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1. **How should LHCSA planning areas be designated and what factors should be considered? Planning areas often include one county or two or more contiguous counties. Factors to consider when designating planning areas may include, but are not limited to, provider travel patterns including driving time, the availability of public transportation, and the availability of existing service providers.**

The Department should establish a workgroup to examine the designation of planning areas and other aspects of LHCSA need review. Planning and service areas have historically been by county, following local social services district lines of Medicaid responsibility, county health department lines, service/geographic equity and proportionality, and commitment to serve all the residents of the community, and other planning and service goals. As roles and delivery system areas have changed, in particular under managed care and other collaboratives (i.e. Delivery System Reform Incentive Payment (DSRIP) Program, bundles or other integrated models), natural service area alignments are often no longer county-bound. Accordingly, the Associations recommend requisite flexibility in service areas aligned with the new realities of service and new models of care and coverage so as to promote the goals of equitable consumer access. In the granting of such flexibility, however, the Department of Health should consider whether such flexibility would result in disproportionate fiscal and service burden to existing providers approved to serve the entire county region, including the residual areas.

The Department should examine need on a more granular level than the county level to better ascertain whether and where need is being met, especially in rural areas. Perhaps the Department can utilize claims and encounter data to identify the specific areas predominantly served by each LHCSA within planning areas and those that lack access to services.

For example, there may be no home care need in southeastern County X due to its proximity to a nearby city, but the northern part of County X may lack any access to home care services. If a LHCSA applicant demonstrates need in northern County X, its application should not be denied based on a county-wide assessment of need.

To assess need in New York City, the Department should use the counties (or boroughs) or portions of counties, rather than the entire city, as the planning area. There are significant differences in transportation infrastructure, demographics, and service utilization within each borough that justify treating each borough as its own planning area. Again, the regulations should accommodate sub-county or multi-county planning areas in New York City based on utilization patterns or transportation. For example, it may make sense to assess need in the remote areas of Brooklyn separate from need in neighborhoods closer to Manhattan. A rigid adherence to county borders as planning areas may inadvertently contribute to lack of capacity in certain areas both upstate and in New York City.

Regardless of how the Department establishes planning areas, DOH should not assume there is adequate access to home care based on the number of licensed providers per county or planning area. While many providers are currently authorized to provide care in several counties, the service areas included in their licenses may extend beyond the areas in which they actually deliver services.

Other factors to be considered includegeographic and socio-economic conditions and variations in the region; natural patterns of service by the provider and the provider’s partners and health plan; provider specialization; transportation; population distribution; impact on workforce, provider stability, operations and quality; and extent of collaboration with existing providers serving a region or which should be brought into service to the region.

1. **What factors should be included when determining the need for LHCSAs? Factors may include, but are not limited to, population estimates and demographics, including estimates of the potential patients to be served in each county or designated area, disease and disability prevalence, as well as capacity of existing providers. Please be specific in your response (i.e. include specific demographic information or disease prevalence rates to consider, if appropriate).**
* The Department should consider demographic and health status data and trends. It should also consider need for additional agencies as demonstrated by underserved areas or populations (i.e., remote, inner city, cultural/ethnic, nature of condition such as ventilator, developmental disability, serious mental health, etc. Need may also be based on lack of timely access to care and lack of existing agencies fulfilling their roles in systems and/or patient care.
* Workforce availability and accessibility and impact of adding a new agency on workforce availability for existing providers, or the prospective agency’s ability to contribute to the workforce.
* Use of telehealth and other technology by LHCSAs.
* Quality and accessibility of services in the region.
* Compliance record of existing agencies in the planning area.
* Projected impact of new market entrants on existing agencies.
1. **What type of experience should be required of a LHCSA operator?**

The Department should distinguish competency and experience requirements applicable to the operator from the requirements applicable to executive/administrative staff of the agency. An operator should have experience in operating a business or non-profit, finance, and compliance. Within the executive team of a LHCSA, the staff should have experience in home care or clinical services.

1. **Should quality measures be considered when reviewing LHCSA applications for licensure and/or change of ownership? If yes, what measures should be included?**
* Yes. In addition, LHCSAs should be in compliance with Annual Statistical and Cost Reports; Registration; and audits should be limited in citations and penalties. If a LHCSA seeks expansion of an existing agency, the agency should have to show substantial compliance on surveys, and if deficient, a plan of correction that has been successfully implemented should be produced.
* For a new LHCSA application submitted by an applicant that operates another provider type (e.g., a hospital, CHHA, Accountable Care Organization) or a home care agency licensed in another state, the applicant should: 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 operators’ and clinical directors’ supported standing in the community; provide evidence of the cultural/ethnic capability and a plan to address health disparities in the region that is connected with the operator’s line of service; and submit the operator’s plan to provide patient-centered care.
* For new applications, the State should consider, but not require, evidence of accreditation by a recognized accrediting organization; CMS 3, 4 or 5 Star Ratings earned by other facilities or agencies operated by the applicant; high consumer satisfaction scores on recognized surveys; participation or documented plans to participate in new models.
* While we believe that quality should be a consideration in reviewing LHCSA applications, it is important to recognize that, unlike nursing homes, hospitals, and certified home health agencies, neither state nor federal government agencies have established a set of standard quality measures for LHCSAs. Some of the MLTC quality measures could potentially be used to evaluate personal care quality. However, these measures are not risk adjusted. Thus, they cannot be used to compare one LHCSA to another. The Department would have to develop a risk adjustment methodology for those measures prior to applying them to LHCSAs as part of the CON process.
1. **Should the number of LHCSAs be capped in a single county?**
* No. LHCSAs applications should be granted based upon need. Neither the number of LHCSAs per county nor the number of LHCSAs per health plan should be a basis for a cap.
1. **Should there be exceptions to the need methodology? If so, identify.**
* Upon review, the Department may determine there are exceptions to the need methodology, including but not limited to, instances of special care cases, cultural and linguistic needs, the need for an article 36 agency to enable a new model of care or a primary care, public health or long term care role in the system that would not be forthcoming from the existing provider base.
* There should be exemptions from need review and exclusions from the need methodology for multi-service level long term care providers seeking to establish a LHCSA to serve their contract holders and residents. For example, Continuing Care Retirement Communities (CCRCs), other campus-based continuum providers, and new LHCSAs seeking establishment to serve only an associated Assisted Living Program (ALP) population, and not the broader community, should also be exempt from the LHCSA need methodology. If a LHCSA applicant for an ALP wishes to also serve the community, the community portion of the LHCSA should be subject to a need review.
1. **When would adjustments to the need methodology within a planning area be acceptable?**
* The need methodology should be periodically reviewed (e.g., every three years) to determine whether it is working to promote appropriate access to high-quality home care. It could also be subject to revision in cases of, including but not limited to, major demographic or epidemiological shifts, changes in technology or medical practice that justify a way to assess home care need.
1. **How often should need be recalculated?**
* DOH should develop a workable methodology first and then recalculate periodically as determined by the workgroup or more frequently if influential factors (e.g., model changes, demographic or epidemiological changes, technology, or other such factors) arise affecting the system.
1. **What additional requirements, if any, should be included for LHCSA applications for initial licensure?**
* Experience, quality, compliance, workforce as outlined in questions 3 and 4.
* A requirement that applicants submit a workforce development plan might spur innovative ways to build the home care workforce and minimize the churn in home care workers that too often accompanies new entrants into the market.
1. **What special considerations, if any, should be prioritized when reviewing LHCSA applications for initial licensure? For example, special considerations may be given to applicants that provide training programs for personal care aides and home health aides or those that provide services to special populations.**
* Those that are providing, or intend to provide, Medicaid services, and not just private pay services should be given priority.
* Evidence of unmet need in underserved and vulnerable populations at risk of hospitalization or prolonged hospitalizations, or long term care facility placement (or inability to discharge to home).
* Evidence of the agency’s plan for meeting priority public health or social determinants of health needs.
* Evidence that agency completes a component of a community or systemic project intended to achieve state policy goals.
* A strategic plan for utilizing new technology to reach and serve a patient population and/or assist workers.
* A strategic plan to recruit and train new home care workers.
* A strategic plan for transportation alternatives for workers.
* Existing established partnerships and/or experience in long term care or senior or disability services; and
* A strategic plan for optimizing performance on quality measures relevant to LHCSA services.

**12. Should initial applications for licensure be limited for service area until the operator demonstrates competency and compliance?**

* The Associations believe this question can be interpreted in a number of ways and seek clarity from the Department. Does the Department mean to ask whether an initial application for licensure be limited *to a single planning area* until an operator demonstrates competency and compliance? This question should be considered by the workgroup.
1. **Should the provision of specific services be considered as part of a need methodology? (i.e., Medicaid waiver services offer through the Traumatic Brain Injury (TBI) waiver program or the Nursing Home Transition and Diversion (NHTD) waiver program).**
* The Associations believe this question can be interpreted in a number of ways and seeks clarity from the Department. Does the Department intend to ask whether *an agency seeking to* provide waiver services should be exempt from need review?
* The Associations believe that if an applicant to establish a new LHCSA is seeking to provide waiver services it should be subject to need review.
* Existing LHCSAs that seek to add waiver services within their approved service areas should be subject only to an administrative review consisting of regulatory compliance and appropriate policies and staffing, but not a need review.
1. **Should a need methodology consider services to specialty populations such as pediatrics or specialty services such as IV infusion services or flu shot immunizations?**

The Associations believe this question can be interpreted in the same manner as question 13.

* If an applicant to establish a new LHCSA is seeking to provide specialty services it should be subject to need review.
* Existing LHCSAs that seek to add specialty services within their approved service areas should be subject to an administrative review, but not a need review.

However, the question of which specialty services should also be considered by the workgroup.

1. **Should a need methodology consider or eliminate from its calculation those agencies that are proposing to provide personal care services only and license those organizations discretely?**
* No.
1. **Should the availability of appropriate staffing for a LHCSA planning region be considered in public need?**
* Yes, it should be considered. Applicants should be required to include a plan for developing new home care workers for their agencies in their service areas. Applications should not be categorically denied based on the existence of workforce shortages. It is possible that a new agency may be able to implement innovative methods for recruiting and training new workers.

1. **Should the Department consider whether a LHCSA will service public payment (Medicare/Medicaid) beneficiaries in determining LHCSA need?**
* The Associations believe the workgroup should consider the issue of whether entities that propose to serve private pay only should be subject to a need methodology.
1. **Should the need methodology regulations cover change of ownership applications?**
* No. Change of ownership or change of corporate status (proprietary to voluntary, or vice versa) should be an administrative review to both expedite review and action, and to eliminate the burden on PHHPC. Such actions have nothing to do with need, but simply a leadership change. The Department already has a process for reviewing this type of action and should continue with this practice.
1. **Should the need methodology regulations apply to existing LHCSA operators requesting to expand services into other planning areas (counties and/or regions)?**
* The Associations agree that need methodology regulations should narrowly apply to existing LHCSA operators requesting to expand services into other planning areas based upon a relaxed review process.
* Existing LHCSAs should be fully exempt from the need methodology for adding new services or branches to their license in their approved service areas.
* A relaxed review process should allow existing LHCSAs to expand into adjacent counties or planning areas, notwithstanding the results of the need methodology, for reasons including but not limited to, if the expansion is part of a multi-county program, a collaborative initiative with another provider, or a response to a demonstrated need in the region. The relaxed review process should consider the impact on current providers in the proposed planning area.
* Relaxed review should apply to both existing traditional LHCSAs and ALP LHCSAs already licensed to serve the broader community.