

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(b) of section 600.2 is amended to include additional titles of applicant individuals, it removes a reference to outdated reporting requirements that no longer appear in statute, it clarifies establishment application review criteria, and defines the terms ‘recurrent’ and ‘prompt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 of a health care related facility, agency, or program 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.

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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 several 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.

Finally, before going to PHHPC, a call was held with industry representatives highlighting the proposed regulation and to answer any questions industry representatives had regarding the regulation and the process of regulation adoption.

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.

SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

Proposed amendments to 10 NYCRR § 600.1 articulate notice requirements for nursing home establishment applications, as required by new Subdivision 2-b of Article 2801-a of the Public Health Law. Proposed amendments to 10 NYCRR § 600.2 make the “character, competence, and standing in the community” review standard comparable for all applicants; and 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.

Following the assessment of public comment, the Department has determined that no substantive changes to the regulations were necessary, and no additional requirements were added as a result of the comments received. The New York State Department of Health (“Department” or “DOH”) received comments from LeadingAge New York and Center for Elder Law and Justice regarding proposed amendments. The general theme of the comments were seeking clarification on implementation and suggested recommendations for additional requirements that furthered the intent of the proposed regulations under 10 NYCRR §§ 600.1 and 600.2. The Department responded to the comments made, and the issues stated will be addressed when the amended regulations are presented publicly to the Public Health and Health Planning Council (“PHHPC”) and in public discussions of the PHHPC going forward as the new requirements under the amended regulations are implemented. There was a comment that identified a typo in the proposed regulations, which will be addressed in the version to be presented for adoption.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (Department) received comments from LeadingAge New York and Center for Elder Law and Justice regarding proposed amendments to 10 NYCRR Sections 600.1 and 600.2. The comments and the Department's responses are summarized below.

Comment: A comment was received on new regulation 10 NYCRR § 600.1(d)(1) stating that the proposed rulemaking does not address the process by which the Office of the LTC Ombudsman would undertake a review of the proposed establishment action, the content of such a review and the standards it would apply, or the method by which the currently established operator or the proposed new operator would be able to lodge any objections against a recommendation of the Office of the LTC Ombudsman.

Response: The Department is working with the Office of the LTC Ombudsman to provide guidance and develop policy on how the required review will be conducted. Objections made to the recommendation of the Office of the LTC Ombudsman can be made in the same manner as objections are made to recommendations by other review entities. Objections and rebuttals can be made in person or in writing to the Public Health and Health Planning Council for consideration. An Article 78 proceeding can be used to appeal a decision if the recommendation is believed to lead to a negative determination by the Public Health and Health Planning Council. The Department has considered this public comment and deemed it does not warrant a revision to the proposed regulations.

Comment: A comment was received on new regulation 10 NYCRR § 600.1(d)(2)(i) stating to ensure resident, family and staff confidentiality, it would be more practical for the current operator to actually deliver these notices to the noted individuals. The commentor states the current operator could collaborate with the applicant on the content of the notice.

Response: The comment appears to be a misinterpretation of the proposed regulation. Nothing in 10 NYCRR § 600.1(d)(2) prevents the current applicant and the operator from collaborating on a joint notice to residents and family that is delivered by the current operator. The Department has considered this public comment and deemed it does not warrant a revision to the proposed regulations.

Comment: A comment was received on new regulation § 600.1(d)(2)(ii) to recommend a more realistic standard of 48-72 hours be permitted instead of the proposed 24 hours, or the wording of § 600.1(d)(1)(ii) be used.

Response: Applicants and operators are not able to anticipate the timing of notice for when an application will be considered by the Public Health and Health Planning Council Committee on Establishment and Project Review. Applicants and the public are simultaneously made aware an application is being considered via a public notice of the meeting agenda posted to the DOH website. Adequate time must be afforded to resident, family, staff, and other stakeholders to file public comments or to attend public meetings in person to make public comment. The authorizing statute, Public Health Law 2801-a(2-b)(c), states the notification shall occur immediately, and the proposed language in the regulation is intended to be compliant with the requirement for immediate

notification. The Department has considered this public comment and deemed it does not warrant a revision to the proposed regulations.

Comment: A comment was received on new regulation § 600.1(d)(2) to recommend that a facility be able to designate one or two standard methods for making required notifications to minimize the administrative burden of providing customized, person-specific methods.

Response: The proposed regulation recognizes the need to provide notification to a population that communicates via various methods and is not intended to restrict communication to a specific method(s) that may result in a stakeholder not receiving the required notification. It is reasonable to expect a residential health care facility to be able to provide resident specific communication and to also be able to employ resources to communicate with resident representatives as per normal course of business. The Department has considered this public comment and deemed it does not warrant a revision to the proposed regulations.

Comment: A comment was received on proposed amendments to regulation § 600.2(b)(2)(iv) in support of the amendment.

Response: No response required.

Comment: A comment was received on proposed amendments to regulation § 600.2(b)(4) to state it is unclear whether the provisions of §600.2(b)(4) apply to nursing homes, as well as other Article 28 facilities, or whether nursing homes are covered

exclusively under §600.2(b)(5). The commentor states this should be specified more clearly in the regulation.

Response: The amended provisions of §600.2(b)(4) apply to all Article 28 facilities. The provisions of proposed new paragraph §600.2(b)(5) apply exclusively to an application to incorporate or establish a nursing home, which is stated in the lead sentence of the new paragraph 5. The Department has considered this public comment and deemed it does not warrant a revision to the proposed regulations.

Comment: A comment was received on proposed amendments to regulation § 600.2(b)(4)(iii)(a) to state the lack of definition of “root cause” as used in the amended regulation nor is there an acceptable standard definition of the term in the relevant State or Federal regulations. The commentor states the final rulemaking should clearly define this term, so it is understood by all regulated parties and by the general public, and it is consistently applied by the Department’s CON staff and the PHHPC.

Response: Root cause is a common phrase used to describe the cause of a problem and is accepted terminology for State and Federal purposes. It is determined based on a review of specific information provided within the violations and surveillance findings leading to the violations. The Department has considered this public comment and deemed it does not warrant a revision to the proposed regulations.

Comment: A comment was received on proposed amendments to regulation § 600.2(b)(4)(iii)(b) to state the language includes an extraneous “to” on line two after the word “been”.

Response: This comment correctly notes an extraneous “to” on line two after the word “been”. The extraneous “to” will be removed from the final regulation when adopted. This will not be considered a substantial change to the proposed regulations.

Comment: A comment was received on new regulation § 600.2(b)(5) to request clarification on how the new regulation would impact the process of evaluating transactions involving Not-for-profit entities.

Response: As referenced in the proposed new regulation, the authorizing statute Public Health Law 2801-a(3-b)(b) sets forth the criteria for evaluating transactions regardless of the type and class of the applicant entity. Proposed new regulation § 600.2(b)(5)(ii) allows for the Public Health and Health Planning Council to consider the manner in which the individual applicant/operator exercised supervisory responsibility over the facility and whether a reasonably prudent applicant/operator should be aware of conditions that existed. The proposed § 600.2(b)(5)(iv) allows for applicants with an ownership interest for at least a 48-month period in less than 5 facilities to be reviewed on a case-by-case basis using the criteria set forth in § 600.2(b)(5)(ii). The language within the proposed regulation, as written, should accommodate a review of an applicant’s ownership interest where the facilities being reviewed have little or no bearing on the quality of care to be delivered by the applicant. The Department has considered this public comment and deemed it does not warrant a revision to the proposed regulations.

Comment: A comment was received on new regulation § 600.2(b)(5)(i)(b) stating it is unclear whether this refers to the rating at the time of the application or at any point in the during the applicant’s affiliation. The timeframe of the two-star ratings to be considered by PHHPC (e.g., at the time of the application or during a specified period prior to the application) should be clarified in the regulations.

Response: CMS star ratings will be assessed at the time of application, and while the application is under review by the Department, for facilities where a proposed operating member has an ownership interest for 48 months or more. Although, guidance by the PHHPC may require the Department to detail CMS star ratings for a proposed operating member’s ownership facilities over the entire ownership period. The Department has considered this public comment and deemed it does not warrant a revision to the proposed regulations.

Comment: A comment was received on new regulation § 600.2(b)(5) noting that the section includes two different provisions governing recurrent violations with different lookback periods. 600.2(b)(5)(i)(c) uses a three-year evaluation period for repeat deficiencies for the same or similar violations while 600.2(b)(5)(iii)(d) states in the prior five years, a violation is recurrent if it has the same root cause as a violation previously cited within the last seven years. The commentor requests clarification on how PHHPC will proceed to evaluate repeat violations, what lookback period it will apply, and under what circumstances.

Response: The proposed new regulation has different criteria depending on the circumstances. 600.2(b)(5)(i)(c) uses a three-year evaluation period for repeat

deficiencies for the same or similar violations as a factor that PHHPC must consider at a minimum, in conjunction with other factors in 600.2(b)(5)(i), when making its determination on an application. The 600.2(b)(5)(iii)(d) criteria mandates that there shall not be a determination of a consistency high level of care if in the past 5 years a violation has occurred that has the same root cause as a violation previously cited within the last 7 years. The consideration of same or similar violations is a lower standard than a determination that a violation has the same root cause as a previous violation. A violation that is the same or similar to a previous violation based on the nature of the citation (i.e. F tag) and enforced upon as a repeat violation may not necessarily be considered to have the same root cause when inspection records for each violation are examined. The Department has considered this public comment and deemed it does not warrant a revision to the proposed regulations.

Comment: A comment was received on new regulation § 600.2(b)(5) requesting recognition of the strengths and weaknesses of the CMS Compare Care system's star rating system. The commentor notes that while the ratings simplify data points to act as a consumer guide, the data often lags current reality. The commentor also notes DOH administers Standard Health Inspections that help make up the ratings through a regional office system that may skew data on a regional basis. The commentor urges State regulator bodies to use the underlying data to the Star ratings with attention to possible disparity in the data due to regional variations to develop a more accurate picture of past performance of a proposed operator.

Response: While the CMS star rating is not without its flaws, it is a federal and industrywide standard that is updated regularly by CMS and easily understood by PHHPC, consumers and the nursing home industry. While individual facilities may suffer low CMS star ratings due to a single surveillance survey outcome or other serious enforcement, the regulation establishes the PHHPC will consider a proposed operating member's entire ownership interest portfolio to develop a more accurate picture of past performance rather than relying solely on individual surveillance outcomes at specific facilities. The proposed regulations allow the Department and the PHHPC to use the CMS Compare Care system's star ratings in conjunction with other factors noted in the proposed regulations to develop an overview of the historical quality of care being provided at health care facilities operated by the applicant throughout the Country. Reliance on data driven evaluations will always be dependent on the timing and accuracy of the data used, which is why the proposed regulations allow for other factors to be presented and considered. The Department has considered this public comment and deemed it does not warrant a revision to the proposed regulations.

Comment: A comment was received on new regulation § 600.1(d) encouraging the Department to revise the proposed regulation to require DOH and PHHPC to formally address comments raised by the Office of the LTC Ombudsman, residents, staff, and others as submitted in response to the new notification requirements of Public Health Law 2801-a(2-b)(a)-(c). The commentor states Department regulations must mandate the applicant issue a written plan, to be provided to residents, their representatives, and the

Office of the LTC Ombudsman, on how they will work to improve care and address other issues raised through public comment.

Response: The comment is outside of the scope of the public comment for this proposed regulation. However, the Department wishes to address this comment; the Office of the LTC Ombudsman acts on behalf of residents to ensure rights are not violated, while identifying, investigating, and working towards resolution of resident complaints. When resolution through the Ombudsman program is not achievable, complaints are referred to the New York State Department of Health or other appropriate agencies as part of that process. Additionally, PHHPC has the authority to address concerns raised as part of the public approval process, which can include but is not limited to having the applicant respond publicly to such concerns. The Department has considered this public comment and deemed it does not warrant a revision to the proposed regulations.

Comment: A comment was received on new regulation § 600.1(d)(2) noting the proposed regulation does not provide details, nor does it direct, nursing homes on how residents, their representatives, and others can designate a delivery method for notification of an application. The commentor encourages the Department to revise the regulation such that it requires written notification to residents, their representatives, and others regardless of whether email is requested. The commentor further encourages the Department to require by regulation that written and oral notification of the application for establishment of existing nursing homes is provided at both resident and council meetings.

Response: The comment appears to be an incorrect interpretation of the proposed new regulation which allows for varying methods of notification and allows the stakeholder to choose a preferred method of notification. The resident and their representatives can notify the operator of the preferred delivery method, including written notification, in the same manner they use to communicate with the facility regarding all other matters. The proposed regulation offers flexibility to allow residents and families to designate a delivery method and does not prohibit oral notification to residents and family at resident council meetings or other group meetings held by the facility. The Department has considered this public comment and deemed it does not warrant a revision to the proposed regulations.

Comment: A comment was received on new regulation § 600.1(d)(2)(i)(a) and (ii)(a) recommending the Department issue a standardized notice and that the regulation is amended to require use of this standardized notice to guarantee that residents and their representatives will be able to understand what the notice entails, and how the resident can submit comment.

Response: The authorizing statute Public Health Law § 2801-a(2-b) requires the established operator and applicant to issue the notification. New regulation § 600.1(d)(2)(i)(a) outlines the required content of the notice, which is sufficient to address this comment. The Department has considered this public comment and deemed it does not warrant a revision to the proposed regulations.

Comment: A comment was received on new regulation § 600.1(d)(2) to encourage the Department to review all submitted comments timely and implement policies/procedures such that comments are also investigated as complaints.

Response: The commentor acknowledged within the comment that this is outside of the scope of the public comment for this proposed regulation. However, the Department wishes to address this comment; any comments received on an application for establishment that would raise concerns of a regulatory nature would be referred for further review outside of the Certificate of Need process and possible follow up as a potential complaint by the appropriate area within the Department. The Department has considered this public comment and deemed it does not warrant a revision to the proposed regulations.

Comment: A comment was received on new regulation § 600.1(d)(2)(ii) disagreeing with the language of the proposed regulation for notification to residents and their representatives within twenty-four hours. The commentor states the language in the regulation must be changed to immediately notification in order to comply with Public Health Law 2801-a(2-b)(c). The commentor states operators and applicants should be reasonably expected to have the ability to immediately notify residents, their representatives, and others as they have already issued such notification for the Department's acknowledgement of the application.

Response: As defined in the proposed regulation, within 24 hours should be considered immediate in the context of this requirement. The Department has considered this public comment and deemed it does not warrant a revision to the proposed regulations.