

ADDENDUM

STATE OF NEW YORK
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL

COMMITTEE DAY

AGENDA

September 23, 2021
10:15 a.m.

Empire State Plaza, Concourse Level, Meeting Rooms 2-4, Albany

I. COMMITTEE ON CODES, REGULATIONS AND LEGISLATION

Angel Gutiérrez, Chair

For Discussion	Program Area	Unit Representative
21-19 Amendment of Sections 600.1 and 600.2 of Title 10 NYCRR (Article 28 Nursing Homes; Establishment; Notice and Character and Competence Requirements)	Division of Legal Affairs	Marthe Ngwashi
	Office of Primary Care and Health Systems Management	Shelly Glock

SUMMARY OF EXPRESS TERMS

This regulation amends Title 10 NYCRR Sections 600.1 and 600.2.

Subdivision (d) is added to section 600.1 to articulate notice requirements for nursing home establishment applications, as required by new *Subdivision 2-b* of Article 2801-a of the Public Health Law. The State Long-Term Care Ombudsman and residents, staff, and other parties affiliated with an existing nursing home, will be notified once a nursing home establishment application has been acknowledged by the Department and also, when a nursing home establishment application is placed on the Establishment and Project Review Committee agenda of the Public Health and Health Planning Council, for consideration.

Paragraph (2) of subdivision (b) of section 600.2 is amended to make the “character, competence, and standing in the community” review standard comparable for all applicants; and to include a limited liability company as an acceptable legal entity applicant, whose members are subject to the “character, competence, and standing in the community” review.

Paragraph (4) of subdivision (b) of section 600.2 is amended to include additional titles of applicant individuals, it removes a reference to outdated reporting requirements that no longer appear in statute, it clarifies establishment application review criteria, and defines the terms ‘recurrent’ and ‘prompt correction’ related to violations at article 28 facilities.

Paragraph (5) is added to subdivision (b) of section 600.2 to incorporate additional information the Public Health and Health Planning Council is required to consider when making a determination about a “consistently high level of care” rendered at a nursing home. This required information is found in the new *Subdivision 3-b* of Article 2801-a of the Public Health Law. In addition, the proposed regulation clearly sets forth five (5) occurrences that automatically render a determination that a consistently high level of care is not found, including determining the percentage of nursing homes in an applicant individual’s portfolio with a CMS star rating of two stars or less. And finally, it also includes the amendments made to paragraph (4) of subdivision (b) of section 600.2, which applies to all article 28 facilities, generally.

Altogether, the proposed regulation in paragraph (5) of subdivision (b) of section 600.2 responds to legislative actions and recommendations and sets forth uniform, transparent, and outcome-based standards to determine when a “consistently high level of care” has been delivered by applicant operators in the nursing homes that they own or have owned over the last seven years.

Together the proposed regulations in Sections 600.1 and 600.2 of Title 10 NYCRR, strengthen the establishment application review process for all article 28 facilities, generally and nursing homes, specifically. They also provide the transparency and clarity necessary to determine when a nursing home establishment application (includes changes of ownership and transfers of ownership applications) will be considered by the Establishment and Project Review Committee of the Public Health and Health Planning Council.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 2803 of the Public Health Law, Sections 600.1 and 600.2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended, to be effective after publication of Notice of Adoption in the New York State Register, to read as follows:

New subdivision (d) is added to section 600.1 to read as follows:

(d) Notice about an application for establishment shall be administered in the following manner:

(1) Long-term care ombudsman (LTCO)

(i) Once an application for establishment of a nursing home has been acknowledged by the Department, the Department shall notify the office of the LTCO of such application for establishment, by regular mail or email, within thirty days of acknowledgement of an application for establishment.

(ii) Once an application for establishment of a nursing home has been scheduled for consideration by a committee designated by the public health and health planning council, the Department shall notify the office of the LTCO by regular mail or email.

(2) Residents, staff, and others

(i) Once an application for establishment of an existing nursing home has been acknowledged by the Department, the current operator of the facility and the applicant, shall notify the residents and their designated

representatives and the staff, including their union representatives, if applicable, of such application for establishment. Notification shall be completed by regular mail, email, or the delivery method designated by the resident, their designated representative, the staff, and union representatives, within thirty days of the Department's acknowledgement of an application for establishment.

(a) The notification shall include the pending change of ownership, as well as the legal entity and individual name(s) of the proposed buyer; the application number; instruction on how to submit comments about the application; and a link for the general public to view the application using the New York State Electronic Certificate-of-Need (NYSE-CON) system where applications are submitted.

(ii) Once an application for establishment of an existing nursing home has been scheduled for consideration by a committee designated by the public health and health planning council, within twenty-four (24) hours, the current operator of the facility and the applicant shall notify the residents and their designated representatives and the staff, including their union representatives, if applicable by regular mail, email, or the delivery method designated by the resident, their designated representative, the staff, and union representatives.

(a) The notification shall include the date, location(s), and time of the meeting of the committee designated by the public health and health planning council.

Paragraph (2) of subdivision (b) of section 600.2 is amended to read as follows:

(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 facility or the proposed facility;

(ii) if a proprietary business, that the owner, or all the partners, if a partnership, are persons of good moral character [who are competent] 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 facility or the proposed facility;

(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 facility or the proposed facility;

(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 patients or residents to be served by the facility or the proposed facility;

Paragraph (4) of subdivision (b) of section 600.2 is amended to read as follows:

(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 facility as specified in paragraph (b) of subdivision (3) of *section 2801-a of the Public Health Law*, a substantially consistent high level of care has been rendered in each such facility [with which] the applicant is or has been affiliated [during the past 10 years or during the period of affiliation, as appropriate]. [In reaching this determination, the Public Health Council shall consider findings of facility inspections, including but not limited to the title XVIII and XIX (of the Social Security Act) and article 28 survey findings, as such pertain to violations of this Chapter, periodic medical review/independent professional review (PMR/IPR) findings, routine and patient abuse complaint investigation results, and other available information. The Public Health Council's determination that a substantially consistent high level of care has been rendered shall be made after reviewing the following criteria: the gravity of any violation, the manner in which the applicant/operator exercised supervisory responsibility over the facility

operation, and the remedial action, if any, taken after the violation was discovered.]

(i) In reaching this determination, the Public Health and Health Planning Council shall consider findings of facility inspections, including but not limited to the title XVIII and XIX (of the Social Security Act) and article 28 survey findings, as such pertain to violations of this Chapter and routine and patient abuse complaint investigation results; and other available information.

(ii) The Public Health and Health Planning Council's determination that a substantially consistent high level of care has been rendered shall be made after evaluating the aforementioned information, with the following criteria: the gravity of any violation, the manner in which the applicant/operator exercised supervisory responsibility over the facility operation, and the remedial action, if any, taken after the violation was discovered.

(a) In [reviewing] evaluating the gravity of the violation, the Public Health and Health Planning Council shall consider whether the violation threatened, or resulted in direct, significant harm to the health, safety or welfare of patients/residents.

(b) In [reviewing] evaluating the manner in which the applicant/operator exercised supervisory responsibility over the facility operation, the Public Health and Health Planning 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 was notified about the conditions which resulted in the violation and whether the individual of the applicant/operator was notified about the condition(s) which resulted in the violation.

(c) In [reviewing] evaluating any remedial action taken, the Public Health and Health Planning 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.

(iii) 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 [reoccurred] 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 ten (10) years.

(b) A violation is not promptly corrected if a plan of correction has not been submitted to the Department within ten (10) calendar days of the issuance of the statement of deficiencies, Form CMS-2567 and the facility has failed to provide an acceptable date of compliance based on the violation(s) requiring correction.

New Paragraph (5) of subdivision (b) of section 600.2 is added to read as follows:

(5) that, with respect to an application to incorporate or establish a nursing home, an applicant who is already or within the past 7 years, been an incorporator, director, sponsor, stockholder, or member, has held a controlling interest or has been a controlling person, principal stockholder or principal member, or operator of a nursing home as specified in paragraph (b) of subdivision (3-b) of *section 2801-a of the Public Health Law*, has demonstrated satisfactory character, competence and standing in the community and a consistently high level of care has been rendered in each such nursing home that the applicant is or has been affiliated.

(i) In reaching this determination, the Public Health and Health Planning Council shall consider, at a minimum, the following:

(a) findings of facility inspections, including but not limited to the title XVIII and XIX (of the Social Security Act) and article 28 survey findings, as such pertain to violations of this Chapter and routine and patient abuse complaint investigation results;

(b) any instance of a facility affiliated with the applicant/operator earning a two-star rating or less by the federal centers for Medicare and Medicaid Services (CMS) (or a comparable rating under a successor CMS rating system); provided that a further consideration and mitigating factor in determining whether such star rating reflects a consistently high level of care is where an

applicant's ownership interest in the star rated facility commenced within the prior five years;

(c) any instance where there have been violations of the state or federal nursing home code, or other applicable rules and regulations, that threatened to directly affect the health, safety or welfare of any patient or resident, including but not limited to a finding of immediate jeopardy, or actual harm, and were recurrent or were not promptly corrected, including but not limited to repeat deficiencies for the same or similar violations over a three year period or during the entire duration of ownership if less than three years, or any facility which has been in receivership;

(d) any instance where a facility has closed or has closed as a result of a settlement agreement from a decertification action or licensure revocation.

(e) any instance where a health care related facility, agency, or program was the subject of a decertification action or licensure revocation;

(f) any involuntary termination from the Medicare or Medicaid program; and

(g) any instance of a nursing home being designated a Special Focus Facility or Special Focus Facility Candidate.

The applicant shall be provided with the opportunity to submit an explanation and other supporting documentation regarding any of the

aforementioned occurrences which shall be considered by the Public Health and Health Planning Council prior to reaching a determination.

(ii) The Public Health and Health Planning Council's determination that a consistently high level of care has been rendered shall be made after evaluating the aforementioned information, with the following criteria: (i) the gravity of any violation, the manner in which the applicant/operator exercised supervisory responsibility over the facility operation, and the remedial action, if any, taken after the violation was discovered and (ii) the percentage of nursing homes in a portfolio with a two-star or less rating.

(a) In evaluating the gravity of the violation, the Public Health and Health Planning 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 facility operation, the Public Health and Health Planning 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 whether the individual of the applicant/operator was notified about the condition(s) which resulted in the violation.

(c) In evaluating any remedial action taken, the Public Health and Health Planning 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.

(d) In evaluating instances of a facility affiliated with the applicant/operator earning a two-star or less rating, the Public Health and Health Planning Council shall determine the percentage of nursing homes in the portfolio, that each individual of the applicant/operator has held an ownership interest for forty-eight (48) months or more and has earned a CMS star rating of two-stars or less.

(iii) When any of the following has occurred in the prior five years, there shall not be a determination of a consistently high level of care:

(a) Closure of a facility or a facility has closed as a result of a settlement agreement from a decertification action or licensure revocation.

(b) A health care related facility, agency, or program was the subject of a decertification action or licensure revocation.

(c) Involuntary termination from the Medicare or Medicaid program.

(d) Violations 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, and were recurrent or were not promptly corrected.

(1) A violation is recurrent if it has the same root cause as a violation previously cited within the last seven (7) years.

(2) A violation is not promptly corrected if a plan of correction has not been submitted to the Department within ten (10) calendar days of the issuance of the statement of deficiencies, Form CMS-2567 and the facility has failed to provide an acceptable date of compliance based on the violation(s) requiring correction.

(iv) When any individual of the applicant/operator has greater than 40% of the nursing homes in their portfolio with a CMS star rating of two stars or less and has held an ownership interest in such nursing home for forty-eight (48) months or more, there shall not be a determination of a consistently high level of care; unless the portfolio contains fewer than five (5) facilities, then the Public Health and Health Planning Council shall make a determination on a case-by-case basis, using the criteria set forth in subparagraph (ii) of this paragraph.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) section 2803(2) authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, including the establishment or incorporation of health care facilities.

Legislative Objectives:

The legislative objective of PHL Article 2801-a is to provide a deliberate and reasonable application process for the establishment or incorporation of health care facilities in New York. The purpose of the establishment application process is to codify an application review process that includes an assessment of character and competence, quality of care metrics, financial feasibility, and other relevant factors, for the benefit of those who seek health care services at State-regulated facilities.

Needs and Benefits:

Rulemaking was necessitated by revisions to Public Health Law section 2801-a via Chapter 102 and 141 of the Laws of 2021. Regulations are being amended to codify the procedure for the notification to the Long-term care ombudsman (LTCO), Residents, staff, and others of an application for the establishment of a nursing home operator. Notification will occur when an application has been received and acknowledged by the State Department of Health (Department) and again when the application has been

scheduled for consideration by a committee designated by the Public Health and Health Planning Council. Notification to those who may be impacted by a nursing home establishment application will allow a chance for public comment to be submitted for consideration by the Public Health and Health Planning Council (PHHPC) before PHHPC acts upon the application. Regulations are being amended to add language for limited liability corporations for character and competence, consistent with other business types. Regulations are being amended for character and competence to require PHHPC to consider, in some cases, specified information and evaluate the gravity of any violation, the manner in which the applicant/operator exercised supervisory responsibility over the facility operation, and the remedial action, if any, taken after the violation was discovered before determining that a substantially consistent or a consistently high level of care has been rendered. New language has been added to codify standards of review for nursing home character and competence, using certain quality of care metrics when evaluating and making a determination that a consistently high level of care has or has not been rendered. The changes reflect the intent of the law to provide increased transparency to those with an interest in the establishment of a nursing home operator and to codify the metrics used for evaluating character and competency of proposed operators.

Costs:

Costs to Regulated Parties:

Nominal costs may be incurred by nursing home providers to adhere to the notification requirements when the establishment of a new operator is proposed. This

cost will be incurred by the current operator of the facility and the applicant for establishment. The nominal costs will be related to postage, supplies, and staff time to prepare the notice and establish distribution lists for those to be notified. Labor, legal and consulting costs may be incurred by applicants who have previously filed an establishment application which is pending PHHPC consideration, should they feel the need to revise their application based on the rule changes.

Costs to State Government and the Department of Health:

The Office of the State Long-Term Care Ombudsman will incur costs related to the labor involved in reviewing notices filed on nursing home establishment applications and, thereafter, submitting a recommendation about the application to the Department. The Department will incur additional staff time required to re-review pending establishment applications and revise materials previously prepared during the review of such applications. Costs to the Department for notification requirements will be absorbed into current costs.

Costs to Local Governments:

There should be no local government costs unless a County operated facility is the subject of a new operator nursing home establishment application. Should this occur the County would incur the costs associated with the current operator outlined in the Cost to the Regulated Parties Section.

Local Government Mandates:

There are no local mandates in the amended regulations. However, County operated nursing homes will be required to meet the notification requirements under the amended regulations.

Paperwork:

Under the amended regulations, the current facility and the applicant for establishment will be required to prepare written notification to residents, staff and other impacted parties after a nursing home establishment application has been acknowledged by the Department. Distribution lists for notifications will be required. All other requirements are consistent with the paperwork currently required during the establishment application process.

Duplication:

There are no duplicative or conflicting rules identified.

Alternatives:

The Department considered current standards used in character and competence review and alternative metrics, ratings, and data available. The Department also considered the impact of the use of absolute thresholds to be achieved for determining that a consistently high level of care has been rendered. The Department found that currently published ratings, such as the CMS Star rating system, take into account many of the alternative factors and data being considered. To avoid duplication and promote

transparency, the Department incorporated the CMS Star Ratings, surveillance findings and enforcements that are available to the public via the NYS Nursing Home Page of the Department's website, and CMS special focus facility designations available to the public – all information and data familiar to the health care industry, in general, and the nursing home industry, specifically, to make a determination about a consistently high level of care at facilities. This combination of information incorporates a cross section of factors relevant to assessing quality of care at nursing homes. The Department also included additional factors to supplement information that may not be apparent in the main evaluation criteria such as length of time a facility was owned, the overall number of facilities owned, revocation of a license, involuntary closure of a facility, and if severe deficiencies were recurrent or were not promptly corrected.

The amended regulations reflect a regulatory framework to evaluate the general quality of care rendered by a proposed operator historically and incentivizes improvement in quality as a condition to acquiring additional facilities in New York State.

Federal Standards:

The amended regulations do not exceed any minimum standards of the federal government.

Compliance Schedule:

The amended regulations will take effect upon a Notice of Adoption in the New York State Register.

Contact Person:

Katherine E. Ceroalo
NYS Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Rm 2438
Empire State Plaza
Albany, NY 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

Local governments and small businesses will not be affected by this rule, unless they operate a nursing home and, in such cases, will be impacted by the new, statutory notification requirements defined in Section 600.1. The current number of local governments and identified-small businesses (employ less than 100 staff) that operate a nursing home are seventy-nine (79). The Department does not anticipate an increase in nursing home establishment applications by such applicants as a result of the proposed regulations.

Compliance Requirements:

Regulated parties are expected to be in compliance with the amended regulations upon adoption. The amended regulations will define new, statutory notice requirements when an application for the establishment of a nursing home has been acknowledged by the Department and when the application has been scheduled for consideration by a committee designated by the Public Health and Health Planning Council.

Professional Services:

These regulations are not expected to require any additional use of professional services.

Compliance Costs:

Nominal costs may be incurred by a nursing home operator and applicant to adhere to the notification requirements after a nursing home establishment application has been acknowledged by the Department. This cost will be incurred by the current operator of the facility and the applicant for establishment. The nominal costs will be related to postage, supplies, and staff time to prepare the notice and establish distribution lists for individuals to be notified.

Economic and Technological Feasibility:

The Department has considered feasibility and the amended regulations are economically and technically feasible.

Minimizing Adverse Impact:

Minimal flexibility exists to minimize impact since the new requirements are statutory and apply to all nursing home establishment applicants, however, an effort was made to broaden the method used for notice distribution.

Small Business and Local Government Participations:

Organizations who represent the affected parties will have several opportunities for participation. There are two opportunities to provide public comment, both written and orally, at the Public Health and Health Planning Council (PHHPC). Initially, the regulations will be presented twice in a public PHHPC meeting; first, for discussion and second, for final adoption. In both instances, the public, including any affected party, is

invited to provide comments during the PHHPC Committee on Codes, Regulations and Legislation meeting.

Second, the affected parties have the opportunity via the 60-day State Register process to provide comments and suggestions to the regulation. If substantial and material changes are made as a result of the public comments, the amended regulation will be subject to an additional 45-day comment period.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (<http://quickfacts.census.gov>).

Allegany	Hamilton	Schenectady
Cattaraugus	Herkimer	Schoharie
Cayuga	Jefferson	Schuyler
Chautauqua	Lewis	Seneca
Chemung	Livingston	Steuben
Chenango	Madison	Sullivan
Clinton	Montgomery	Tioga
Columbia	Ontario	Tompkins
Cortland	Orleans	Ulster
Delaware	Oswego	Warren
Essex	Otsego	Washington
Franklin	Putnam	Wayne
Fulton	Rensselaer	Wyoming
Genesee	St. Lawrence	Yates
Greene		

The following eleven counties have certain townships with population densities of 150 persons or less per square mile:

Albany	Monroe	Orange
Broome	Niagara	Saratoga
Dutchess	Oneida	Suffolk
Erie	Onondaga	

Reporting, Record Keeping and Other Compliance Requirements and Professional Services:

Nursing home operators and applicants for establishment of new operators are expected to be in compliance with the amended regulations upon adoption. There are several licensed nursing homes in rural areas. The amended regulations will define new, statutory notice requirements when an application for the establishment of a nursing home has been acknowledged by the Department and when the application has been scheduled for consideration by a committee designated by the Public Health and Health Planning Council. There are no new reporting requirements, but record keeping will be required by nursing home operators and applicants for establishment of a new operator to ensure notification to required parties. No additional professional staff are expected to be needed as a result of the amended regulations.

Costs:

Nominal costs may be incurred by a nursing home operator and applicant to adhere to the notification requirements after a nursing home establishment application has been acknowledged by the Department. This cost will be incurred by the current operator of the facility and the applicant for establishment.

Minimizing Adverse Impact:

The amended regulations do not create any adverse effect on regulated parties.

Rural Area Impact:

Organizations who represent the affected parties and the public can obtain the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council and a copy of the proposed regulation on the Department's website. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

**STATEMENT IN LIEU OF
JOB IMPACT STATEMENT**

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

Further, the new notification requirements in Section 600.1 will only impact an employer over a limited period and can be performed by existing staff resources. The amended regulations for Section 600.2 should not cause a change to the workload of applicants for establishment of new nursing home operators and will not increase nor decrease jobs and employment opportunities.