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January 11, 2018

VIA HAND DELIVERY AND
ELECTRONIC MAIL

Paul Parker, Director
Center for Health Care Facilities Planning and Development
MARYLAND HEALTH CARE COMMISSION
4160 Patterson Avenue
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RE: *Comment Guidance – General Hospice Services*
MHCC CON Study – 2017-2018

Dear Mr. Parker:

On behalf of Gilchrist Hospice, please accept this response to Chairman Dr. Moffit's November 21, 2017 request for comments on potential reforms of the General Hospice Services certificate of need (CON) program. Enclosed you will find answers to the directed questionnaire, but I ask that you please also consider Gilchrist's additional comments below, which provide valuable context for our current CON program and purpose.

Maryland's decision to adopt the certificate of need process reflects the State's position that regulation of the size, scope, and location of health care facilities and services is preferable to unfettered competition in order to control accessibility and affordability of health care services, and that only facilities and services that respond to an unmet need in the affected community for the proposed service can be approved. We support this underlying concept – that need for a facility or service subject to CON review should remain the cornerstone of the CON process.

According to Maryland's State Health Plan, hospice is "a team-oriented approach to expert medical care, pain management, and emotional and spiritual support expressly tailored to the patient's needs and wishes. Support is provided to the patient's loved ones as well. Physical, social, spiritual, and emotional care is provided during the last stages of illness, during the dying process, and during bereavement, by a medically-directed interdisciplinary team consisting of patients, families, professionals, and volunteers. The focus is on caring, not curing and, in most cases, care is provided in the patient's home." (COMAR 10.24.13.03.) The most common type of hospice care is home-based care, which is a routine level of hospice care that is provided in the patient's residence (whether that is the patient's home or some other location, such as a nursing home). Hospice providers also must be able to provide general inpatient care – a higher level of hospice care – to their patients, either by themselves or through arrangements with other

providers, including hospitals. (*See* 42 C.F.R. § 418.108.) This level of care, however, is limited by Medicare law, which limitation should be recognized in the CON process.

The State Health Plan also recognizes that hospice utilization has increased in locations other than the patient's home. (COMAR 10.24.13.03.) Nursing homes and assisted living facilities more frequently utilize hospice, and residential hospices and inpatient units have increased in number. Furthermore, historically different population groups that, in the past, have been reluctant to utilize hospice, have increasingly turned to hospice providers. The cultural barriers that once prevented use have been increasingly addressed through public information and education and positive hospice experiences in those communities.

A hospice provider's size, scope, and location are critical elements to serving Maryland's hospice population. In the State of Maryland, the majority of hospice providers are not-for-profit entities. Non-profit hospice programs are the programs more often providing services to Maryland's more vulnerable populations, including children. These populations often seek inpatient services and have a shorter length of stay than for-profit entities.

As further detailed in the attached form, Gilchrist believes that the CON regulation of general hospice services should, in general, be maintained in its current form. If the Triple Aim framework is truly a goal, we believe that the CON regulations help achieve these goals of patient safety, access to quality care, and lower costs. But the process could be improved. It is noteworthy that "[h]ospice enrollment rates are unrelated to the number of hospices in a state." (MedPAC 2010 Report to Congress, p. 149, Figure 2E-1.) We recommend that the MHCC CON Workgroup consider our comments, which include suggestions to revisit the current need methodology for general hospice licensure and to establish a need basis for acute inpatient care facility beds.

Sincerely,

Catherine Y. Hamel
President

cc: Richard E. Moffitt, PhD (via email: robert.moffit@heritage.org)

COMMENT GUIDANCE – GENERAL HOSPICE SERVICES
MHCC CON STUDY
2017-2018

Please consider your answers in the context of Maryland's commitment to achieve the goals of the Triple Aim[1] and its aspiration to bring health care spending under a total cost of care model beginning in 2019. Please provide a brief explanation of the basis for your position(s) in each area of inquiry beginning with the overarching question regarding continuation of general hospice CON regulation. All responses will be part of the Maryland Health Care Commission's public record for the CON Workgroup.

Need for CON Regulation

Which of these options best fits your view of general hospice CON regulation?

□ CON regulation of general hospices should be eliminated. [If you chose this option, many of the questions listed below will be moot, given that their context is one in which CON regulation would continue to exist. However, please respond to Questions 12 and 13.]

□ CON regulation of general hospice services should be reformed.

■ CON regulation of general hospice services should, in general, be maintained in its current form.

ISSUES/PROBLEMS

The Impact of CON Regulation on General Hospice Service Competition and Innovation

1. In your view, would the public and the health care delivery system benefit from more competition among general hospice programs?

Neither the public nor the health care delivery system would benefit from more competition. In Maryland's urban jurisdictions, there are six to seven current licensed providers. In the rural areas of the state, there are sole providers who by rights are protected from undue competition. These more rural areas would not support the fiscal requirements of additional hospice organizations.

It is also important to note that current CON regulation doesn't entirely eliminate competition. It provides limits to entry into or expansion in the market, but the free market determines the provider's survival. As competition among existing hospice providers is adequate and sufficient to offer patients choice, removing the barriers to entry will not necessarily improve services. In fact, it may have a detrimental impact. Removal of the CON process will likely result in an influx of new hospice providers all over the State. Each new provider would have to be

[1] The Institute for Healthcare Improvement's "Triple Aim" is a framework that describes and approach to optimizing health system performance. It is IHI's belief that new designs must be developed to simultaneously pursue three dimensions: 1) improving the patient experience of care (including quality and satisfaction); 2) improving the health of populations; and 3) reducing the per capital cost of health care.

reviewed and licensed. Each new provider would open and market heavily for new patients. But a truly free market anticipates that many providers will not survive, which is the case in many parts of the country. Hospice care is not a service well-suited for the whims of the free market. In hospice, one expects to be cared for until life expires. An oversaturated market would guaranty that providers may abruptly close, potentially creating trauma for hospice patients and their families. This also can cause patient confusion with facilities open one day and closed the next. In addition, the careful selection of hospice providers into the market based upon need helps ensure that patients most in need receive quality services in their same geographic area. Without the CON process, more populous areas attract providers, less populated areas are ignored. Utilization drives revenue, and more heavily populated areas drive more utilization;

The Hospice & Palliative Care Network of Maryland has performed research that indicates that Maryland might experience the following negative impacts should CON be relaxed or removed:

- **Growth in Number of Hospices.** If the CON process was removed in Maryland, some amount of growth in the number of providers is a certainty, based on the pace of growth in states without CON in recent years. For instance, between 2009 and 2014, the number of hospice agencies in California expanded from 231 to 501, a startling 117% increase. Non-CON states more comparable to Maryland in population and percentage of population over 65 have also experienced growth across a wide range. Over all 50 states, the total number of new agencies in CON states was 15; whereas non-CON states added 736. In general, more growth has occurred in southwestern and western states (average 36%) and in the for-profit sector (739 new for-profit agencies versus 12 new non-profit). On average, the number of hospices in CON states has increased by one new agency over the five-year span. In non-CON states, the number of hospices has increased by an average of 21 new agencies.

- **Growth in For-Profit and Multistate or National Service Providers.** Growth in the number of agencies is one issue; another is the kind of agency that would likely be added and how that might impact overall quality of care. In large part, due to controlled growth in the number of agencies, CON states have maintained a higher percentage of community-based, freestanding, and nonprofit agencies versus corporate, multi-location for-profit agencies. On average nationally, nonprofit hospices are 32% of the total; in non-CON states, over 50%. In general, and not as an absolute rule with respect to any one hospice agency, for-profit hospices tend to perform less well (i.e., divergent from national averages and industry norms) in currently available quality measures such as length of stay, percent patients discharged alive, average Medicare reimbursement per patient, etc. In Maryland, currently, of the 27 active hospices, seven are for-profit and six of the seven are branches of multistate or national corporate entities. Significant new growth in this class of agency is to be expected if CON is discontinued.

- **Growth from Outside Hospice.** If the hospice CON process was eliminated in Maryland, there may be extensive growth in the number of hospices from outside the hospice community by other provider types. Growth from this sector would likely contribute to a number of new agencies at the high end of the projected range and from providers not as thoroughly steeped in hospice philosophy or trained in specialized palliative skills. Growth in this sector is likely also to be for-profit and multistate or national.

Adding more hospices will not assure more hospice access. As the Medicare Payment Advisory Commission has noted, "recognizing that the raw number of hospices may not be the best measure of provider capacity, we examined the relationship between the supply of hospices and the rate of hospice use among Medicare decedents across states." (MedPAC 2010 Report to Congress, p. 148). MedPAC further concluded, "**Hospice enrollment rates are unrelated to the number of hospices in a state.**" (*Id*, p. 149, Figure 2E-1.)

2. Does CON regulation impose substantial barriers to market entry for new general hospices or expansion of general hospice service areas? If so, what changes in CON regulation should be implemented to enhance competition that would benefit the public?

The CON regulations impose barriers to market entry, but that is part of the point of the CON process, and sufficient competition exists in the market with the existing CON process in place. The regulations impose barriers that regulate need and sufficiency of services, but the CON process does not regulate those providers once they enter the market. It is up to each provider to ensure its own survival once approved. The CON process does not eliminate market influences, it merely delays them a little. We are unaware in the markets served by Gilchrist of waiting lists that would indicate a need for more care.

Furthermore, CON regulation in and of itself, is not the answer. The entire health care community must engage to improve end of life. Given the penetration of academic teaching institutions, Maryland hospice ranks **42nd for its use and 37th for its length of stay**, out of all 50 states (with 1st being the highest). It would be in the best interest of Marylanders for the Commission to educate the medical community and the community at large about the benefits of high quality end of life care. While the hospices spend a fair amount of time and resources in these activities, Gilchrist alone spends over **$1 million** annually in these activities. The MHCC and other government entities should participate as well. Requiring other areas of the health system and physicians to engage in appropriate end of life discussions would be a welcome addition to our work. As noted, by MedPAC, enrollment rates are <u>not</u> related to the number of hospices.

3. How does CON regulation stifle innovation in the delivery of general hospice services under the current Maryland regulatory scheme?

The current CON regulations do not stifle innovation in the delivery of general hospice services. As noted above, the CON regulations restrict entry into the market, but do not restrict competition or innovation among existing providers. There is little need for additional market competition in the hospice industry. Gilchrist alone has engaged in the following innovations since 2010:

- Created a hospice program, Gilchrist Kids, serving children and those who love them. Together with seven other hospices in Maryland and Delaware, we now operate Alliance Kids a network of not-for-profit hospices providing care throughout most of the state of Maryland, DC and Delaware.

- Expanded our Towson inpatient unit by ten beds and opened a new facility, the first of its kind in Howard County.

- We acquired the Joseph Richey Hospice, **invested $6.1 million** in operating and capital investments for this operation to assure that Baltimore's Homeless have a safe, comfortable place to die.

- We now operate a music therapy program, (three full time employees) caring for hundreds of dying patients suffering from memory loss disorders who would otherwise die agitated and without a voice.

- We established an Elder Medical Program where we care for older adults who can no longer safely get to a medical office for care. On average these patients are 75 years of age or older, are suffering from a serious illness, need assistance with activities of daily living, and take 20-25 medications daily. We have 350 patients enrolled well in advance of hospice care. Our CRISP reports indicate that we save **$30,000 per enrollee** annually in avoidable healthcare utilization. Twenty of these enrollees have telehealth units in their homes through a grant with the MHCC. This is approximately **$10.5 million in savings** to the state. In addition, we have an additional 5,500 nursing facility patients under the Elder Medical Program.

- We are one of 70 hospices enrolled in the Medicare Choices innovation grant. This allows us to offer hospice eligible patients suffering from Cancer, CHF, COPD or HIV who want to pursue active treatment the option of continuing their traditional Medicare benefits, allowing them to pursue treatment while also receiving hospice care. Our program has over 70 current enrollees and is one of the largest programs in the country. 93% of the enrollees ultimately enroll in traditional hospice.

- We have established a partnership with a hospice in Tanzania. We raise their annual operating budget, which is just shy of $70K annually. We have provided access to morphine,

arranged for the purchase and delivery of an ambulance, providing training in wound care and drug therapy and hosted their team in the USA twice. We have sent two travel teams to Africa where we learn how to do more with less.

In addition to these highly innovative programs, Gilchrist has doubled its overall hospice census and maintained its reputation for providing the finest care through the end of life. We believe that an increase in providers would actually diminish our ability to innovate. Our colleagues in non CON states report spending much of their time "hunting" and competing for patients. We would contend that the CON regulation actually assure the highest level of innovation.

4. Outline the benefits of CON given that hospice services do not require major capital investment, do not induce unneeded demand, are not high costs and usually do not involve advanced or emerging medical technologies.

The key benefit of the CON process with regard to hospice care, and particularly care for the needy, is that it supports avoidance of unnecessary services and encourages more services where they are needed. Note that non-profits hospice providers rely on donations to fund high cost acute inpatient hospice care, care for the poor and homeless, and care for children.

Free-market competition among hospice providers would not leave room for non-profit hospice providers who largely care for patients who are not the focus of for-profit facilities: the poor and the homeless, even children. Nonprofit hospice programs would suffer the most without the CON process, and those programs are the ones that serve children, and the underserved populations, have a shorter length of stay, and tend to have more inpatients. In states without CON the amount of fraud is higher than what we see in Maryland. (*See* MedPAC Report to Congress: Medicare Payment Policy (March 2014), p. 221.) Additionally, the Hospice and Palliative Care Network, (our state association) provides a venue for all Maryland based hospices to share best practices. This collegial partnership assures that care is consistent throughout the state for all Marylanders.

Scope of CON Regulation

Generally, Maryland Health Care Commission approval is required to establish a general hospice, increase the bed capacity (general inpatient hospice care) of a general hospice, or expand the service area of an existing general hospice into new jurisdictions. For a more detailed understanding of the scope of CON and exemption from CON review requirements, you may wish to review COMAR 10.2f 01.02 - .04, which can be accessed at:
http:// www.dsd.state.md.us/comar/Subtitle5earch.aspx?search=10.24.01.

5. Should the scope of CON regulation be changed?
   A. Are there general hospice projects that require approval by the Maryland Health Care Commission that should be deregulated?

The scope of the CON regulation appears sufficient at this time. We are not aware of any general hospice programs that should be deregulated.

B. Are there general hospice projects that do not require approval by the Maryland Health Care Commission that should be added to the scope of CON regulation?

We are not aware of any general hospice projects that do not require approval by the MHCC that should be added to the scope of the CON regulation.

The Project Review Process

6. What aspects of the project review process are most in need of reform? What are the primary choke-points in the process?

The timeliness of the CON process is in the most need of reform. While there are existing regulations which set forth the timeline for review, they typically are neither followed nor upheld. In addition, for hospice providers, the need methodology and timeliness of data upon which the need methodology is determined should be re-examined. While there is a current methodology for the addition of general hospice programs, the current methodology does not make adequate adjustments for the well-known and well-documented "under" utilization of hospice by minorities, specifically African Americans. To be held to a Caucasian standard when Maryland minority percentage is 30% when compared to 14% nationally, is inappropriate. In addition, when there is a bona fide need for additional hospice providers, there is no agreement on the number of providers that will be added at any given time. Adding a provision that defines this, making an adjustment for the number of providers to be granted CON's and establishing a "need" methodology for acute inpatient beds, would be welcome additions to the current regulations.

7. Should the ability of competing general hospice programs or other types of providers to formally oppose and appeal decisions on projects be more limited?

   Are there existing categories of exemption review (see COMAR 10.24.01.04) that should be eliminated? Should further consolidation of health care facilities[2] be encouraged by maintaining exemption review for merged asset systems?

Competing general hospice programs or other providers should continue to have an opportunity to contribute to and participate in the CON process. For one, this is statutorily mandated. In addition, the State's goal should be to continue to make health care transparent. Transparency would include giving other providers an opportunity to oppose or comment on proposed facilities. Currently, there is wide berth to who might participate in a CON discussion. Under

[2] Under Maryland CON law, home health agencies are classified as "health care facilities".

COMAR 10.24.01.01(20), an "Interested Party" means a person recognized by a reviewer as an interested party and may include: the applicant for a proposed project; the staff of the Commission; a third-party payor who can demonstrate substantial negative impact on overall costs to the health care system if the project is approved; a local health department in the jurisdiction, or, in the case of regional services, in the planning region in which the proposed service is to be offered; and a person who can demonstrate to the reviewer that the person would be adversely affected, in an issue area over which the Commission has jurisdiction, by the approval of a proposed project. This broad definition permits broad participation in the process and should be maintained.

8. Are project completion timelines, i.e., performance requirements for implementing and completing projects, realistic and appropriate? (See COMAR 10.24.01.12.)

Project timelines appear to be realistic and appropriate at this time.

The State Health Plan for Facilities and Services

9. In general, do State Health Plan regulations for general hospice services provide adequate and appropriate guidance for the Commission's decision-making? What are the chief strengths of these regulations and what do you perceive to be the chief weaknesses?

The State Health Plan adopted by the Commission does not provide a specific need methodology for acute inpatient facility hospice beds, which is a problem. But the Commission still is required to consider whether the applicant has met its burden of persuasion that the applicant has demonstrated "unmet needs of the population to be served." The Commission's application form asks the applicant to "discuss the need of the population served or to be served by the Project" and notes that "[r]esponses should include a *quantitative analysis* that, at a minimum, *describes the Project's expected service area, population size, characteristics, and projected growth.*" It also adds, "For applications proposing to address the need of special population groups identified in this criterion, please specifically identify those populations that are underserved and describe how this Project will address their needs." *Id.* This is not the same thing as a market analysis to determine whether to enter a market, which focuses solely on profitability.

Other chief weaknesses of the SHP for hospice are the lack of projections and infrequent reviews. We note and agree with the comments of the Hospice Palliative Network with regard to their concerns and data supporting a reconsideration of the formula upon which need is determined.

10. Do State Health Plan regulations focus attention on the most important aspects of general hospice projects? Please provide specific recommendations if you believe that the

regulations miss the mark.

SHP regulations seem sufficient for the most important aspects of general hospice projects. We agree with the Hospice Palliative Network, however, that the SHP would benefit by adding quality markers related to impacting the total payor model, and specifically, the establishment of KPI's related to hospice and the SHP.

11. Are the typical ways in which MHCC obtains and uses industry and public input in State Health Plan development adequate and appropriate? If you believe that changes should be made in the development process for State Health Plan regulations, please provide specific recommendations.

The manner in which MHCC obtains and uses industry and public input seems to be appropriate at this time.

General Review Criteria for All Project Reviews

COMAR 10.24.01.08G(3)(b)-(f)) contains five general criteria for review of all CON projects, in addition to the specific standards established in the State Health Plan: (1) Need; (2) Availability of More Cost-Effective Alternatives; (3) Viability; (4) Impact; and (5) the Applicant's Compliance with Terms and Conditions of Previously Awarded Certificates of Need.

12. Are these general criteria adequate and appropriate? Should other criteria be used? Should any of these criteria be eliminated or modified in some way?

Additional criteria that should be considered in the CON process:

- In what manner does the proposed project support the State's commitment to total cost of care restraint? Note that the only way the State of Maryland can survive in a total cost of care environment is to control and avoid unnecessary utilization. The Total Medicare Spend annually is estimated at $600 billion annually. A third of those expenses are attributed to care during the last year of life by 5% of the total Medicare beneficiaries. Only 15% of the $200 billion is spent on hospice care which means that 85% of these costs are likely "futile" treatments. Increasing the use of hospice care is critical to Maryland's success with Phase II of the CMS waiver. Lowering costs is irrelevant to any service other than a hospital because providers get paid the same under Medicare (except for modest differences due to location). Significant reductions in hospital expenditures are insufficient to make up for increased Part B expenditures and nonhospital Part A expenditures provided by nonhospital providers. Elimination of the CON process entirely will encourage additional providers which, in order to survive, have to attract additional patients. Total cost of care control is impossible in that setting.

- In what manner does the proposed project consider affordability to the patients?

  The provision of charitable care should be deemed an important element in the CON evaluation process.

CHANGES /SOLUTIONS

Alternatives to CON Regulation

13. If you believe that CON regulation of general hospices should be eliminated, what, if any, regulatory framework should govern establishment and service area expansion of home health agencies?

We do not believe the CON regulation of general hospices should be eliminated.

14. Are there important benefits served by CON regulation that could be fully or adequately met with alternative regulatory mechanisms? For example, could expansion of the scope and specificity of general hospice licensure requirements administered by the Maryland Department of Health serve as an alternative approach to assuring that these services are well-utilized and provide an acceptable level of care quality, with appropriate sanctions to address under-utilization or poor quality of care?

The Department of Health and Human Services should not be involved in the CON process. The DHHS serves a different purpose. It ensures existing providers meet the minimum regulatory requirements for the provision of services. As noted above, the CON process is and should remain a benchmark for entry into the market, not for continuation in the market.

The Impact of CON regulation on General Hospice Competition and Innovation

15. Do you recommend changes in CON regulation to increase innovation in service delivery by existing general hospice programs and new market entrants? If so, please provide detailed recommendations.

We do not recommend changes in CON regulation to increase innovation in service delivery. We have discussed the innovation that the CON process promotes in some detail in question number three.

16. Should Maryland shift its regulatory focus to regulation of the consolidation of general hospice programs to preserve and strengthen competition for home health agency services?

We do not believe Maryland should shift its regulatory focus to regulation of the consolidation of general hospice programs to preserve competition for home health services. The two services

respond to different factors, treat different patients, and are paid under a different regulatory scheme.

The Impact of CON Regulation on General Hospice Access to Care and Quality

17. At what stage (prior to docketing or during project review) should MHCC take into consideration an applicant's quality of care performance? How should applicants be evaluated if they are new applicants to Maryland or to the industry?
Note: docketing is the determination by the MHCC when an application is judged complete and ready for review.

The MHCC should take into consideration the applicant's quality of care performance throughout the CON application process. The CMS PEPPER report, HIS and CAHPS data and accreditation survey information should be considered when evaluating new applicants.

Scope of CON Regulation

18. Should MHCC be given more flexibility in choosing which general hospice projects require approval and those that can go forward without approval, based on adopted regulations for making these decisions? For example, all projects of a certain type could require notice to the Commission that includes information related to each project's impact on spending, on the pattern of service delivery, and that is based on the proposals received in a given time period. The Commission could consider staff's recommendation not to require CON approval or, based on significant project impact, to require the general hospice project to undergo CON review.

The MHCC should not necessarily be given more flexibility in choosing which general hospice projects require approval and those that can go forward without approval. To do so would take away the ability of the public to oppose or comment on new projects, and puts more power in the hands of the Commission. We would suggest, however, that the Commission consider making the process to move a bed more streamlined. An existing provider should be able to move beds with a much more abbreviated review, simply because most of the requirements under consideration for the bed need already have been evaluated and determined.

19. Should a whole new process of expedited review for certain projects be created? If so, what should be the attributes of the process?

With the exception of moving a bed, as noted above, a whole new process of expedited review for certain projects should not be created for hospice projects.

The Project Review Process

20. Are there specific steps that can be eliminated?
21. Should post-CON approval processes be changed to accommodate easier project

modifications?

22. Should the regulatory process be overhauled to permit more types of projects to undergo a more abbreviated form of review? If so, please identify the exemptions and describe alternative approaches that could be considered?
23. Would greater use of technology, including the submission of automated and form-based applications, improve the application submission process?

Elimination of steps, easier project modifications, and abbreviated reviews each may contribute to improving the process, but these proposals are fact-specific. If there is a specific proposal related to any of these elements, it should be considered, but not simply approved for the sake of eliminating a step. It is recommended that the CON application process remain consistent with technological trends in general, once they have had an opportunity to be tested and proven useful. At this time, the technological use appears to be consistent with trend.

Duplication of Responsibilities by MHCC and MDH.

24. Are there areas of regulatory duplication in general hospice regulation that can be streamlined between MHCC and MDH?

Not at this time, the departments serve different functions.

Thank you for your responses.