



EDUCATIONAL RESOURCES

WELCOME

Preparing New Organizations:
An Introduction to Dialysis Services

DIALYSIS SERVICES BACKGROUND

- In 1962 the world's first free-standing outpatient dialysis unit, the Seattle Artificial Kidney Center (SAKC) – now the Northwest Kidney Centers – was opened.
- 1960-Scribner and colleagues described most of the medical complications and the social, financial, and ethical problems associated with ESRD treatment.
- 1962-Insurers and other funding sources did not cover treatment for ESRD, and demand far exceeded available financial resources. Solutions?
 - Admissions Committee
 - The committee continued until 1971

OVERVIEW: BRIEF HISTORY OF MEDICARE END-STAGE RENAL DISEASE (ESRD) REIMBURSEMENT

- Medicare coverage for ESRD patients took effect on July 1, 1973 at the time there were 10,000 patients on dialysis
 - On December 31, 2017, there were 746,557 prevalent cases of ESRD of which nearly 600,000 patients were on dialysis
- Insurance Coverage
- Medicare is the primary insurer for approximately 80- 85% of patients in the U.S and includes Medicare Advantage Plans
- Medicaid coverage ranges from 5-10% of the patients and includes emergency Medicaid
- Commercial coverage ranges 8-12% and includes contract plans – HMO, PPO, etc.
- Self pay and charity accounts for 5% or less

ESRD PROSPECTIVE PAYMENT SYSTEM (PPS)

- In 2018 Medicare paid claims for ESRD services and supplies totaling over \$37 billion.
- In order to control cost Medicare established the ESRD PPS in effect January 1, 2011. All dialysis **associated** costs were bundled under one payment including:
 - Treatment supplies and personnel
 - Equipment acquisition and maintenance
 - Physical plant
 - Administrative costs
 - All pharmaceuticals and laboratory tests

ESRD PPS IN 2020

Current Base rate \$239.33

- Adjustments to base rate:
 - Patient specific (age, body surface area, comorbidity)
 - Facility adjustment
 - Wage index
 - Low volume <4000 treatments each year
 - Onset of dialysis
 - Training

TO PROMOTE QUALITY

- Medicare implemented the ESRD Quality Incentive Program (QIP) designed to improve patient outcomes by establishing payment incentives for dialysis facilities to meet performance standards established by CMS
- Under the ESRD QIP, ESRD facilities' performance on a set of quality measures is assessed and scored, and a payment reduction of up to 2 percent of Medicare reimbursement is applied to those facilities that do not achieve a minimum total performance score (mTPS)

QIP PY 2020 MEASURES AND SCORING METHODOLOGIES

Clinical Measure Domain – 75% of TPS

Patient and Family Engagement/ Care Coordination Subdomain – 40% of Clinical Measure Domain score

1. ICH CAHPS
2. SRR

Clinical Care Subdomain – 60% of Clinical Measure Domain score

1. STrR
2. Kt/V Dialysis Adequacy (comprehensive)
3. VAT Measure Topic –AVF
4. VAT Measure Topic – Catheter ≥ 90 days
5. Hypercalcemia
- ★ 6. Standardized Hospitalization Ratio (SHR)

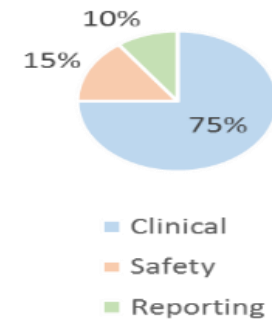
Safety Measure Domain – 15% of TPS

1. NHSN BSI Measure Topic –
NHSN Bloodstream Infection Clinical
2. NHSN BSI Measure Topic –
NHSN Reporting

Reporting Measure Domain – 10% of TPS

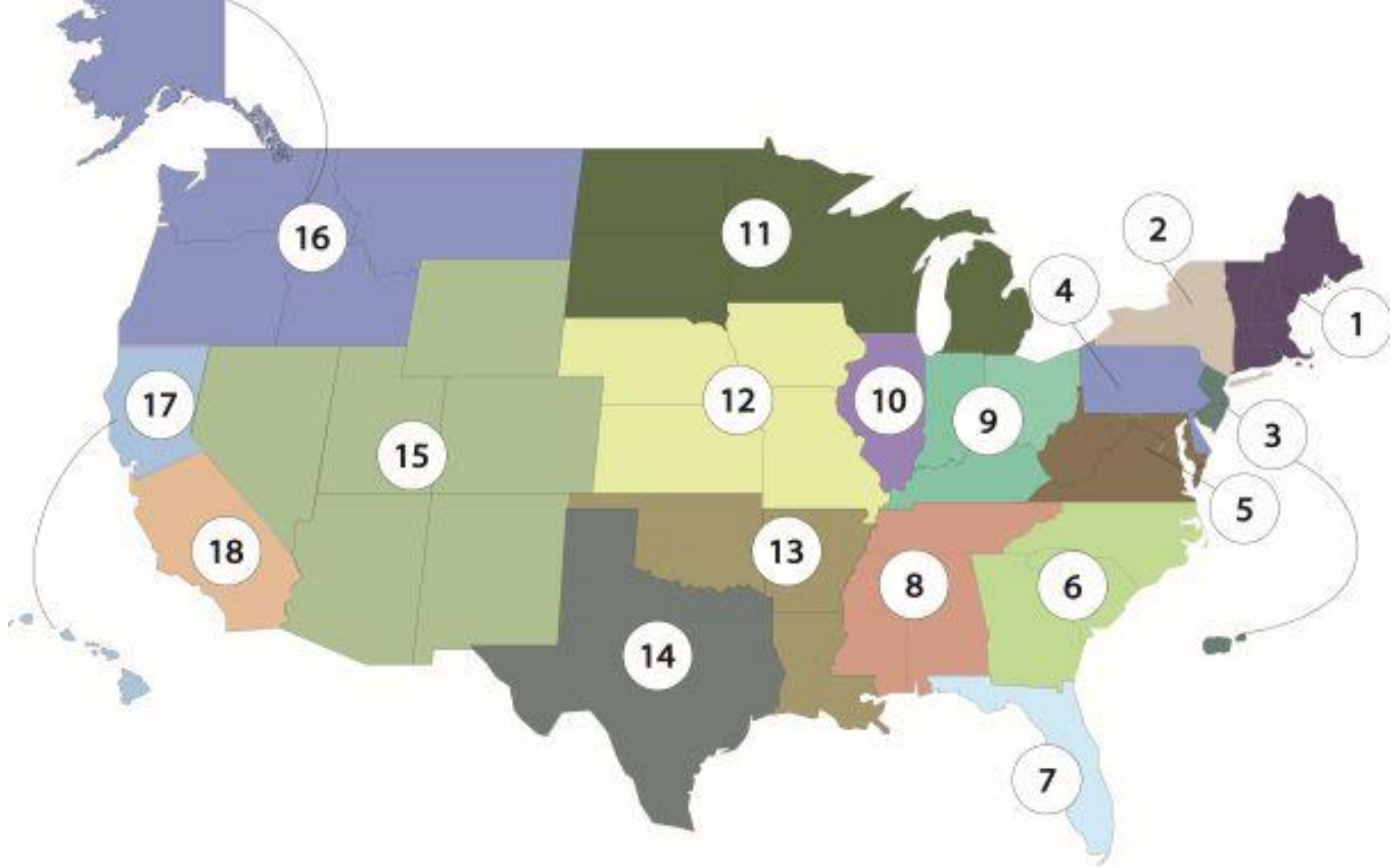
- ★ 1. Serum Phosphorus
2. Anemia Management
3. Pain Assessment and Follow-Up
4. Clinical Depression Screening and Follow-Up
5. NHSN Healthcare Personnel Influenza Vaccination
- ★ 6. Ultrafiltration Rate

★ new measure for PY 2020



ESRD NETWORKS

- There are eighteen (18) ESRD (End-stage Renal Disease) Network Organizations under contract to CMS and serve as liaisons between the federal government and the providers of ESRD services.
- The Network Organizations are defined geographically by the number and concentration of ESRD beneficiaries in each area. Some Networks represent one state, others multiple states.
- The Forum of ESRD (End-stage Renal Disease) Networks advocates for the organizations that monitor the quality of chronic kidney disease, dialysis and kidney transplant care in the United States.



DIALYSIS PROVIDERS

Table 1. The largest dialysis providers in 2018

Dialysis Provider	Number of patients	In-Center Conv. HD	Home HD	PD	Units	Patient growth 5/18 (vs. 5/17)
1. Fresenius Medical Care North America	201,180	179,212	3,693	18,275	2,521	8,216 (8,880)
2. DaVita Kidney Care	199,000	174,800	3,300	20,900	2,563	8,500 (8,700)
3. U.S. Renal Care	24,817	22,079	183	2,555	336	- 303 (1,128)
4. American Renal Associates	15,776	14,247	137	1,392	228	1,041 (1,315)
5. Dialysis Clinic Inc.	14,958	13,154	177	1,627	248	-41 (26)
6. Satellite Healthcare	7,954	6,381	219	1,354	83	347 (291)
7. Atlantic Dial. Man.	2,283	2,219	6	58	13	67 (-85)
8. Northwest Kidney Centers	1,765	1,488	49	228	16	50 (75)
9. Centers for Dialysis Care	1,568	1,568			14	66 (-88)
10. Rogosin Institute	1,485	1,356	44	85	7	n/c (0)
2018 Totals	470,786	416,504	7,808	46,474	6,030	
2017 Totals	453,043	402,325	7,004	43,714	5,888	

Source: Mark E. Neumann, *Nephrology News & Issues*

GROWTH IN PD & HHD POPULATION

Table 2. Growth in PD and HHD among the 10 largest providers: 2013-2018

Year	PD	HHD
2013	34,067	5,783
2014	38,424	6,098
2015	39,817	6,558
2016	41,624	6,932
2017	43,714	7,004
2018	46,474	7,808
Growth from 2013-2018	12,407	2,025

Source: Mark E. Neumann, *Nephrology News & Issues*

BREAKDOWN OF PREVALENT PATIENTS BY MODALITY

- On December 31, 2017
 - 62% of patients received incenter hemodialysis
 - 7.1% of patients received peritoneal dialysis at home
 - 4% of patients received home hemodialysis

PROPOSED CHANGES & UPDATES TO THE ESRD PPS FOR CY 2021

- Under the ESRD PPS for CY 2021, Medicare expects to pay \$10.3 billion to approximately 7,400 ESRD facilities for the costs associated with furnishing renal dialysis services.
- **Update to the ESRD PPS base rate:** The proposed CY 2021 ESRD PPS base rate is \$255.59, an increase of \$16.26 to the current base rate of \$239.33. The proposed rate includes:
 - The application of the proposed wage index budget-neutrality adjustment factor (0.998652)
 - The addition of \$12.06 to include calcimimetics
 - A productivity-adjusted market basket increase of 1.8%
- Formula: $((\$239.33 \times .998652) + \$12.06) \times 1.018 = \$255.5$

ADJUSTMENTS TO THE PPS RATE IN 2021

- The ESRD PPS provides a training add-on payment adjustment for home and self-dialysis modalities and, for high-cost patients, an ESRD facility may be eligible for outlier payments.
- Low volume
- Onset of dialysis
- Comorbidities
- A transitional drug add-on payment adjustment (TDAPA) and the TPNIES, to facilitate patient access to certain qualifying new and innovative dialysis equipment and supplies.

ESRD CONDITIONS FOR COVERAGE (CFC)

- The ESRD CfCs are the minimum health and safety rules that all Medicare and Medicaid participating dialysis facilities must meet.
- The regulations are defined in four “subpart categories”:
 - Subpart A
 - Subpart B
 - Subpart C
 - Subpart D

SUBPART A - GENERAL PROVISIONS

- Basis and scope
- Definitions
- Condition: Compliance with Federal, State, and local laws and regulations

SUBPART B –PATIENT SAFETY

- Condition: Infection control
- Condition: Water and dialysate quality
- Condition: Reuse of hemodialyzers and bloodlines
- Condition: Physical environment

SUBPART C – PATIENT CARE

- Condition: Patient Rights
- Condition: Patient Assessment
- Condition: Patient Plan of Care
- Condition: Care at Home
- Condition: Quality Assurance Performance Improvement
- Condition: Special Purpose Renal Dialysis Facilities
- Condition: Laboratory Services

SUBPART D - ADMINISTRATION

- Condition: Personnel Qualifications
- Condition: Responsibilities of the Medical Director
- Condition: Medical records
- Condition: Governance



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RENAL DIALYSIS

Key Steps to Opening a Medicare-Certified
Renal Dialysis Facility

KEY STEPS

Certificate of Need (CON)

- State endorsement
 - Application process
- More information visit:
 - National Conference of State Legislatures
www.ncsl.org
 - American Health Planning Association
www.ahpanet.org



KEY STEPS

State Licensure Requirements

- To determine if state licensure is required in the state where you want to operate a renal dialysis facility, call or visit your state's Department of Health and Human Services website

KEY STEPS

National Provider Identifier (NPI)

- Who gets a National Provider Identifier (NPI)?
 - All Individuals and Organizations who meet the definition of health care provider as described at 45 CFR 160.103 are eligible to obtain a National Provider Identifier, or NPI. If you are a HIPAA covered provider or if you are a health care provider/supplier who bills Medicare for your services, you need an NPI
- What is the purpose of NPI?
 - An NPI is a unique 10-digit identification number
 - Type 1
 - Type 2
- When should an NPI be obtained?
 - You will need an NPI prior to enrolling with Medicare
- How do I get an NPI?
 - Complete the on-line application at the NPPES web site; <https://NPPES.cms.hhs.gov/NPPES/Welcome.do>
 - Download the paper application form at www.cms.hhs.gov/NationalProvIdentStand/ and mail it to the address on the form.
 - Authorize an employer or other trusted organization to obtain an NPI for you through bulk enumeration, or Electronic File Interchange.

KEY STEPS

CMS - Centers for Medicare & Medicaid Services

- Medicare Enrollment Application for Institutional Providers, for approval from a Medicare Administrative Contractor (MAC)
 - Internet-based Provider Enrollment, Chain of Ownership System (PECOS), or
 - Paper enrollment application process (CMS 855A)

**Visit www.cms.gov, search enrollment application, and click on “Enrollment Application”

KEY STEPS

CMS-3427

- End Stage Renal Disease Application, and Survey, and Certification Report
 - Medicare certification/recertification for a new facility, existing facility, expansion of stations/services, relocation, or change of ownership
 - Completed by facility and the information is reviewed by the surveyor
 - Send the completed form to either:
 - Local State Survey Agency (SA)
 - CMS-approved Accreditation Organization (AO)

*FYI - CMS 3427-Updated 06/04/2020

KEY STEPS

Compliance with rules and regulations of the Centers for Medicare & Medicaid Services (CMS) is required in order to become accredited. The CMS essential manuals are located at www.cms.gov

- Essential CMS manuals:
 - **State Operations Manual Appendix H** contains the Medicare Conditions for Coverage (CfCs) along with the interpretive guidelines for ESRD facilities.
 - **State Operations Manual Chapter 2** - The Certification Process covers topics such as initial CMS Regional Office (RO) approval, expansion or addition of services, participation in network activities, laboratory services requirements, and furnishing data and information for ESRD program administration.
 - **Medicare Benefit Policy Manual Chapter 11** - provides guidance on definitions related to ESRD, home dialysis training, equipment and supplies, the ESRD Prospective Payment System (PPS), and other renal dialysis items and services.
 - **State Operations Manual Appendix Z** - Emergency Preparedness specific to ESRD facilities, section §494.62 contains guidelines and survey procedures for the Emergency Preparedness Final Rule.

KEY STEPS

Compliance with Life Safety Code (LSC) in End Stage Renal Disease (ESRD) Facilities

- Limited LSC Applicability to ESRD Facilities
- Retained Compliance by ESRD Facilities
- Attestation by ESRD Facilities for Exemption
- More information available at: <https://www.cms.gov/Medicare/ProviderEnrollment-and-Certification/GuidanceforLawsAndRegulations/LSC>



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Model Attestation Statement

Life Safety Code Attestation for Exempt ESRD Facilities

Facility Name: _____ CCN: _____

Facility address:

I attest to the following:

- The above named facility provides one or more exits to the outside at grade level from the patient treatment area level. *(Note that the patients' exit path from the treatment area may include an accessibility ramp that complies with the Americans with Disabilities Act (ADA));*
AND
- The above named facility is not adjacent to a high hazardous occupancy. *(Note: This type of occupancy is defined in NFPA 101, 2000 Edition at § A.3.3.134.8.2 as "occupancies where gasoline and other flammable liquids are handled, used, or stored under such conditions that involve possible release of flammable vapors; where grain dust, wood, or plastic dusts, aluminum or explosives are manufactured, stored, or handled; where cotton or other combustible fibers are processed or handled under conditions that might produce flammable flyings; and where other situations of similar hazard exist.")*

The facility agrees to notify CMS if there are any structural changes that would cause the facility to no longer meet the exemption requirements.

Signature of Facility Administrator

Date

ADDITIONAL INFORMATION

CMS – CfC: 494.140 Personnel Qualifications

- **Medical Director:** Must be a board-certified physician in internal medicine or pediatrics by a professional board who has completed a board-approved training program in nephrology and has at least 12 months of experience providing care to patients receiving dialysis
- **Nurse Manager:** The facility must have a nurse manager responsible for nursing services in the facility who must— (i) Be a full time employee of the facility; (ii) Be a registered nurse; and (iii) Have at least 12 months of experience in clinical nursing, and an additional 6 months of experience in providing nursing care to patients on maintenance dialysis.
- **Self-Care and Home dialysis training nurse:** Must (i) Be a registered nurse; and (ii) Have at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training.
- **Registered Dietitian:** (1) Be a registered dietitian with the Commission on Dietetic Registration; and (2) Have a minimum of 1-year professional work experience in clinical nutrition as a registered dietitian.
- **Social Worker:** Must (1) Holds a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education; or (2) Has served at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under § 494.140 (d)(1).

ADDITIONAL INFORMATION

- Consulting Services
 - Health Design Specialist (HDS)
- Accrediting Organizations (AO)
 - Accreditation Commission for Health Care (ACHC)



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RENAL DIALYSIS

QUESTIONS?

(855) 937-2242 | www.achc.org

REFERENCES

- U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. (2008). ESRD Interpretive Guidance: Conditions for Coverage for ESRD facilities. Retrieved from <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCletter09-01.pdf>
- ESRD Network Organizations | CMS. (n.d.). [www.cms.gov](https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations). Retrieved September 24, 2020, from <https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations>