comply with personnel requirements consistent with any waiver.

(b) Minimum compliance requirements. Each case will have to be decided on its individual merits, and while the degree and extent of compliance will vary, the institution must, as a minimum, meet all of the statutory conditions in section 1861(e)(1)-(8), in addition to meeting such other requirements as the Secretary finds necessary under section 1861(e)(9). (For further information relating to the exception in section 1861(e)(5) of the Act, see paragraph (c) of this section.)

(c) Temporary waiver of 24-hour nursing requirement of 24-hour registered nurse requirement. CMS may waive the requirement contained in section 1861(e)(5) that a hospital must provide 24-hour nursing service furnished or supervised by a registered nurse. Such a waiver may be granted when the following criteria are met:

(1) The hospital’s failure to comply fully with the 24-hour nursing requirement is attributable to a temporary shortage of qualified nursing personnel in the area in which the hospital is located.

(2) A registered nurse is present on the premises to furnish or supervise the nursing services during at least the daytime shift, 7 days a week.

(3) The hospital has in charge, on all tours of duty not covered by a registered nurse, a licensed practical (vocational) nurse.

(4) The hospital complies with all requirements specified in paragraph (a) of this section.

(d) Temporary waiver for technical personnel. CMS may waive technical personnel requirements, issued under section 1861(e)(9) of the Act, contained in the Conditions of Participation; Hospitals (part 482 of this chapter). Such a waiver must take into account the availability of technical personnel and the educational opportunities for technical personnel in the area in which the hospital is located. CMS may also limit the scope of services furnished by a hospital in conjunction with the waiver in order not to adversely affect the health and safety of the patients. In addition, the hospital must also comply with all requirements specified in paragraph (a) of this section.

§ 488.60 Special procedures for approving end stage renal disease facilities.

(a) Consideration for approval. An ESRD facility that wishes to be approved or that wishes an expansion of dialysis services to be approved for coverage, in accordance with part 494 of this chapter, must secure a determination by the Secretary. To secure a determination, the facility must submit the following documents and data for consideration by the Secretary:

1. Certification by the State agency referred to in §488.12 of this part.
2. Data furnished by ESRD network organizations and recommendations of the Public Health Service concerning the facility's contribution to the ESRD services of the network.
3. Data concerning the facility's compliance with professional norms and standards.
4. Data pertaining to the facility's qualifications for approval or for any expansion of services.

(b) Determining compliance with minimal utilization rates: Time limitations—(1) Unconditional status. A facility which meets minimal utilization requirements will be assigned this status as long as it continues to meet these requirements.

2. Conditional status. A conditional status may be granted to a facility for not more than four consecutive calendar years and will not be renewable (see §405.2122(b) of this chapter). Its status may be examined each calendar year to ascertain its compliance with Subpart U.

3. Exception status. Under unusual circumstances (see §405.2122(b) of this chapter) the Secretary may grant a time-limited exception to a facility which is not in compliance with the minimal utilization rate(s) for either unconditional status or conditional status. This exception status may be granted, and may be renewed on an annual basis, under circumstances where rigid application of minimal utilization rate requirements would adversely affect the achievement of ESRD program objectives.

(c) New applicant. A facility which has not previously participated in the ESRD program must submit a plan detailing how it expects to meet the conditional minimal utilization rate status by the end of the second calendar year of its operation under the program and meet the unconditional minimal utilization rate status by the end of the fourth calendar year of its operation under the program.

(d) Notification. The Secretary will notify each facility and its network coordinating council of its initial and its subsequent minimal utilization rate classification.

(e) Failure to meet minimal utilization rate. A facility failing to meet standards for unconditional status or conditional status, or if applicable, for exception status, will be so notified at the time of such classification.

(f) Interim regulations participant. A facility previously participating under the interim regulations will not be approved under the program established by subpart U until it has demonstrated that it meets all the applicable requirements of this subpart, including the appropriate minimal utilization rate. It may continue under the interim program only for a period not to exceed 1 year from the effective date of these amendments (see §405.2100(c) of this chapter). During this period it may demonstrate its ability to meet the appropriate minimal utilization rate. Failure to qualify under this subpart will automatically terminate coverage of such facility's services under Subpart U.