

CHAPTER 7
OTHER HEALTH SERVICES

Chapter 7 Other Health Services

Other ambulatory health services consist of primary, specialty, and supportive medical services provided on an outpatient basis, in contrast to services provided in the home or to persons who are inpatients. The term ambulatory care implies that patients must travel to a location outside the home to receive services that do not require an overnight hospital stay. This chapter describes several organizations which provide ambulatory care in Mississippi. In addition, this chapter discusses home health services in Mississippi.

100 Ambulatory Surgery Services

During FY 2013, 72 of the state's medical/surgical hospitals reported a total of 274,834 general surgical procedures. This number included 174,198 ambulatory surgeries, almost a 0.97 percent increase of the 169,801 ambulatory surgeries performed in hospitals during 2012. The percentage of surgeries performed on an outpatient basis in hospitals has risen from 6.6 percent in 1981 to 63.4 percent in 2013. Table 7-1 displays hospital affiliated surgery data by general hospital service area.

Mississippi licenses 20 freestanding ambulatory surgery facilities. Table 7-2 shows the distribution of facilities and related ambulatory surgery data. The 20 facilities reported 79,933 procedures during fiscal year 2013. Total outpatient surgeries (hospitals and freestanding facilities combined) comprised 71.63 percent of all surgeries performed in the state. The number of procedures performed in freestanding facilities was 22.53 percent of total surgeries in 2013.

**Table 7-1
Selected Hospital Affiliated Ambulatory Surgery Data by General Hospital Service Area
FY 2013**

General Hospital Service Area	Total Number of Surgeries	Number of Hospitals	Number of Ambulatory Surgeries	Ambulatory Surgeries / Total Surgeries (Percent of)	Number of Operating Rooms / Suites	Average¹ Number of Surgical Procedures per Day / Suite
Mississippi	274,834	72	174,198	63.4	453	2.43
1	7,429	5	4,428	59.6	21	1.42
2	30,577	5	20,016	65.5	44	2.78
3	21,772	7	15,929	73.2	35	2.49
4	25,874	8	18,555	71.7	39	2.65
5	85,982	17	48,007	55.8	140	2.46
6	22,847	9	17,769	77.8	43	2.13
7	18,577	6	12,820	69.0	35	2.12
8	23,628	6	14,062	59.5	42	2.25
9	38,148	9	22,612	59.3	54	2.83

¹ Based on 250 working days per year

Source: Applications for Renewal of Hospital License for Calendar Year 2014 and FY 2013 Annual Hospital Report

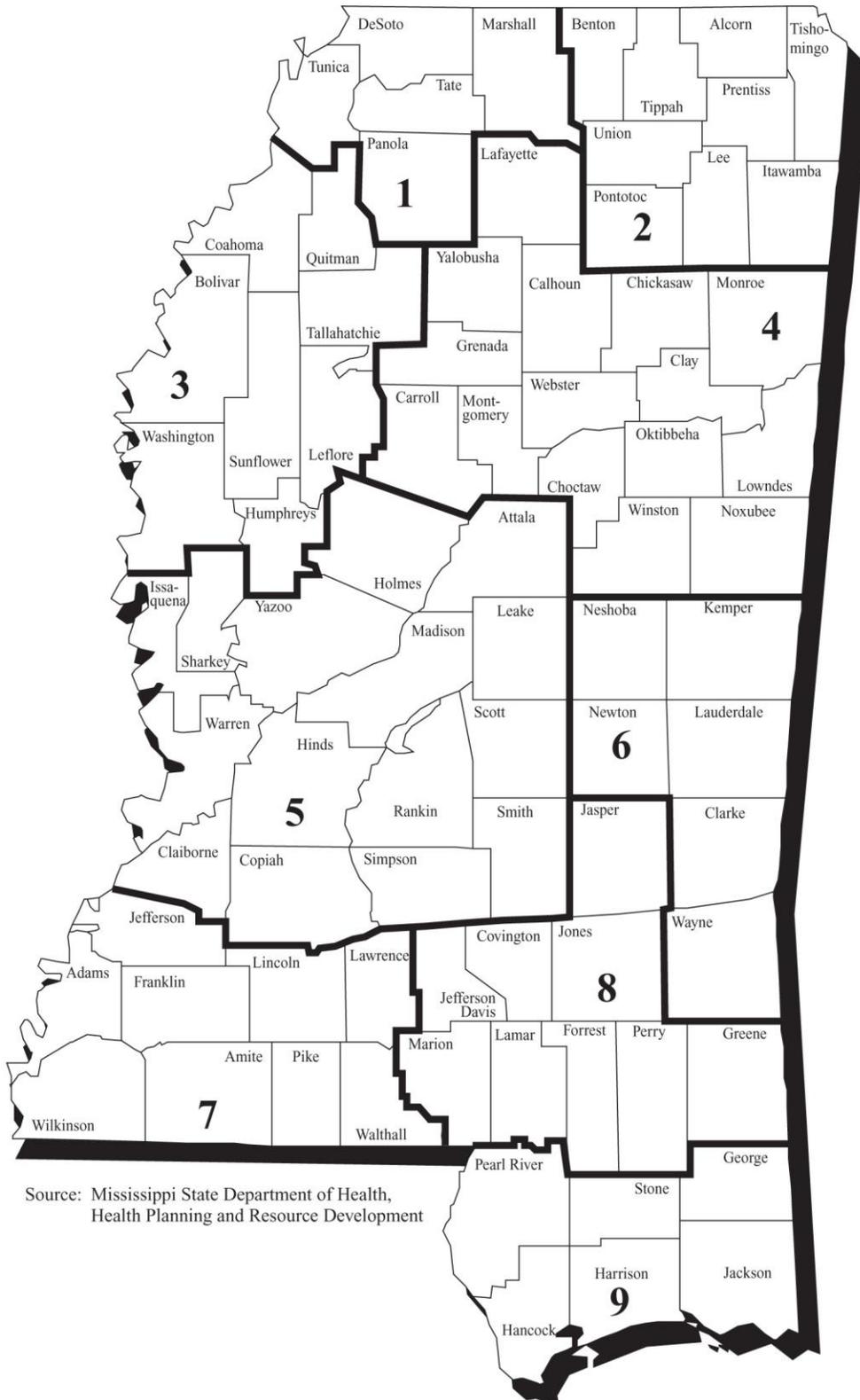
**Table 7-2
Selected Freestanding Ambulatory Surgery Data by County
FY 2013**

Ambulatory Surgery Planning Area	County	Number of Freestanding Ambulatory Surgery Centers	Number of Ambulatory Surgeries Performed	Number of Operating Rooms/Suites	Number¹ of Surgical Procedures Per Day/O.R. Suite
(ASPAs)	Mississippi	20	79,933	81	3.95
1	DeSoto	1	1,962	3	2.62
2	Lee	1	6,506	8	3.25
4	Lafayette	1	3,430	4	3.43
5	Hinds	4	24,635	19	5.19
5	Rankin	1	4,201	5	3.36
6	Lauderdale	1	3,081	3	4.11
8	Forrest	4	20,593	16	5.15
8	Jones	1	1,622	3	2.16
9	Harrison	3	8,923	11	3.24
9	Jackson	3	4,980	9	2.21

¹ Based on 250 working days per year

Source: Survey of individual ambulatory surgery centers conducted April 2014; Division of Health Planning and Resource Development, Mississippi State Department of Health

**Map 7-1
Ambulatory Surgery Planning Areas**



Source: Mississippi State Department of Health,
Health Planning and Resource Development

AMBULATORY SURGERY SERVICES

101 Certificate of Need Criteria and Standards for Ambulatory Surgery Services

Note: Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

101.01 Policy Statement Regarding Certificate of Need Applications for Ambulatory Surgery Services

1. Ambulatory Surgery Planning Areas (ASPAs): The Mississippi State Department of Health (MSDH) shall use the Ambulatory Surgery Planning Areas as outlined on Map 7-1 of this Plan for planning and Certificate of Need (CON) decisions. The need for ambulatory surgery facilities in any given ASPA shall be calculated independently of all other ASPAs.
2. Ambulatory Surgery Facility Service Areas: An applicant's Ambulatory Surgery Facility Service Area must have a population base of approximately 60,000 within 30 minutes normal driving time or 25 miles, whichever is greater, of the proposed/established facility. Note: Licensure standards require a freestanding facility to be within 15 minutes traveling time of an acute care hospital and a transfer agreement with said hospital must be in place before a CON may be issued. Additionally, the ambulatory surgery facility service area must have a stable or increasing population.
3. Definitions: The Glossary of this Plan includes the definitions in the state statute regarding ambulatory surgery services.
4. Surgeries Offered: The MSDH shall not approve single service ambulatory surgery centers. Only multi-specialty ambulatory surgery center proposals may be approved for a CON.
5. Minimum Surgical Operations: The minimum of 1,000 surgeries required to determine need is based on five (5) surgeries per operating room per day x 5 days per week x 50 weeks per year x 80 percent utilization rate.
6. Present Utilization of Ambulatory Surgery Services: The MSDH shall consider the utilization of existing services and the presence of valid CONs for services within a given ASPA when reviewing CON applications.
7. Optimum Capacity: The optimum capacity of an ambulatory surgery facility is 800 surgeries per operating room per year. The MSDH shall not issue a CON for the establishment or expansion of an additional facility(ies) unless the existing facilities within the ASPA have performed in aggregate at least 800 surgeries per operating room per year for the most recent 12-month reporting period, as reflected in data

supplied to and/or verified by the MSDH. The MSDH may collect additional information it deems essential to render a decision regarding any application. Optimum capacity is based on four (4) surgeries per operating room per day x 5 days per week x 50 weeks per year x 80 percent utilization rate.

8. Conversion of Existing Service: Applications proposing the conversion of existing inpatient capacity to hospital-affiliated ambulatory surgical facilities located within the hospital shall receive approval preference over detached or freestanding ambulatory surgical facilities if the applicant can show that such conversion is less costly than new construction and if the application substantially meets other adopted criteria.
9. Construction/Expansion of Facility: Any applicant proposing to construct a new facility or major renovation to provide ambulatory surgery must propose to build/renovate no fewer than two operating rooms.
10. Indigent/Charity Care: The applicant shall be required to provide a “reasonable amount” of indigent/charity care as described in Chapter 1 of this Plan.

101.02 Certificate of Need Criteria and Standards for Ambulatory Surgery Services

The MSDH will review applications for a CON for new ambulatory surgery facilities, as defined in Mississippi law, under the statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972 Annotated, as amended. The MSDH will also review applications submitted for Certificate of Need in accordance with the rules and regulations in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The offering of ambulatory surgery services is reviewable if the proposed provider has not provided those services on a regular basis within twelve (12) months prior to the time such services would be offered. In addition, ambulatory surgery services require CON review when the establishment or expansion of the services involves a capital expenditure in excess of \$2,000,000.

1. **Need Criterion: The applicant shall demonstrate that the proposed ambulatory surgery facility shall perform a minimum average of 1,000 surgeries per operating room per year.**
2. The applicant must document that the proposed Ambulatory Surgery Facility Service Area has a population base of approximately 60,000 within 30 minutes travel time.
3. An applicant proposing to offer ambulatory surgery services shall document that the existing facilities in the ambulatory surgery planning area have been utilized for a minimum of 800 surgeries per operating room per year for the most recent 12-month reporting period as reflected in data supplied to and/or verified by the Mississippi State Department of Health. The MSDH may collect additional information it deems essential to render a decision regarding any application.
4. The applicant must document that the proposed program shall provide a full range of surgical services in general surgery.

5. The applicant must provide documentation that the facility will be economically viable within two years of initiation.
6. The proposed facility must show support from the local physicians who will be expected to utilize the facility.
7. Medical staff of the facility must live within a 25-mile radius of the facility.
8. The proposed facility must have a formal agreement with a full service hospital to provide services which are required beyond the scope of the ambulatory surgical facility's programs. The facility must also have a formal process for providing follow-up services to the patients (e.g., home health care, outpatient services) through proper coordination mechanisms.
9. Indigent/Charity Care: The applicant shall affirm that the applicant will provide a "reasonable amount" of indigent/charity care by stating the amount of indigent/charity care the applicant intends to provide.

HOME HEALTH SERVICES

102 Home Health Care

Mississippi licensure regulations define a home health agency as: a public or privately owned agency or organization, or a subdivision of such an agency or organization, properly authorized to conduct business in Mississippi, which is primarily engaged in providing to individuals at the written direction of a licensed physician, in the individual's place of residence, skilled nursing services provided by or under the supervision of a registered nurse licensed to practice in Mississippi, and one or more of the following additional services or items:

1. physical, occupational, or speech therapy
2. medical social services
3. home health aide services
4. other services as approved by the licensing agency
5. medical supplies, other than drugs and biologicals, and the use of medical appliances
6. medical services provided by a resident in training at a hospital under a teaching program of such hospital."

All skilled nursing services and the services listed in items 1 through 4 must be provided directly by the licensed home health agency. For the purposes of this *Plan*, "directly" means either through an agency employee or by an arrangement with another individual not defined as a health care facility in Section 41-7-173 (h), Mississippi Code 1972, as amended. The requirements of this paragraph do not apply to health care facilities which had contracts for the above services with a home health agency on January 1, 1990.

102.01 Home Health Status

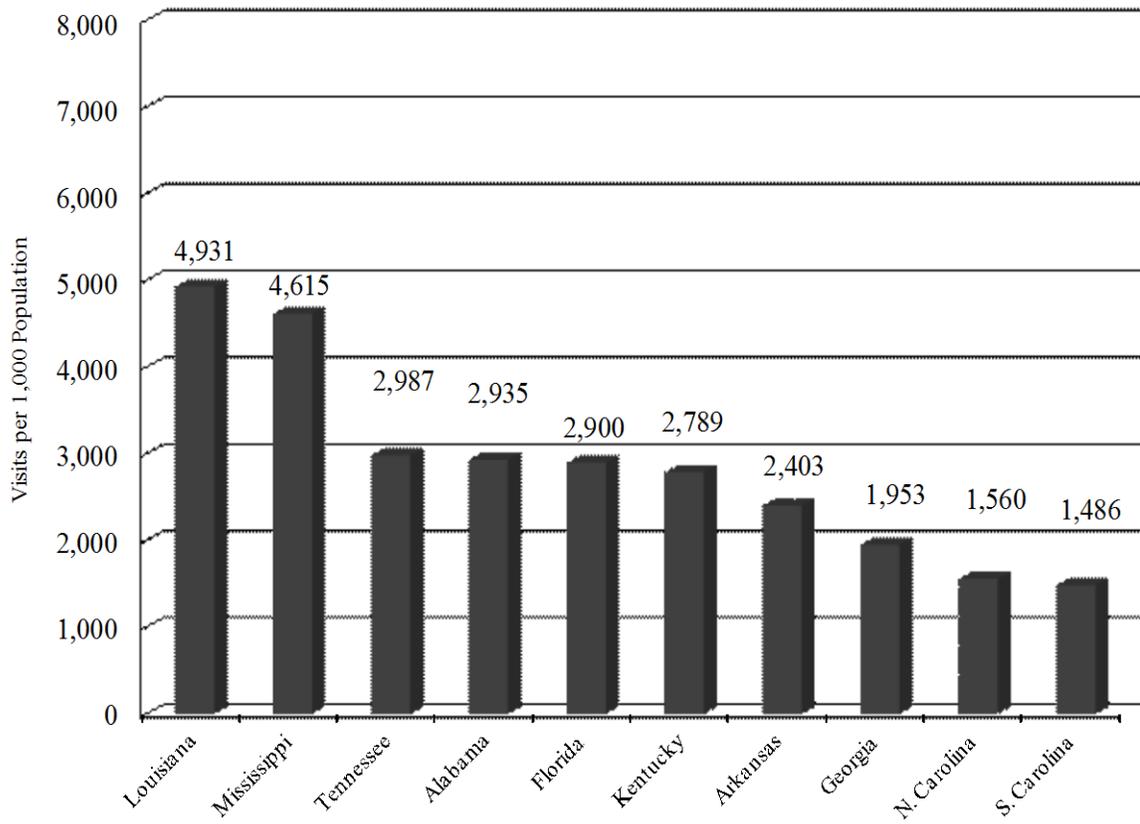
The latest Mississippi's 2012 *Report on Home Health Agencies* (the latest available) indicated that 88,408 Mississippians (non-duplicate count) received home health services during the year, an increase of 1.7 percent from the 86,923 patients served in 2012. There were 3,242,592 home health care visits made in 2012. Each patient (all payor sources) received an average of 36.68 visits. Mississippi has 9 hospital-based home health agencies, 40 freestanding agencies and 4 regional home health agencies operated by the MSDH.

7-3
Medicare Home Health Statistics
in the Ten-State Region
January 1, 2012 – December 31, 2012

	2020 Population 65+	2012 Total Medicare- Paid Home Health Visits	Medicare-Paid Home Health Visits per 1,000 Population 65+	Total Medicare Reimbursement	Total Medicare Home Health Patients	Average Reimbursement per Patient	Average Visits per Patient
Region Total	13,488,705	36,577,786	2,712	\$5,457,514,756	982,613	\$5,554	37
Alabama	842,607	2,472,715	2,935	\$357,498,026	71,395	\$5,007	35
Arkansas	531,028	1,276,081	2,403	\$159,990,765	35,483	\$4,509	37
Florida	5,106,857	14,810,817	2,900	\$2,194,992,017	355,080	\$6,182	42
Georgia	1,409,923	2,753,624	1,953	\$426,827,528	87,001	\$4,906	32
Kentucky	729,741	2,034,991	2,789	\$302,351,441	61,096	\$4,949	33
Louisiana	763,468	3,764,993	4,931	\$523,238,910	75,026	\$6,974	50
Mississippi	499,190	2,303,737	4,615	\$341,326,801	55,579	\$6,141	41
North Carolina	1,618,578	2,524,479	1,560	\$429,220,677	107,916	\$3,977	23
South Carolina	866,250	1,287,463	1,486	\$216,977,522	50,935	\$4,260	25
Tennessee	1,121,063	3,348,886	2,987	\$505,091,069	83,102	\$6,078	40

Source: Palmetto GBA – Medicare Statistical Analysis Department, HCIS (Health Care Information System), May 29, 2014

Figure 7-1
Total Medicare Paid Home Health Visits Per 1,000 Population
Aged 65+ in the Ten-State Region
2012



Note: 2012 Average Home Health Visits per 1,000 Population Aged 65+ in the Ten-State Region is 2,712

103 Certificate of Need Criteria and Standards for Home Health Agencies/Services

Note: Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

103.01 Policy Statement Regarding Certificate of Need Applications for the Establishment of a Home Health Agency and/or the Offering of Home Health Services

1. Service Areas: The need for home health agencies/services shall be determined on a county by county basis.
2. Determination of Need: A possible need for home health services may exist in a county if for the most recent calendar year available that county had fewer home health care visits per 1,000 elderly (65+) population than the average number of visits received per 1,000 elderly (65+) in the "ten-state region" consisting of Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee. That number is currently 2,712 as shown in Table 7-3 (FY 2012 is most recent data available).
3. Unmet Need: If it is determined that an unmet need exists in a given county, the unmet need must be equivalent to 50 patients in each county proposed to be served. Based on 2012 data 2,712 visits approximates 40 patients.
4. All CON applications for the establishment of a home health agency and/or the offering of home health services shall be considered substantive and will be reviewed accordingly.

103.02 Certificate of Need Criteria and Standards for the Establishment of a Home Health Agency and/or the Offering of Home Health Services

If the present moratorium were removed or partially lifted, the MSDH would review applications for a CON for the establishment of a home health agency and/or the offering of home health services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications submitted for CON according to the general criteria as listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the MSDH; and the specific criteria and standards listed below.

The development or otherwise establishment of a home health agency requires CON. The offering of home health services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

1. **Need Criterion: The applicant shall document that a possible need for home health services exists in each county proposed to be served using the methodology contained in this section of the *Plan*.**
2. The applicant shall state the boundaries of the proposed home health service area in the application.
3. The applicant shall document that each county proposed to be served has an unmet need equal to 50 patients, using a ratio of 2,712 patient visits equals 40 patients.
4. The applicant shall document that the home office of a new home health agency shall be located in a county included in the approved service area of the new agency. An existing agency receiving CON approval for the expansion of services may establish a sub-unit or branch office if such meets all licensing requirements of the Division of Licensure.
5. The application shall document the following for each county to be served:
 - a. Letters of intent from physicians who will utilize the proposed services.
 - b. Information indicating the types of cases physicians would refer to the proposed agency and the projected number of cases by category expected to be served each month for the initial year of operation.
 - c. Information from physicians who will utilize the proposed service indicating the number and type of referrals to existing agencies over the previous 12 months.
 - d. Evidence that patients or providers in the area proposed to be served have attempted to find services and have not been able to secure such services.
 - e. Projected operating statements for the first three years, including:
 - i. total cost per licensed unit;
 - ii. average cost per visit by category of visit; and
 - iii. average cost per patient based on the average number of visits per patient.
6. Information concerning whether proposed agencies would provide services different from those available from existing agencies.

103.03 Statistical Need Methodology for Home Health Services

The methodology used to calculate the average number of visits per 1,000 elderly (65+) in the 10-state region is:

1. The 10-state region consists of Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee.
2. The 2020 projected population aged 65 and older are estimates from each state.

3. Table 7-3 shows the average number of Medicare paid home health visits per 1,000 elderly (65+) for the 10-state region, according to 2012 data from Palmetto GBA - Medicare Statistical Analysis Department of the Centers for Medicare and Medicaid Services. Figure 7-1 shows the total number of Medicare paid home health visits per 1,000 elderly in the 10-state region.
4. In 2012, the region average of home health visits per 1,000 population aged 65 and older was 2,712. An average patient in the region received 37 home health visits. Therefore 2,712 visits equal 37 patients. Note: The Mississippi average for 2012 was 3,327 visits (Medicare reimbursed) per 1,000 population aged 65 and older, and an average patient received 38 visits.

END STAGE RENAL DISEASE SERVICES

104 End Stage Renal Disease

End stage renal disease (ESRD) describes the loss of kidney function from chronic renal failure to the extent that the remaining kidney function will no longer sustain life. The kidney's function of filtering waste products from the blood and removing fluid and salts from the body is essential for life; consequently, if untreated, end stage renal disease results in death.

Treatment generally consists of either transplantation or dialysis. Dialysis consists of either peritoneal dialysis or hemodialysis. In peritoneal dialysis, the patient's own abdominal membrane is part of the "equipment". A dialyzing fluid is placed in the abdominal cavity through a plastic tube, and waste products (fluid and salts) exchange across the peritoneal membrane between the patient's blood and the dialyzing fluid. Hemodialysis is the process by which an artificial kidney machine "washes" metabolic waste products from the bloodstream and removes fluids and salts.

The kidney machine or peritoneal dialysis mimics the function normally done by the kidney. Dialysis can be done either by the patient and an assistant in the home, in a facility, or by professional staff in a hospital or limited care facility. Mississippi had 61 ESRD facilities providing maintenance dialysis services as of May 2014, and two additional facilities CON-approved but not yet operational (most recent data available). BMA of MS, Inc. d/b/a FMC-West Hinds County received CON Authority to establish a 10 Station Satellite ESRD facility in Clinton, Hinds County, MS. Map 7-1 shows the facility locations and Table 7-4 shows the number of existing and CON approved ESRD facilities by county.

Kidney transplantation is the treatment of choice for most patients with end stage renal failure. Unfortunately, suitable kidneys will probably never be available in the number that would be required to treat everyone with this mode of therapy. In kidney transplantation, a healthy kidney is removed from a donor and placed into an ESRD patient. Donors for kidney transplantation may come either from a close relative, such as a sibling or parent, or from an emotionally connected donor, such as a spouse or close associate. Kidneys may also be obtained from cadaver donors who have the closest matching tissue type. Living donors are preferred because they function longer than cadaver kidneys – 30 years for a living donor versus 15 years for a cadaver kidney.

The University of Mississippi Medical Center, the only kidney transplant program in the state, performed 103 cadaver and 0 living-donor transplants during the calendar year 2013. It is certified by membership in the United Network of Organ Sharing, a private agency under contract from the Health Care Financing Administration. Transplant results are comparable to those with transplant programs with similar population basis and can be viewed on the Internet under www.ustransplants.org. Approximately, 100 additional transplants in Mississippi residents are performed in neighboring states.

**Table 7-4
Number of Existing and CON Approved ESRD Facilities by County**

ESRD Facilities by County	Number of Certified and CON Approved Stations
Adams	29
RCG of Natchez	29
Alcorn	22
RCG of Corinth	22
Attala	20
FMC Kosciusko	20
Bolivar	60
Fresenius Medical Care	28
RCG of Cleveland	32
Claiborne	10
FMC - Port Gibson	10
Clarke	9
Pachuta Dialysis Unit	9
Coahoma	40
RCG of Clarksdale	40
Copiah	25
FMC Hazlehurst	13
Hazlehurst Dialysis fka NRI of Hazlehurst	12
Covington	21
Collins Dialysis Unit - Collins	21
DeSoto	50
FMC Southaven	50
Forrest	60
Hattiesburg Clinic Dialysis Unit	60
George	16
Lucedale Dialysis	16
Grenada	29
RCG of Grenada	29
Hancock	12
FMC-South Miss Kidney Center - Diamondhead	12

FY 2013 Annual ESRD Dialysis Utilization Survey conducted April 2014.

¹ CON Approved but not yet licensed

Table 7-4 (Continued)
Number of Existing and CON Approved ESRD Facilities by County

ESRD Facilities by County	Number of Certified and CON Approved Stations
Harrison	90
FMC-South Mississippi Center of Biloxi	20
FMC-South Miss Kidney Center - Diamondhead/Gulfport	20
FMC-South Miss Kidney Center - Orange Grove	18
FMC-South Miss Kidney Center - D'Iberville	12
FMC-South Miss Kidney Center - North Gulfport	20
Hinds	201
FMC Jackson	38
FMC Southwest Jackson	31
Davita Jackson North fka NRI - Jackson North	46
Davita Jackson South fka NRI - Jackson South	28
Davita Jackson Southwest fka NRI-Jackson Southwest	17
University MS Medical Center Hospital and Clinics Outpatient Dialysis - Jackson	35
University Pediatric & ESRD Adult Outpatient Clinic	6
Holmes	21
Davita RCG of Lexington fka NRI - Lexington	21
Humphreys	9
RCG of Belzoni	9
Jackson	42
Davita Ocean Springs Dialysis	16
Davita Singing River Dialysis	26
Jasper	21
Bay Springs Dialysis Unit - Bay Springs	21
Jefferson	8
DRG Fayette	8
Jones	34
Laurel Dialysis Center - Laurel	34
Kemper	6
BMA, Inc. d/b/a FMC-Dekalb ¹ (opened 12/2013)	6
Lafayette	28
RCG Oxford	28
Lauderdale	61
RCG of Meridian	61
Lawrence	18
Silver Creek Dialysis	18
Leake	15
Renal Care Group of Carthage fka NRI of Carthage	15

¹ CON Approved but not yet licensed

Table 7-4 (Continued)
Number of Existing and CON Approved ESRD Facilities by County

ESRD Facilities by County	Number of Certified and CON Approved Stations
Lee RCG of Tupelo	50 50
Leflore RCG of Greenwood	34 34
Lincoln RCG of Brookhaven	32 32
Lowndes RCG of Columbus	37 37
Madison FMC Canton Canton Renal Center	35 18 17
Marion Columbia Dialysis Unit - Columbia	30 30
Marshall RCG of Holly Springs	20 20
Monroe RCG of Aberdeen	32 32
Montgomery RCG of Winona	15 15
Neshoba RCG of Philadelphia	36 36
Newton RCG of Newton	16 16
Noxubee RCG of Macon	24 24
Oktibbeha RCG of Starkville	25 25
Panola RCG of Sardis	24 24
Pearl River Pearl River Dialysis Center - Picayune	20 20

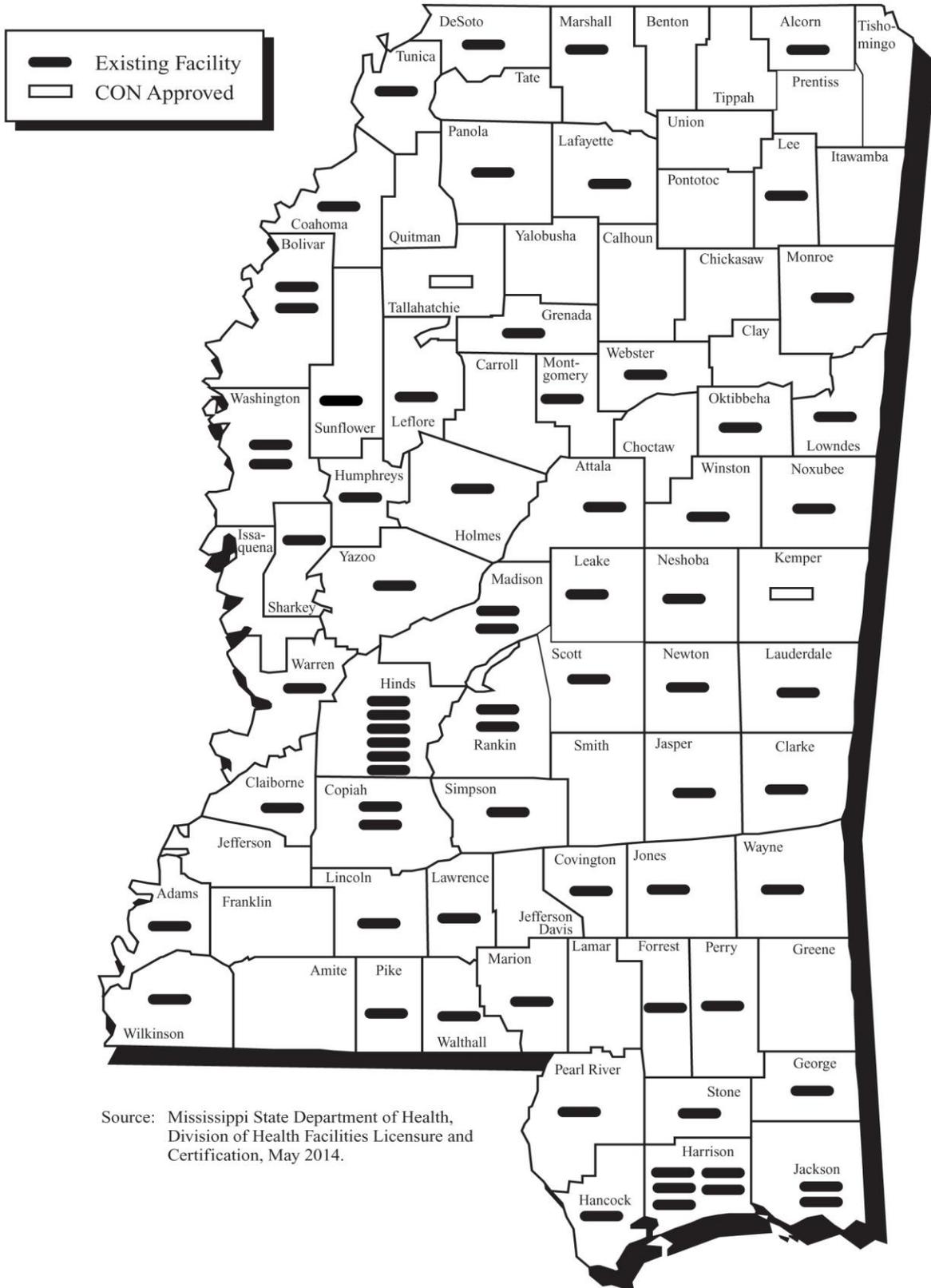
¹ CON Approved but not yet licensed

Table 7-4 (Continued)
Number of Existing and CON Approved ESRD Facilities by County

ESRD Facilities by County	Number of Certified and CON Approved Stations
Perry	20
Richton Dialysis Unit	20
Pike	32
FMC of McComb	32
Rankin	45
FMC Dialysis Services of Rankin County-Brandon	21
NRI-Brandon	24
Scott	18
Davita Brandon fka Central Dialysis Unit of Forest	18
Sharkey	13
RCG of Mayersville	13
Simpson	17
FMC of Magee	17
Stone	12
Wiggins Dialysis Unit	12
Sunflower	21
RCG of Indianola	21
Tallahatchie	6
Healthcare Engineers - Charleston ¹	6
Tunica	12
Tunica Dialysis	12
Walthall	20
Tylertown Dialysis Unit	20
Warren	23
RCG of Vicksburg	23
Washington	47
Mid-Delta Kidney Center, Inc (Peritoneal -9)	9
RCG of Greenville	38
Wayne	15
Waynesboro Renal Dialysis Unit	15
Webster	14
RCG of Europa	14
Wilkinson	17
RCG of Centerville	17
Winston	17
RCG of Louisville	17
Yazoo	21
FMC Yazoo City	21
State Total	1,757

¹ CON Approved but not yet licensed

Map 7-2 End Stage Renal Disease Facilities



Source: Mississippi State Department of Health, Division of Health Facilities Licensure and Certification, May 2014.

104 Certificate of Need Criteria and Standards for End Stage Renal Disease Facilities

Note: Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

104.01 Policy Statement Regarding Certificate of Need Applications for the Establishment of End Stage Renal Disease (ESRD) Facilities

1. Establishment of an ESRD Facility: The provision or proposed provision of maintenance dialysis services constitutes the establishment of an ESRD facility if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.
2. Annual Review Cycle: The MSDH shall accept and process CON applications proposing the establishment of ESRD facilities in accordance with the following review cycle:
 - a. Applications may be submitted only during the period beginning July 1 and ending September 1 (5:00 p.m.) each year.
 - b. All applications received during this period (July 1 through September 1 each year) which are deemed "complete" by October 1 of the year of submission, will be entered into the 90-day review cycle (October-December cycle).
 - c. The State Health Officer will make CON decisions on "complete" applications in the month of December each year.
 - d. Any CON application received other than in accordance with the above review cycle shall not be accepted by the Department, but shall be returned to the applicant.
3. Type of Review: CON applications for ESRD services shall be considered substantive as defined under the appropriate *Mississippi State Health Plan*, and "complete" competing applications from the same ESRD Facility Service Area shall be batched.
4. ESRD Facility Service Area: An ESRD Facility Service Area is defined as the area within a thirty (30) mile radius of an existing or proposed ESRD facility. ESRD Facility Service Areas, including the Service Areas of existing facilities which overlap with the proposed Service Area, shall be used for planning purposes.
5. CON Approval: A CON application for the establishment of an ESRD facility shall be considered for approval only when each individual facility within an applicant's

proposed ESRD Facility Service Area has maintained, at a minimum, an annual or prorated utilization rate of 80 percent as verified by the MSDH. The 12 months prior to the month of submission of the CON application shall be used to determine utilization, if such information is available and verifiable by the Department.

6. Need Threshold: For planning and CON purposes a need for an additional ESRD facility may exist when each individual operational ESRD station within a given ESRD Facility Service Area has maintained an annual utilization rate of 80 percent, i.e. an average of 749 dialyses per station per year.
7. Utilization Definitions:
 - a. Full Utilization: For planning and CON purposes, full (100 percent) utilization is defined as an average of 936 dialyses per station per year.
 - b. Optimum Utilization: For planning and CON purposes, optimum (65 percent) utilization is defined as an average of 608 dialyses per station per year.
 - c. Need Utilization: For planning and CON purposes, need (80 percent) utilization is defined as an average of 749 dialyses per station per year.

These utilization definitions are based upon three (3) shifts per day six (6) days per week, or eighteen (18) shifts per week. Only equipment (peritoneal or hemodialysis) that requires staff assistance for dialysis and is in operation shall be counted in determining the utilization rate. Utilization of equipment in operation less than twelve (12) months shall be prorated for the period of time in actual use.

8. Outstanding CONs: ESRD facilities that have received CON approval but are not operational shall be considered to be operating at 50 percent, which is the minimum utilization rate for a facility the first year of operation.
9. Utilization Data: The Department may use any source of data, subject to verification by the Department, it deems appropriate to determine current utilization or projected utilization of services in existing or proposed ESRD facilities. The source of data may include, but is not limited to, Medicare Certification records maintained by the Division of Health Facilities Licensure and Certification, ESRD Network #8 data, and Centers for Medicare and Medicaid Services (CMS) data.
10. Minimum Expected Utilization: It is anticipated that a new ESRD facility may not be able to reach optimum utilization (608 percent) of ten ESRD stations during the initial phase of operation. Therefore, for the purposes of CON approval, an application must demonstrate how the applicant can reasonably expect to have 50 percent utilization of a minimum of ten ESRD stations by the end of the first full year of operation and 65 percent utilization by the end of the third full year of operation.
11. Minimum Size Facility: No CON application for the establishment of a new ESRD facility shall be approved for less than ten (10) stations.

12. Expansion of Existing ESRD Facilities: Existing ESRD facilities may add ESRD stations without certificate of need review, as long as the facility does not add, over a period of two (2) years, more than the greater of four (4) stations or 15% of the facility's current number of certified stations.
13. Home Dialysis Programs: Each existing ESRD facility may establish or relocate one home dialysis program to any location within a 5-mile radius of the existing facility without certificate of need review; provided, however, that the facility shall submit an application for determination of non-reviewability prior to the establishment of the dialysis program. If such established or relocated home dialysis program is a freestanding program, the freestanding home dialysis program shall document that it has a back-up agreement for the provision of any necessary dialysis services with the existing ESRD facility. If an existing ESRD facility wants to create, either through establishment or relocation, more than one home dialysis program, the project shall be subject to CON review as the establishment of a new ESRD facility.
14. Establishment of Satellite ESRD Facilities: Any existing ESRD facility which reaches a total of 30 ESRD stations, may establish a ten (10) station satellite facility. If a proposed satellite ESRD facility is to be located more than one (1) mile from the existing facility, a certificate of need must be obtained by the facility prior to the establishment of the satellite facility.
15. Non-Discrimination: An applicant shall affirm that within the scope of its available services, neither the facility nor its staff shall have policies or procedures which would exclude patients because of race, color, age, sex, or ethnicity.
16. Indigent/Charity Care: An applicant shall be required to provide a "reasonable amount" of indigent/charity care as described in Chapter 1 of this *Plan*.
17. Staffing: The facility must meet, at a minimum, the requirements and qualifications for staffing as contained in 42 CFR § 494.140. In addition, the facility must meet all staffing requirements and qualifications contained in the service specific criteria and standards.
18. Federal Definitions: The definitions contained in 42 CFR Subpart A § 494.10 shall be used as necessary in conducting health planning and CON activities.
19. Affiliation with a Renal Transplant Center: ESRD facilities shall be required to enter into a written affiliation agreement with a renal transplant center.

104.02 Certificate of Need Criteria and Standards for End Stage Renal Disease (ESRD) Facilities

The Mississippi State Department of Health will review applications for a Certificate of Need for the establishment of an ESRD facility under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria as listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

When a provider proposes to offer ESRD services in an ESRD facility service area where he does not currently provide services or proposes to transfer an existing ESRD unit(s) from a current location into a different ESRD facility service area, it will constitute the establishment of a new ESRD health care facility. (Note: The transfer of dialysis stations from an existing ESRD facility to any other location is a relocation of a health care facility or portion thereof and requires Certificate of Need review. Likewise, new dialysis stations placed into service at a site separate and distinct from an existing ESRD facility constitutes the establishment of a new health care facility and requires Certificate of Need review. Dialysis stations placed into service in an individual patient's home or residence, solely for the treatment of the individual patient concerned, are exempt from this regulation.)

104.02.01 Establishment of an End Stage Renal Disease (ESRD) Facility

1. **Need Criterion for Establishment of New ESRD Facilities:** An applicant proposing the establishment of a limited care renal dialysis facility or the relocation of a portion of an existing ESRD facility's dialysis stations to another location shall demonstrate, subject to verification by the Mississippi State Department of Health, that each individual existing ESRD facility in the proposed ESRD Facility Service Area has maintained a minimum annual utilization rate of eighty (80) percent.
2. Need Criterion for Expansion of Existing ESRD Facilities: In the event that an existing ESRD facility proposes to add more than the greater of four (4) stations or 15% of the facility's current number of certified stations within a two-year period, then the facility must apply for a certificate of need, and shall document that it has maintained a minimum annual utilization rate of 65% for the 12 months prior to the month of the submission of the CON application. NOTE: ESRD Policy Statements 2, 4, 5 and 6, and Need Criterion 1, do not apply to applications for the expansion of existing ESRD facilities.
3. Need Criterion for Establishment of ESRD Satellite Facilities: In order for a 30 station ESRD facility to be approved for the establishment of a ten (10) station satellite facility through the transfer and relocation of existing stations within a five mile radius or less from the existing facility, the facility must (a) document that it has maintained a minimum annual utilization rate of 55% for the 12 months prior to the month of the submission of the CON application; (b) justify the need for the project, which may include, but is not limited to, physical or space limitations at the existing facility; and (c) document that it is more cost effective to establish a satellite facility than to expand the existing facility. If the proposed satellite facility will be established at a location between a five and twenty-five mile radius of the existing facility, the facility must (a) document that it has maintained a minimum annual utilization rate of 55% for the 12 months prior to the month of the submission of the CON application; (b) justify the need for the project, which may include, but is not limited to, physical or space limitations at the existing facility; and (c) document that it is more cost effective to establish a satellite facility than to expand the existing facility; and (d) demonstrate that the proposed satellite facility's location is not within thirty miles of an existing facility without obtaining the existing facility's written support. NOTE: ESRD Policy Statements 2, 4, 5 and 6, and Need Criterion 1, do not apply to applications for the establishment of satellite ESRD facilities. An ESRD satellite facility established under this Need Criterion 3

shall not be used or considered for purposes of establishing or determining an ESRD Facility Service Area.

4. Number of Stations: The applicant shall state the number of ESRD stations that are to be located in the proposed facility. No new facility shall be approved for less than ten (10) dialysis stations.
5. Minimum Utilization: The application shall demonstrate that the applicant can reasonably expect to meet the minimum utilization requirements as stated in ESRD Policy Statement #10.
6. Minimum Services: The application shall affirm that the facility will provide, at a minimum, social, dietetic, and rehabilitative services. Rehabilitative services may be provided on a referral basis.
7. Access to Needed Services: The application shall affirm that the applicant will provide for reasonable access to equipment/facilities for such needs as vascular access and transfusions required by stable maintenance ESRD patients.
8. Hours of Operation: The application shall state the facility's hours of operation each day of the week. The schedule should accommodate patients seeking services after normal working hours.
9. Home Training Program: The application shall affirm that the applicant will make a home training program available to those patients who are medically eligible and receptive to such a program. The application shall affirm that the applicant will counsel all patients on the availability of and eligibility requirements to enter the home/self-dialysis program.
10. Indigent/Charity Care: The application shall affirm that the applicant will provide a "reasonable amount" of indigent/charity care. The application shall also state the amount of indigent/charity care the applicant intends to provide.
11. Facility Staffing: The application shall describe the facility's staffing by category (i.e., registered nurse, technologist, technician, social worker, dietician) as follows:
 - a. Qualifications (minimum education and experience requirements)
 - b. Specific Duties
 - c. Full Time Equivalents (FTE) based upon expected utilization
12. Staffing Qualifications: The applicant shall affirm that the staff of the facility will meet, at a minimum, all requirements and qualifications as stated in 42 CFR, Subpart D § 494.140.
13. Staffing Time:
 - a. The applicant shall affirm that when the unit is in operation, at least one (1) R.N. will be on duty. There shall be a minimum of two (2) persons for each dialysis shift, one of whom must be an R.N.

- b. The applicant shall affirm that the medical director or a designated physician will be on-site or on-call at all times when the unit is in operation. It is desirable to have one other physician to supplement the services of the medical director.
 - c. The applicant shall affirm that when the unit is not in operation, the medical director or designated physician and a registered nurse will be on-call.
14. Data Collection: The application shall affirm that the applicant will record and maintain, at a minimum, the following utilization data and make this data available to the Mississippi State Department of Health as required. The time frame for the submission of the utilization data shall be established by the Department.
- a. Utilization data, e.g., days of operation, shifts, inventory and classification of all stations, number of patients in dialysis, transplanted, or expired.
 - b. The number of charity/indigent patients (as defined in this *Plan*) served by the facility and the number of dialysis procedures provided to these patients free of charge or at a specified reduced rate.
15. Staff Training: The application shall affirm that the applicant will provide an ongoing program of training in dialysis techniques for nurses and technicians at the facility.
16. Scope of Privileges: The applicant shall affirm that the facility shall provide access to doctors of medicine or osteopathic medicine licensed by the State of Mississippi who possess qualifications established by the governing body of the facility.
17. Affiliation with a Renal Transplant Center: The applicant shall affirm that within one year of commencing operation the facility will enter into an affiliation agreement with a transplantation center. The written agreement shall describe the relationship between the transplantation facility and the ESRD facility and the specific services that the transplantation center will provide to patients of the ESRD facility. The agreement must include at least the following:
- a. time frame for initial assessment and evaluation of patients for transplantation,
 - b. composition of the assessment/evaluation team at the transplant center,
 - c. method for periodic re-evaluation,
 - d. criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and
 - e. signatures of the duly authorized persons representing the facilities and the agency providing the services.
 - f. Furthermore, the application shall affirm that the applicant understands and agrees that failure to comply with this criterion may (after due process) result in revocation of the Certificate of Need.

104.02.02 Establishment of a Renal Transplant Center

- 1. Need Criterion: The applicant shall document that the proposed renal transplant center will serve a minimum population of 3.5 million people.**
2. The applicant shall document that the proposed facility will provide, at a minimum, the following:
 - a. medical-surgical specialty services required for the care of ESRD transplant patients;
 - b. acute dialysis services;
 - c. an organ procurement system;
 - d. an organ preservation program; and
 - e. a tissue typing laboratory.
3. The applicant shall document that the facility will perform a minimum of 25 transplants annually.

