I. Request for Declaratory Ruling

Gambro Healthcare (Gambro) submitted a request for a declaratory ruling from the State Board. The request seeks two determinations: 1) that a demonstration program offered by Gambro to provide dialysis service to residents of skilled nursing facilities does not require a Certificate of Need (CON) or a Certificate of Exemption (COE) from the State Board; and, 2) that when clinical and other programmatic/administrative safeguards required by the demonstration program (or subsequent rules or regulations promulgated by the Centers for Medicare and Medicaid Services are met), that the provision of dialysis service to residents of skilled nursing facilities does not require a CON or COE for the long-term care facility, the dialysis training facility or the dialysis services and equipment providers even if the provision of this service occurs outside the parameters of the demonstration program.

II. Background Information

On January 20, 2004, the State Board received a request from Gambro seeking a declaratory ruling on the applicability of CON and COE requirements for the provision of dialysis services in nursing care facilities. Specifically, Gambro seeks a determination confirming that home dialysis training and support services for nursing home residents is not subject to the State Board's jurisdiction.

On October 24, 2003, the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services (CMMS) approved a demonstration program whereby a limited number of nursing home residents will formally receive home dialysis service within the confines of the nursing care facility where they reside. An overall goal of the demonstration program is to provide dialysis service to this medically fragile population within their primary residence. Providing the service under the demonstration program would not require the transport of these residents to a freestanding chronic dialysis facility nor would it require the establishment of a fully-certified dialysis unit within the nursing care facility. Gambro stated that under the demonstration program, it would be the provider of dialysis services; while Omnicare Infusion Services (Omnicare) would be the provider of dialysis equipment and supplies.
As part of the demonstration program, both Gambro and Omnicare will provide home dialysis services to nursing home residents in the Chicago area through a new dialysis training site in Des Plaines. Gambro emphasizes that an original purpose of the demonstration program is to develop a training facility dedicated to assisting nursing home residents, who elect the home dialysis provision, to have dialysis services within the skilled nursing facility. Gambro also states this will be the only demonstration program in the country offering home dialysis to nursing facility residents.

Under current CMMS guidelines, dialysis service to nursing care residents is provided in two fashions. First, a nursing care facility could establish a chronic dialysis facility. This type of service would allow the establishment of dialysis stations. These stations would subsequently be shared by residents and/or the general public. The establishment of this type of dialysis service would require a CON from the State Board. A second type of service available to nursing care residents is to provide dialysis under a home care option. Under this format, a nursing care resident could receive dialysis treatment directly at the nursing home; thus, effectively providing the service at the resident's "home." Under this home care option, however, each patient must specifically elect home dialysis as his/her treatment choice. Unlike a typical dialysis facility, each nursing home dialysis patient must complete an approved home dialysis training program that is furnished by an approved dialysis provider. Subsequently, the patient must elect the manner in which he or she will receive dialysis equipment and supplies. Additionally, each patient must have their individual supplies that are segregated from other dialysis patients, as well as a separate dialysis machine and other equipment which cannot be shared or used by other patients.

As part of the demonstration program, Gambro will provide professional assistance to ensure treatments are properly administered. The demonstration program will require care givers and technicians to have at least two years of dialysis experience. Gambro will also provide training to licensed health professionals who must be registered nurses or licensed practical nurses employed by or under contract with Gambro or under arrangements with the nursing facility. Gambro states it will be responsible for the clinical oversight of all facets of the dialysis services.

Gambro stresses that the training center is not designed to meet the continual and ongoing dialysis treatment needs of patients. Instead, it will furnish training to nursing home patients and their respective care givers and provide support services to the nursing care resident as needed. Gambro anticipates that a majority of nursing care residents will receive their training at the nursing home, rather than at the Des Plaines center. As a result, the training center will not function as a fully-certified dialysis facility. It will not provide service to the general dialysis population.

To ensure that these activities are properly executed, Gambro will enter into operational agreements with the participating skilled nursing facilities. These agreements will
encompass the following: 1) development of specific policies and procedures for the proper fulfilment of services; 2) development of appropriate consents and forms; 3) details for the coordination of care and services among the various providers; and, 4) the collection of appropriate clinical data to allow for the detailed study of this mode of treatment. Additionally, Gambro emphasizes it will provide all dialysis-related services. Gambro will also provide the necessary training to the skilled nursing facility staff for the special non-dialysis needs of the program’s patients.

To accomplish these objectives and to provide an optimal level of care, the operational agreements with Gambro and the participating skilled nursing facilities to designate specific portions of the facilities as the area where dialysis services will be provided. The selection of a particular area will allow the skilled nursing facility to make the necessary modifications so that clinical standards can be maintained (i.e., water purification, plumbing requirements, infection control, waste disposal, etc.). Further, the participating skilled nursing facility will need to have a nurse available to perform functions that typically are the responsibility of the nursing home (i.e., administration of medication and responding to emergencies). No skilled nursing facility staff will be responsible for the delivery of dialysis services.

Gambro explains that CMMS will reimburse the demonstration program under its home dialysis provisions. As such, Gambro believes the State Board’s rules on chronic end-stage renal disease treatment facilities do not apply. Because it believes the State Board’s rules are not applicable to the demonstration program, Gambro also believes the State Board should conclude these services are essentially home care services. Gambro clarifies that under CMMS’ rules for home dialysis care, the foremost consideration is the location where the patient receives treatment. Gambro contends that participants in the demonstration program can be viewed as receiving the service in their home. Also, Gambro asserts that the dialysis services are not being provided at a traditional dialysis center.

III. Applicable Statute and Rules

The following Sections of the Illinois Health Facilities Planning Act (Act) [20 ILCS 3960/3] are applicable to this declaratory ruling request:

Section 3 of the Act provides the following definitions:

“Health care facilities" includes:

“ . . . Skilled and intermediate long term care facilities licensed under the Nursing Home Care Act; . . .”
“ . . . Kidney disease treatment centers, including a free-standing hemodialysis unit; . . .”
“Construction or modification"

“... the establishment, erection, building, alteration, reconstruction, modernization, improvement, extension, discontinuation, change of ownership, of or by a health care facility, ..."

“Establishment"

“... the construction of a health care facility or the replacement of an existing facility on another site.”

Section 5 of the Act states the following:

“... no person shall construct, modify or establish a health care facility... without first obtaining a permit or exemption from the State Board.”

“A permit or exemption shall be obtained prior to the acquisition of major medical equipment or to the construction or modification of a health care facility which:

(a) requires a total capital expenditure in excess of the capital expenditure minimum; or 
(b) substantially changes the scope or changes the functional operation of the facility; or 
(c) changes the bed capacity of a health care facility by increasing the total number of beds or by distributing beds among various categories of service or by relocating beds from one physical facility or site to another by more than 10 beds or more than 10% of total bed capacity as defined by the State Board, whichever is less, over a 2 year period.”

The following administrative rules are applicable to this declaratory ruling request:

77 Ill. Adm. Code 1100.220 defines “Category of Service” as:

“... grouping by generic class of various types or levels of support functions, equipment, care or treatment provided to patient/residents.”
77 Ill. Adm. Code 1100.630 provides the State Board's policies in regards to the Chronic Renal Dialysis Category of Service. These policies include planning areas, utilization standards and need determination.

77 Ill. Adm. Code 1110.1420 lists the following definitions for the Chronic Renal Dialysis Category of Service:

“Chronic Renal Dialysis” means a category of service in which dialysis is performed on a regular long-term care basis in patients with chronic irreversible renal failure. The maintenance and preparation of patients for kidney transplantation (including the immediate post-operative period and in case of organ rejection) or other acute conditions within a hospital does not constitute chronic renal dialysis category of service.”

“Hemodialysis” is a type of dialysis that involves the use of an artificial kidney through which blood is circulated on one side of a semipermeable membrane while the other side is bathed by a salt dialysis solution. The accumulated toxic products diffuse out of the blood into the dialysate bath solution. The concentration and total amount of water and salt in the body fluid is adjusted by appropriate alternations in composition of the dialysate fluid.”

“Peritoneal Dialysis” is a type of dialysis in which the dialysate fluid is injected slowly into the peritoneum, causing dialysis of water and waste products to occur through the peritoneal sac which acts as a semipermeable membrane. The fluid and waste, after accumulating for a period of time (1 hour), is drained from the abdomen and the process is repeated. This procedure is much slower than hemodialysis, requiring the patient to be immobilized for a long period of time.”

“Renal Dialysis Facility” means a freestanding facility or a unit within an existing health care facility that furnishes routine chronic dialysis service(s) to chronic renal disease patients. Such types of services are: self-dialysis, training in self-dialysis, dialysis performed by trained professional staff and chronic maintenance dialysis including peritoneal dialysis.”

“Self-Care Dialysis Training is a program which trains Chronic Renal Disease patients or their helpers, or both, to perform self-care dialysis.”
“Self-Dialysis” or “Self-Care Dialysis” is maintenance dialysis performed by a trained patient at home or in a special facility with or without the assistance of a family member or other helper.”

77 Ill. Adm. Code 1110.1430 lists the criteria the State Board will use to evaluate a proposed Chronic Renal Dialysis facility. Included in these criteria is a requirement for Self-Care and Home Dialysis Training (1110.1430(f)). This is defined as:

“The applicant proposing to establish a renal dialysis facility must document that self-care dialysis, self-care instruction, home dialysis and home training will be provided at the applicant facility or that a written agreement with another facility for the provision of these services exists.”

77 Ill. Adm. Code 1130.140 lists the following definitions that are germane to the declaratory ruling request:

1. “Establish" or “Establishment"
   
   “. . . the construction of a new health care facility, the licensing of unlicensed buildings or structures as a health care facility, the replacement of an existing health care facility on another site, or the development, licensing, or certification (if licensing is not applicable) of a category of service.”

2. “Existing Health Care Facility”:
   
   “. . . any health care facility or any person or organization that owns or operated a health care facility subject to the Act that:

   has a license issued by IDPH and has provided services within the past 12 months, unless the failure to provide such service is the result of pending license revocation procedures, and has not surrendered or abandoned its license or had its license revoked or voided or otherwise deemed invalid by IDPH; or
is certified under Titles XVIII or XIX of the Social Security Act; or

is a facility operated by the State of Illinois.

3. “Substantially Changes the Scope or Changes the Functional Operation of the Facility”

“... the addition or discontinuation of a category of service as defined at 77 Ill. Adm. Code 1100.220";

“... an increase of more than three dialysis stations or more than 10% of the facility's total number of dialysis stations, whichever is less, over a two-year period.”

77 Ill. Adm. Code 1130.210 states:

“The following persons are subject to the Act:
 a) Hospitals licensed pursuant to the Hospital Licensing Act [210 ILCS 85];
 b) Ambulatory Surgical Treatment Centers required to be licensed pursuant to the Ambulatory Surgical Treatment Center Act [210 ILCS 5];
 c) Long-term care facilities licensed pursuant to the Nursing Home Care Act [210 ILCS 45];
 d) Kidney disease treatment centers, including free standing hemodialysis units;
 e) Any of the above types of facilities operated by the State or any department or agency thereof; and
 f) Any person proposing to establish, construct or modify any of the above types of facilities or proposing to acquire major medical equipment.”

77 Ill. Adm. Code 1130.310(a)(2) states that a permit must be obtained if a facility engages in a transaction that substantially changes the scope or changes the functional operation of the facility as defined in Section 1130.140.

77 Ill. Adm. Code 1130.310(a)(3) states that a permit must be obtained if a transaction results in the establishment of a health care facility as defined in Section 1130.140.
77 Ill. Adm. Code 1130.554 provides a process whereby an existing dialysis facility can petition the State Board for an exemption to add stations.

77 Ill. Adm. Code 1130.810 (Declaratory Rulings) states:

“The State Board shall render determinations on various matters relating to permits and the applicability of the statute and regulations. Requests for determination shall be made in writing . . . The following matters shall be subject to declaratory rulings by the State Board:

i. reviewability of a proposed transaction;
ii. corrections to the facility inventories utilized by the State Board;
iii. recognition that a particular service was in existence prior to permit requirements;
iv. amount of fees required;
v. project classification as substantive or non-substantive; and
vi. applicability of rules."

Additionally, pursuant to Section 5-150 of the Illinois Administrative Procedure Act, decisions rendered by the State Board in relation to a declaratory ruling request are final and not subject to appeal by the permit holder.

In addition to the above-referenced items, there are two other points for State Board consideration. On May 16, 2002, the State Board issued a CON permit to Direct Dialysis to establish a six-station end stage renal disease (ESRD) facility within a long-term care facility known as Crestwood Care Centre (Project #02-010). This project created an ESRD facility within an existing nursing home. The ESRD facility, however, will also serve the general public in need of dialysis service. As part of the project, the facility will meet all requirements regarding the segregation of all non-licensed areas from the skilled care facility. Additionally, there will be a separate entrance for non-residents. The project's estimated cost is $416,341. The anticipated project completion date is December 31, 2004.

Second, on July 1, 2003, Public Act 92-0794 became effective. The Act, known as the End Stage Renal Disease Facility Act, mandates that all ESRDs be licensed and regulated by the Illinois Department of Public Health (IDPH). This Act defines an ESRD as:
A facility that provides dialysis treatment or dialysis training to individuals with end stage renal disease.”

Skilled nursing facilities are not exempt from the provisions and requirements of this Act. IDPH is currently in the process of developing administrative rules to implement the requirements of the Act. The State Agency notes, however, that the Health Facilities Planning Act was not amended to incorporate the requirements of the End Stage Renal Disease Facility Act.

IV. Discussion

There are three central questions before the State Board in relation to this declaratory ruling request. The first two questions relate directly to the dialysis training facility. Specifically, does the development of the proposed dialysis training facility constitute the establishment of a healthcare facility? If so, does this establishment require a CON or a COE? The final question is more broad in scope. Specifically, by allowing for the provision of dialysis service within the skilled nursing facility, is the facility engaging in a change of scope or functional operation? Also, by allowing for this service to commence within its licensed premises, is the skilled nursing facility establishing the chronic renal disease category of service?

Should the State Board determine that the development of this training facility constitutes the establishment of a healthcare facility, it could require Gambro to obtain a CON. A CON application would be reviewed under the applicable criteria and standards of Parts 1100, 1110 and 1120. The State Agency notes, however, that the State Board's rules do not specifically address dialysis training facilities.

Also, if the State Board determined that the participating skilled nursing facility was engaging in a transaction that changed the scope or functional operation of the facility, it could also require the nursing home to obtain a CON. As with the dialysis provider, the skilled nursing facility's CON application would be reviewed against the standards and criteria contained in the State Board's rules regarding the chronic renal disease category of service. The State Agency notes that a similar proposal was approved by the State Board in May 2002 (Direct Dialysis at Crestwood Care Center - CON Project #02-010).

Should the State Board determine it has jurisdiction over the establishment of this facility, a COE would not be applicable. As the regulations relate to ESRDs, COEs are limited to the change of ownership of a facility (77 Ill. Adm. Code 1130.520) or for the addition of stations to an existing ESRD facility (77 Ill. Adm. Code 1130.544). Neither type of transaction is proposed by Gambro in connection with this declaratory ruling request. Further, the
participating skilled nursing facilities could not apply for a COE for the provision of these services under the same reasons enumerated above.

In addition to the request as to whether the establishment of the dialysis training facility requires a CON or COE, Gambro also made a second request. The second request is for the State Board to determine that the performance of dialysis service in skilled care facilities for patients who elect the home dialysis option does not require a CON or COE. Should the State Board concur with the requestor, a CON or COE would not be required of the skilled care facility, the dialysis training facility, the dialysis provider or the dialysis equipment provider to furnish dialysis service to nursing home residents under the home care option. This second request would ask the State Board to make a general determination. Thus, this decision would apply to all facets of the home dialysis program; even those that are outside the parameters of the demonstration program proposed by Gambro.

The State Agency notes that on previous requests, skilled nursing facilities sought Advisory Opinions from the State Board on this issue. Specifically, nursing facilities sought clarification from the State Board that providing dialysis services to nursing facility residents within the skilled nursing facility under CMMS' home care option, did not require approval from the State Board. On these specific instances, the State Board determined that as long as the service qualified as home dialysis under CMMS' definitions and applicable regulations, no approval from the State Board was needed.

V. State Agency Finding(s)

The State Agency notes the following for the State Board's consideration:

A. This is a case of first impression for the State Board. As a matter of policy, the State Board has only issued CONs to applicants that propose either a freestanding ESRD or to existing healthcare facilities that wanted to provide the chronic renal dialysis service. Historically, the State Board has not been presented with the issue of dialysis training facilities and whether these facilities are under the State Board's jurisdiction.

2. Under the Health Facilities Planning Act [20 ILCS 3960/3], the State Board has jurisdiction over the establishment of healthcare facilities. The definition of "healthcare facilities" includes kidney disease treatment centers, including a freestanding hemodialysis unit.

3. The State Board, through its administrative rules, developed standards and criteria to evaluate a proposal for the establishment or expansion of an ESRD facility (77 Ill. Adm. Code 1100.630, 1110.1430 and 1130.544). Included in this section of the State
Board's rules are definitions for “Self-Care Dialysis Training” and “Self-Care Dialysis” (77 Ill. Adm. Code 1110.1420).

D. As referenced in item C, the State Board recognizes the Chronic Renal Dialysis Category of Service. However, there are no specific provisions in the State Board's administrative rules on whether a dialysis training facility constitutes an ESRD.

E. Certain policy statements of general applicability regarding what “substantially changes the scope or changes the functional operation” of a health care facility has been promulgated by the State Board in Section 1130.140.

F. As referenced above, Section 1130.140 of the State Board's rules define “Substantially changes the scope or changes the functional operation” of a health care facility as, in part, “. . . the addition or discontinuation of a category of service as defined in Parts 1100.220: . . .” Specifically, the establishment of a category of service by a healthcare facility could be viewed as a change in scope and functional operation. Thus, a CON would be required prior to the commencement of this transaction.

G. On July 1, 2003, Public Act 92-0794 became effective. This Act requires the Illinois Department of Public Health to regulate and license ESRD facilities. This Act defines ESRD to include a facility that provides dialysis treatment or dialysis training. As stated, the Health Facilities Planning Act was not amended to incorporate the requirements of this Act.

VI. Other Information

Appended to this report is Gambro's letter (dated January 20, 2004) to the State Board requesting the Declaratory Ruling.