

Summary of Express Terms

The proposal would amend various provisions of Part 765 of Title 10 NYCRR to implement recently enacted legislation.

Section 765-1.2. Applications for licensure. This section will be amended to require applications for licensure as a Licensed Home Care Services Agency (LHCSA) to include information on the public need for additional LHCSAs and the financial resources of the proposed agency as required by law, in addition to the existing requirement of a character and competence review. Amendments would specify that applications for licensure based on change of ownership for LHCSAs actively serving at least 25 patients shall only be evaluated based on financial feasibility and the character and competence of the proposed operator.

Section 765-1.3. Requirements for approval. This section will be amended to require applicants for licensure as a LHCSA to satisfactorily demonstrate to the Public Health and Health Planning Council (PHHPC) the public need for the agency and the financial resources of the agency in order to be approved for licensure, in addition to the existing requirement of a character and competence review.

Section 765-1.4. Amendments to applications. This section will be amended to add to the list of actions that constitute an amendment to a pending application for licensure for a home care services agency, requiring review and approval by PHHPC. The proposal will require that any significant change to the proposed patient capacity, any change in the agency's proposed service area, and any significant change to the agency's proposed annual operating budget will constitute an amendment and require approval by PHHPC, in addition to the existing language stating that changes to services and changes in the principles of the applicant as considered by PHHPC are

amendments. A new section will be added specifying that failure to disclose this information prior to the issuance of a license shall be grounds for revocation, limitation, or annulment of the approval for licensure. This is consistent with the approval processes for other types of home care agencies including certified home health agencies and hospices.

This proposal would also add a new section 765-1.16, Determinations of public need, to detail the public need methodology to be used to implement recent statutory changes. Subdivisions of this new section will include planning area designations, determination of public need, public need exemption criteria and additional requirements for applications seeking PHHPC approval, and priority considerations for the Department.

The regulations will affect all agencies applying for licensure as a home care services agency or for changes of ownership on or after April 1, 2020.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 3612 of the Public Health Law, Subpart 765-1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective on April 1, 2020.

Section 765-1.2 is amended to read as follows:

765-1.2 Applications for licensure. (a) An application to the Public Health and Health Planning Council for its approval, as required by law, shall be in writing on application forms provided by the department and subscribed by the chief executive officer duly authorized by the board of a corporate applicant, a general partner or proprietor of the proposed licensed home care services agency, or, where an application is to be submitted by a governmental subdivision as the applicant, the president or chairman of the board of the proposed agency 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 principal stockholders or directors. If a local government applicant submitting an application has not designated a president, chairman or chief executive officer for the proposed agency, the application shall be subscribed by the chairman or president of the local legislature or board of supervisors having jurisdiction, or another appropriate executive officer. If available, the application must be electronically submitted to the Department of Health in a form designated by the commissioner. In the absence of an electronic system, [A]an original application and five copies thereof shall be prepared and

filed with the Public Health and Health Planning Council through the project management unit in the department's central office in Albany [, which shall transmit one copy to the health systems agency having jurisdiction].

(b) Applications to the council shall contain information and data as applicable with reference to:

(1) the public need for the existence of the licensed home care service agency or proposed agency at the time and place and under the circumstances proposed as outlined in Section 765-1.16 of this Title;

(2) the character, experience, competence and standing in the community of the proposed persons, incorporators, directors, controlling persons, officers, principal stockholders, sponsors, governmental subdivisions, individual operators or partners of the applicant or of any parent or health-related subsidiary corporation as applicable. The application shall include copies of personal qualifying and disclosure information, as appropriate, as may be required by the council with regard to any such individual or organization[.];

[(1)] (i) Disclosure information shall include, but not be limited to, a list of health care, adult care or mental health facilities, programs or agencies controlled or operated in the United States by an individual or organization specified in this subdivision; the name and address of each such facility, program or agency; and the dates of control or operation of each such facility, program or agency.

[(2)] (ii) In the event that any such health care, adult care or mental health facility, program or agency, while under the control or operation of an individual or organization specified in this subdivision, has been subjected to financial penalties, or suspension or revocation of its operating certificate, license or certification because of a failure to comply with provisions governing the conduct and operation of the facility, program or agency, then information must be

provided which describes the nature of the violation, the agency or body enforcing the violation (including its name and mailing address), the steps taken by the facility, program or agency to remedy the violation or violations, and an indication of whether the suspension, revocation or accreditation has since been restored.

(3) the financial resources of the proposed licensed home care service agency and its projections of revenues and expenses. The standards of this review will require, at a minimum:

(i) an examination of the sources of available working capital that the proposed licensed home care services agency operators have, with a minimum requirement equal to at least two months of estimated operating expenses of the agency;

(ii) that the application passes a reasonableness test with respect to the financial capability of the agency or sources for start-up funding; and

(iii) an examination of the financial feasibility of the agency or projections indicating that the agency's revenues, including but not limited to operating revenue, will be equal to or greater than projected expenditures over time.

(4) any other information that the commissioner shall deem pertinent for inclusion in the application.

(c) The following documents shall be filed as attachments to the application: (1) where the applicant will be operating the licensed home care services agency under an assumed name, a photocopy of the applicant's existing or executed proposed certificate of doing business;

(2) 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 changes in the membership of the partnership. The partners also acknowledge that the prior written approval of the Public Health and Health Planning Council 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 the Public Health and Health Planning Council 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."

(3) where the applicant or licensed operator has or proposes to have a controlling person or a parent corporation, or is affiliated with a health-related subsidiary corporation, full and true copies of any such corporation's bylaws, certificate of incorporation and any existing or proposed amendments thereto, all agreements between the applicant and any such controlling person or parent corporation relating to the manner and mechanisms by which any such controlling person or parent corporation controls or will control the applicant and/or all agreements by which the applicant is affiliated with any health-related subsidiary corporation, and a detailed description of such control or affiliation relationship;

(4) where an applicant corporation is formed pursuant to the requirements of section 3611 of the Public Health Law, documentation demonstrating the designation of an agent for service of process pursuant to section 305 of the Business Corporation Law or section 305 of the Not-for-Profit Corporation Law, as applicable; and

(5) such additional pertinent information or documents necessary for the council's consideration, as requested.

Section 765-1.3 is amended to read as follows:

765-1.3 Requirements for approval. (a) The application must be complete and in proper form. It shall provide all the information essential for the Public Health and Health Planning Council's consideration.

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

(1) that there is a public need for the licensed home health care service agency pursuant to the methodology outlined in Section 765-1.16 of this Title;

(2) that there are adequate finances and sources of future revenue to properly establish and operate the licensed home care service agency pursuant to the minimum requirements outlined in Section 765-1.2 of this Title;

[1)] (3)(i) if a not-for-profit corporation, that the controlling persons and sponsors, if any, the members of the board of directors and the officers of the corporation are of such character, experience, competence and standing in the community as to give reasonable assurance of their ability to conduct the affairs of the corporation in the best interests of the agency and in the public interest, and to provide proper care for those to be served by the licensed home care services agency;

[2)] (ii) if a proprietary business, that the owner, or all the partners of a partnership, are persons of such character, experience, competence and standing in the community as to give reasonable assurance of their ability to conduct the affairs of the business in the best interests of the agency and in the public interest, and to provide proper care for those to be served by the licensed home care services agency;

[3)] (iii) if a business corporation, that the controlling persons and sponsors, if any, the members of the board of directors, the officers and the principal stockholders of the corporation or, in the

case of an application solely for a change in the principal stockholder(s), that the proposed new principal stockholder(s) of the corporation, are of such character, experience, competence and standing in the community as to give reasonable assurance of their ability to conduct the affairs of the corporation in the best interests of the agency and in the public interest, and to provide proper care for those to be served by the licensed home care services agency;

[(4)] (iv) with respect to any parent corporation or health-related subsidiary corporation, that the directors, sponsors, controlling persons and principal stockholders of any such corporation, insofar as applicable, are of such character, competence and standing in the community as to give reasonable assurance that, to the extent they have or will have the ability, through control or influence, to direct or cause the direction of the actions, management or policies of the applicant, such control or influence will be exercised in the best interests of the applicant and in the public interest, in order to ensure the provision of proper care for those to be served by the licensed home care services agency;

[(5)] (v) with respect to any application solely for the acquisition of control of an operator of a licensed home care services agency by a controlling person or a change of a controlling person, that such new controlling person, insofar as applicable, is of such character, competence and standing in the community as to give reasonable assurance that, to the extent it has or will have the ability to direct or cause the direction of the actions, management or policies of the applicant, such control or influence will be exercised in the best interests of the applicant and in the public interest, in order to ensure the provision of proper care for those to be served by the licensed home care services agency; or

[(6)] (vi) if a public or government agency, that the governing authority of the governmental subdivision applying to operate the agency has provided reasonable assurance of its ability to

conduct the affairs of the agency in the best interests of the agency and in the public interest, and to provide proper care for those to be served by the licensed home care services agency.

[(c)] (4) that the proposed operator has demonstrated satisfactory character and competence. In conducting a character and competence review, the Public Health and Health Planning Council shall, as applicable, evaluate any parent or health-related subsidiary corporation, the controlling persons, sponsors, members of the board of directors, the officers and principal stockholders, if any, of a corporate applicant, any sole proprietor, all partners in a partnership or, in the case of a governmental subdivision as the applicant, the governmental subdivision and the governing body thereof as a whole rather than the individual elected or appointed members thereof, by:

[(1)] (i) reviewing the findings of inspection reports, patient care reviews, complaint investigations and any other pertinent information relating to the operation of any health care, adult care or mental health facility, program or agency located in New York approved to operate by the Department of Health, [Department of Social Services] or the Department of Mental Hygiene or, if located outside New York, would require the approval to operate by any one of such agencies if located in New York, with which an individual, corporation, other organization or governmental subdivision has been affiliated as a director, sponsor, controlling person, principal stockholder, sole proprietor, partner or governmental operator;

[(2)] (ii) reviewing whether such individual, corporation, other organization or governmental subdivision exercised supervisory responsibility of the facility/agency operation to assure a consistent pattern of compliance with applicable standards and to prevent conditions which could result in harm to the health, safety or welfare of patients/residents; and

[(3)] (iii) determining that, if a violation of applicable standards did occur, the applicant investigated the circumstances surrounding the violation and took steps appropriate to the gravity

of the violation which a reasonably prudent operator would take to promptly correct and to prevent the reoccurrence of the violation. [; and]

[(4) considering such other pertinent matters relating to the character, competence and standing in the community of the applicant(s).]

(5) any other pertinent matters that the commissioner shall deem appropriate for inclusion in the application.

[d](c) The applicant must supply:

(1) any additional information requested by the department within 30 days of such request, or must obtain from the department an extension of the time in which to provide such information.

Any request for such extension of time shall set forth the reasons why such information could not be obtained within the prescribed time. The granting of such extension of time shall be at the discretion of the commissioner, provided such extensions are not for more than 30 days and the commissioner is satisfied as to the reasons why such information could not be obtained within the prescribed time. The commissioner is authorized to deny a request for an extension of time. Failure to provide such information within the time prescribed shall constitute an abandonment and withdrawal of the application by the applicant.

(2) any authorization the department requests in order to verify any information contained in the application or to obtain additional information which the department finds is pertinent to the application. Failure to provide such authorization shall constitute an abandonment and withdrawal of the application.

Section 765-1.4 is amended to read as follows:

765-1.4 Amendments to applications. (a) An application made to the Public Health and Health Planning Council pursuant to this Subpart may be amended while the matter is pending before the council. Such amendments shall be made on appropriate forms supplied by the department.

(b) Any amendment to an application which constitutes a substantial change in the information contained in the original application, or any prior amendments thereto, must be accompanied by a satisfactory written explanation as to the reason such information was not contained in the original application.

(c) Prior to the issuance of a license, any change as set forth in this subdivision shall constitute an amendment to the application and the applicant shall submit appropriate documentation as may be required in support of such amendment. The amended application shall be referred to the [health systems agency having geographic jurisdiction and the State Hospital Review and] Public Health and Health Planning Council for [their] its comments. The approval of the Public Health and Health Planning Council must be obtained for any amended application. Each of the following shall constitute an amendment:

(1) any change in the types of licensed services to be provided; [and/or]

(2) any significant change in the principals of the applicant as considered by the council[.];

(3) any significant change in the proposed patient capacity;

(4) any change in the agency's proposed service area; and/or

(5) any significant change to the agency's proposed annual operating budget.

(d) Failure to disclose an amendment prior to the issuance of a license shall constitute sufficient grounds for the revocation, limitation or annulment of the approval.

A new Section 765-1.16 is added to Subpart 765-1 of Part 765 of 10 NYCRR to read as follows:

765-1.16. Determinations of public need. (a) The process of determining need in this section will be used in the evaluation of certificate of need applications requiring a review of the public need by the Public Health and Health Planning Council.

(b) Planning areas. The commissioner shall designate each county as a separate planning area.

(c) Determination of need.

(1) There shall be a rebuttable presumption of no need for additional licensed home care service agencies in a planning area if there are 5 or more Licensed Home Care Service Agencies (LHCSA) actively serving patients within the planning area as of April 1, 2020. Beginning in 2021, the commissioner shall have the authority to adjust the target date for determining need for additional LHCSAs in a planning area, in subsequent years.

(2) Applications for licensure based on change of ownership for Licensed Home Care Service Agencies actively serving at least 25 patients will not be subject to public need review and shall be evaluated only on financial feasibility and the character and competence of the proposed operator unless the proposed operator seeks to serve patients outside of the approved planning area.

(3) The determination of need for licensed home care service agencies in accordance with this subdivision does not include licensed home care services agencies affiliated with an Assisted Living Program (ALP), Program of All-Inclusive Care for the Elderly (PACE), Nurse Family Partnership (NFP), or Continuing Care Retirement Community (CCRC). ALP, PACE, NFP, or CCRC-affiliated agencies are not subject to the public need review unless the agency seeks to serve patients outside the ALP, NFP, or CCRC programs or who are not PACE members. For the purpose of this paragraph, affiliated shall mean common ownership. Any limitation on the

population an agency is allowed to serve resulting from an exemption made under this paragraph shall be noted on the LHCSA's license.

(4) The department shall review the adequacy of the need methodology set forth under paragraph (1) of this subdivision and issue a report to the commissioner, the Public Health and Planning Council, and other interested parties at the discretion of the Department of Health no later than three years from adoption.

(d) Notwithstanding any other provision of this section, factors to be considered when determining need for licensed home care service agencies shall include, but are not limited to:

(1) the demographics and/or health status of the residents in the planning area or the state, as applicable;

(2) documented evidence of the unduplicated number of patients on waiting lists who are appropriate for and desire admission to a licensed home care service agency but who experience a long waiting time for placement;

(3) the number and capacity of currently operating licensed home care services agencies;

(4) the quality of services provided by existing agencies;

(5) the availability and accessibility of the workforce;

(6) personnel and resources dedicated to adding and training additional members of the workforce including committed resources in an organized training program;

(7) cultural competency of existing agencies; and

(8) subpopulations requiring specialty services.

When making recommendations to the Public Health and Health Planning Council concerning the impact of the factors set forth above, the department shall, to the extent practicable, indicate the relative priority of such factors.

(e) In addition to meeting the other applicable provisions of this section, an applicant for initial certification shall be approved as meeting public need only if the applicant agrees to serve population groups in the planning area that have difficulty gaining access to appropriate licensed home care service agency care due to minority status, age, medical history, case complexity, payment source, or geographic location.

(f) Any application wherein a determination of public need is made pursuant to this section shall be subject to the following: (1) The Public Health and Health Planning Council and/or the commissioner, as appropriate, may, during the processing of an application, propose to disapprove the application solely on the basis of a determination of public need in advance of the consideration of the other review criteria required by article 36 of the Public Health Law without, however, waiving the right to consider such other criteria at a later date.

(2) In the event the Public Health and Health Planning Council and/or the commissioner proposes to disapprove an application on the basis of a lack of public need and the applicant requests a hearing according to the provisions provided in Section 765-1.9 of this Title, the Public Health and Health Planning Council and/or the commissioner, as appropriate, may direct the completion of the other reviews required by Article 36 of the Public Health Law. The application shall then be returned to the Public Health and Health Planning Council and/or the commissioner as appropriate, to consider such reviews, the results of which may then be included as grounds for the proposed disapproval to be considered at the hearing. If the Public Health and Health Planning Council and/or the commissioner, as appropriate, directs the completion of such reviews, a copy of the report containing the results of the reviews shall be mailed to the applicant at least 60 days prior to the date set for hearing.

(3) In the processing of an establishment application, the commissioner may recommend disapproval based on a review limited to a determination of public need. In the event the Public Health and Health Planning Council does not concur with the commissioner's recommendation of disapproval, it shall return the application to the department at which time all other required reviews shall be completed. When all other reviews are completed, the application shall be returned to the Public Health and Health Planning Council for action.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) § 3612 authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations to effectuate the provisions and purposes of PHL Article 36 with respect to licensed home care service agencies (LHCSAs). Additionally, Section 9-b, Part B of Chapter 57 of the Laws of 2018 (codified at Public Health Law § 3605[4]) requires PHHPC to consider the public need for new LHCSAs as well as the financial resources and revenues of the proposed LHCSA when PHHPC reviews initial licensure and change of ownership applications.

Legislative Objectives:

PHL Article 36 was intended to promote the quality of home care services provided to residents of New York State and to assure adequate availability as a viable alternative to institutional care.

Needs and Benefits:

The proposed regulation is necessary to implement statutory changes required under Section 9-b, Part B of Chapter 57 of the Laws of 2018. The proposal will revise Part 765 of Title 10 NYCRR to include the relevant statutory requirements related to the new public need determination for licensed home care services agencies, the review of the proposed agency's financial feasibility, and the process for reviewing applications for licensure.

Part 765 of Title 10 of the NYCRR regulates the approval and licensure of home care services agencies. Sections 765-1.2 and 765-1.3 outline what is required to be included in applications for licensure as a home care services agency and the information that an applicant for licensure must supply to PHHPC for approval. Section 765-1.4 includes what types of changes to a pending application for licensure constitute an amendment and what an applicant must submit to PHHPC for the amendment to be considered.

These current regulations were developed to govern the approval of licensure applications for home care services agencies when PHHPC was only required to conduct a character and competence review of applicants and was prohibited from considering the public need for these agencies under Public Health Law. To comply with changes made to the Public Health Law under Section 9-b, Part B of Chapter 57 of the Laws of 2018, the regulations must be updated to include the new requirement of public need review and financial feasibility review.

With the existing regulatory prohibition on public need consideration for new agencies, the Department of Health (Department) and PHHPC have been unable to limit the growth of unnecessary agencies. Currently, there are approximately 1,100 approved licensed home care operators with over 1,300 licensed, registered sites statewide. An average of 40 new LHCSA sites have been approved on an annual basis over the past ten years. There is no consideration of the need for additional services based on the public demand. Applications for licensure are submitted to the Department and are subject to approval by PHHPC. As part of the application process, applications are reviewed to ensure the character, competence, and standing in the community of the applicant's incorporators, directors, sponsors, stockholders, or operators.

Applications must be submitted for initial licensure, purchase or mergers, change of stock ownership, or other acquisition or control change.

Given the new statutory mandate, new regulations are required to define the public need methodology and the process that will be used to apply the methodology to new licensure applications. The public need methodology will also assist the Department in planning for the appropriate number of licensed agencies and may also inform policy and practice around the types of services needed, underserved populations that require additional focus, and other factors that contribute to the long term care landscape, such as workforce issues or transportation infrastructure.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

The rule does not impose any new implementation or compliance costs on regulated parties.

Costs to the State and Local Governments:

The proposed changes are not expected to impose any costs upon New York State or local governments.

Costs to the Department of Health:

Additional work by Department staff to determine public need and to process applications with the new requirements will be managed with existing resources.

Local Government Mandates:

The proposed regulations do not impose any new mandates on local governments.

Paperwork:

Consistent with the statutory provisions, the proposed regulations will require a new application form to be completed by home care services agencies seeking initial licensure or change of ownership on or after April 1, 2020. New documentation will be required as part of the application process that was not included in the application for licensure prior to April 1, 2020.

Duplication:

There are no relevant rules or other legal requirements of the Federal or State governments that duplicate, overlap, or conflict with this rule.

Alternatives:

There are no viable alternatives to this proposal. The regulatory changes are necessary to implement a statutory mandate, which directs PHHPC to include public need and financial feasibility in the review process for initial applications for licensure of home care services agencies.

One alternative considered including the development of a county normative use rate using the number of cases and visits/hours for LHCSA services for each agency in a planning area as reported on the LHCSA Statistical Report. This alternative may account for variation in the amount of services used per patient, however, and it is a more complex methodology that may

lead to greater error in ongoing need methodology calculations. As such, this option was rejected as unviable.

A second alternative considered establishing estimates of need based on demographics. Under this proposal, the Department would undertake a review of the total number of residents in each planning area with a reported disability resulting in a limitation in completing activities of daily living. The information could be broken down by age group and projected to accommodate the expected growth in the older adult population. This method to determine use rates may better reflect the number of residents in need of care, rather than using the patient count. However, reporting on disease and disability status and limitations in functional abilities has proven difficult, as various definitions of disability exist with multiple reporting methods. Therefore, this alternative was also rejected.

Federal Standards:

The proposed regulations do not duplicate or conflict with any federal regulations.

Compliance Schedule:

The amendments will take effect on April 1, 2020.

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**STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

**STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

**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.

SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (“Department”) received public comments in response to the proposed rulemaking amending Part 765 of Title 10 of the NYCRR relating to licensed home care services agencies (LHCSAs). The comments and responses are summarized below.

Comments in support: Two commenters supported the provision that change of ownership applications for agencies serving 25 or more patients not be subjected to public need review; one commenter noted its support of the proposed LHCSA need methodology and suggested that workforce be a primary consideration; and one commenter supported the inclusion of the financial feasibility review parameters. These supportive comments are noted by the Department.

Comment (multiple stakeholders): Clarify various terms used in the regulation, including “significant change” and “reasonableness.”

Response: The Department will provide terminology clarification in guidance documents. No changes to the regulation are necessary.

Comment: Assisted Living Program (ALP)-affiliated LHCSAs should be allowed to continue to serve a patient after ALP discharge.

Response: The ALP’s discharge plan should accommodate the patient and their home care provider if one is needed. No changes to the regulation are necessary.

Comment (two stakeholders): ALP-affiliated LHCSAs should be allowed to serve patients outside of the ALP without requiring public need review.

Response: As the regulation appropriately addresses the conditions under which an ALP-affiliated LHCSA will be exempt from public need review, regulatory changes are unnecessary.

Comment: The word “operating” should be removed from the term “operating revenues”.

Response: The Department made a technical amendment in response to this comment.

Comment (two stakeholders): There should be a flexible definition of planning areas.

Response: As the Department believes the regulation’s definition of planning areas is sufficiently flexible, no changes were made to the regulation in response to this comment.

Comment (five stakeholders): Clarify that an existing LHCSA seeking to expand into an additional county or add services to an existing license would not be subject to public need review.

Response: There is no statutory basis to apply the new LHCSA public need methodology to actions that are defined as construction under Article 36 of the Public Health Law. No changes were made to the regulation in response to this comment.

Comment (five stakeholders): The Department should withdraw the proposed methodology, reconsider the limit of five agencies, or clarify that the presumption of no need is rebuttable.

Response: The Department made technical amendments to clarify that the presumption of no need is rebuttable, and the regulation sets forth the requirements for this rebuttable presumption.

Comment: LHCSAs that are only providing Fiscal Intermediary services should not be counted towards the threshold of five LHCSAs per planning area.

Response: Only agencies that are actively serving patients are counted towards the planning area threshold; regulatory changes are therefore unnecessary.

Comment: Clarify the criteria that the Department will use to review the adequacy of the public need methodology.

Response: As the need methodology is new, the Department believes it is more useful to review its adequacy once it has been in use; therefore, no changes were made due to this comment.

Comment: Omit the following phrase in Section 765-1.16(d)(2): “and who cannot be served adequately in other settings.”

Response: The Department agrees with the comment and has made a technical amendment to section 765-1.16(d)(2).

Comment: Clarify how LHCSAs can obtain information on the number of patients on waiting lists to access LHCSA services.

Response: The Department will work with applicants to develop this information using existing resources. No changes were made to the regulation in response to this comment.

Comment (two stakeholders): Clarify the quality measures to be evaluated in determining need.

Response: Quality measures will be further clarified in guidance documents. No changes were made in response to this comment.

Comment: Clarify how the cultural competency of existing agencies can be determined by a LHCSA applicant.

Response: The Department does not believe the addition of such information in regulation is necessary; therefore, no changes were made.

Comment: Provide information on the Department's plan to monitor and enforce LHCSA compliance.

Response: The Department will utilize existing surveillance tools to monitor compliance with the proposed requirements; therefore, no changes were made.

Comment (four stakeholders): LHCSAs that do not receive Medicaid reimbursement should be exempt from the public need methodology.

Response: The Public Health Law requires that applications for licensure be reviewed for public need without consideration of payor source; therefore, no changes were made.

Comment: There should not be a presumption of adequate access to home care based on the number of LHCSAs per county, as LHCSAs may not be providing services in all areas of the counties included on their license.

Response: Based on Department policy, if a LHCSA is licensed to operate in a county it must provide access in all areas of the county; thus, changes to the regulation are unnecessary.

Comment: The public need methodology should be based upon the development of a population-based formula.

Response: Due to the lack of available and current data, the Department rejected this proposal; therefore, no changes were made to the regulation.

Comment: Setting the presumption of no need at five LHCSAs per county does not accurately capture the need for services in the planning area.

Response: There is no evidence presented by the commenter that supports this assertion. The Department thus declines to make changes to the regulation.

Comment (two stakeholders): The report on the adequacy of the need methodology should be issued no later than three years from adoption.

Response: The Department made technical amendments to the regulation to require the report be issued no later than three years from adoption and be delivered to numerous parties.

Comment: The Department should provide guidance on the resources available to applicants to detail the factors set forth in section 765-1.16(d).

Response: The Department will work with applicants to develop this information using existing resources; therefore, no changes were made to the regulation.

Comment: The Department should provide guidance relating to the relative priority of factors to be considered when determining need.

Response: As it would be more effective to determine the priority of factors after the regulation has been in place and applications are reviewed, no changes were made to the regulation in response to this comment.

Comment: Clarify whether the requirement that an applicant agree to serve population groups who have difficulty accessing services precludes a LHCSA from being approved if it only serves private pay patients.

Response: The regulation applies to all payor sources. Therefore, the Department declines to make the requested change.

Comment: Language should be added to require the timely review and approval of applications.

Response: The Department is committed to the timely review of applications but does not believe the addition of such language is necessary in regulation; thus, no changes were made to the regulation in response to this comment.

Comment: The Certificate of Need process should be simple so LHCSAs can adapt to changes in the health care market.

Response: The proposed regulations do not limit an agency's ability to adapt to changes in the health care market; therefore, no changes were made to the regulation as a result of this comment.

Comment (two stakeholders): LHCSAs should be exempt from the public need methodology based on their affiliation with specific programs.

Response: The Department agrees that Nurse Family Partnership (NFP) and Continuing Care Retirement Community affiliated LHCSAs should be excluded from the public need methodology, and therefore has made technical amendments to the final rule.

Comment: LHCSAs only providing NFP services should not count toward the five-agency limit.

Response: Agencies affiliated with a NFP, ALP, PACE, or CCRC, which exclusively serve patients within those programs, will not count towards the five-agency limit; thus, no changes were made in response to this comment.

Comment: There should be flexibility in the financial feasibility review to account for unique categories of providers.

Response: The final rule allows flexibility, and the Department can issue additional clarifying guidance; therefore, no changes have been made in response to this comment.

Comment: Although the need methodology addresses the establishment of new agencies, it does not address the standards of currently-operating agencies; therefore, new standards should be established for all agencies.

Response: This recommendation is outside the scope of this regulation; therefore, no changes were made.

Comment: The character and competence review requirements for a new LHCSA application should be revised.

Response: The provisions in the proposed regulation are intended to be flexible to account for a variety of situations, and the Department can issue additional guidance documents. Therefore, no changes were made to the regulation.

Comment: Confirm that Section 765-1.4 of the regulation only applies to agencies making changes to a pending application.

Response: Section 765-1.4 only applies to agencies seeking to make an amendment to a pending application for licensure.

Comment: The definition of “affiliated” should be revised to include common ownership or control.

Response: The Department will evaluate all relevant information to determine “affiliation”; therefore, no changes were made in response to this comment.

Comment: Requiring documented evidence of waiting list information is not realistic.

Response: As this information is important in understanding the scope of need across the State, no changes were made to the regulation due to this comment.

Comment: Applicants should be required to describe their plans to develop the home care workforce.

Response: Section 765-1.16(d) sufficiently addresses this request; therefore, no changes were made due to this comment.

Comment: Populations that have difficulty accessing home care due to geographic location should be added to the list of populations that applicants must agree to serve.

Response: The Department agrees and has made a technical amendment to the regulation.

Comment: Public need review should not apply to changes of ownership that would result in the consolidation of two or more LHCSA licenses.

Response: Due to concerns that this suggestion would create a mechanism for proposed agencies to avoid public need review, the Department declines to make this change.

Comment: The exemption threshold for change of ownership applications should be reduced from 25 to 5 patients.

Response: The Department finds the 25-patient standard to be reasonable to ensure operational activeness; therefore, no changes were made to the regulation.

Comment: All change of control transactions that do not result in a new license and that involve parties who have previously passed a character and competence review for direct or indirect control of a LHCSA should be exempt from the public need review, regardless of the corporate structure.

Response: The commenter raises an issue that the Department will review over the next two years and include in its report on the adequacy of the need methodology. However, changes to the regulation are currently unnecessary.

Comment: The financial feasibility review in the proposed regulation should be completed by the regional offices with recommendation to PHHPC.

Response: The process for the financial feasibility review will be established through guidance documents; therefore, no changes were made in response to this comment.

Comment: Confirm that the proposed regulation, as it relates to changes in ownership applications, applies to the purchase of the assets of an existing LHCSA, which would require termination of the existing license and approval of a new license.

Response: An applicant must submit sufficient proof to the Department that a change of ownership has occurred; accordingly, changes to the regulation are unnecessary.

Comment: Provide information on which entities store, publish, or have access to the number of LHCSAs in a planning area and the number of LHCSAs serving 25 patients and how that information can be accessed by the public.

Response: The Department maintains general information on LHCSAs, including service areas and number of patients served. No changes were made to the regulation in response to this comment.

Comment: Clarify that ALP-affiliated LHCSAs are not required to serve specific population groups.

Response: The Department will work with prospective ALP-affiliated LHCSAs on their unique patient population. No changes were made to the regulation in response to this comment.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (“Department”) received public comments in response to the proposed rulemaking amending Part 765 of Title 10 of the Codes, Rules and Regulations of the State of New York relating to licensure of licensed home care services agencies (LHCSAs). The comments and the Department’s responses are summarized below.

Comment: The Department received comments requesting clarification of various terms used in the proposed regulation, such as “actively serving patients,” “reasonableness,” “over time,” “significant change,” and “long waiting times.”

Response: The Department will provide additional clarification of the requested terms as needed in policy and guidance documents, which will be developed upon the adoption and implementation of the proposed regulation. Therefore, no changes to the regulation are necessary.

Comment: A commenter requested that Assisted Living Program (ALP)-affiliated LHCSAs that are not licensed to provide services in the community be allowed to continue to serve a patient who is discharged from the ALP, either to their home or to another setting, until the end of the home care episode.

Response: The ALP’s discharge plan should accommodate the patient and their home care provider in the community if one is needed. As such, no changes to the regulation are necessary.

Comment: The Department received two comments requesting that ALP-affiliated LHCSAs be allowed to serve patients outside of the ALP without requiring public need review. One

commenter requested that the exemption be extended to ALP-affiliated LHCSAs serving patients in housing programs at the same site as the ALP, such as an Assisted Living Residence (ALR), and another requested these agencies be allowed to serve patients in other community settings without requiring public need review.

Response: If the ALP-affiliated LHCSA only serves patients within the ALP, it will be exempt from the public need methodology. ALP-affiliated LHCSAs seeking to serve non-ALP patients will be allowed to do so if the agency is approved upon review of public need and other factors, as outlined in the proposed regulations. No changes were made to the regulation in response to this comment.

Comment: A commenter requested the removal of the word “operating” from the term “operating revenues” to allow for other revenue sources to be considered when determining the financial resources of a proposed licensed home care services agency under Section 765-1.2.

Response: The Department made a technical amendment to the final rule to clarify that other revenue sources, in addition to operating revenue, will be considered.

Comment: Two commenters requested flexibility in how planning areas are defined.

Response: The Department believes that the regulation’s definition of planning areas is sufficiently flexible to address current needs. No changes were made to the regulation in response to this comment; however, the Department will reconsider this request in the future should amendments to the final rule be necessary upon review of the adequacy of the public need methodology set forth in the proposed regulation.

Comment: The Department received five comments requesting clarification that an existing LHCSA seeking to expand into an additional county or add services to an existing license would not be subject to the public need methodology set forth in the proposed regulation. One commenter requested a revision to paragraph (a) of 10 NYCRR 765-2.2, which is not amended by the proposed regulation, to clarify that an agency requesting to add up to two counties to its current service area shall submit an application to the Department following the existing procedures in place for adding a service to an existing license.

Response: There is no statutory basis to apply the new LHCSA public need methodology to actions that are defined as construction under Article 36 of the Public Health Law, including requests for changes to an existing agency's geographic service area or the services it provides. Instead, established agencies seeking to add or delete services or change their geographic scope of practice will continue to follow current administrative procedures. Therefore, the requested change is unnecessary and outside the scope of the proposed regulation. No changes were made to the regulation in response to this comment.

Comment: The Department received five comments requesting that it either withdraw the proposed methodology, which presumes no public need in a county if five or more LHCSAs are actively serving patients within the planning area; that it reconsider the limit of five agencies; or that it clarifies that the presumption of no need is rebuttable. One commenter noted that since almost all counties have five LHCSAs, the regulation would be a continuation, not an elimination, of the moratorium as intended by statute. The same commenter requested more discerning parameters of need than the number of licensed providers per county. One commenter

requested that the target year for determining whether five LHCSAs are operating in a county be updated annually.

Response: The Department made technical amendments to the final rule to clarify that the presumption of no need is rebuttable, and the regulation sets forth the requirements for this rebuttable presumption. Applicants seeking to rebut the presumption will have the opportunity to present evidence at the time their licensure application is submitted to the Department. However, the Department finds that no changes are necessary with respect to the request to annually update the five-LHCSA threshold, insofar as the proposed regulation grants the Commissioner the authority to adjust the target year beginning in 2021.

Comment: A commenter suggested that LHCSAs that are only providing Fiscal Intermediary (FI) services, and not providing home care services, not be counted towards the threshold of five LHCSAs in a planning area.

Response: Only agencies that are actively serving patients are counted towards the planning area threshold limit. The Department will provide additional clarification of the term “actively serving patients” as needed in policy and guidance documents to be developed upon the adoption of the proposed regulation. No changes were made to the regulation in response to this comment.

Comment: A commenter supported the exemption of ALP- and PACE-affiliated LHCSAs from the need methodology but requested that the Department include provisions that the determination of need would apply if the agency seeks to serve patients in the community outside of the ALP program or who are not PACE members.

Response: The comments in support are noted by the Department. The proposed regulation states that ALP- or PACE-affiliated agencies are not subject to the public need review unless the agency seeks to serve patients outside the ALP program or who are not PACE members. The Department believes this language addresses the commenter’s concern and does not believe additional amendments are necessary.

Comment: The Department received two comments in support of the provision that change of ownership applications for agencies actively serving 25 or more patients not be subjected to the public need methodology but be evaluated on financial feasibility and character and competence.

Response: The comments in support are noted by the Department.

Comment: A commenter requested clarification of the criteria that the Department will use to review the adequacy of the need methodology.

Response: Given that the regulations and the need methodology are new to the Department, it is the Department’s opinion that it is more appropriate and useful to review the adequacy of the need methodology once it has been in use, rather than at this stage when regulations are initially promulgated. Therefore, no changes will be made to the regulation in response to this comment.

Comment: A commenter suggested omitting the wording “and who cannot be served adequately in other settings” in Section 765-1.16(d)(2), as it contradicts the intent of that paragraph.

Response: The Department agrees with the comment and has made a technical amendment to the final rule in section 765-1.16(d)(2) to read, “documented evidence of the unduplicated

number of patients on waiting lists who are appropriate for and desire admission to a licensed home care service agency but who experience a long waiting time for placement.”

Comment: A commenter asked how LHCSAs could obtain information on the number of patients on waiting lists to access LHCSA services.

Response: The Department will work with applicants to develop this information using existing resources, as available. Further guidance will be developed by the Department upon the adoption of this proposed regulation, as necessary. No changes were made to the regulation in response to this comment.

Comment: The Department received two comments in support of the consideration of quality measures (when quality is a factor in determining need), but both requested clarification of the quality measures to be evaluated for this purpose.

Response: The quality measures may include, but not be limited to, surveillance records, adherence with reporting requirements, and complaint history. Quality measures will be further clarified, as necessary, in policy and guidance documents to be developed upon the adoption of the proposed regulation and Department review of the public need methodology once in use. No changes were made to the regulation in response to this comment.

Comment: A commenter requested clarification on how the cultural competency of existing agencies could be determined by a LHCSA applicant in the need review process. The commenter suggested the criterion be revised to indicate perceived underserved populations in the proposed catchment area, be otherwise explained, or be eliminated.

Response: The Department expects that a LHCSA applicant requesting licensure on the basis that it will offer services to an underserved population will provide information to the Department in the licensure application as to why the proposed agency is well-positioned to provide culturally-competent care to a specific population, including information as to why the existing provider pool is not sufficient to meet the need that will be addressed by the proposed agency. Therefore, the Department does not believe the addition of such information in regulation is necessary. No changes were made to the regulation in response to this comment.

Comment: A commenter requested information on the Department’s plan to monitor and enforce LHCSA compliance with the proposed requirement that an applicant “agrees to serve population groups in the planning area that have difficulty gaining access to appropriate LHCSA care due to minority status, age, medical history, case complexity, or payment source.”

Response: The Department will utilize its existing surveillance tools to monitor compliance with the requirements set forth in the proposed regulation. No changes were made to the regulation in response to this comment.

Comment: Four commenters requested that LHCSAs that do not receive Medicaid reimbursement be exempt from the public need methodology as outlined in the proposed regulations.

Response: The Public Health Law requires that applications for licensure be reviewed for public need without consideration of payor source. All agencies, including those that only accept private pay patients, must satisfy public need requirements at the time of application. No changes were made to the regulation in response to this comment.

Comment: A commenter noted that there should not be a presumption of adequate access to home care based on the number of LHCSAs per county as LHCSAs may not be providing services in all areas of the counties included on their license. The commenter noted that this measure may not accurately capture the need for LHCSA services.

Response: Based on Department policy, if a LHCSA is licensed to operate in a county it must provide access in all areas of the county. Therefore, no changes to the regulation are necessary.

Comment: A commenter suggested that the need methodology be based upon the development of a population-based formula based on Medicaid enrollees and existing caseload of LHCSAs in the planning area and include other factors such as geographic and socioeconomic conditions, transportation, and workforce.

Response: Due to the lack of available and current data, the Department rejected this proposal. Therefore, no changes will be made to the regulation in response to this comment.

Comment: A commenter noted support for the elimination of the requirement for public need in its entirety, allowing the market to drive the need for additional LHCSAs.

Response: New York State law requires a need methodology for LHCSAs. Therefore, no changes will be made to the regulation in response to this comment.

Comment: A commenter noted concern that setting the presumption of no need at five LHCSAs per county does not accurately capture the need for services in the planning area.

Response: There is no evidence presented by the commenter that supports this assertion.

Therefore, the Department declines to make changes to the proposed regulation in response to this comment.

Comment: The Department received two comments requesting that the report on the adequacy of the need methodology be issued no later than three years from adoption. One commenter requested an interim report be issued no later than one year from adoption and that the report be delivered to the leadership and appropriate standing committee chairs in the Legislature.

Response: The Department made technical amendments to the regulation to require the report on the adequacy of the need methodology to be issued no later than three years from adoption, to be delivered to the commissioner, Public Health and Health Planning Council (PHHPC), and other interested parties at the discretion of the Department. However, the Department does not believe an interim report issued one year from adoption is necessary or helpful, as one year is not sufficient time to determine the impact of the adopted regulation.

Comment: A commenter requested that the Department provide guidance on the resources available to applicants to provide the appropriate documentation to detail the factors set forth in section 765-1.16(d) of the proposed regulation.

Response: The Department will work with applicants to develop this information using existing resources, as available. Further guidance will be developed by the Department as necessary. No changes were made to the regulation in response to this comment.

Comment: A commenter requested that the Department provide guidance relating to the relative priority of factors to be considered when determining need as outlined in section 765-1.16(d) in the proposed regulation.

Response: The Department finds it more effective to determine the relative priority of factors after the regulation has been in place and applications are received and reviewed, rather than attempting to set forth the priority of factors at this pre-adoption stage. Therefore, no changes will be made to the regulation in response to this comment.

Comment: A commenter requested clarification that the requirement that an applicant must agree to serve population groups in the planning area that have difficulty gaining access to services due to payment source, among other factors, does not preclude a LHCSA from being approved if it only serves private pay patients. The commenter requested this clarification be added to the language of the regulation.

Response: Pursuant to the governing statute, the regulation applies to all payor sources. The Department believes that there is enough flexibility in the regulation, as a whole, to balance legitimate public health needs with business concerns. Therefore, the Department declines to make the requested change.

Comment: A commenter requested that language be added to require the timely review and approval of applications not to exceed six months.

Response: The Department is committed to the timely review of applications but does not believe the addition of such language is necessary in regulation. No changes were made to the regulation in response to this comment.

Comment: A commenter recommended that the Certificate of Need (CON) process be simple to allow agencies to adapt and respond to changes in the health care market.

Response: The Department believes that the public need and financial feasibility guidelines set forth in the proposed regulation are appropriate and do not limit an agency's ability to adapt to changes in the health care market. Therefore, no changes will be made to the regulation as a result of this comment.

Comment: The Department received two comments requesting that LHCSAs be exempt from the public need methodology based on their affiliation with specific programs, similar to the exemptions in the proposed regulation for ALP and PACE-affiliated agencies. One commenter requested the exemption apply to LHCSAs affiliated with the Nurse Family Partnership (NFP) and another requested the exemption apply to LHCSAs affiliated with a Continuing Care Retirement Community (CCRC).

Response: Given their similarity with LHCSAs that are affiliated with an ALP or PACE in terms of unique populations served, the Department agrees that NFP- and CCRC-affiliated agencies should be excluded from the public need methodology, and therefore has made technical amendments to the final rule at Section 765-1.16(c)(3) to exempt NFP- and CCRC-affiliated LHCSAs from public need review. The limitation on the population the agency is allowed to serve resulting from an exemption under the proposed regulation will be noted on the LHCSA's license. If the agency seeks to serve patients outside of the NFP or the CCRC, it will be required to undergo a public need review, as is required of LHCSAs affiliated with an ALP or PACE under the proposed regulations.

Comment: A commenter requested that LHCSAs only providing NFP services not count toward the five-agency limit.

Response: Agencies affiliated with a NFP, ALP, PACE, or CCRC, which exclusively serve patients within those programs, will not count towards the limit of five agencies per county. No changes were made to the regulation in response to this comment.

Comment: A commenter requested that there be flexibility in the financial feasibility review to take into account various funding streams for unique categories of providers, such as NFP-affiliated LHCSAs. The commenter offered modifications to Section 765-1.2(b)(3) to read: “the financial resources of the proposed licensed home care services agency and its projections of revenues and expenses. To the extent appropriate, given the nature of the services provided by the proposed licensed home care services agency, the standards of review will require...”

Response: The final rule allows flexibility, and the Department has the ability to issue additional guidance, as necessary. In addition, the Department will work with prospective NFP programs on their unique financial situations. Therefore, the Department declines to make the requested change.

Comment: A commenter noted its support of the proposed LHCSA need methodology, including the use of factors to determine need, and suggested that workforce availability be a primary consideration in need determinations.

Response: The comment in support is noted by the Department. The Department will consider the suggestion to prioritize workforce availability when determining need using the proposed factors set forth in Section 765-1.16(d).

Comment: A commenter noted that while the need methodology set forth in the proposed regulation addresses the establishment of new agencies, it does not address the standards of currently-operating agencies. The commenter recommended new standards be established for all agencies, including requiring all LHCSAs to operate a training program, requiring Medicaid-funded LHCSAs to hold VBP contracts with MLTC plans, and incorporating MLTC plan input into regulation development.

Response: The comment and recommendations are outside the scope of this proposed regulatory package. The recommendations are noted by the Department and will be considered in any review of the current practices and standards in place for existing agencies.

Comment: A commenter supported the inclusion of the financial feasibility review parameters for new LHCSA applicants.

Response: The comment in support is noted by the Department.

Comment: A commenter requested revisions to the character and competence review for a new LHCSA application requiring the applicant to demonstrate financial stability and compliance with audits and surveys and similar information for its owners or sponsors; demonstrate that its facility or agency has provided substantially compliant care; disclose any criminal convictions or disciplinary actions against the operator, directors and key executives; demonstrate that it conducts criminal record checks as required by law; provide evidence of the cultural/ethnic capability and a plan to address health disparities in the region that relates to the operator's line of service; and submit the operator's plan to provide patient-centered care.

Response: The character and competence provisions in the proposed regulation are intended to be flexible to account for a variety of situations that may occur. However, the Department understands the value of guidance on factors assessed during character and competence review, and therefore will provide additional guidance documents following promulgation of this regulation.

Comment: A commenter supported PHHPC’s review of specified amendments during the application process and requested confirmation that this section of the regulation only applies to agencies when making changes to a pending application for licensure.

Response: The comment in support is noted by the Department. Section 765-1.4 only applies to agencies seeking to make an amendment to a pending application for licensure that is before PHHPC for review.

Comment: A commenter supported the exemptions provided for LHCSAs affiliated with ALP or PACE applications but requested that the definition of “affiliated” be revised to include common ownership or control for the purposes of this regulation.

Response: The Department will evaluate all relevant information to determine “affiliation” and common ownership and control. No changes were made to the regulation in response to this comment.

Comment: A commenter noted that requiring documented evidence of waiting list information is unrealistic, inappropriate and unreliable for the establishment of need.

Response: Waiting list information is one factor that may be demonstrated to rebut the presumption of no need in a county when an agency applies for licensure. The Department understands that this information may be difficult to ascertain. However, the Department believes this information is important in understanding the scope of need across the State and will work with applicants to develop this information using existing resources, as available. No changes were made to the regulation in response to this comment.

Comment: A commenter requested that applicants be required to describe their plans to develop the home care workforce through innovative training and recruitment strategies, community partnerships, and/or other initiatives in order to be considered for licensure.

Response: Section 765-1.16(d) of the proposed regulation includes the factors to be considered when determining need, including an applicant’s “personnel and resources dedicated to adding and training additional members of the workforce including committed resources in an organized training program”. The Department believes that this requirement sufficiently addresses the commenter’s request. No changes were made to the regulation in response to this comment.

Comment: A commenter requested adding populations that have difficulty accessing home care due to geographic location to the list of populations that applicants must agree to serve to be approved for licensure.

Response: The Department agrees that populations may have difficulty gaining access to appropriate LHCSA services due to their geographic region, and therefore has revised the regulation to include populations that have difficulty accessing home care due to geographic

location to the list of populations that applicants must agree to serve to be approved for licensure under Section 765-1.16(e).

Comment: A commenter suggested that the public need review not apply to changes of ownership that would result in the consolidation of two or more LHCSA licenses, whether or not a new license would be issued and regardless of how many patients are actively served by the involved LHCSAs or the counties in which the LHCSAs are approved to operate.

Response: This suggestion was considered by the Department but ultimately not included in the proposed regulation due to concerns that it would create a mechanism for proposed agencies to avoid public need review. However, the Department will review this issue at a later date, which will give the Department an opportunity to review how the need methodology is functioning for all stakeholders and whether changes are advisable. If necessary, the Department may consider this suggestion in a subsequent regulation amendment.

Comment: A commenter requested that change of ownership applications where no new license will be issued, regardless of how many patients are being served by the LHCSA, be exempt from public need review. The commenter suggested that new owners and operators be subject to character and competence review and financial feasibility review as these are relevant to such business transactions. If the existing proposed regulation remains, the commenter requested reducing the exemption threshold for change of ownership applications from 25 to five patients.

Response: The Department finds the 25-patient standard to be reasonable because it reflects an activity level greater than only several patients, while still accounting for small businesses that may operate a LHCSA. However, the Department will review the implications of the 25-patient

threshold over the next two years and include the issue in its report on the adequacy of the need methodology, as outlined in the proposed regulation. No changes were made to the regulation in response to this comment.

Comment: A commenter requested that all change of control transactions subject to PHHPC review that do not result in a new license and that involve a change of ownership to parties who have previously passed a character and competence review for direct or indirect control of a LHCSA be exempt from the public need review, regardless of the corporate structure involved.

Response: The commenter raises an issue that the Department will review over the next two years during its assessment of the need methodology and include in its report on the adequacy of the need methodology, as outlined in the proposed regulation. Therefore, no changes to the regulation are necessary at this time.

Comment: A commenter requested that the financial feasibility review in the proposed regulation be completed by the regional offices with recommendation to PHHPC. The commenter requested that the financial feasibility review occur prior to the submission of a full application subject to the public need review. The commenter requested that the regulations be clarified to state that PHHPC will take the recommendation of the regional office, unless it is found to be unreasonable, and to include the documents that will be required for financial feasibility review unless the Department issues guidance concurrent with the adoption of the regulations.

Response: The exact process for the financial feasibility review will be established through policy and guidance documents to be developed upon the adoption of the regulation. The

Department will consider the commenter's suggestions in that process but does not believe such information is necessary to include in the regulation. No changes were made to the regulation in response to this comment.

Comment: A commenter requested confirmation that the proposed regulation, as it relates to changes in ownership applications, applies to the purchase of the assets of an existing LHCSA, which would require termination of the existing license and approval of a new license. The commenter further requested that a definition for "change in ownership" be added to the proposed regulation, which would include the purchase of stock or substantially all assets of a LHCSA by a new entrant or an existing agency.

Response: The Department finds that no changes are necessary to the regulation. If an applicant believes that public need review is unnecessary pursuant to 10 NYCRR 765-1.16(c)(2), such applicant must submit sufficient proof to the Department that a change of ownership has occurred and that such change will effectively maintain the patients and services of a previously-established LHCSA.

Comment: A commenter requested information on which entities store, publish, or otherwise have access to the number of LHCSAs in a planning area by county and the number of LHCSAs actively serving at least 25 patients and how that information can be accessed by the public.

Response: The Department maintains general information on LHCSAs, including service areas and number of patients served. Information specific to the proposed need methodology will be developed by the Department and shared with the public as necessary. No changes were made to the regulation in response to this comment.

Comment: A commenter requested clarification that ALP-affiliated LHCSAs are excluded from the provision requiring an applicant for initial certification to serve specific population groups that have difficulty gaining access to LHCSA services. The commenter provided a suggested revision to the proposed regulation under 765-1.16(e) to reflect that clarification.

Response: The Department will work with prospective ALP-affiliated LHCSAs on their unique patient population. The implementation of this regulation will allow that flexibility and subsequent policy and guidance documents will be developed and issued as necessary.

Therefore, the Department disagrees that a regulatory change is required. No changes were made to the regulation in response to this comment.