BEFORE THE ARKANSAS HEALTH SERVICES PERMIT COMMISSION

In the Matter of
Arkansas Staff Assisted Hemodialysis
File # HSPA (1422)14

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

FINDINGS OF FACT

1. On April 28, 2014, the Health Services Permit Agency received an application for the June Cycle from Arkansas Staff Assisted Hemodialysis (Applicant) seeking a Permit of Approval (POA) for a Home Health Agency to serve Faulkner County from an office located in Little Rock, AR (Pulaski County).

2. The services to be offered are described in the application as:

   Patients will receive; Peritoneal Dialysis and Hemodialysis treatments at home with staff assisted nurse, along with individualized plan of care, which includes Social Worker & Dietitian individualized care.

3. The population based methodology set out at HSC Regulation 300M.A. reflects that the service area of Faulkner County has a minus six (-6) negative net need for home health agencies. This is acknowledged by applicant who relies on the “Exception” set out at HSC Regulation 300M.A.2.

4. The Exception to the methodology set out in HSC Regulation 300M.A. provides that “Approvals may be granted when the methodology does not show a need if the applicant offers documentation to prove that existing agencies are not meeting the needs of the service area population.”

5. In response to the need criterion, the Applicant provided the following:

   The need that the population served or to be served has for the proposed project. Explain the need for the proposed project by addressing each of the following items A. Methodology. Answer: Network 13, 2012 Annual Report show there was 702 Home Dialysis patients in the state of Arkansas. At that time and to present, there are no Staff-Assisted Home Dialysis Program in state of Arkansas, which offers patients the option to be dialyzed in the comfort and convenience of their home under the guidance of a licensed professional nurse.
Exception: Approvals may be granted when the methodology does not show a need if the applicant offers documentation to prove that existing agencies are not meeting the needs of the service area population. The application must meet the home health definition as required by the core services, etc. Answer: The existing Home Health Agencies do not provide, the proposed Home-Assisted Hemodialysis Service that Arkansas Staff Assisted Hemodialysis will provide.

6. In support of its exception claim, the Applicant provided the following:
   a. Statistical data compiled by Network 13, an organization that is part of a nationwide system of 18 Networks contracted by the Centers for Medicare Medicaid Services under the ESRD Program. ESRD Network 13 works with dialysis and kidney transplant centers and their patients in the states of Arkansas, Louisiana and Oklahoma.
   b. April 28, 2014 letter from Dr. Fakhar Ijaz, Nephrologist, Kidney Care Center, PLLC, Little Rock, Arkansas.
   c. May 21, 2014 letter from Q. Steve Ficklin, Project Consultant for applicant with attached Home Care Association of Arkansas information on services provided by existing Home Health agencies in the intended service area.
   d. May 19, 2014 letter report by Nancy Knighten, ASBDT Business Consultant, Arkansas Small Business and Technology Development Center, UALR College of Business, Little Rock, Arkansas with information on demographics, consumer spending on health care, and dialysis treatment in the proposed service area, including information from End Stage Renal Disease (ESRD) Network 13 Annual Report.

7. (a). Applicant attaches a “letter of interest” from Arkansas Capital Corporation Group stating that it is not a commitment to lend, but an expression of interest only, and is subject to numerous loan requirements. There are attached bank statements on three accounts that are in the names of the two “partners” of the applicant corporation with balances totaling $82,000. There is attached a bank statement on one account in the name BKG ESRD Nurse Consultant Company in the amount of $52,000, and there is a statement on an account that does not identify the owner except by the handwritten notation by applicant that is “Bank A/C for Ark Staff Assisted Hemodialysis, Balbeer K. Godwin, Monica E. Brooks” with a balance of $18,500. Assuming applicant’s entitlement to access all of these funds the total amount represents approximately one month’s operating expenses. No balance sheet or other financial information is supplied to establish the financial means and stability of applicant or any of its principals. Neither is there any information from which it can be determined if those partners have other assets or liabilities.
   (b). Applicant states that “the proposed agency will serve private pay and commercial insurance patients”. The projected annual operating budget included with the application
identifies “Private Insurance (Treatments)” as being the source of 95% of total anticipated revenues ($2,990,000.00 of projected total of $3,150,150.00).

8. To satisfy the cost containment criterion, applicant states its intention that “The proposed Agency will serve private pay and commercial insurance patients”. The Arkansas Medicaid program provides little if any payment for dialysis treatment. For a patient diagnosed with End Stage Renal Disease and requiring dialysis, Medicare and private insurance is the source of almost all dialysis treatment funding. Payment by either is generally limited to in dialysis center or hospital treatment or training of the patient or a caregiver for in home treatment. A Home Health Agency offering staff assisted dialysis treatment services, appears to be financially unstable and does not satisfy the criterion of Economic Feasibility. Staffing cost for skilled personnel would be extremely high and there is no evidence that it would be reimbursable by any potential payor source.

A Home Health Agency POA requires applicant to be capable of and therefore authorized to provide all “core home health services” The providing or coordinating of acute, restorative, rehabilitative, maintenance, preventive or health promotion services through professional nursing or by other therapeutic services such as physical therapy, occupational therapy, speech therapy, home health aide or personal services in a client's residence (HSC Reg. 001. Sec II. J). If the Agency issues the requested Permit of Approval for a Home Health Agency, applicant can implement any or all of these “core home health services” even though no evidence is offered of applicant’s intention or ability to do so. For the Agency to issue the requested POA would amount to a total disregard of the population based methodology that has been consistently applied to all other applicants wishing to engage in this type of Long Term Care activity. If, as applicant has stated, it merely wishes to engage in dialysis services only, there are numerous therapeutic, rehabilitative and health maintenance services which may wish to seek similar specialty permits and licenses.

The agency contacted Blue Cross Blue Shield which provides over 60% of private health insurance market in Arkansas. Their response indicated serious doubts about the proposal of applicant, raising serious questions about providing hemodialysis in a home setting and indicating it would not pay for such service without first conducting a serious medical investigation, before accepting applicant into their network of qualified providers. The agency contacted DaVita Kidney Care a major dialysis provider with four locations in central Arkansas. Their response indicated that their service includes in home dialysis training and follow-ups with their patients. The agency contacted UAMS, End Stage Renal Disease Department regarding a potential Home Health agency providing in home dialysis. The response given indicated serious doubt about cost associating with staffing of staff assisted in the home dialysis due to the numbers of trained and certified nurses and other specialists required for multiple hours of treatment on multiple days per week. They advised if the patient was not capable of performing their own dialysis then the patient would need to be in a setting other than a home. The agency also consulted the US government web sites on available dialysis services and on finding
certified dialysis facilities published by the Center for Medicare and Medicaid Services (CMS) and found at [www.medicare.gov/Pubs/pdf/10128.pdf](http://www.medicare.gov/Pubs/pdf/10128.pdf), and [http://www.medicare.gov/Dialysis](http://www.medicare.gov/Dialysis).

**CONCLUSIONS OF LAW**

1. Applicant’s application does not meet the need requirement as set forth in the Population-Based Home Health Methodology published in the Bed Need Book pursuant to HSC Reg. 300M.A.1.

2. Applicant has failed to meet the burden of proving an entitlement to a POA under the Exception provision of HSC Reg. 300M.A.2, for the following reasons:
   a. The nature and scope of the Applicant’s proposed services is undefined and contradictory. Applicant states that it will “teach the patient” but also says that it will provide “treatments at home with a staff assisted nurse”.
   b. There is no need for Home Health agencies to provide these services. The evidence shows that they are available through CMS certified dialysis service providers. The data supplied by applicant contains information to the effect that in 2012, 19.6% of Arkansas dialysis patients were utilizing home dialysis (Knighten letter of May 19, 2014, referencing ESRD Network 13 and CMS surveys). Applicants own narrative acknowledges that there are at least two Dialysis Centers that provide services for in-home hemodialysis patients, and some unstated number of others providing services for in-home peritoneal dialysis patients. The only such services which applicant asserts are totally unavailable are “after 5 P.M. and nocturnal”.
   c. Applicant does not provide sufficient evidence showing that there is an unmet demand for these services, or that they cannot be met by existing CMS Certified Dialysis Centers. All evidence indicates that existing certified dialysis providers are adequately serving the End Stage Renal Disease population for Faulkner County and central Arkansas. There is no indication based on information from the applicant or other sources that patients in Faulkner County are in need of services which cannot be provided by existing agencies either directly or by contract. Applicant has offered no reasons why, if it feels there is a gap in available dialysis services, it cannot itself apply to become so certified.
   d. A Home Health Agency POA requires applicant to be capable of and therefore authorized to provide all “core home health services”. HSC Reg. 001. Sec II. J. Applicant has provided no evidence of its intention or ability to do so.

3. The Agency cannot determine that the applicant has satisfied the requirement that the project can be adequately staffed and operated as required by HSC Reg. 001. Sec. IV.A.2. Although the proposed treatment services are stated to be delivered by two (2) RN’s and two (2) LPN’s, the staffing schedule only reflects two of each will be employed. Applicant in its own narrative states that, in the area to be served, there are “currently an estimated 92 openings for positions similar to those offered by” applicant.
4. Applicant does not satisfy the economic feasibility criteria for a Home Health POA as required by HSC Reg. 001. Sec. IV.A.3.

5. Applicant does not meet the cost containment criteria required by HSC Reg. Sec. IV. A.4.

6. The applicant plans to offer specialty services to the community but the awarding of a permit of approval would entitle the applicant to provide a full range of home health services in addition to the specialty services mentioned in the application. If limited specialty permits are to be issued, that would need to be authorized by action of the Commission or the Legislature.

ORDER

Based on the above Findings of Fact and Conclusions of Law, the Agency hereby orders that the applicant, Arkansas Staff Assisted Hemodialysis be **DENIED** a Permit of Approval (POA) for the purpose of providing Home Health Services to Faulkner County from an office in Little Rock, AR (Pulaski County).

Appeals before the Health Services Commission are provided for under Section V.B. 15, Policies and Procedures for Permit of Approval Review, and will be conducted in accordance with the State Administrative Procedure Act, Act 434 of 1967, as amended. Appeals will be heard on September 18, 2014 at the AR Dept. of Environmental Quality, 5301 Northshore Drive, North Little Rock, AR at 10:00 AM.

IT IS SO ORDERED THIS ____ DAY OF JULY 2014

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James Luker
DIRECTOR, HEALTH SERVICES PERMIT AGENCY