

Craig Tanio, M.D.
CHAIR

STATE OF MARYLAND

Ben Steffen
EXECUTIVE DIRECTOR



MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

STATE HEALTH PLAN FOR FACILITIES AND SERVICES:

HOME HEALTH AGENCY SERVICES

Proposed Permanent Regulations

COMAR 10.24.16

*Written Public Comments
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Send To: Cathy Weiss
Program Manager
Center for Health Care Facilities
Planning and Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215-2299
e-mail: Cathy.Weiss@maryland.gov*

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.01 Incorporation by Reference. This Chapter is incorporated by reference in the Code of Maryland Regulations.

.02 Introduction.

A. Purposes of the State Health Plan for Facilities and Services.

The Maryland Health Care Commission (Commission) has prepared this Chapter of the State Health Plan for Facilities and Services (State Health Plan) to ensure that actions by the Commission are guided by the objective of meeting the current and future needs of Maryland residents.

The State Health Plan serves two purposes:

(1) It establishes health care policy to guide the Commission’s actions. Maryland law requires that all State agencies and departments involved in regulating, funding, or planning for the health care industry carry out their responsibilities in a manner consistent with the State Health Plan and available fiscal resources.

(2) It is the foundation for the Commission’s decisions in its regulation of health care facilities and services. These programs ensure that changes in health care facilities and services are appropriate and consistent with the Commission’s policies. The State Health Plan articulates the policies guiding the Commission’s regulation of health care facilities and services, establishes the criteria and standards that state the Commission’s expectations about the facility or service development proposals it considers, and may contain methodologies that forecast need or demand for health care facilities or services, to inform the Commission and the public about appropriate considerations for Certificate of Need (“CON”) decisions.

The State Health Plan should provide a vision for positive change in the delivery of health care services. It should provide useful guidance for resource allocation decisions that appropriately balance the population's need for available, accessible, affordable, and high quality health care services.

B. Legal Authority for the State Health Plan.

The State Health Plan is adopted under Maryland's health planning law, Health-General Article §19-114, *et seq.*, Maryland Code Annotated (Health-General). This Chapter partially fulfills the Commission's responsibility to adopt a State Health Plan at least every five years and to review and amend the State Health Plan as necessary. Health-General §19-118(a)(2) provides that the State Health Plan shall include:

- (1) The methodologies, standards, and criteria for Certificate of Need review; and
- (2) Priority for conversion of acute care capacity to alternative uses where appropriate.

C. Organizational Setting of the Commission.

The Commission is an independent agency, which is located within the Department of Health and Mental Hygiene for budgetary purposes. The purposes of the Commission, as enumerated at Health-General §19-103(c), include responsibilities to:

- (1) Develop health care cost containment strategies to help provide access to appropriate quality health care services for all Marylanders, after consulting with the Health Services Cost Review Commission; and
- (2) Promote the development of a health regulatory system that provides, for all Marylanders, financial and geographic access to quality health care services at a reasonable cost by advocating policies and systems to promote the efficient delivery of and improved access to

health care services, and enhancing the strengths of the current health care service delivery and regulatory system

Health-General §19-110(a) provides that the Secretary does not have power to disapprove or modify any regulation, decision, or determination that the Commission makes regarding or based upon the State Health Plan. The Commission has sole authority to prepare and adopt the State Health Plan and to issue Certificate of Need decisions and exemptions based on the State Health Plan. Health-General §19-118(e) provides that the Secretary of Health and Mental Hygiene shall make annual recommendations to the Commission on the State Health Plan and permits the Secretary to review and comment on the specifications used in its development. The Commission pursues effective coordination with the Secretary and State health-related agencies in the course of developing the State Health Plan and plan amendments.

D. CON Applicability to a Home Health Agency.

Under Health-General §19-120(f), a Certificate of Need (CON) is required before a new health care facility is built, developed, or established. The definition of health care facility, found at Health-General 19-114(d), includes a home health agency (HHA). More specifically, Health-General §19-120(j)(2)(iii)⁴ provides that a Certificate of Need is required prior to the “[e]stablishment of a ... home health program” A Certificate of Need is also required for an existing Maryland HHA to expand its authority to serve clients in a jurisdiction not previously authorized to serve, as provided in Health-General §19-120(j)(3)(ii). A CON is required “[b]efore an existing home health agency or health care facility establishes a home health agency or home health care service at a location in the service area not included under a previous certificate of need or license.” Also under Health-General §19-120(k) (2), a capital expenditure by a health care facility that exceeds an applicable capital expenditure threshold requires a CON.

The Commission's procedural regulations, COMAR 10.24.01.02 - .03, describe the scope of CON regulation of home health agency services. A CON is required for: (1) the establishment of a home health agency; (2) the establishment of a new subunit by an existing home health agency; (3) the expansion of a home health agency into a jurisdiction that the agency was not previously authorized to serve; (4) a transfer of ownership of a subunit or a facility based home health care service of an existing health care facility that separates the ownership of the subunit from the home health agency or home health care service that established the subunit; and (5) a capital expenditure by a home health agency that exceeds the applicable capital expenditure for this category of health care facility.

A CON is not required for the acquisition of an existing licensed home health agency, as long as the type or scope of services provided by the home health agency being sold is not changed. A merger or consolidation of two or more licensed home health agencies reducing the supply of agencies operating in Maryland requires the Commission's issuance of an exemption from CON review, consistent with COMAR 10.24.01.04.

E. Overview of the Home Health Agency Chapter of the State Health Plan.

This Chapter of the State Health Plan implements an approach to regulating the development and expansion of HHA services in Maryland that is based on ensuring consumer choice of high quality providers in which better performance by HHAs is encouraged by development and expansion opportunities. The first step in this regulatory process is the determination of whether jurisdictional populations or multi-jurisdictional regional populations need new HHA service providers, based on certain qualifying characteristics as described in Regulation .04 of this Chapter. Periodically, the Commission will evaluate the characteristics of jurisdictions using the qualifying criteria described in Regulation .04 and establish project review

cycles, as described in Regulation .05 of this Chapter, so that qualified applicants could propose meeting the identified population need.

The second step in the process is qualification of applicants described in Regulation .06 of this Chapter. Only an applicant that demonstrates the ability to perform well in the delivery of HHA services may submit an application that is capable of being docketed for review. Because quality and performance measures are evolving, the qualifying criteria that will be used in a given review cycle will be considered by the Commission and posted before any given review cycle begins. The Commission will publish proposed quality measures and performance levels for review and comment before officially establishing the criteria as applicable to a review cycle. As described in Regulation .07, the Commission will choose quality measures that are important, feasible, scientifically sound, and actionable, including performance measures that: (1) are of importance to consumers, providers, and health officials; (2) are endorsed by a nationally recognized organization engaged in health care quality and performance measurement such as the National Quality Forum (NQF); (3) apply to most Maryland home health agencies; and (4) show a reasonable amount of variation among HHAs without excessive random variation over time.

Upon determination that an applicant has met all the applicable minimal qualifications, including performance-related criteria, as described in Regulations .06 and .07 of this Chapter, its application will be considered for docketing. After docketing, the next step in the regulatory process will be the review of the qualified CON applications. Compliance or consistency with the CON review standards found in Regulation .08 and the general review criteria found in COMAR 10.24.01.08G will be determined, either by a Commissioner serving as reviewer in a

contested or comparative review or by Commission staff in an uncontested or non-comparative review.

The review process shall use preference rules, as described in Regulation .09 of this Chapter, in comparative reviews where the number of qualifying applicants exceeds the number of new projects that it is reasonable to authorize simultaneously for a jurisdiction or multi-jurisdictional region. The preference rules will be used to determine which among several proposed projects are likely to best meet the needs identified. Such determination may be necessary in order to allow for gradual growth in the number of HHAs permitted to ensure that existing markets can absorb new entrants without destabilizing the existing base of HHAs and without straining the labor market or other resources. Additionally, such limitations will provide new market entrants with a better chance for success by avoiding saturation of the existing market with additional providers. Rules permitting gradual entry of new market entrants are described in Regulation .10.

Because acquisitions of HHAs that fall outside the scope of CON review can profoundly affect the manner in which HHA services are delivered, Regulation .11 of this Chapter specifies procedural rules that are intended to help assure that acquisitions of HHAs do not result in reductions in the availability or accessibility of HHA services for any class of patient, reduced quality of care, or the introduction of HHA owners and operators of questionable character and competence.

Regulation .12 addresses procedural rules used in reviewing requests for an exemption from CON, in the case of proposed mergers or consolidation of two or more HHAs. The procedural rules under Regulations.11 and .12 build on the generic rules governing acquisitions and exemptions from CON at COMAR 10.24.01.03 and .04 and are intended to assure the

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maintenance of access to HHA services for all patients, greater transparency, and improved accountability whenever changes in the supply, distribution, or ownership of HHAs occur.

.03 Issues and Policies: Home Health Agency Services

A. Background

In Maryland, a variety of licensed entities provide home care services to sick or disabled persons in their places of residence. In addition to HHAs, Maryland also licenses residential service agencies (RSAs) and nursing referral service agencies (NRSAs).¹ The Commission regulates only one of these entities, home health agencies, through its Certificate of Need program.

Maryland law² defines a home health agency as a health-related institution, organization, or part of an institution that:

- (1) Is owned or operated by 1 or more persons, whether or not for profit and whether as a public or private enterprise; and
- (2) Directly or through a contractual arrangement, provides to a sick or disabled individual in the residence of that individual, skilled nursing services, home health aide services, and at least one other home health care service that are centrally administered.

Only a home health agency that meets Maryland licensure requirements, found at COMAR 10.07.10.02, may be certified to receive Medicare reimbursement. Types of home health services covered by Medicare include the following six major disciplines: part-time or intermittent skilled nursing;³ home health aide; physical therapy; occupational therapy; speech therapy; and medical social services. A patient is eligible for the Medicare home health benefit if

¹ Home health agencies are licensed under COMAR 10.07.10; Residential Service Agencies under COMAR 10.07.05, and Nursing Referral Service Agencies under COMAR 10.07.07.

² Health-General § 19-401(b).

³ Medicare defines “part-time” as fewer than eight hours per day; “intermittent” means from as much as every day for recurring periods of 21 days – if there is a predictable end to the need for daily care – to as little as once every 60 days.

the patient: is homebound;⁴ is under the care of a physician; is receiving services provided under a plan of care established by a physician; and, requires skilled nursing care on an intermittent basis or physical therapy or speech therapy services, or has a continued need for occupational therapy.⁵

B. Availability and Accessibility of Quality Home Health Agency Services.

Each Maryland HHA, for the most part, has specified authority to serve clients in designated jurisdictions. An agency's potential size and service volume is dependent on the number of authorized jurisdictions and the population of those jurisdictions. However, some HHAs do not actually serve all of the jurisdictions which they are authorized to serve. For example, based on FY 2013 data reported by the agencies in response to the Commission's annual HHA Survey, while nine agencies (18%) have authority to serve 11 or more jurisdictions, only five of those agencies (10%) actually served at least one client in 11 or more jurisdictions. In FY 2013, 80 percent of the 50 general HHAs were authorized to serve more than one jurisdiction.

Availability of, and access to, HHA services is a function of both the supply of agencies and the geographic distribution of agencies. There are variations in the geographic distribution of HHAs, as measured by the number of agencies per jurisdiction across Maryland. As would be expected, the majority of agencies operate in the most populous areas of Maryland – the Baltimore metropolitan area,⁶ the suburban Washington, D.C. counties of Montgomery and

⁴ To be homebound and considered “confined to the home” means you have trouble leaving your home due to your illness or injury; leaving your home is not recommended because of your medical condition; and, you are unable to leave your home because it is a major effort and assistance is required. A doctor must certify that the patient is homebound. Department of Health & Human Services, CMS; CMS Manual System Pub. 100-2 Medicare Benefit Policy, Transmittal 192, August 1, 2014

⁵Department of Health & Human Services (DHHS), Centers for Medicare & Medicaid (CMS), Medicare Benefit Policy Manual, CMS Pub. 110-2.

⁶ Baltimore metropolitan area includes the following five jurisdictions: Anne Arundel, Baltimore, Harford and Howard Counties, and Baltimore City.

Prince George's, and exurban Carroll and Frederick Counties. Client use rates per 1,000 population (all ages) ranged from a regional low of 12.9 in Southern Maryland to a regional high of 23.7 on the Eastern Shore in FY 2013.

Current law requires that HHA services regulation be implemented on a jurisdictional basis. For rural or less densely populated areas of the State, successfully establishing and operating an HHA limited to serving a small jurisdictional population is challenging. Creating a larger population base for consideration of proposed HHA projects by combining two or more contiguous jurisdictions may provide greater incentives for HHA providers to serve these less densely populated parts of the State, providing consumers with more choices and, potentially, higher quality choices.

Since the delivery of home health agency services does not require a resource base of buildings or equipment, agencies have great flexibility in expanding or contracting their service capacity and production expenses to fit the level of demand they are experiencing. As long as qualified personnel can be recruited, HHAs have, theoretically, an infinite capacity to expand staffing resources to absorb growth in their base of clients. There is no standard measure for determining the minimum or maximum number of home health clients needed to support an HHA or to assure the ability to achieve high quality performance. There is great variation in the size of HHAs in Maryland, in terms of patient caseloads. For these reasons, this Chapter takes the approach of regulating HHA services by emphasizing the importance of providing consumers with meaningful choices for obtaining high quality services, in which one HHA or a small number of HHAs do not command overwhelming dominance. It sets a benchmark of sufficient consumer choice as the availability of at least three high performing agencies in each jurisdiction. It targets highly concentrated HHA markets, as measured by the Herfindahl-

Hirschman Index (HHI), for consideration of new HHA providers, through new agency establishment or expansion of existing HHA(s). Research indicates that quality and performance scores improve over time in more competitive markets.⁷

- Policy 1. Promote development and expansion of HHA services to address the changing needs of the population and the HHA marketplace by enhancing consumer choice of high quality providers in highly concentrated markets.**
- Policy 2. Create the opportunity for combining certain less densely populated and contiguous jurisdictions into regional service areas for the purpose of establishing CON review cycles.**
- Policy 3. Create opportunities for HHA development in jurisdictions where there is a limited choice of quality HHA providers.**

C. Home Health Agency Quality Measures and Performance.

The adoption of standardized measures for quality and performance of home health agencies by the Centers for Medicare and Medicaid Services (CMS) and the anticipated change in the way CMS will pay for HHA services, using a value-based purchasing model, support the use of a regulatory process for HHAs in Maryland designed to give the most opportunity for growth to agencies that can demonstrate high quality and good value.

Thus, unlike previous HHA Chapters that attempted to define the need for HHA services by focusing on rates of population demand for services and changes in population, this Chapter identifies need for new HHA service providers on whether there is reasonable consumer choice of quality performing HHA providers in a jurisdiction and takes the position that more good quality choices should be encouraged when a market is dominated by a small number of providers.

⁷ *Public Reporting as a Quality Improvement Strategy*, an evidence-based report (No. 208) issued in July 2012 by the Agency for Healthcare Research and Quality. “The Association of Nursing Home Compare Quality Measures with Market Competition and Occupancy Rates,” published in the March/April 2008 issue of the *Journal for Healthcare Quality*.

Qualifying factors for an application to be considered would depend on the type of applicant. An existing Medicare-certified HHA in Maryland seeking to expand will need to demonstrate high quality performance on the CMS Star Rating system for HHAs and Home Health Compare measures. Applicants with experience in operating Medicare-certified HHAs in Maryland and other states will need to apply as a Maryland HHA seeking to expand and demonstrate high quality performance on the CMS Star Rating system for HHAs and Home Health Compare measures for the applicant Maryland HHA. For those applicants with multiple Medicare-certified HHAs but no Maryland HHA that seek to establish an HHA in Maryland, the average performance score for all of its Medicare-certified HHAs will be used.⁸ An applicant with no previous experience in providing HHA services but with experience in providing RSA services (including skilled nursing care) in Maryland or in providing hospital or nursing home services in any state will also have an opportunity to gain entry to the regulatory process but will, of necessity, be allowed to offer another type of demonstration that it has a strong quality of care track record.

Since quality measures and the art of evaluating quality are evolving, this Chapter describes the process by which consideration of quality will be used in qualifying applicants for scheduled review cycles. The Chapter does not include the specific quality measures, performance thresholds, or improvement targets that will be used. Rather, these would be published for review and comment prior to the initiation of review cycles in which applications could be filed. After review of any comments received, the specific quality measures, performance thresholds and improvement targets, and other qualifying criteria will be established by the Commission and published in the *Maryland Register* and on the Commission's website,

⁸ An applicant's average performance score would be calculated based on the individual scores of all its Medicare-certified HHAs reporting on CMS' Home Health Compare and HHCAHPS.

along with the review schedule. This way, the Commission can be responsive to the changing measures of quality performance collected and reported by CMS and others.

There are generally two types of quality measures collected and publically reported for existing Medicare-certified HHAs, process and outcome measures. Additionally, there are experience of care measures, based on consumer evaluations of agency performance. Numerous process and outcome measures of quality are collected using the Outcome and Assessment Information Set (OASIS) instrument, a requirement for all Medicare-certified HHAs. OASIS consists of data elements collected at the point of care that include the core items of a comprehensive assessment for the home health agency client. CMS selects a subset of quality measures and calculates agency-specific scores for each selected process and outcome measure. An agency's performance for each selected measure is then compared to Maryland and national average scores.⁹

Experience of care measures, based on the consumers' perspectives regarding their experiences with the services/care received, are collected using the Home Health Consumer Assessment of Healthcare Providers and Systems (HHAHPS) survey. Five measures – three composite measures and two global ratings – are derived from the HHAHPS survey. Each of the three composite measures consists of four or more individual survey items regarding one of the following topics: patient care; communication between providers and patients; and specific care issues on medications, home safety, and pain. The two global ratings are: the overall rating of care provided by the HHA, and, the patient's willingness to recommend the HHA to family

⁹ Refer to the Commission's *White Paper* (Appendix Table 12) for agency-specific scores calculated for each of the selected 22 process and outcome measures comparing Maryland and national average scores for the 2012 and 2013 reporting years, at http://mhcc.maryland.gov/mhcc/pages/home/workgroups/workgroups_hha.aspx

and friends. Agency-specific scores are calculated for each of the five experience of care measures, and are compared to the average scores for Maryland and the nation.¹⁰

For an applicant not currently Medicare-certified as an HHA, but licensed and accredited as a hospital, nursing home or Maryland RSA providing skilled nursing services, submission of evidence of an established quality program that systematically collects process and outcome measures comparable to Home Health Compare, and experience of care measures similar to HHCAHPS, is required. The population being served and assessed for quality should also be described.

- Policy 4. Permit growth through the expansion of existing HHAs with high levels of performance and permit gradual development of new agencies with documented experience in providing high quality health care services.**
- Policy 5. Continue to assess, and revise as needed, the qualifying factors for jurisdictions and applicants, to account for changes in the health care delivery and financing systems, the needs of the population and HHA marketplace, and changes in quality measurement.**
- Policy 6. Streamline the CON review process by defining need and establishing docketing and procedural rules that permit most applications that qualify for docketing to be quickly reviewed.**

D. Home Health Agency Data Collection and Public Reporting.

An HHA seeking Medicare certification is required to meet the Medicare Conditions of Participation including, but not limited to, compliance with requirements for collecting and reporting performance and experience of care data for Medicare and Medicaid HHA clients. Medicare-certified HHAs are required to submit data on both the OASIS and HHCAHPS.

CMS created the Home Health Compare website as a national tool which enables consumers and providers to compare quality and performance information across all Medicare-

¹⁰ Refer to the Commission's *White Paper* (Appendix Table 13) for agency-specific scores calculated for each of the five experience of care measures comparing Maryland and national average scores for the 2012 and 2013 reporting years, at http://mhcc.maryland.gov/mhcc/pages/home/workgroups/workgroups_hha.aspx

certified HHAs. CMS selects a subset of process and outcome quality measures that it reports publicly on Home Health Compare. Similarly, the Commission's Consumer Guide to Long Term Care Services reports Home Health Compare quality measures for each Maryland Medicare-certified HHA. Agency-specific scores are calculated for each of the selected process and outcome measures, and are compared to Maryland and national average scores.

CMS' Star Ratings for HHAs are also reported on Home Health Compare, which provides symbols and summary data to help consumers more quickly identify differences in quality and make use of the information when selecting an HHA. In addition to summarizing performance, Star Ratings can also help HHAs identify areas for improvement.

Such quality reporting on public websites creates the potential for greater awareness by consumers of an HHA's performance relative to that of other HHAs. Moreover, every HHA can also use this data to compare its performance to that of other agencies, which can spur quality improvement programs.

Under COMAR 10.07.11, licensed HHAs in Maryland are required to submit an annual report in the format prescribed by the Secretary of the Department of Health and Mental Hygiene. The Maryland Home Health Agency Annual Report Survey, conducted by the Commission, constitutes the format prescribed by the Secretary. The HHA Annual Survey collects utilization, demographic, and financial information for all licensed Maryland Home Health Agencies, both for the facility and by its authorized jurisdictions. This comprehensive database of information reported on the Annual HHA Survey is made available to the public on the Commission's website.

Policy 7. Continue to collect data from all home health agency providers in order to obtain timely, Maryland-specific data to support planning and regulation of home health agency services.

Policy 8. Update and maintain the Commission’s Consumer Guide to Long Term Care Services to reflect the most recent quality and performance measures collected and reported by CMS as an important tool for aiding Maryland consumers to identify high performing HHAs.

.04 Need Determination for Home Health Agency Services.

A. A jurisdiction shall be identified as having a need for additional home health agency services if it is determined that the jurisdiction has insufficient consumer choice of HHAs, a highly concentrated HHA service market, or an insufficient choice of HHAs with high quality performance. A jurisdiction shall not be identified as having need for additional home health agency services if the jurisdiction has an existing HHA with less than three years of operational experience or has a newly authorized HHA that has not yet been implemented.

(1) Insufficient consumer choice is considered to exist in any jurisdiction in which consumers have two or fewer Medicare-certified HHAs that served 10 or more clients each year during the most recent three-year period for which data is available.

(2) A jurisdiction is considered to have a highly concentrated HHA market when it has a Herfindahl-Hirschman Index (HHI) of 0.25 or higher.

(3) A jurisdiction is considered to have an insufficient choice of quality performing HHAs if HHAs serving 60 percent or more of the clients in that jurisdiction in the most recent year for which data is available, did not meet the applicable quality performance requirements designated by the Commission. Before establishing review cycles, these quality performance requirements will be posted for review and comment, along with the qualifying jurisdictions and any multi-jurisdictional regions proposed for use in CON regulation. After review and consideration of the comments, the final quality performance requirements and jurisdictions/regions established by the Commission will be published in the Maryland Register and on the Commission's website.

B. A specialty home health agency awarded a CON by the Commission prior to the adoption of these regulations shall maintain its authority, provided that the specialty HHA retains Medicare certification and otherwise complies with State law and regulations.

(1) No new specialty HHAs will be established. Any proposed new establishment of an HHA shall address jurisdictional need as defined in Regulation .04.

(2) An existing CCRC-based HHA exclusively serving its own CCRC residents may expand its authority within its existing authorized jurisdiction to exclusively serve the residents of another CCRC that has common ownership with the CCRC at which the existing specialty HHA is based.

.05 Use of Multi-Jurisdictional Regions in Certificate of Need Review of Home Health Agency Services.

The Commission may create the opportunity for the submission of CON applications for proposed development of new HHAs or expanding the services of existing HHAs into regional service areas composed of two or more contiguous jurisdictions. These opportunities will only be created when the regional service area has met one of the specified qualifying criteria for a determination of need consistent with Regulation .04 of this Chapter:

A. Any multi-jurisdictional region created for the review of CON applications will be geographically contiguous. No jurisdiction will be included in a region that does not share a land border with a least one other jurisdiction in the region.

B. Jurisdictions with a total population size of 300,000 or more will not be combined with other jurisdictions to create regional service areas.

C. An applicant seeking to establish an HHA in or expand HHA services into a multi-jurisdictional region shall meet all the applicable qualifications for an applicant described in Regulation .06 of this Chapter and be found to be in compliance with or consistent with the CON review standards found in Regulation .08 of this Chapter.

.06 Certificate of Need Application Acceptance Rules: Home Health Agency Services.

The Commission will use rules in this section to determine whether an application to establish a new home health agency (HHA) in Maryland or to expand the services of an existing Maryland HHA to a jurisdiction that the HHA was not previously authorized to serve can be accepted for review. The Commission will only review and issue decisions to approve or deny docketed applications.

A. Jurisdictional Need.

(1) The Commission will not accept an application for establishment of a new HHA in Maryland, or an expansion of the services of an existing Maryland HHA, unless there is an identified need for additional HHA services in the jurisdiction proposed for such agency establishment or expansion, in accordance with the need determination rules described in Regulation .04.

(2) The Commission will not accept an application for establishment of a new HHA in Maryland proposing to serve a multi-jurisdictional region, or an expansion of the services of an existing Maryland HHA into a multi-jurisdictional region, unless there is an identified need for additional HHA services in the multi-jurisdictional region proposed for such agency establishment or expansion, in accordance with the rules described in Regulation .05 of this Chapter.

B. Qualified Applicants.

The Commission will accept an application from applicants that meet applicable qualifications. An applicant shall apply as one of three types of applicants:

(1) Existing Medicare-certified HHA licensed in Maryland and proposing to add one or more jurisdictions to its authorized service area;

(2) Existing Medicare-certified HHA licensed in another state and proposing to establish a new HHA in Maryland; or

(3) Non-HHA service providers currently licensed and accredited, in good standing, as a hospital, a nursing home, or a Maryland residential service agency (RSA) providing skilled nursing services, and proposing to establish a new HHA in Maryland.

C. Qualifications for All Applicants.

The Commission will only accept a CON application submitted by an applicant that:

(1) Has not had its Medicare or Medicaid payments suspended within the last five years;

(2) Has not been convicted of Medicare or Medicaid fraud or abuse within the last ten years;

(3) Has received at least satisfactory findings reflecting no adverse citations on the most recent two survey cycles from its respective state agency or accreditation organization, as applicable;

(4) Has maintained accreditation through a state-recognized deeming authority, as applicable, for at least the three most recent years;

(5) Has submitted an acceptable plan of correction for any valid and serious patient-related complaint investigated over the past three years;

(6) Has complied with all applicable federal and State quality of care reporting requirements and performance standards;

(7) Can document availability of sufficient financial resources to implement the proposed project within the applicable timeframes set forth in the Commission's performance requirements at COMAR 10.24.01.12;

(8) Demonstrates a record of serving all applicable payer types, such as Medicare, Medicaid, private insurance, HMOs, and self-pay patients; and

(9) Affirms under penalties of perjury, that none of its owners or senior management or an owner or senior management of any related or affiliated entity has within the last ten years been convicted of a felony or crime or pleaded guilty, nolo contendere, entered a best interest plea of guilty, or received a diversionary disposition regarding a felony or crime.

D. Performance-Related Qualifications.

In addition to meeting the qualifications required for all applicants described in Regulation .06C of this Chapter, performance-related qualifications necessary for accepting an application will vary by type of applicant. The specific quality measures used to assess an applicant's performance and to determine qualification for acceptance will be addressed in a process used to set these qualifications for any given review cycle, as detailed in Regulation .07 of this Chapter. The notice provided by the Commission in the *Maryland Register* and on its website will include, at a minimum:

(1) Quality measures that will be used to define a quality provider, for purposes of accepting CON applications;

(2) Performance levels that will be required to be achieved for the identified quality measures by prospective CON applicants in order for its application to be accepted; and

(3) The format of the performance measurement information to be submitted by non-HHA applicants.

.07 Establishment of HHA Quality Measures and Performance Levels for Applicants.

A. Review and Comment on Quality Measures, Performance Levels, and Public Notice.

When one or more jurisdictions has need identified for additional home health agency services consistent with Regulation .04, Commission staff shall publish draft quality measures and required performance levels for those quality measures that must be achieved by an applicant in order to be considered in the review cycle. The experience of Maryland HHAs will be used to select performance levels. The Commission will consider the comments and Commission staff's recommendation in establishing the applicable quality measures and performance levels for a given review cycle.

B. Quality Measures for Maryland Medicare-certified HHAs.

In order for an application from a Maryland Medicare-certified HHA to be accepted, it shall:

- (1) Achieve the specified rating on the CMS Star Rating system; and
- (2) Achieve the specified performance level on selected process and outcome measures from CMS' Home Health Compare for the most recent 12-month reporting period.

C. Quality Measures for Non-Maryland Medicare-certified HHAs.

In order for an application to be accepted by an applicant that has any common ownership with a Medicare-certified HHA in a state other than Maryland, it shall demonstrate that:

- (1) The average rating on the CMS Star Rating system of all the Medicare-certified HHAs with which it has any common ownership met or exceeded the specified rating level; and

(2) The average performance level on selected process and outcome measures from CMS' Home Health Compare for the most recent 12-month reporting period of all the Medicare-certified HHAs with which it has any common ownership met or exceeded the specified performance level.

D. Quality Measures for Licensed and Accredited Hospital, Nursing Home, or Maryland Residential Service Agency (RSA) Providing Skilled Nursing Services.

In order for an application to be accepted by an applicant or entity with any common ownership that is not the licensee of an HHA in Maryland or any state, but is the licensee of a hospital or nursing home in any state or is the licensee of an RSA in Maryland consistent with the requirements of Subsection .06B(3), it shall demonstrate that:

(1) In the case of a Maryland licensed RSA applicant, it has operated with an established quality assurance program that includes systematic collection of process and outcome measures, and experience of care measures and has maintained accreditation through a deeming authority recognized by Maryland's Department of Health and Mental Hygiene for at least the three most recent years;

(2) In the case of a Maryland hospital applicant, it has achieved and maintained the minimum CMS Star Ratings required by the Commission for the applicable review cycle for its Maryland hospital and, on average, for all the Maryland hospitals with which it has any common ownership for at least the three most recent years of operation;

(3) In the case of a hospital applicant that only operates a hospital or hospitals in states other than Maryland, it has, for at least the three most recent years of operation, on average, achieved and maintained the minimum CMS Star Rating required by the Commission for the applicable review cycle for all the hospitals with which it has any common ownership;

(4) In the case of a Maryland nursing home applicant, it has for at least the three most recent years of operation achieved and maintained the minimum CMS Star Ratings required by the Commission for the applicable review cycle for its Maryland nursing home and, on average, for all the Maryland nursing homes with which it has any common ownership; or

(5) In the case of a nursing home applicant that only operates a nursing home or nursing homes in states other than Maryland, it has for at least the three most recent years of operation, on average, achieved and maintained the minimum CMS Star Rating required by the Commission for the applicable review cycle of all the nursing homes with which it has any common ownership.

.08 Certificate of Need Review Standards for Home Health Agency Services.

The Commission shall use the following standards, as applicable, to review an application for a Certificate of Need to establish a new home health agency in Maryland or expand the services of an existing Maryland home health agency to one or more additional jurisdictions.

A. Service Area.

An applicant shall:

(1) Designate the jurisdiction or jurisdictions in which it proposes to provide home health agency services; and

(2) Provide an overall description of the configuration of the parent home health agency and its interrelationships, including the designation and location of its main office, each subunit, and each branch, as defined in this Chapter, or other major administrative offices recognized by Medicare.

B. Populations and Services.

An applicant shall describe the population to be served and the specific services it will provide.

C. Financial Accessibility.

An applicant shall be or agree to become licensed and Medicare- and Medicaid-certified, and agree to maintain Medicare and Medicaid certification and to accept clients whose expected primary source of payment is either or both of these programs.

D. Fees and Time Payment Plan.

An applicant shall make its fees known to prospective clients and their families at time of patient assessment before services are provided and shall:

(1) Describe its special time payment plans for an individual who is unable to make full payment at the time services are rendered; and

(2) Submit to the Commission and to each client a written copy of its policy detailing time payment options and mechanisms for clients to arrange for time payment.

E. Charity Care and Sliding Fee Scale.

Each applicant for home health agency services shall have a written policy for the provision of charity care for indigent and uninsured patients to ensure access to home health agency services regardless of an individual's ability to pay and shall provide home health agency services on a charitable basis to qualified indigent and low income persons consistent with this policy. The policy shall include provisions for, at a minimum, the following:

(1) **Determination of Eligibility for Charity Care and Reduced Fees.** Within two business days following a client's initial request for charity care services, application for medical assistance, or both, the home health agency shall make a determination of probable eligibility for medical assistance, charity care, and reduced fees, and communicate this probable eligibility determination to the client.

(2) **Notice of Charity Care and Sliding Fee Scale Policies.** Public notice and information regarding the home health agency's charity care and sliding fee scale policies shall be disseminated, on an annual basis, through methods designed to best reach the population in the HHA's service area, and in a format understandable by the service area population. Notices regarding the HHA's charity care and sliding fee scale policies shall be posted in the business office of the HHA and on the HHA's website, if such a site is maintained. Prior to the provision of HHA services, a HHA shall address clients' or clients' families concerns with payment for

HHA services, and provide individual notice regarding the HHA's charity care and sliding fee scale policies to the client and family.

(3) Discounted Care Based on a Sliding Fee Scale and Time Payment Plan Policy. Each HHA's charity care policy shall include provisions for a sliding fee scale and time payment plans for low-income clients who do not qualify for full charity care, but are unable to bear the full cost of services.

(4) Policy Provisions. An applicant proposing to establish a home health agency or expand home health agency services to a previously unauthorized jurisdiction shall make a commitment to, at a minimum, provide an amount of charity care equivalent to the average amount of charity care provided by home health agencies in the jurisdiction or multi-jurisdictional region it proposes to serve during the most recent year for which data is available.

The applicant shall demonstrate that:

(a) Its track record in the provision of charity care services, if any, supports the credibility of its commitment; and

(b) It has a specific plan for achieving the level of charity care to which it is committed.

F. Financial Feasibility.

An applicant shall submit financial projections for its proposed project that must be accompanied by a statement containing the assumptions used to develop projections for its operating revenues and costs. Each applicant must document that:

(1) Utilization projections are consistent with observed historic trends of HHAs in each jurisdiction for which the applicant seeks authority to provide home health agency services;

(2) Projected revenue estimates are consistent with current or anticipated charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision, as experienced by the applicant if an existing HHA or, if a proposed new HHA, consistent with the recent experience of other Maryland HHAs serving each proposed jurisdiction; and

(3) Staffing and overall expense projections are consistent with utilization projections and are based on current expenditure levels and reasonably anticipated future staffing levels as experienced by the applicant if an existing HHA or, if a proposed new HHA, consistent with the recent experience of other Maryland HHAs serving the each proposed jurisdiction.

G. Impact.

An applicant shall address the impact of its proposed home health agency service on each existing home health agency authorized to serve each jurisdiction or regional service area affected by the proposed project. This shall include impact on existing HHAs' caseloads, staffing and payor mix.

H. Financial Solvency.

An applicant shall document the availability of financial resources necessary to sustain the project. Documentation shall demonstrate an applicant's ability to comply with the capital reserve and other solvency requirements specified by CMS for a Medicare-certified home health agency.

I. Linkages with Other Service Providers.

An applicant shall document its links with hospitals, nursing homes, continuing care retirement communities, hospice programs, assisted living providers, Adult Evaluation and

Review Services, adult day care programs, the local Department of Social Services, and home-delivered meal programs located within its proposed service area.

(1) A new home health agency shall provide this documentation when it requests first use approval.

(2) A Maryland home health agency already licensed and operating shall provide documentation of these linkages in its existing service area and document its work in forming such linkages before beginning operation in each new jurisdiction it is authorized to serve.

J. Discharge Planning.

An applicant shall document that it has a formal discharge planning process including the ability to provide appropriate referrals to maintain continuity of care. It will identify all the valid reasons upon which it may discharge clients or transfer clients to another health care facility or program.

K. Data Collection and Submission.

An applicant shall demonstrate ongoing compliance or ability to comply with all applicable federal and State data collection and reporting requirements including, but not limited to, the Commission's Home Health Agency Annual Survey, CMS' Outcome and Assessment Information Set (OASIS), and CMS' Home Health Consumer Assessment of Healthcare Providers (HCAHPS).

.09 Certificate of Need Preference Rules in Comparative Reviews.

Consistent with COMAR 10.24.01.09A(4)(b), the Commission shall use the following preferences, in the order listed, to limit the number of CON applications approved in a comparative review:

A. Performance on Quality Measures.

Higher levels of performance will be given preference over lower levels of performance.

B. Maintained or Improved Performance.

An applicant that demonstrates maintenance or improvement in its level of performance on the selected process and outcome measures during the most recent three-year reporting period will be given preference over an applicant that did not maintain or improve its performance.

C. Proven Track Record in Serving all Payor Types, the Indigent and Low Income Persons.

An applicant that served a broader range of payor types and the indigent will be given preference over an applicant that served a narrower range of payor types and provided less service to the indigent and low income persons.

D. Proven Track Record in Providing a Comprehensive Array of Services.

An applicant that provided a broader range of services will be given preference over an applicant that provided a narrower range of services.

E. These preferences will only be used in a comparative review of applications when it is determined that approval of all applications that fully comply with standards in Regulation .08 of this Chapter would exceed the permitted number of additional HHAs provided for in a jurisdiction or multi-jurisdictional region as provided in Regulation .10.

.10 Gradual Entry of New Market Entrants.

In order to promote gradual growth in the number of HHAs in Maryland and avoid excessive disruption or destabilization of the existing HHA staffing resources, the Commission will consider the number of existing parent HHAs annually serving at least 10 or more clients in a jurisdiction during the most recent three-year period for which data is available, and limit the number of new entrants authorized by CON approval for any given review cycle to:

A. No more than 40 percent of the number of existing HHAs in a jurisdiction or multi-jurisdictional region with four or more agencies; and

B. No more than one additional HHA in a jurisdiction or multi-jurisdictional region with fewer than four existing HHAs.

.11 Acquisition of a Home Health Agency.

The following additional rules will be used in consideration of a request for determination of coverage under COMAR 10.24.01.03A regarding the proposed acquisition of an HHA.

A. Acquisition of Authority to Serve Jurisdictions.

(1) The purchaser of a freestanding HHA shall acquire the authority to serve each jurisdiction which the HHA being acquired has been authorized to serve.

(2) The purchaser of a hospital-based HHA shall only acquire the authority to serve the residents in the jurisdiction in which the hospital-based agency's parent hospital is located, unless the hospital-based agency has obtained authority to serve other jurisdictions through issuance of a CON or earlier acquisition of an existing HHA. The purchaser will not acquire the authority to follow patients to any jurisdiction after discharge from the parent hospital of the HHA, unless the HHA is being acquired as part of an acquisition of the parent hospital.

B. Persons Who May Acquire an HHA.

An HHA may not be acquired by an entity with an owner or member of senior management or an owner or member of senior management of a related or affiliated entity who has been convicted of a felony or crime or pleaded guilty, nolo contendere, entered a best interests plea of guilty, or received a diversionary disposition regarding a felony or crime within the last ten years, unless all the individuals involved in the fraud or abuse are no longer working for the HHA and the HHA has fully complied with each applicable plan of correction.

C. Commitment to Serve All Payor Types and the Uninsured.

A purchaser of an HHA shall commit to serving Medicare, Medicaid, commercial, self-pay and uninsured clients, as well as to providing charitable services and reduced charge services

for indigent and low income clients. This commitment shall be explicitly stated by the purchaser, and will be identified in the determination of coverage issued for the HHA acquisition.

D. Acquisition of the Entire HHA.

An HHA can only be acquired in its entirety. Authority to serve jurisdictions that an HHA has been authorized to serve cannot be sold or acquired except in the case of an acquisition of an entire HHA.

E. Acquisition of an HHA with Ongoing CON Conditions.

The purchaser of an HHA with an ongoing CON condition shall commit to meeting each condition in its operation of the acquired HHA.

F. Information Required to Obtain a Determination of Coverage for an HHA Acquisition.

The Commission requires the following information from the purchaser and seller of an HHA, in addition to information required under COMAR 10.24.01.03A:

(1) A purchaser shall affirm that it will provide, at a minimum, the services historically provided by the HHA being acquired;

(2) A purchaser shall provide information on corporate structure and affiliations of the purchaser, the purchase price, and the source of funds;

(3) A purchaser, any of its principals, a related entity, or a principal of a related entity shall not have pled guilty to, been convicted of, or received a diversionary disposition for a felony within the last ten years;

(4) A purchaser, any of its principals, a related entity, or a principal of a related entity shall not have pled guilty to, been convicted of, or received a diversionary disposition for a felony involving Medicare or Medicaid fraud or abuse within the last ten years;

(5) A purchaser shall agree to maintain Medicare and Medicaid certification;

(6) A purchaser shall indicate whether it is maintaining the seller's Medicare provider agreement and, if not, it shall provide a plan for operating the HHA prior to obtaining Medicare certification within 18 months of the acquisition;

(7) If the purchaser is an existing provider of Medicare-certified HHA services, whether in Maryland or another state, it shall disclose condition-level deficiencies cited by the applicable state agency or accreditation organization for the most recent two survey cycles and document completion of any required plan of correction; and

(8) The seller and the purchaser shall agree to collaborate in providing a full 12-months of data to the Commission's Annual HHA Survey for the reporting year in which the acquisition occurs and the purchaser shall agree to participate in the Annual HHA Survey going forward.

.12 Merger or Consolidation of HHAs.

The Commission will use the following rules to consider requests for an exemption from CON to merge or consolidate two or more HHAs, in addition to the requirements at COMAR 10.24.01.04.

A. Jurisdictional Authority.

(1) Freestanding HHAs that merge or consolidate shall combine authorized jurisdictions as the resulting service area.

(2) A merger with a hospital-based HHA shall result in the surviving entity acquiring from the hospital-based HHA only the authority to serve the residents in the jurisdiction in which the hospital-based HHA's parent hospital is located, unless such hospital-based HHA obtained authority to serve other jurisdictions through issuance of a CON or earlier acquisition of an existing HHA. Merger or consolidation of a hospital-based HHA with another HHA will not provide the resulting entity with authority to follow patients to any jurisdiction after discharge from the parent hospital of the former hospital-based HHA, unless the hospital-based HHA is part of an overall merger or consolidation of the parent hospital.

B. Commitment to Serve All Payor Types and Uninsured.

In a proposed merger of two or more HHAs, the resulting entity shall commit to serve Medicare, Medicaid, commercial, self-pay and uninsured clients, as well as to provide charitable service and reduced charge service for the indigent, following the merger. This commitment shall be explicitly stated by the merging entities and will be a condition of the exemption from CON.

C. Merger of HHAs with Ongoing CON Conditions.

Should one or more of the merging HHAs have one or more ongoing CON conditions, the HHA surviving the merger shall commit to compliance with each such condition in its operation of the HHA surviving the merger.

D. Public Interest Finding.

In determining whether a proposed merger or consolidation of two or more HHAs is in the public interest, the Commission will consider appropriate factors including: geographic and financial access; market concentration pre- and post- merger based on Herfindahl-Hirschman Index (HHI); and quality performance of the surviving entity.

.13 Definitions.

A. In this Chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) *Accreditation organization* means a recognized professional accrediting agency responsible for ensuring that healthcare organizations meet predetermined criteria and standards of quality.

(2) *Acquisition* means any transfer of stock or assets that results in a change of the person or persons who control the home health agency, or the transfer of any stock or ownership interest in excess of 25 percent.

(3) *Adult day care center* means a planned program of services provided in a protective group setting licensed by the Maryland Department of Health and Mental Hygiene that provides services which improve or maintain health or functioning and social activities for seniors and persons with disabilities. The services offered can vary but are designed to meet the needs of participants during the day, while allowing individuals to continue living with their families or in the community. Examples of services provided include physical and speech therapy, medication management, mental health services, and support groups.

(4) *Adult Evaluation and Review Services (AERS)* means a Maryland Medicaid program that provides comprehensive evaluations for aged and functionally disabled adults who need long term care and are at risk for institutionalization. AERS staff are nurses and social workers who identify services that can help individuals either remain in the community or in the least restrictive environment where they are able to function at the highest possible level of independence.

(5) *Assisted living program* means a residential or facility-based program licensed under COMAR 10.07.14 that provides housing and supportive services, supervision, personalized assistance, health-related services, or a combination of those services to meet the needs of residents who are unable to perform, or who need assistance in performing, the activities of daily living or instrumental activities of daily living, in a way that promotes optimum dignity and independence for the residents.

(6) *Branch* means an office (previously known as a “satellite” office) of a parent home health agency or subunit that is located at a different site, but is sufficiently close to share administration, supervision and services with the parent agency or subunit on a daily basis. A branch is not autonomous from the parent home health agency or subunit.

(7) *Charity care.*

(a) Charity care means care for which there is no means of payment by the patient or any third-party payer.

(b) Charity care does not mean uninsured or partially insured days of care designated as deductibles or co-payments in patient insurance plans, nor that portion of charges not paid as a consequence of either a contract or agreement between a provider and an insurer, or a waiver of payment due to family relationship, friendship, or professional courtesy. Charity care does not include bad debt.

(8) *Client* means an individual who has been receiving or may receive home health agency services.

(9) *Community-based long term care services* means services delivered to functionally disabled persons in their communities to help meet their needs for health care and

social support, to enable them to achieve or maintain an optimal degree of independence, and to improve their quality of life.

(10) *Condition-level deficiency* means noncompliance with the conditions of participation or conditions of coverage where the deficiencies are of such character as to substantially limit the provider's capacity to furnish adequate care or which adversely affect the health and safety of patients (42 CFR §488.705 and §488.24).

(11) *Consumer Assessment of Healthcare Providers and Systems (CAHPS®)* means a standardized series of surveys, developed by the Agency for Healthcare Research and Quality (AHRQ), which ask consumers and patients to report on and evaluate their experiences with health care providers. Home Health CAHPS® is designed to measure the experiences of people receiving home health care from Medicare-certified home health agencies.

(12) *Contiguous jurisdiction* means a jurisdiction which geographically shares a land boundary with that of another jurisdiction's land boundary. Distinct jurisdictions separated by a body of water are not considered contiguous jurisdictions, as the perimeters of the jurisdictions are not joined by common land boundaries.

(13) *Continuing care* means providing shelter plus health services consistent with the requirements of the laws located at Title 10, Subtitle 4, of the Human Services Article, Annotated Code of Maryland, and Code of Maryland Regulations (COMAR) 32.02.01. According to the Maryland Department of Aging, although the legal definition of "continuing care" is complex, in general, "continuing care" exists when all three of the following are present:

(a) The consumer pays an entrance fee that is, at a minimum, three times the average monthly fee;

(b) The provider furnishes or makes available shelter and health-related services to persons 60 years of age or older; and

(c) The shelter and services are offered under a contract that lasts for a period of more than one year, usually for life.

(14) *Continuing care retirement community (CCRC)* means a legally organized entity to provide continuing care in a facility that has been certified by the Maryland Department of Aging.

(15) *Freestanding home health agency* means a licensed home health agency that is an independent business not directly operated as a department of a hospital, nursing home, or other type of facility.

(16) *General home health agency* means a licensed home health agency that provides a full range of home health services.

(17) *Herfindahl-Hirschman Index (HHI)* is a measure of the size of firms (HHAs) in relation to the overall HHA industry and an indicator of the amount of competition among them. It is defined as the sum of the squares of the market shares of all the HHAs authorized and actually serving a jurisdiction. Results can range from 0 to 1.0; a competition index of 1.0 indicates a monopoly or a totally concentrated market. Conversely, a competition index close to 0 generally indicates a fair share of the market among an increasing number of HHA providers and, thus, an HHA market offering greater access to a variety of HHA providers. (Note: the competition index is divided by 10,000 for ease of interpretation.)

(18) *Highly concentrated market* means having an HHI measure greater than 2,500 (0.25 when dividing by 10,000) according to the U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) *2010 Horizontal Merger Guidelines*.

(19) *Home health agency.*

(a) “Home health agency” means a health-related organization, institution, or part of an institution that directly, or through a contractual arrangement, provides to a sick or disabled individual in the residence of that individual skilled nursing and home health aide services, and at least one other home health care service that is centrally administered, as provided under Health-General Article, § 19-401, et seq., Annotated Code of Maryland.

(b) “Home health agency” includes both parent (previously known as branch) and subunit, as defined by the Centers for Medicare and Medicaid Services in 42 CFR §484.2.

(c) “Home health agency” does not mean a residential service agency as defined in Health-General Article, §19-4A, Annotated Code of Maryland.

(20) *Home Health Agency Service* means any or all of the following services that are provided in accordance with Health-General Article, §19-401, Annotated Code of Maryland, under the general direction of licensed health professionals practicing within the scope of their practice acts:

- (a) Audiology and speech pathology;
- (b) Dietary and nutritional services;
- (c) Drug services;
- (d) Home health aide;
- (e) Laboratory services;
- (f) Medical social services;
- (g) Skilled nursing;
- (h) Occupational therapy;

- (i) Physical therapy; and
- (j) Provision of medically necessary sick room equipment and supplies.

(21) *Home Health Compare* means a website created and maintained by the Centers for Medicare & Medicaid Services (CMS). Home Health Compare contains information about the quality of care provided by Medicare-certified home health agencies throughout the nation. Quality measures displayed on Home Health Compare include process, outcome, and experience of care measures.

(22) *Hospice care program*.

(a) *General hospice care program* means a coordinated, interdisciplinary program provided in accordance with Health-General Article, §19-901, and regulations under COMAR 10.07.21 meeting the special physical, psychological, spiritual, and social needs of dying individuals and their families by providing palliative and supportive medical, nursing, and other health services through home or inpatient care during the illness and bereavement to:

- (i) Individuals who have no reasonable prospect of cure as estimated by a physician; and
- (ii) Families of those individuals.

(b) *Limited hospice care program* means a coordinated, interdisciplinary program of provided in accordance with Health-General Article, §19-901, Annotated Code of Maryland, and regulations under COMAR 10.07.21 to meet the special physical, psychological, spiritual, and social needs of dying individuals and their families, by providing palliative and supportive non-skilled services through a home-based hospice care program during illness and bereavement to individuals who have no reasonable prospect of cure as estimated by a physician and to the families of those individuals.

(23) *Hospital-based home health agency* means a home health agency directly operated as a department of a hospital whose cost report data is included as part of a hospital's overall cost report.

(24) *Indigent* means a person whose annual income, based on the number of persons in the family, falls within the most recently published poverty guidelines of the U.S. Department of Health and Human Services.

(25) *Jurisdiction* means any of the 23 Maryland counties or Baltimore City.

(26) *Licensed* means a facility that has received approval to operate from the Office of Health Care Quality of the Maryland Department of Health and Mental Hygiene.

(27) *Long term care* means the array of medical, social, and support services needed by individuals who, because of chronic illness or disability, need another person's help in caring for themselves over an extended period of time.

(28) *Low income*: "a low-income person" is a person whose annual income, based on the number of persons in the family, falls above the most recently published poverty guidelines of the U.S. Department of Health and Human Services but below 200 percent of the poverty guideline.

(29) *Medicaid* means the Maryland Medical Assistance Program administered by the State under Title XIX of the Social Security Act to reimburse comprehensive medical and other health-related care for categorically eligible and medically needy persons.

(30) *Medicare* means the federal health insurance program administered under Title XVIII of the Social Security Act that pays for certain health care expenses for people who are 65 years or older, certain younger people with disabilities, and people with end-stage renal disease.

(31) *Nursing home* means a health care facility licensed for comprehensive care beds under COMAR 10.07.02 that admits patients suffering from disease or disabilities, or advanced age, requiring medical service and nursing service rendered by or under the supervision of a registered nurse.

(32) *Nursing referral service agency* means one or more individuals licensed consistent with COMAR 10.07.07 and engaged in the business of screening and referring, directly or in accordance with contractual arrangements that may include independent contractors, licensed health professionals or care providers to clients for the provision of nursing services, home health aide services, or other home health care services at the request of the clients.

(33) *Outcome Assessment Information Set (OASIS)* means a group of standard data elements developed, tested and refined through extensive research by the Centers for Medicare and Medicaid Services. OASIS data elements are designed to enable comparative measurement of home health care patient outcomes, with appropriate adjustment for patient risk factors affecting those outcomes. Data is collected for adult skilled Medicare and Medicaid home health care patients. OASIS data items address sociodemographic, environmental, support system, health status, functional status, and health service utilization characteristics of the patient. The data are collected at start of care, 60-day follow-ups, and discharge (and surrounding an inpatient facility stay). Selected outcome measures derived from OASIS are reported for Medicare-certified home health agencies on the federal website *Home Health Compare*.

(34) *Parent home health agency* means the home health agency that develops and maintains administrative controls of subunits and branch offices.

(35) *Person* means an individual, receiver, trustee, guardian, executor, administrator, fiduciary, or representative of any kind and any partnership, firm, association, limited liability company, limited liability partnership, public or private corporation, or other entity.

(36) *Regional service area* means a multi-jurisdictional region for the purpose of creating a larger population base for consideration of proposed HHA projects by combining two or more jurisdictions which are geographically contiguous. Jurisdictions with a total population size of 300,000 or more will not be combined with other jurisdictions to create regional service areas.

(37) *Residential service agency (RSA)* means an individual, partnership, firm, association, corporation, or other entity of any kind and licensed in accordance with COMAR 10.07.05 that is engaged in a nongovernmental business of employing or contracting with individuals to provide at least one home health care service, as defined in Health-General Article, §19-4A-01, Annotated Code of Maryland, for compensation to an unrelated sick or disabled individual in the residence of that individual or an agency that employs or contracts with individuals directly for hire as home health care providers

(38) *Skilled care* means a service or services that may be provided only by an individual who:

(a) Is licensed under Health Occupations Article, Annotated Code of Maryland, and

(b) Exercises specialized knowledge, judgment, and skill.

(39) *Specialty Home Health Agency* means a home health agency awarded a Certificate of Need prior to January 1, 2016 that provides services which could not otherwise be provided by a general home health agency:

- (a) Services exclusively to the pediatric population;
- (b) An array of services exclusively to a population group limited by the nature of its diagnosis or medical condition;
- (c) To all population groups a highly limited set of services that can offer acceptable quality only through specialized training of staff and an adequate volume of experience to maintain specialized skills; or
- (d) Services exclusively to the residents of a specific continuing care retirement community.

(40) *Subunit* means a semi-autonomous independent entity of a parent home health agency that is located at such a distance from the parent agency that it is incapable of sharing administration, supervision, and services on a daily basis. A subunit serves home health clients in a different geographic area from the parent agency.