COVID-19 FAQs

As of 5/13/2020

National Dialysis Accreditation Commission (NDAC) is providing this Frequently Asked Questions update about COVID-19. For the additional up-to-date information, please continue to reference the following sites:

The Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare/quality-safety-oversight-general-information/coronavirus

Centers for Disease Control: https://www.cdc.gov/coronavirus/2019-ncov/index.html

Q: Is NDAC conducting initial surveys for new dialysis providers?

A: Yes. NDAC is conducting onsite initial surveys with some limitations in locations that have travel restrictions or those with COVID positive patients.

Q: What is the latest news regarding virtual surveys?

A: NDAC is conducting virtual surveys for new dialysis providers seeking an initial accreditation and deemed status for Medicare certification. NDAC was the first Accreditation Organization approved by CMS in April 2020 to offer such a service. Successfully passing NDAC's virtual accreditation survey will allow a provider to receive temporary certification from Medicare and a provider number under which to bill for services. Once the national emergency is lifted, the provider must successfully pass a full on-site initial survey to demonstrate compliance with all ESRD CfCs in order to be fully Medicare certified.

Q: Are service additions and station expansion able to be conducted remotely by NDAC?

A: Yes. Dialysis providers that are already NDAC accredited and seeking a service modality addition are eligible for a virtual survey by NDAC. A subsequent full on-site survey would need to be conducted after the national emergency is lifted to award full accreditation and deemed status certification of that modality. NDAC is also able to conduct desk reviews and approval for station expansions for NDAC accredited facilities.

Q: What safety measure are your surveyors taking?

A: NDAC staff are self-monitoring their health and following CDC guidelines to prevent the spread of COVID-19. Providers continue to be required to provide personal protective equipment (PPE) for all visitors to their facilities, including NDAC survey staff.

Q: If we are running low on PPE, is substituting products, and modifying our infection control procedures acceptable?

A: Yes. At this time, it is most important to meet the needs of your patients using the best methods you can. We recommend that you document the effective date of this decision and the rationale. Retain this documentation with your performance improvement materials.

KEY COVID-19 EMERGENCY DECLARATION BLANKET WAIVERS FOR ESRD BELOW.

FROM 5/11/2020 RELEASE

PLEASE REFERENCE THE CMS WEBSITE ABOVE FOR THE MOST UP-TO-DATE INFORMATION.

Training Program and Periodic Audits. CMS is waiving the requirement at 42 CFR §494.40(a) related to the condition on Water & Dialysate Quality, specifically that on-time periodic audits for operators of the water/dialysate equipment are waived to allow for flexibilities.

Defer Equipment Maintenance & Fire Safety Inspections. CMS is waiving the requirement at 42 CFR §494.60(b) for on-time preventive maintenance of dialysis machines and ancillary dialysis equipment. Additionally, CMS is also waiving the requirements under §494.60(d) which requires ESRD facilities to conduct on-time fire inspections. These waivers are intended to ensure that dialysis facilities are able to focus on the operations related to the Public Health Emergency.

Emergency Preparedness. CMS is waiving the requirements at 42 CFR §494.62(d)(1)(iv) which requires ESRD facilities to demonstrate as part of their Emergency Preparedness Training and Testing Program, that staff can demonstrate that, at a minimum, its patient care staff maintains current CPR certification. CMS is waiving the requirement for maintenance of CPR certification during the COVID-19 emergency due to the limited availability of CPR classes.

Ability to Delay Some Patient Assessments. CMS is not waiving subsections (a) or (c) of 42 CFR §494.80, but is waiving the following requirements at 42 CFR §494.80(b) related to the frequency of assessments for patients admitted to the dialysis facility. CMS is waiving the "on- 23 5/11/2020 1 time" requirements for the initial and follow up comprehensive assessments within the specified timeframes as noted below. This waiver applies to assessments conducted by members of the interdisciplinary team, including: a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. These waivers are intended to ensure that dialysis facilities are able to focus on the operations related to the Public Health Emergency. Specifically, CMS is waiving:

> §494.80(b)(1): An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.

§494.80(b)(2): A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in §494.90.

Time Period for Initiation of Care Planning and Monthly Physician Visits. CMS is modifying two requirements related to care planning, specifically:

42 CFR §494.90(b)(2): CMS is modifying the requirement that requires the dialysis facility to implement the initial plan of care within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. This modification will also apply to the requirement for monthly or annual updates of the plan of care within 15 days of the completion of the additional patient assessments.

§494.90(b)(4): CMS is modifying the requirement that requires the ESRD dialysis facility to ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, and periodically while the hemodialysis patient is receiving in-facility dialysis. CMS is waiving the requirement for a monthly in-person visit if the patient is considered stable and also recommends exercising telehealth flexibilities, e.g. phone calls, to ensure patient safety.

Dialysis Home Visits to Assess Adaptation and Home Dialysis Machine Designation. CMS is waiving the requirement at 42 CFR §494.100(c)(1)(i) which requires the periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel. For more information on existing flexibilities for in-center dialysis patients to receive their dialysis treatments in the home, or long-term care facility, referenceQSO-20-19-ESRD. 24 5/11/2020 1

Home Dialysis Machine Designation – Clarification. The ESRD Conditions for Coverage (CFCs) do not explicitly require that each home dialysis patient have their own designated home dialysis machine. The dialysis facility is required to follow FDA labeling and manufacturer's directions for use to ensure appropriate operation of the dialysis machine and ancillary equipment. Dialysis machines must be properly cleaned and disinfected to minimize the risk of infection based on the requirements at 42 CFR §494.30 Condition: Infection Control if used to treat multiple patients.

Special Purpose Renal Dialysis Facilities (SPRDF) Designation Expanded. CMS authorizes the establishment of SPRDFs under 42 CFR §494.120 to address access to care issues due to COVID19 and the need to mitigate transmission among this vulnerable population. This will not include the normal determination regarding lack of access to care at §494.120(b) as this standard has been met during the period of the national emergency. Approval as a Special Purpose Renal Dialysis Facility related to COVID-19 does not require Federal survey prior to providing services.

Dialysis Patient Care Technician (PCT) Certification. CMS is modifying the requirement at 42 CFR §494.140(e)(4) for dialysis PCTs that requires certification under a state certification program or a national commercially available certification program within 18 months of being hired as a dialysis PCT for newly employed patient care technicians. CMS is aware of the challenges that PCTs are facing with the limited availability and closures of testing sites during the time of this crisis. CMS will allow PCTs to

continue working even if they have not achieved certification within 18 months or have not met on time renewals.

Transferability of Physician Credentialing. CMS is modifying the requirement at 42 CFR §494.180(c)(1) which requires that all medical staff appointments and credentialing are in accordance with state law, including attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists. These waivers will allow physicians that are appropriately credentialed at a certified dialysis facility to function to the fullest extent of their licensure to provide care at designated isolation locations without separate credentialing at that facility, and may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.

Expanding Availability of Renal Dialysis Services to ESRD Patients. CMS is waiving the following requirements related to Nursing Home residents: o Furnishing Dialysis Services on the Main Premises: (Revised since 4/30 Release) ESRD requirements at 42 CFR §494.180(d) require dialysis facilities to provide services directly on its main premises or on other premises that are contiguous with the main premises. CMS is waiving this requirement to allow dialysis facilities to provide service to its patients who reside in the nursing homes, long-term care facilities, assisted living facilities and similar types of facilities, as licensed by the state (if applicable). CMS continues to require that services provided to these patients or residents are under the direction of the same governing body and professional staff as the resident's usual 25 5/11/2020 1 Medicare-certified dialysis facility. Further, in order to ensure that care is safe, effective and is provided by trained and qualified personnel, CMS requires that the dialysis facility staff: 1) furnish all dialysis care and services; 2) provide all equipment and supplies necessary; 3) maintain equipment and supplies in off-premises location; 4) and complete all equipment maintenance, cleaning and disinfection using appropriate infection control procedures and manufacturer's instructions for use.

Clarification for Billing Procedures. Typically, ESRD beneficiaries are transported from a SNF/NF to an ESRD facility to receive renal dialysis services. In an effort to keep patients in their SNF/NF and decrease their risk of being exposed to COVID-19, ESRD facilities may temporarily furnish renal dialysis services to ESRD beneficiaries in the SNF/NF instead of the offsite ESRD facility. The in-center dialysis center should bill Medicare using Condition Code 71 (Full care unit. Billing for a patient who received staff-assisted dialysis services in a hospital or renal dialysis facility). The in-center dialysis center should also apply condition code DR to claims if all the treatments billed on the claim meet this condition or modifier CR on the line level to identify individual treatments meeting this condition. The ESRD provider would need to have their trained personnel administer the treatment in the SNF/ NF. In addition, the provider must follow the CFCs. In particular, under the CFCs is the requirement that to use a dialysis machine, the FDA approved labeling must be adhered to § 494.100 and it must be maintained and operated in accordance with the manufacturer's recommendations (§ 494.60) and follow infection control requirements at § 494.30.