February 19, 2016

Cathy Weiss
Program Manager
Center for Health Care Facilities Planning and Development
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Submitted Electronically

RE: State Plan for Facilities and Services: Home Health Agency Services, Proposed Permanent Regulations at COMAR 10.24.16

Dear Ms. Weiss:

On behalf of the 730 nurses and allied health professionals that we employ in the State of Maryland and the hundreds of Marylanders that we serve, Maxim Healthcare Services ("Maxim") appreciates this opportunity to provide public comments on the Maryland Health Care Commission's (MHCC's) proposed changes in regulation of home health agencies (HHAs), HHA licensing, and Certificates of Need (CONs) for home health services in Maryland service areas. Founded and based in Columbia, Maryland in 1988, Maxim is the nation's leading provider of home-based skilled private duty nursing services, with a unique and important focus on home healthcare for complex, medically fragile pediatric patients. As a licensed residential service agency (RSA) geared towards these vulnerable patients, we believe that Maxim can provide important insights into areas where the Commission must ensure flexibility in its HHA licensing approach in order to better account for all targeted populations with home healthcare needs.

MORE FLEXIBILITY IN QUALITY MEASURES FOR ASSESSING APPLICANTS

Maxim strongly agrees that assessing the quality of care that HHAs provide is an important component of evaluating the fitness of a new home healthcare provider that seeks to deliver care for patients in geographic areas with demonstrated need of additional provider choice and capacity. Ensuring that new entrants into HHA service areas are accredited, high performing, and experienced home care providers is critical to improving care coordination, controlling health care costs, and maximizing the ability of Marylanders to remain in their homes and communities despite having complex medical needs.

However, we are very concerned that the Commission's approach to assessing the quality of care provided by HHAs is overly-focused on traditional therapy and rehabilitative care, at the expense of patients for whom the primary goal is maintenance of the patient's ability to remain in the home. Often for these medically fragile patients who require assistance with life-sustaining technologies, including ventilator services and enteral tube feeding, functional improvement in "activities of daily living" (ADLs), such as ambulation or the ability to feed oneself, is neither expected nor possible. In spite of this, the Commission's proposal for assessing quality of care focuses almost entirely on Medicare's quality measurement for home health services, which is based primarily on functional improvement measures for ADLs.

The proposed regulation—at COMAR 10.24.16.07(B)—would require that applicants for new HHA licenses that are Medicare-certified HHAs demonstrate a geographic service area-specific minimum Star Rating under Medicare's Home Health Star Rating system. For applicants that are not themselves Medicare-certified, but share common ownership with out-of-state HHAs that are Medicare-certified, the proposed regulation—at COMAR 10.24.16.07(C)—would require that the out-of-state Medicare-certified HHAs with which the applicant shares common ownership must also demonstrate a geographic service area-specific minimum achievement threshold on Star Ratings, as aggregated and averaged across the applicable out-of-state HHAs. Unfortunately, Medicare Home Health Star Ratings are dictated and derived from Medicare's Outcome and Assessment Information Set (OASIS) measures. OASIS measures are predominantly focused on functional improvement assessments that are, for the most part, an inapplicable metric for Maxim's medically fragile patients receiving custodial and maintenance care as opposed to therapy and rehabilitation services.

Because OASIS is an outcome-based measurement system based on ADLs and instrumental ADLs (IADLs), it cannot fairly measure the quality of care provided for individuals with disabilities, genetic disorders, and other conditions not immediately transferable to an outcome assessment like that in OASIS. As a result, providers that focus on medically fragile patients often do not receive Star Ratings (due to lack of a sufficient number of applicable patient encounters) or receive low Star Ratings scores, despite providing excellent care that helps patients meet maintain their abilities to reside in the home and avoid requiring care in the institutional setting.

We believe that there are better, alternative approaches to simply establishing this barrier for home care providers that focus on specified vulnerable subpopulations that would be ill-suited for care delivered by a traditional rehabilitation-focused provider. Instead, Maxim urges the Commission to provide that the care quality criteria for licensed RSA applicants can be based on the demonstrated maintenance of an Accreditation Commission for Health Care (ACHC)-accredited quality assurance program—regardless of whether the RSA has common ownership with an out-of-state Medicare-certified HHA. While the demonstration of maintenance of an ACHC-accredited quality assurance program is the proposed standard for RSAs without common ownership with out-of-state Medicare-certified HHAs, we are concerned that the proposed regulation would unfairly set a different standard for RSAs that are part of a larger national organization, like Maxim.

At minimum, the Commission should establish an exception process to the Star Rating threshold requirement for applicants falling into this classification under COMAR 10.24.16.07(C), to allow such applicants the opportunity to explain out-of-state Home Health Star Ratings scores, after which the Commission could, at its discretion, provide an exception from the minimum Star Rating requirement.

ALIGN LOOKBACK PERIOD FOR CONVICTIONS & SANCTIONS WITH EXISTING MEDICARE AND FALSE CLAIMS ACT LOOKBACK TIMEFRAMES

The proposed regulations would require that all applicants for new HHA licenses must not have been convicted of Medicare or Medicaid fraud or abuse within the previous ten years. In addition, the proposed regulations would require that an acquirer of a licensed HHA must not have pled guilty to, been convicted of, or received a diversionary disposition for a felony involving Medicare and Medicaid fraud within the last ten years.

We believe that it is important for the Commission to protect patients and consumers from the market entrance of bad actors in the area of home healthcare. However, Maxim is concerned that the ten-year "lookback" periods will establish an overly stringent barrier to entry for organizations that have implemented significant corrective action plans to improve institutional controls and oversight and address prior indiscretions. Consumers and patients could be best served by improved provider choice, while simultaneously being protected from bad actors, if the lookback period was more closely aligned with the

mostly commonly applied False Claims Act (FCA) statute of limitations and the Medicare lookback period for return of overpayments.

Under the FCA, civil actions for FCA violations must be brought within the later of: (A) six years after the date on which the violation was committed; or (B) within three years after the date when facts material to the right or action are known or reasonably should have been known…but in all cases within ten years of the date on which the violation is committed. In practice, the statute of limitations for FCA claims is more commonly assessed through the first standard, the six-year standard. Recently, the Centers for Medicare and Medicaid Services (CMS) finalized regulations to establish a six-year lookback period for demands that providers return overpayments in Medicare reimbursement.[1] Under the proposed rule on return of Medicare overpayments, CMS had originally proposed a ten-year lookback period, to be consistent with the "outer limits" of the FCA statute of limitations.

However, CMS ultimately elected to establish a six-year lookback period for the return of Medicare overpayments because, among other things, a six-year period would be consistent with the six-year component of the FCA statute of limitations and with the six-year limitation that the Social Security Act applies for CMS authority to assess Civil Money Penalties (CMPs)[2] against providers and entities for violations of Medicare policies.

In order to allow for a wider array of high-quality applicants for HHA licenses and to better align the MHCC lookback rules with Medicare and FCA lookback timeframes, we urge the Commission to revise its proposals at COMAR 10.24.16.06(C)(2) and COMAR 10.24.16.11(F)(2)-(3) to provide for a six-year lookback period, rather than a ten-year lookback period.

CLARIFICATION ON ADVERSE CITATIONS FROM STATE AGENCIES AND ACCREDITATION ORGANIZATIONS

Under the proposed regulations—at COMAR 10.24.16.06(C)(3)—the Commission would require that HHA applicants must have received satisfactory findings reflecting no adverse citations on the two most recent cycles from their respective state agency or accreditation organization, as applicable.

Maxim urges the Commission to provide a clarification regarding the meaning of "as applicable," for the purposes of determining which state agency or accreditation organizations would be the appropriate source of adverse citation information that would need to be identified for HHA applicants.

We appreciate the opportunity to provide these public comments and we look forward to working with the Commission to improve and modernize the HHA licensing and home health CON processes. If you have any questions, please do not hesitate to contact me at shgahs@maxhealth.com or 410-910-4708.

Sincerely,

/s/

Shannon Grace Gahs
Program Manager for Government Affairs
Maxim Healthcare Services Inc.

[1] 81 *Fed. Reg*. 7654 at 7672 (February 12, 2016).

[2] Social Security Act § 1128A(c)(1) [42 U.S.C. § 1320a—7a(c)(1)]