be exercised in the utilization and analysis of the criteria. All of the listed criteria need not be present in a given instance for there to be an improper delegation of authority.

Section 98-5.10 Agents, nominees, and fiduciaries.

(a) Agents, nominees, and fiduciaries, whether testamentary or inter vivos, shall not be considered proper applicants for licensure, transfer of interest, or transfer of stock of a PACE program except that the following persons may apply for licensure approval in accordance with and subject to the requirements and conditions set forth in relevant portions outlined in article 29-ee, and if relevant, article 28, article 36, and article 44 of the Public Health Law:

(1) a natural person appointed as trustee of an express testamentary trust created by a deceased sole proprietor, partner, or shareholder in the operation of a hospital for the benefit of a person less than 25 years of age; or

(2) a natural person appointed conservator pursuant to article 77 of the Mental Hygiene Law or a natural person appointed committee of the property of an incompetent pursuant to article 78 of the Mental Hygiene Law or a sole proprietor, partner, or shareholder of a hospital, with respect to a hospital owned by a conservatee or incompetent person.

Section 98-5.11 Name changes or purpose changes of operators and medical facilities.

(a) Any change in the following shall require the prior approval of the council and the department, in accordance with the requirements of this section, section 98-5.5 of this Subpart, and any other applicable requirements of law:

(1) the name of a not-for-profit corporation operating a PACE program under article 29-ee, or, if relevant, article 28 of the Public Health Law or the not-for-profits purposes thereof;

(2) the name of a not-for-profit corporation authorized to solicit contributions for the establishment, licensure, or maintenance of any hospital pursuant to article 29-ee or article 28 of the Public Health Law;

(3) the assumed name of a sole proprietor or a not-for-profit corporation operating a PACE program under article 29-ee or, if relevant, article 28 or article 36 of the Public Health Law or of a not-for-profit corporation authorized to solicit contributions for the establishment, licensure, or maintenance of any hospital pursuant to article 28 of the Public Health Law, whenever the prior assumed name was approved by the council or its predecessor; and the department and;

- (4) the name or assumed name of a business corporation, partnership, or governmental subdivision operating a PACE program under article 29-ee and, if relevant article 28, article 36, and article 44 of the Public Health Law whenever the prior name or prior assumed name was approved by the council and the department.
- (b) Applicants requesting council and the department approval of a change of name or assumed name shall submit a written request to the executive secretary of the council, and the Office of Aging and Long Term Care at the department's central office in Albany, which shall include the following information and documentation as appropriate:
- (1) a letter specifying the current and proposed names and explaining the nature of and the reasons for the requested name or purpose of change;
 - (2) a photocopy of the executed proposed certificate of amendment for the certificate of incorporation or articles of organization, as appropriate, certificate of authority to conduct business in the State of New York, or certificate of conducting business under an assumed name; and,
 - (3) such other pertinent information and documents necessary for the council's and department's consideration, as requested.
- (c) Whenever the name of a business corporation, partnership, limited liability company, or governmental subdivision, or the assumed name of a business corporation, not-for-profit corporation, partnership, limited liability company, governmental subdivision, or sole proprietor operating a PACE program or fundraiser under article 29-ee or, if relevant, article 28, and article 36, of the Public Health Law was not specifically approved by the council and the department, any proposed change in said name or assumed name or initial use of an assumed name shall not

require the approval of the council but shall require the approval of the department in accordance with section 401.3 of this Title.

(d) The approval of the council and the department of a proposed name or assumed name or purposes may be withheld if the proposed name or assumed name or purposes indicates or implies that the corporation, partnership, limited liability company, governmental subdivision, or individual is authorized to engage in activities for which it is not authorized, provide a level of care it is not authorized to provide, is misleading, causes confusion with the identity of another facility, or violates any provision of the law.

(e) An approved name change under this Subpart is deemed a material change under 98-5.1(c) of this Subpart.

(f) Nothing contained within this section shall limit the authority of the council and the department to approve or disapprove the initial use of a name or assumed name for a not-for-profit corporation, business corporation, partnership, limited liability company, governmental subdivision, or sole proprietor when such name or assumed name is before the council and the department as part of an application for the establishment or licensure of a PACE program or fundraiser.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for the new Subpart 98-5 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is Article 29-EE of the Public Health Law which authorizes the Department of Health (Department), subject to approval of the Commissioner to develop regulations for the new Program of All-Inclusive Care of the Elderly (PACE) licensure process.

Legislative Objectives:

The legislative objective of Article 29-EE is to create a streamlined single application process for the Program of All-Inclusive Care of the Elderly (PACE) programs.

PACE is a federally recognized model of provider-sponsored, comprehensive care for persons 55 years of age or older who are otherwise eligible for nursing home admission. The PACE program fully integrates, coordinates, and pays for the continuum of Medicare and Medicaid-covered services to enable individuals with long-term care needs to live safely in the community.

This legislative objective is to streamline the regulation of PACE programs by developing a consolidated and uniform authorization process, encompassing all program requirements into singular licensure, and improve oversight of PACE organizations.

These changes maintain the same level of oversight of all PACE programs that exist today across all program areas.

Needs and Benefits:

The regulations are needed to comply with a new statutory provision, Article 29-EE of the Public Health Law, which creates a new licensure category for the Program of All-Inclusive Care of the Elderly (PACE) program. PACE programs are established to provide community-based, risk-based, and capitated long-term care services as optional services under Medicaid and, when applicable, under Medicare as well as under contracts among CMS, the Department, and PACE organizations.

Specifically, these regulations are required under Section 2999-u of the Public Health Law which states that the Commissioner of Health “shall establish in regulation” a unified licensure process for PACE organizations that includes the applicable program requirements of Article 29-EE, Articles 28, 36, and 44 of the Public Health Law.

PACE programs directly provide medical care, home health care, and social support services (typically at a PACE Center), unlike partially capitated managed long-term care (MLTC) plans that only provide certain Medicaid-covered long-term services and supports. PACE programs provide over 5,900 New Yorkers with the opportunity to remain safely in their communities and improve their quality of life, while also effectively controlling healthcare expenditures. Nationwide, PACE participants have shown reduced hospitalizations, readmissions, and reliance on emergency medical services, along with improved quality of life and higher satisfaction with their care. Yet, New York pays PACE programs less than the cost of caring for a comparable population through other Medicaid services, including nursing homes and MLTC programs.

However, PACE organizations operate in a confusing and complicated regulatory structure which hinders their ability to expand and further development of PACE programs in

New York. Statutory reforms were made to eliminate barriers to the development, expansion, and efficient operation of PACE programs in New York while preserving vitally important protections to those receiving services.

Currently, PACE organizations in New York must be licensed as MLTC plans, clinics, and licensed home care agencies (under Articles 44, 28, and 36 of New York's Public Health Law, respectively). This has created an administratively burdensome authorization process, which has limited the expansion of this critical product and does not reflect its unique role in the healthcare system.

There are several benefits to creating a uniform PACE licensure structure within the Department. The regulation will streamline the licensure and establishment of PACE programs by developing a uniform authorization process, encompassing all program requirements into a singular licensure which will assist in improving oversight of PACE organizations.

These changes maintain the same level of oversight of all PACE programs that exist today across all program areas.

Both nationally and here in New York, PACE programs have demonstrated the ability to allow individuals to reside safely in their communities for longer, improve their quality of life and deliver a high satisfaction with their care. Contrary to costing the State money, PACE programs deliver this desired level of care for elderly individuals for less than the cost of caring for a comparable population through other Medicaid services.

COSTS:

Costs to regulated parties:

This regulation will reduce the costs for regulated parties. Instead of three separate application fees, there will only be a single application to prepare and submit in addition to the

capital construction fee in Section 2802 of the Public Health Law. Outside of the unified and reduced standard application processing fee of \$2000 dollars, it is not expected that any new compliance costs will be associated with this rule. Under the current three license tier structure there is an Article 28 Diagnostic and Treatment Center Certificate of Need filing fee of \$2,000 and an additional \$2,000 filing fee for any Article 36 Licensed Home Care Agency Certificate of Need. There is no filing fee associated for an Article 44 Managed Long Term Care application.

Costs to Local and State Governments:

This regulation will not impact local or State governments unless they operate a PACE program, in which case the costs will be the same as costs for private entities. Currently, there are no PACE programs run by local governments in New York State.

Costs to the Department of Health:

Costs associated are the implementation of ten new staff within the Office of Aging and Long-Term Care to administer the licensure process and surveillance and operations of the new PACE licensure developed under the new statute and regulations. The Department is prepared to absorb the cost of the new hires in existing staff allocation but is seeking an additional staff package that is pending.

Paperwork:

This regulation imposes no additional paperwork.

Local Government Mandates:

This regulation imposes no local government mandates.

Duplication:

There is no duplication in State or federal law.

Alternatives:

An alternative would be to leave in place the current structure which consists of three different licenses. Any alternative short of full unification would fail to accomplish the directives of the statute and the goals of the program. The current structure is burdensome, confusing, and unnecessarily bureaucratic, and the statute requires a new regulation.

Federal Standards:

PACE programs must adhere to all federal PACE requirements. Currently, all PACE programs must be reviewed and approved by the federal Centers for Medicare and Medicaid Services (CMS) and nothing in this regulation will affect federal laws, rules and regulations regarding federal compliance with PACE programs.

Compliance Schedule:

These regulations will become effective upon publication of a Notice of Adoption in the New York State Register.

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