STATE OF MARYLAND

Robert E. Moffit, Ph.D.
CHAIR

Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

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

July 31, 2018

By E-Mail and USPS

Howard L. Sollins, Esquire
Baker Donelson
100 Light Street
Baltimore, Maryland 21202

Re: P-B Health Home Care Agency
Deficiencies in Pending Application
Prince George's County Hospice Review.
Docket No.: 16-16-2385

Dear Mr. Sollins:

By letter dated June 29, 2018, I advised the four applicants in the Prince George's County Hospice Review that no application met all the required standards and criteria applicable to this review. I suggested a method by which, if all applicants agreed, each applicant would be able to modify its Certificate of Need ("CON") application to correct deficiencies more quickly than through the traditional project status conference procedure set out in COMAR 10.24.01.09A(2). The four applicants – Amedisys Maryland, LLC d/b/a Amedisys Hospice of Greater Chesapeake ("Amedisys"); BAYADA Home Health Care, Inc. d/b/a BAYADA Hospice ("Bayada"); Montgomery Hospice, Inc.; and P-B Health Home Care Agency ("P-B Health") – agreed to proceed by way of project status conference that will be conducted in writing.

As I noted in my earlier letter, I will identify the deficiencies in each of the applications filed in this review in separate letters to each applicant. Each applicant will have an opportunity to correct the identified deficiencies.

Procedural status of P-B Health's application

P-B Health's application is in a different procedural posture than the other three applications. All four applications were docketed on April 28, 2017 by notice published in the *Maryland Register*, 44 *Md. Reg.* 453. The notice provided that interested party comments were due on May 30, 2017. Each applicant except P-B Health filed comments on the other applications and sought interested party status.

Important to the procedural posture of P-B Health's application are the requirements in COMAR 10.24.01.08E(2), which detail the three circumstances under which an application in a comparative review may be modified: (1) within 45 days of docketing; (2) as the "result of a project status conference held pursuant to Regulation .09A"; or (3) with the consent of each applicant in the comparative review. P-B Health's current counsel provided notice to the Maryland Health Care Commission ("Commission") on June 11, 2017 that the firm was representing P-B Health. On June 12, P-B Health's counsel advised the other applicants that his firm was representing P-B Health and sought their agreement for extension until June 21, 2017 for filing responses to comments and for P-B Health to file a modification of its application. The other applicants agreed that all four applicants could have until June 21, 2017 to respond to comments, but did not agree to an extension for filing modifications to the application.

P-B Health submitted a modification of its application to the Commission on June 14. Counsel to the Commission notified P-B Health that its modification was not submitted within 45 days of docketing as required by COMAR 10.24.01.08, and that consent of the other three applicants was required for a modification to be accepted. The three applicants agreed to the two-day extension, permitting P-B Health's June 14, 2017 filing to be accepted as a modification of its application.

On June 21, 2017, all four applicants filed responses to comments as agreed. In its responses to comments, however, P-B Health went beyond responding to comments made by the other applicants, which in accordance with COMAR 10.24.01.08F(1)(c),

> state[d] with particularity the State Health Plan standards or the review criteria in §G of this regulation that the person seeking interested party status believes have not been met by the applicant and the reasons why the applicant does not meet those standards or criteria.

In its June 21, 2017 response to comments, P-B Health stated that it agreed to take certain actions or make changes. Such statements could not modify P-B Health's application. I find that those statements and any later explanations, to the extent they purport to modify the application, are outside the record in this review. COMAR 10.24.01.08E(2), the CON procedural rule regarding modification to an application, is precise, unambiguous, and must be followed. Through this written project status conference, however, P-B Health will have an opportunity to modify its application in accordance with the procedural rules.

I will detail the deficiencies in P-B Health's application[1] by reference to the applicable standard in COMAR 10.24.13, the State Health Plan for Facilities and Services: Hospice Services ("Hospice Chapter") and to the CON review criteria, COMAR 10.24.01.08G(3). Included in the identified deficiencies are those that P-B Health attempted to correct outside the regulatory framework for modifying an application.

[1] My reference to P-B Health's application in this letter includes P-B Health's original application, its responses to the three rounds of completeness questions asked by Commission staff, and (if applicable) its June 14, 2017 modified application.

COMAR 10.24.13.05B. Admissions Criteria. An applicant shall identify:

(1) Its admission criteria; and

In its application, P-B Health responded to this standard by stating that, prior to admission, each patient must have: "Advance Care Directives for Finances"; "Advance Care Directives for Health Care"; and a "Do Not Resuscitate (DNR) order …." (DI #3, pp 16-17).

In its response to comments by Bayada and Montgomery Hospice regarding this standard, P-B Health stated that it would not require advance directives and would assist patients who desire them. It also stated that it would not require Do Not Resuscitate orders. (DI #24GF, p.11).

I conclude that the requirement in P-B Health's application for legal documentation such as medical and financial directives prior to admission is unreasonable because, unfortunately, many patients are unlikely to discuss these topics in advance of a crisis. Furthermore, it is inconsistent with the Medicare conditions of participation. A requirement that a patient have a Do Not Resuscitate order prior to admission is also inappropriate. P-B Health must modify its application formally to detail its admission criteria appropriately in response to Subsection (1) of this standard.

(2) Its proposed limits by age, disease, or caregiver.

P-B Health addressed this standard in its application by stating that it would service patients who are 35 years of age or older and who did not have certain contagious diseases.

In its response to interested party comments regarding this standard, P-B Health stated that it would admit all adult hospice patients, not just those who are 35 years and older. (DI #24GF, pp 6-7). It also stated that it would accept patients with communicable diseases, (*Id.* at 11).

I conclude that it is important that new hospice entrants into Prince George's County serve adults under 35 (admittedly a small portion of those needing hospice services) so that the Commission's goal of increasing the use of this service in the County will more likely be achieved. P-B Health should also clarify that it will not be more restrictive than federal regulations in admitting patients with communicable diseases. P-B Health must modify its application formally to detail its responses to proposed limits in Subsection (2) of this standard.

COMAR 10.24.13.05C. Minimum Services.

…

(2) An applicant shall provide the following services … directly or through contractual arrangements:

…

(g) Volunteer services;

In its application, P-B Health responded to this standard by stating that "[v]olunteer services shall be direct thru patient family, close friends, and P-B Health Hospice's volunteers as needed." (DI #3, p. 23).

In response to interested parties' comments, P-B Health stated that it had contacted the leaders of the Maryland Chapter for Volunteers of several sororities and fraternities, as well as church and ministerial staff to recruit volunteers. (DI # 24GF, p. 7).

I note that, in response to interested parties' comments, P-B Health did not directly address its original statement that volunteer services would be provided by "patient family, close friends, and [its] volunteers as needed." P-B Health's initial response indicated that it did not have the requisite understanding of the important roles that volunteers play in a hospice program and that volunteers are a required component of hospice. It is likely that a hospice patient's family and close friends are already serving as caregivers. Trained hospice volunteers who are not closely connected to the patient and family can provide support and relief to the patient's family and close friends. Volunteers can also help to support the hospice staff by performing administrative tasks as needed. I note that Medicare's conditions of participation require that a hospice's volunteers provide administrative and/or direct patient care services in an amount that equals or exceeds 5% of the total patient care hours of all paid hospice employees and contract staff. 42 CFR 418.78(e). P-B Health's response to comments show that it has started to make strides in establishing a volunteer base that is more likely to serve better the needs of its program and patients; however, P-B Health must modify its application formally to detail its response to Paragraph .05C(2)(g) of this standard.

(i) Pharmacy services

P-B Health's application stated that it would provide pharmacy services through CVS, Walgreens, and a patient's pharmacy in accordance with the patient's health care benefits.

Bayada's comments raised valid questions regarding how P-B Health would assure needed access to compounded and Schedule II controlled medications, as well as routine and after-hours delivery of medications. In its response to comments, P-B Health stated that it had "reached out to pharmacies experienced in working with hospice providers for hospice pharmacy services."

I conclude that P-B Health must modify its application in response to Paragraph (i) of the standard to state whether, as indicated in its response to comments, it will provide pharmacy services contractually. Ideally, it will identify the pharmacies to whom it has reached out that are experienced providers of hospice services, including routine and after-hours delivery of compounded, controlled substance, and other medications that may be needed for hospice patients. I would like for P-B Health to provide at least one letter expressing such an experienced pharmacy's interest in providing these services.

My discussion of P-B Health's response to Paragraph (i) regarding pharmacy services completes my analysis of attempted changes raised in P-B Health's June 21, 2017 response to

comments, for which it must formally modify (and expand as necessary) its responses to applicable standards in its application.

Minimum Services, COMAR 10.24.13.05C(2), continued.

> **(a) Physician services and medical direction;** [and]
> **(c) Spiritual services** . . ..

P-B Health must clarify whether each of the above listed types of services will be provided directly or through contractual arrangements, that is whether the person(s) providing the service in each category will be employee(s) of P-B Health or whether the services will be delivered by person(s) with whom P-B Health has or will establish contractual arrangements.

COMAR 10.24.13.08J. Charity Care and Sliding Fee Scale Standard
Each applicant shall have a written policy for the provision of charity care for indigent and uninsured patients to ensure access to hospice services regardless of an individual's ability to pay and shall provide hospice services on a charitable basis to qualified indigent persons consistent with this policy. The policy shall include provisions for, at a minimum, the following:

> **(1) Determination of Eligibility for Charity Care. Within two business days following a patient's request for charity care services, application for medical assistance, or both, the hospice shall make a determination of probable eligibility**.

P-B Health does not comply with Subsection (1) of the Charity Care standard, which requires it to have both a policy and a process that assure that it will make and communicate a determination of probable eligibility for charity or reduced fee care within two business days of a patient's request for charity care, application for Medical Assistance ("Medicaid") or both. P-B Health's response to this Subsection stated that it would make "every effort" to make a determination of probable eligibility and communicate that determination within two business days of request for charity care or application for Medicaid. (DI #3, p. 31).

The wording of the Commission's charity care standard regarding a determination of probable eligibility is generally consistent across regulated facilities and services. Some facilities meet the requirement to make a determination of probable eligibility for charity or reduced fee care within two business days of request by having a two-step process. The first step, the determination of *probable* eligibility, should be based on an abridged set of information, and must result in the provider communicating its determination of probable eligibility to the potential patient or family within two business days of request or application for Medicaid. This process may consist simply of an interview that discusses matters such as family size, insurance, and income. The second part of the process, which results in a *final* determination of eligibility for charity care or reduced fees, may be based on a completed application with required documentation.

P-B Health must revise its charity care and sliding fee scale policy and procedures to comply with subsection (1) of the standard. It must distinguish between what is required for a determination of probable eligibility and what is required for a final determination.

> **(2) Notice of Charity Care Policy. Public notice and information regarding the hospice's charity care policy shall be disseminated, on an annual basis, through methods designed to best reach the population in the hospice's service area, and in a format understandable by the service area population. Notices regarding the hospice's charity care policy shall be posted in the business office of the hospice and on the hospice's website, if such a site is maintained. Prior to the provision of hospice services, a hospice shall address any financial concerns of patients and patient families, and provide individual notice regarding the hospice's charity care policy to the patient and family.**

P-B Health stated that it would inform the community of its charity care policy through an annual public notice posted in the classified section of the newspaper and provided the wording of the notice it said it would post. I note that P-B Health's notice gives no information to a potential hospice patient/family that it will make and communicate a determination of probable eligibility within two business days.

I question whether notice in the classified section of a newspaper is one of the "methods designed to best reach the population in the hospice's service area" as provided in the standard. (DI #6, App. D, Exh. 3, p. 26). P-B Health should reconsider whether a notice in the newspaper is a method designed to reach its service area population. Of course, P-B Health may have a newspaper in mind that is actually read by the population that is more likely to need charity or reduced fee hospice care.

Subsection (2) of the standard requires the notice to be posted in the hospice's business office and on its website in an easily accessible location (so that it will be more likely to reach the population). P-B Health must commit to making such postings. P-B Health must also revise its notice to advise a potential hospice patient/family that it will make and communicate a determination of probable eligibility within two business days of request for charity or reduced fee care, application for Medicaid, or both.

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

P-B Health provided a sliding fee scale that identified the level of reduced fees that a patient will receive based on the federal poverty guidelines (FPG). (DI #3, p. 33). The "P-B Health Sliding Scale for Financial Assistance" contained in its application shows that no patient is entitled to a full charity care. In fact, even patients who are at or below the 100% Federal Poverty Guideline ("FPG") only receive a 90% discount. (DI #3, p. 33). While P-B Health's application states that

patients who fall below 200% FPG may apply for charity care, there is no indication that any patient will receive full charity care.

The Hospice Chapter shows that a hospice is expected to provide services at no charge to eligible patients. Specifically, Subsection (3) provides that the sliding fee scale must include provision for "low-income patients who do not qualify *for full charity care*." (emphasis added). P-B Health must revise its sliding fee scale to show who qualifies for full charity care.

> **(4) Policy Provisions. An applicant proposing to establish a general hospice, expand hospice services to a previously unauthorized jurisdiction, or change or establish inpatient bed capacity in a previously authorized jurisdiction shall make a commitment to provide charity care in its hospice to indigent patients. The applicant shall demonstrate that:**

P-B Health did not make a commitment to provide a level of charity care, but instead stated that its home health agency "has provided charity care averaging around the historical averages [for home health] for the past five years." (DI #6, p. 10 and Appx. D, Exh. 6). An applicant must make a commitment to provide a level of charity care that it designates. For frame of reference, I note that, over the three-year period 2014-2016, hospices operating in Prince George's County provided an average percentage of 2.1% charity care days (of total patient days); over this same time period, Maryland hospices overall provided an average percentage of .73 charity care days.

Subsection (4), especially when read in conjunction with Paragraph (4)(b),[2] requires an applicant to commit to achieving a certain level of charity care. Regarding Paragraph (4)(b), P-B Health described its outreach plans which included additions to its "brochures for mailing to Senior Information and Assistance Offices, church organizations, and community resource centers during meet and greet sessions and in services about hospice, and advertised in our office yearly." (DI #6, p. 10). P-B Health's plan is appropriate; however, it must make a commitment to provide a specified level of charity care and, as necessary, revise its responses to Paragraphs (4)(a) and (b).

In addition, P-B Health must provide copies of all applicable (existing or revised) forms, notices, and information that are designed to comply with or implement the Charity Care and Sliding Fee Scale standard. This includes all public notices, posted notices, notices to be posted on its website, in its business office, contained in material/brochures given to potential patients/families, as well as any application(s), etc. for charity care or reduced fees, and the description of processes for its employees to follow in implementing the Charity Care and Sliding Fee Scale standard, and other similar documents. P-B Health should assure that these materials comply with all parts of the standard and make the necessary distinction between: (1) information needed and its process for making a determination of probable eligibility; and (2) application, information, and/or documentation needed and its process for making a final determination of eligibility for charity care or reduced fee care. This is important because having a policy that

[2] COMAR 10.24.13.J(4)(b) requires an applicant to demonstrate that "[i]t has a specific plan for achieving *the level of charity care to which it is committed*." (emphasis added).

contains only the words of the standard, but that will not be implemented through practice, does not comply with the standard.

COMAR 10.24.01.08G(3)(d) Viability of the Proposal. The Commission shall consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project within the time frames set forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project.

To assess P-B Health's ability to sustain the project, I reviewed its projections for the final projected year in its application, as shown in the following tables: Table 2b (Statistical Projections), Table 4 (Revenue and Expense projections), and Table 5 (Manpower Information). I then calculated projected visits per patient-day for each discipline, annual visits per full-time-equivalent employee ("FTE") for each discipline, and cost and revenue per patient-day. I compared the results both among the applicants and with statewide averages to gain insight into the likely accuracy of its respective projections and business plans. See table below.

Comparisons of Visit Frequency, Staff Productivity, and Cost and Revenue/Patient-Day

	Calculated measures	Maryland Hospice average, 2016	Amedisys	Bayada	Montgomery Hospice	P-B Health
Visits by discipline/ pt-day	**Nursing Visits/Pt-day**	**.30**	.45	.31	.21	.33
	Hospice Aide Visits/Pt-day	**.32**	.35	.34	.18	.18
Productivity	**Annual Nursing Visits/FTE**	**893**	854	784	469	1,279
	Annual Hospice Aide Visits/FTE	**1,323**	738	1,149	563	1,385
Financial measures	**Revenue/Pt-day**	**$178.94**	$145.94	$207.57	$175.02	$165.48
	Cost/Pt-day	**$125.13**	$108.73	$175.69	$173.71	$67.23

Sources: Each applicant's projections for its final projection year in Table 2b (Statistical Projections), Table 4 (Revenue and Expense projections), and Table 5 (Manpower Information); and MHCC's 2016 Hospice Survey Public Use Data Files.

This analysis showed that P-B Health's projected nursing productivity, at 1,279 annual visits per FTE nurse, is 143% of the average of hospices in Maryland. P-B Health must explain how it will achieve this high level of productivity or modify its projections as appropriate. It must provide revised application tables as appropriate.

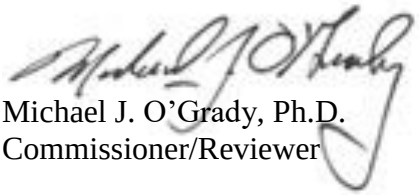
I also note that P-B Health's projected cost-per-patient-day ($67.23) is approximately half of the state average ($125.13) for hospices. P-B Health must explain how it expects to achieve such economies, or revise its projections accordingly. In addition, its hospice aide visits/patient day of .18 is just 56% of the state average. Please explain or revise as necessary.

If P-B Health's review of its response to the Viability criterion results in revisions of its projections, it should submit revised application tables, possibly including Tables 4, 5, and other tables as appropriate.

I request that P-B Health let me know by 4:30 p.m. on August 3, 2018, whether it chooses to modify its application or whether it will go forward with the application as filed. I also request that P-B Health and any other applicant that chooses to modify its application, let me know in its August 3 filing if it can file its modifications on or before August 17, 2018. As always, please copy all persons on the email by which this letter is sent on your response.

I remind all parties that this remains a contested case and that the *ex parte* prohibitions in the Administrative Procedure Act, Maryland Code Ann., State Gov't §10-219, apply to this proceeding until the Commission issues a final decision.

Sincerely,



Michael J. O'Grady, Ph.D.
Commissioner/Reviewer

cc: Marta D. Harting, Esq.
Margaret Witherup, Esq.
Timothy Adelman, Esq.
Paul E. Parker, Director, Center for Health Care Facilities Planning and Development
Kevin McDonald, Chief, Certificate of Need
Mariama Gondo, Program Manager
Suellen Wideman, Assistant Attorney General
Sarah E. Pendley, Assistant Attorney General
Pamela Brown-Creekmur, RN, Prince George's County Health Officer