MEASURE INFORMATION FORM

Project Title:

End-Stage Renal Disease Emergency Department Visits Measure Development

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan's Kidney Epidemiology and Cost Center (UM-KECC) to develop emergency department utilization measures for ESRD patients. The contract name is the ESRD Quality Measure Development, Maintenance, and Support contract. The contract number is HHSM-500-2013-13017I.

Date:

Information included is current on September 25, 2018

Measure Name

Standardized Emergency Department Encounter Ratio (SEDR) for Dialysis Facilities

Descriptive Information
Measure Name (Measure Title De.2.)
Standardized Emergency Department Encounter Ratio (SEDR) for Dialysis Facilities

Measure Type De.1.
Outcome

Brief Description of Measure De.3.
The Standardized Emergency Department Encounter Ratio is defined to be the ratio of the number of emergency department (ED) encounters that occur for adult dialysis patients treated at a particular facility to the number of encounters that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. Note that in this document an "emergency department encounter" always refers to an outpatient encounter that does not end in a hospital admission. This measure is calculated as a ratio but can also be expressed as a rate.

If Paired or Grouped De.4.
N/A

Measure Specifications

Measure-specific Web Page S.1.
N/A

If This Is an eMeasure S.2a.
N/A

Data Dictionary, Code Table, or Value Sets S.2b.
See SEDR_DataDictionary.xlsx

For Endorsement Maintenance S.3.1 and S.3.2
N/A

Numerator Statement S.4.
The observed number of outpatient Emergency Department encounters during the reporting period among eligible patients at a facility.

Numerator Details S.5.
Emergency department (ED) encounters are identified from Medicare outpatient claims using revenue center codes that indicate an ED visit (0450, 0451, 0452, 0453, 0454, 0455, 0456, 0457, 0458, 0459, 0981). Note that this means that we include both outpatient ED visits and those that result in an observation stay, but not those that result in a hospital admission. Outpatient ED claims that have overlapping or consecutive dates of service are combined and considered as a single ED encounter. To further ensure that these outpatient ED encounters are distinct from those associated with hospitalizations, we exclude ED encounters where there is an inpatient claim for the patient that has dates of service including any of the same time period covered by the ED encounter.

The total number of emergency department encounters includes multiple encounters (i.e., second, third, etc.) for the same patient during the reporting period.

See denominator details for additional criteria for a patient to be assigned to a particular facility and criteria for identifying emergency department encounters.

The time period for the measure calculation is one calendar year.

Denominator Statement S.6.
The expected number of Emergency Department encounters among eligible patients at the facility during the reporting period adjusted for the characteristics of the patients at the facility.

Denominator Details S.7.
General Inclusion Criteria for Dialysis Patients
An eligible patient is defined as an adult (aged 18 or more) Medicare dialysis patient with at least 90 days of ESRD treatment. Because we only include a patient's follow-up in the tabulations for this measure after that patient has received chronic renal replacement therapy for at least 90 days, emergency department encounters during the first 90 days of ESRD are not counted.

We assign patients to a particular facility only after they have been on chronic dialysis there for the past 60 days. This 60 day period is used both for patients who started ESRD for the first time and for those who returned to dialysis after a transplant. Emergency Department encounters during the first 60 days of dialysis at a facility do not affect the facility's Standardized Emergency Department Encounter Ratio.

We require that patients reach a certain level of Medicare dialysis bills to be included in the emergency department encounter ratio. Specifically, months within a given dialysis patient-period are used for the Standardized Emergency Department Encounter Ratio calculation when they meet the criterion of being within two months after a month with either: (a) $900+ of Medicare dialysis claims OR (b) at least one Medicare inpatient claim. The intention of this criterion is to assure completeness of information on emergency department encounters for all patients included in the analysis.

Identifying Facility Treatment Histories for Each Patient

For each patient, we identify the dialysis provider at each point in time. Starting with day 91 after onset of ESRD, we attribute patients to facilities according to the following rules. A patient is attributed to a facility once the patient has been treated there for the past 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility. In particular, a patient is attributed to his or her current facility on day 91 of ESRD if that facility had treated him or her for the past 60 days. If on day 91, the facility had not treated a patient for the past 60 days, we wait until the patient reaches day 60 of continuous treatment at that facility before attributing the patient to that facility. When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we do not attribute that patient to any facility. Patients who withdrew from dialysis or recovered renal function remain assigned to their treatment facility for 60 days after withdrawal or recovery.

If a period of one year passes with neither Medicare dialysis claims nor CROWNWeb information to indicate that a patient was receiving dialysis treatment, we consider the patient lost to follow-up and do not include that patient in the analysis. If dialysis claims or other evidence of dialysis reappears, the patient is entered into analysis after 60 days of continuous therapy at a single facility.

Days at Risk for Medicare Dialysis Patients

After patient treatment histories are defined as described above, periods of follow-up in time since ESRD onset are created for each patient. In order to adjust for duration of ESRD appropriately, we define 6 time intervals with cut points at 6 months, 1 year, 2 years, 3 years and 5 years. A new time period begins each time the patient is determined to be at a different facility, or at the start of each calendar year or when crossing any of the above cut points.

The number of days at risk in each of the six time intervals listed above is used to calculate the expected number of emergency department encounters for the patient during that period. The Standardized Emergency Department Encounter Ratio for a facility is the ratio of the total number of observed emergency department encounters to the total number of expected emergency department encounters during all time periods at the facility. Based on a risk adjustment model for the overall national emergency department encounter rate, we compute the expected number of emergency department encounters that would occur for each month that each patient is attributed to a given facility. The sum of all such expectations for patients and months yields the overall number of emergency department encounters that would be expected at the facility given the specific patient mix. This forms the denominator of the measure.

The denominator of the Standardized Emergency Department Encounter Ratio is derived from a proportional rates model (Lawless and Nadeau, 1995; Lin et al., 2000; Kalbfleisch and Prentice, 2002). This is the recurrent event analog of the well-known proportional hazards or Cox model (Cox, 1972; Kalbfleisch and Prentice, 2002). To accommodate large-scale data, we adopt a model with piecewise constant baseline rates (e.g. Cook and Lawless, 2007) and the computational methodology developed in Liu, Schaubel and Kalbfleisch (2012).

References:

- Cook, R. and Lawless, J. The Statistical Analysis of Recurrent Events. New York: Springer. 2007.
- Cox, D.R. (1972) Regression Models and Life Tables (with Discussion). J. Royal statistical Society,

Series B, 34, 187-220.
- Kalbfleisch, J.D. and Prentice, R. L. The Statistical Analysis of Failure Time Data. Wiley, New York, 2002.
- Lawless, J. F. and Nadeau, C. Some simple and robust methods for the analysis of recurrent events, Technometrics, 37 1995, 355-364.
- Lin, D.Y., Wei, L.J., Yang, I. and Ying, Z. Semi parametric regression for the mean and rate functions of recurrent events, Journal of the Royal Statistical Society Series B, 62, 2000, 771-730
- Liu, D., Schaubel, D.E. and Kalbfleisch, J.D. Computationally efficient marginal models for clustered recurrent event data, University of Michigan Department of Biostatistics Technical Reports, 2010.

Denominator Exclusion (NQF Includes "Exception" in the "Exclusion" Field) S.8.
Exclusions that are implicit in the denominator definition include time at risk while a patient:
- Has had ESRD for 90 days or less
- Is less than 18 years of age

The denominator also excludes patient time at risk for calendar months in which a patient is:
- Actively enrolled in hospice at any time during the calendar month

Denominator Exclusion Details (NQF Includes "Exception" in the "Exclusion" Field) S.9.
We exclude from the time at risk for the measure all calendar months in which a patient spends any time enrolled in hospice (enrollment is determined from Medicare hospice claims). Hospice patients are considered to be under the purview of hospice care givers and may have other reasons for Emergency Department use such as pain management.

Stratification Details/Variables S.10.
N/A

Risk Adjustment Type S.11.
Statistical risk model

The modeling process has two stages. At stage I, a stratified model is fitted to the national data with piecewise-constant baseline rates and stratification by facility. Specifically, the model is of the following form

$$Pr(\text{Emergency department encounter on day } t \text{ given covariates } X) = r_{0k}(t)\exp(\beta' X_{ik})$$

where X_{ik} is the vector of covariates for the i^{th} patient in the k^{th} facility and β is the vector of regression coefficients. Time t is measured from the start of ESRD. The baseline rate function $r_{0k}(t)$ is specific to the k^{th} facility, and is assumed to be a step function with break points at 6 months, 1 year, 2 years, 3 years and 5 years since the onset of dialysis. This model allows the baseline emergency department rates to vary between strata (facilities), but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated.

The stratification on facilities is important in this phase to avoid bias due to possible confounding between covariates and facility effects.

At stage II, the relative risk estimates from the first stage are used to create offsets and an unstratified model is fitted to obtain estimates of an overall baseline rate function. That is, we estimate a common baseline rate of encounters, $r_0(t)$, across all facilities by considering the model

$$Pr(\text{Emergency department encounter on day } t \text{ given covariates } X) = r_0(t)\, R_{ik,}$$

where $R_{ik} = \exp(\beta' X_{ik})$ is the estimated relative risk for patient i in facility k obtained from the stage I. In our computation, we assume the baseline to be a step function with 6 unknown parameters, $\alpha_1, \ldots, \alpha_6$, to estimate. These estimates are used to compute the expected number of encounters given a patient's characteristics.

Specifically, let t_{iks} represent the number of days that patient i from facility k is under observation in the s^{th} time interval with estimated rate α_s. The corresponding expected number of emergency department encounters in the s^{th} interval for this patient is calculated as

$$E_{iks} = \alpha_s\, t_{iks}\, R_{ik} \quad .$$

It should be noted that t_{iks} and hence E_{iks} can be 0 if patient i from facility k is never at risk during the s^{th} time interval. Summing the E_{iks} over all 6 intervals and all N_k patients in facility k gives

$$\text{Exp} = \sum_{i=1}^{N_k} \sum_{s=1}^{6} E_{iks} = \sum_{i=1}^{N_k} \sum_{s=1}^{6} \alpha_s t_{iks} R_{ik} \quad ,$$

which is the expected number of emergency department encounters during follow-up at that facility.

Let Obs be the observed total number of emergency department encounters at this facility. The SEDR for emergency department encounters is the ratio of the observed total encounters to this expected value, or

$$\text{SEDR} = \text{Obs}/\text{Exp}$$

- Age: We determine each patient's age for the birth date provided in the CROWNWeb database and group patients into the following categories:
  - 18-24
  - 25-44
  - 45-59
  - 60-74
  - 75+
- Sex: We determine each patient's sex from his/her Medical Evidence Form (CMS-2728) and the CROWNWeb database.
- Diabetes as cause of ESRD: We determine each patient's primary cause of ESRD from his/her CMS-2728.

- ESRD duration: We determine each patient's length of time on dialysis using the first service date from his/her CMS-2728, claims history (all claim types), the CROWNWeb database and the SRTR database and categorize as 91 days-6 months, 6 months-1 year, 1-2 years, 2-3 years, 3-5 years, or 5+ years as of the period start date.
- Nursing home status: Using the Nursing Home Minimum Dataset, we determine if a patient was in a nursing home the previous year.
- BMI: We calculate each patient's BMI as the height and weight provided on his/her CMS 2728. BMI is categorized as underweight, normal weight, overweight, or obese.
- Calendar year
- The following incident comorbidities are included. They are taken from the CMS-2728 form. Each comorbidity is included as a separate covariate in the model.
    - Alcohol dependence
    - Atherosclerotic heart disease
    - Cerebrovascular disease
    - Chronic obstructive pulmonary disease
    - Congestive heart failure
    - Diabetes
    - Drug dependence
    - Inability to ambulate
    - Inability to transfer
    - Malignant neoplasm or cancer
    - Other cardiac disease
    - Peripheral vascular disease
    - Tobacco use (current smoker)
- Prevalent comorbidities (see appendix) are determined using the previous 12 months of CMS claims after the index encounter. The fiscal year 2015 Agency for Healthcare Research and Quality Clinical Classification Software (AHRQ CCS) single-level diagnoses groupers were used to define the prevalent comorbidity risk factors. Each comorbidity is included as a separate covariate in the model. If a patient has less than 6 months of claims in the year before the analysis, we consider prevalent comorbidities to be "missing" for that patient even if there are comorbidities identified in claims.

Reference:
Elixhauser A, Steiner C, Palmer L. Clinical Classifications Software (CCS), 2015. U.S. Agency for Healthcare Research and Quality.
Available: http://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccs.jsp

The coefficients for the patient characteristics resulting from the Cox model are shown below.

Table 1. SEDR model coefficients, 2012-2015

Covariate	Coefficient	P-value
Comorbidities at start of ESRD		
At least one of the comorbidities listed below	0.00	0.51
Atherosclerotic heart disease	0.02	<.0001
Other cardiac disease	0.00	0.61
Diabetes*	0.03	<.0001
Congestive heart failure	0.03	<.0001
Inability to ambulate	-0.02	0.00

Covariate	Coefficient	P-value
Chronic obstructive pulmonary disease	0.02	<.0001
Inability to transfer	-0.03	0.00
Malignant neoplasm, cancer	-0.03	<.0001
Peripheral vascular disease	-0.01	0.00
Cerebrovascular disease, CVA, TIA	0.03	<.0001
Tobacco use (current smoker)	0.08	<.0001
Alcohol dependence	0.01	0.05
Drug dependence	0.16	<.0001
No Medical Evidence (CMS-2728) Form	0.02	0.01
Cause of ESRD		
Diabetes	0.03	<.001
Sex: Female	0.08	<.0001
Age		
18-24	0.69	<.0001
25-44	0.43	<.0001
45-59	0.19	<.0001
60-74	Reference	
75+	-0.02	<.0001
BMI		
Underweight	0.01	0.04
Normal weight	Reference	
Overweight	-0.02	<.0001
Obese	-0.04	<.0001
Calendar year		
2012	Reference	
2013	0.02	<.0001
2014	0.06	<.0001
2015	0.07	<.0001
In nursing home the previous year	-0.09	<.0001
Diabetes as cause of ESRD X time on ESRD interaction term		
91 days-6 months	Reference	
6 months-1 year	0.03	0.00
1-2 years	0.00	0.95
2-3 years	-0.02	0.01
3-5 years	-0.03	<.0001
5+ years	-0.04	<.0001
Cause of ESRD: diabetes X sex: female interaction term	0.02	<.0001
Age X diabetes as cause of ESRD interaction term		
18-24	0.03	0.37
25-44	0.03	<.0001
45-59	0.03	<.0001
60-74	Reference	
75+	-0.02	<.0001
Age X female sex interaction term		
18-24	0.14	<.0001
25-44	0.06	<.0001
45-59	-0.04	<.0001

Covariate	Coefficient	P-value
60-74	Reference	
75+	0.01	0.26
Prevalent comorbidity groupers		
HIV infection	0.08	<.0001
Hepatitis	0.04	<.0001
Viral infection	0.04	<.0001
Other infections; including parasitic; Sexually transmitted infections (not HIV or hepatitis)	0.04	<.0001
Melanomas of skin; Other non-epithelial cancer of skin	-0.09	<.0001
Benign neoplasm of uterus; Other and unspecified benign neoplasm	-0.05	<.0001
Diabetes mellitus with or without complications	0.04	<.0001
Fluid and electrolyte disorders	0.10	<.0001
Encephalitis, Meningitis and other CNS infections	-0.13	<.0001
Epilepsy; convulsions	0.06	<.0001
Headache; including migraine	0.19	<.0001
Otitis, Dizziness, and other ear and sense organ disorders	0.09	<.0001
Neuropathy, pain syndromes, and other neurologic disorders	0.06	<.0001
Essential hypertension	0.10	<.0001
Secondary hypertension and hypertensive complications	0.08	<.0001
Acute myocardial infarction and atherosclerotic heart disease	0.03	<.0001
Nonspecific chest pain	0.20	<.0001
Pulmonary embolism and other pulmonary heart disease	0.01	<.0001
Other and ill-defined heart disease	0.05	<.0001
Conduction disorders; Cardiac dysrhythmias	0.05	<.0001
Other circulatory disease	0.02	<.0001
Phlebitis; thrombophlebitis and thromboembolism	0.02	<.0001
Acute and chronic tonsillitis; Acute bronchitis; Other upper respiratory infections	0.09	<.0001
Chronic obstructive pulmonary disease and bronchiectasis; Asthma	0.06	<.0001
Other lower respiratory disease	0.11	<.0001
Other upper respiratory disease	0.02	<.0001
Disorders of teeth, jaw and mouth	0.12	<.0001
Esophageal disorders	0.01	<.0001
Digestive track disorders (gastritis, gastric ulcers, and other disorders of stomach; appendicitis)	0.05	<.0001
Anal and rectal conditions	0.05	<.0001
Peritonitis and intestinal abscess	-0.10	<.0001
Pancreatic disorders (not diabetes)	0.13	<.0001
Gastrointestinal hemorrhage	0.02	<.0001
Noninfectious gastroenteritis	0.10	<.0001
Other gastrointestinal disorders	0.01	<.0001
Urinary tract infections	0.02	<.0001
Calculus of urinary tract	0.05	<.0001
Other diseases of kidney and ureters (e.g., ureteral stricture or reflux; excludes renal calculus)	0.01	<.0001
Prostate hyperplasia, prostatitis and other male genital disorders	0.03	<.0001
Skin disorders: cellulitis, ulcers, inflammatory and others	0.04	<.0001
Infective arthritis and osteomyelitis	-0.07	<.0001

Covariate	Coefficient	P-value
Other non-traumatic joint disorders	0.05	<.0001
Spondylosis; intervertebral disc disorders; other back problems	0.10	<.0001
Osteoporosis	-0.08	<.0001
Other connective tissue disease; Other bone disease and musculoskeletal deformities	0.07	<.0001
Sprains and strains	0.17	<.0001
Complication of device; implant or graft	0.03	<.0001
Superficial injury; contusion	0.11	<.0001
Poisoning by medications or nonmedicinal substances	0.02	<.0001
Other injuries and conditions due to external causes	0.04	<.0001
Syncope	0.05	<.0001
Gangrene	-0.07	<.0001
Shock	-0.16	<.0001
Nausea and vomiting	0.15	<.0001
Abdominal pain	0.17	<.0001
Malaise and fatigue	0.07	<.0001
Allergic reactions	0.08	<.0001
Anxiety disorders	0.10	<.0001
Attention-deficit, conduct, and disruptive behavior disorders	0.09	<.0001
Developmental disorders	0.09	<.0001
Mood disorders	0.01	<.0001
Personality disorders	0.17	<.0001
Schizophrenia and other psychotic disorders	0.02	<.0001
Alcohol-related disorders	0.20	<.0001
Suicide and intentional self-inflicted injury	0.15	<.0001
Screening and history of mental health and substance abuse codes	0.09	<.0001
Miscellaneous mental health disorders	0.05	<.0001
Missing comorbidity flag	0.82	<.0001

*The diabetes indicator includes all diabetes comorbidities on CMS-2728 and diabetes as cause of ESRD

Type of Score S.12.

Rate/Proportion

Interpretation of Score S.13.
Better quality = Lower score

Calculation Algorithm/Measure Logic S.14.
See appendix

Sampling S.15.
N/A

Survey/Patient-Reported Data S.16.
N/A

Data Source S.17.
Claims, Registry Data

Data Source or Collection Instrument S.18.
Data are derived from an extensive national ESRD patient database, which is primarily based on the CMS Consolidated Renal Operations in a Web-enabled Network (CROWN) system. The CROWN data include the Renal Management Information System (REMIS), CROWNWeb facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form, CMS-2746 Death Notification Form, and CMS-2744 Annual Facility Survey Form data), the historical Standard Information Management System (SIMS) database (formerly maintained by the 18 ESRD Networks until replaced by CROWNWeb in May 2012), the National Vascular Access Improvement Initiative's Fistula First Catheter Last project (in CROWNWeb since May 2012), Medicare dialysis and hospital payment records, transplant data from the Organ Procurement and Transplant Network (OPTN), the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Workbench, which includes data from the Certification and Survey Provider Enhanced Report System (CASPER), the Dialysis Facility Compare (DFC) and the Social Security Death Master File. The database is comprehensive for Medicare patients. Non-Medicare patients are included in all sources except for the Medicare payment records. CROWNWeb provides tracking by dialysis provider and treatment modality for non-Medicare patients. Information on hospitalizations is obtained from Part A Medicare Inpatient Claims Standard Analysis Files (SAFs), and past-year comorbidity data are obtained from multiple Part A types (inpatient, home health, hospice, skilled nursing facility claims) and Part B outpatient types of Medicare Claims SAFs.

Data Source or Collection Instrument (Reference) S.19.
N/A

Level of Analysis S.20.
Facility

Care Setting S.21.
Dialysis Facility

Composite Performance Measure S.22.
N/A

MEASURE JUSTIFICATION FORM

Project Title:
End-Stage Renal Disease Emergency Department Visits Measure Development

Project Overview:
The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan's Kidney Epidemiology and Cost Center (UM-KECC) to develop emergency department utilization measures for ESRD patients. The contract name is the ESRD Quality Measure Development, Maintenance, and Support contract. The contract number is HHSM-500-2013-13017I.

Date:
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Measure Name
Standardized Emergency Department Encounter Ratio (SEDR) for Dialysis Facilities

Type of Measure
Outcome

Importance
1a—Opportunity for Improvement
1a.1. - This is a measure of: Health outcome: Emergency department utilization that does not result in hospitalization
1a.2.—Linkage
Emergency Department (ED) utilization is an important indicator of patient morbidity and quality of life. More than half (55.0%) of all patients with end-stage renal disease (ESRD) visit the ED during their first year of dialysis, and patients with ESRD have a mean of 2.7 visits per patient-year [1]. This rate is 6-fold higher than the national mean rates for US adults in the general population [2]. Measures of the frequency of ED use at the dialysis facility level may help efforts to prevent emergent unscheduled care and control escalating medical costs. There are numerous dialysis care processes that can influence the likelihood of a patient requiring care in the ED that would be distinct from the need for hospitalization (i.e. the ED is not merely a gateway to hospital admission). These processes include:

(1) Inadequate processes related to fluid management/removal. Inadequate control of total body fluid balance and fluid removal can result in fluid overload and congestive heart failure, increasing the possibility of the need for ED use and emergent dialysis. Conversely, overly aggressive fluid removal can lead to hypotension and in extreme situations, the patient may become unresponsive (i.e. syncope). When this happens, patients are often sent to the ED for additional evaluation, but are rarely admitted.
(2) Inadequate management of vascular access: vascular access thrombosis or bleeding, or malfunction of a central venous catheter may require urgent intervention. If facilities do not have established processes of care to manage these access related complications, patients may be referred to the ED for intervention, but would not necessarily require hospital admission. Furthermore, inadequate infection prevention processes can lead to bacteremia or septicemia, increasing the possibility of the need for ED use.
(3) Inadequate management of electrolyte abnormalities. Failure to maintain processes to ensure adequate dialysis and nutritional counseling can lead to hyperkalemia, increasing the possibility

of the need for ED use and emergent dialysis. Once potassium is controlled, patients can often be discharged from the ED without requiring hospitalization.

1a.2.1 Rationale

Among Medicare beneficiaries, 30% of hospital admissions that originate in the ED are for diagnoses that are often dialysis related such as complications of vascular access, congestive heart failure/fluid overload, septicemia, and hyperkalemia[1]. Recent research points to many additional opportunities to further reduce unnecessary ED use in this population.

Programs developed to impact dialysis provider practices have been shown to improve intermediate outcomes (reduced catheter vascular access[3], small solute adequacy, anemia management), hospitalization, and mortality.

Given the association between missed dialysis treatments and increased risk of an ED visit [4], dialysis facility interventions that improve adhearance to the treatment schedule would be expected to decrease ED utilization. Other interventions, such as telehealth, have been demonstrated to reduce ED utilization in high-risk dialysis patients [5]. In the general population, outpatient ED visits were reported to have increased more slowly for Medicare patients being treated by patient-centered medical home practices when compared to non-patient-centered medical homes[6]. While similar data are lacking in the ESRD patient population, the current Comprehensive ESRD Care (ESRD Seamless Care Organization, ESCO) model may provide similar infrastructure to reduce ED utilization.

Low health literacy has been associated with increased use of ED services [7] and some studies have indicated that patient education interventions can reduce ED utilization [8].

References:

1. Lovasik, B.P., et al., Emergency Department Use and Hospital Admissions Among Patients With End-Stage Renal Disease in the United States. *JAMA Intern Med*, 2016. 176(10): p. 1563-1565. Patients with end-stage renal disease (ESRD) have the highest risk for hospitalization among those with chronic medical conditions, including heart failure, pulmonary disease, or cancer.1 However, to our knowledge, no study has examined use of the emergency department (ED) among the national Medicare population with ESRD. We sought to describe ED visits and hospitalizations through the ED and to determine the sociodemographic and clinical characteristics of patients with ESRD who use ED services in the United States.

2. Centers for Disease Control and Prevention. National hospital ambulatory medical care survey: 2011 emergency department summary tables. http://www.cdc.gov/nchs/fastats/injury.htm 2011 [cited 2017 January 9].

3. Ng LJ, Chen F, Pisoni RL, Krishnan M, Mapes D, Keen M, Bradbury BD. Hospitalization risks related to vascular access type among incident US hemodialysis patients. Nephrol Dial Transplant. 26(11):3659-66, 2011

   BACKGROUND: The excess morbidity and mortality related to catheter utilization at and immediately following dialysis initiation may simply be a proxy for poor prognosis. We examined hospitalization burden related to vascular access (VA) type among incident patients who received some predialysis care.

   METHODS: We identified a random sample of incident US Dialysis Outcomes and Practice

Patterns Study hemodialysis patients (1996-2004) who reported predialysis nephrologist care. VA utilization was assessed at baseline and throughout the first 6 months on dialysis. Poisson regression was used to estimate the risk of all-cause and cause-specific hospitalizations during the first 6 months.

RESULTS: Among 2635 incident patients, 60% were dialyzing with a catheter, 22% with a graft and 18% with a fistula at baseline. Compared to fistulae, baseline catheter use was associated with an increased risk of all-cause hospitalization [adjusted relative risk (RR) = 1.30, 95% confidence interval (CI): 1.09-1.54] and graft use was not (RR = 1.07, 95% CI: 0.89-1.28). Allowing for VA changes over time, the risk of catheter versus fistula use was more pronounced (RR = 1.72, 95% CI: 1.42-2.08) and increased slightly for graft use (RR = 1.15, 95% CI: 0.94-1.41). Baseline catheter use was most strongly related to infection-related (RR = 1.47, 95% CI: 0.92-2.36) and VA-related hospitalizations (RR = 1.49, 95% CI: 1.06-2.11). These effects were further strengthened when VA use was allowed to vary over time (RR = 2.31, 95% CI: 1.48-3.61 and RR = 3.10, 95% CI: 1.95-4.91, respectively). A similar pattern was noted for VA-related hospitalizations with graft use. Discussion. Among potentially healthier incident patients, hospitalization risk, particularly infection and VA-related, was highest for patients dialyzing with a catheter at initiation and throughout follow-up, providing further support to clinical practice recommendations to minimize catheter placement.

4. Chan, K. E.;Thadhani, R. I.;Maddux, F. W. Adherence barriers to chronic dialysis in the United States**.** *J Am Soc Nephrol.* 2014 25(11):2642-8 doi:10.1681/asn.2013111160

   Hemodialysis patients often do not attend their scheduled treatment session. We investigated factors associated with missed appointments and whether such nonadherence poses significant harm to patients and increases overall health care utilization in an observational analysis of 44 million hemodialysis treatments for 182,536 patients with ESRD in the United States. We assessed the risk of hospitalization, emergency room visit, or intensive-coronary care unit (ICU-CCU) admission in the 2 days after a missed treatment relative to the risk for patients who received hemodialysis. Over the 5-year study period, the average missed treatment rate was 7.1 days per patient-year. In covariate adjusted logistic regression, the risk of hospitalization (odds ratio [OR], 3.98; 95% confidence interval [95% CI], 3.93 to 4.04), emergency room visit (OR, 2.00; 95% CI, 1.87 to 2.14), or ICU-CCU admission (OR, 3.89; 95% CI, 3.81 to 3.96) increased significantly after a missed treatment. Overall, 0.9 missed treatment days per year associated with suboptimal transportation to dialysis, inclement weather, holidays, psychiatric illness, pain, and gastrointestinal upset. These barriers also associated with excess hospitalization (5.6 more events per patient-year), emergency room visits (1.1 more visits), and ICU-CCU admissions (0.8 more admissions). In conclusion, poor adherence to hemodialysis treatments may be a substantial roadblock to achieving better patient outcomes. Addressing systemic and patient barriers that impede access to hemodialysis care may decrease missed appointments and reduce patient morbidity.

5. Minatodani, D. E.;Berman, S. J. Home telehealth in high-risk dialysis patients: a 3-year study. *Telemed J E Health.* 2013 19(7):520-2 doi:10.1089/tmj.2012.0196

   OBJECTIVE: This study is a continuation of a previous pilot project that demonstrated improved health outcomes and significant cost savings using home telehealth with nurse oversight in patients with end-stage renal disease undergoing chronic dialysis. We are reporting the results

of a larger sample size over a 3-year study period to test the validity of our original observations. SUBJECTS AND METHODS: Ninety-nine patients were included in this study; 43 (18 females, 25 males) with a mean age of 58.6 years were enrolled in the remote technology (RT) group, and 56 (26 females, 30 males) with a mean age of 63.1 years were enrolled in the usual-care (UC) group. Health resource outcome measures included hospitalizations, emergency room (ER) visits, and number of days hospitalized. Economic analysis was conducted on hospital and ER charges.

RESULTS: Hospitalizations (RT, 1.8; UC, 3.0), hospital days (RT, 11.6; UC, 25.0), and hospital and ER charges (RT, $66,000; UC, $157,000) were significantly lower in the RT group, as were hospital and ER charges per study day (RT, $159; UC, $317).
CONCLUSIONS: The results support our previous findings, that is, home telehealth can contribute to improved health outcomes and cost of care in high-risk dialysis patients.

6. Pines, J. M.;Keyes, V.;van Hasselt, M.;McCall, N. Emergency department and inpatient hospital use by Medicare beneficiaries in patient-centered medical homes. *Ann Emerg Med.* 2015 65(6):652-60 doi:10.1016/j.annemergmed.2015.01.002

   STUDY OBJECTIVE: Patient-centered medical homes are primary care practices that focus on coordinating acute and preventive care. Such practices can obtain patient-centered medical home recognition from the National Committee for Quality Assurance. We compare growth rates for emergency department (ED) use and costs of ED visits and hospitalizations (all-cause and ambulatory-care-sensitive conditions) between patient-centered medical homes recognized in 2009 or 2010 and practices without recognition.

   METHODS: We studied a sample of US primary care practices and federally qualified health centers: 308 with and 1,906 without patient-centered medical home recognition, using fiscal year 2008 to 2010 Medicare fee-for-service data. We assessed average annual practice-level payments per beneficiary for ED visits and hospitalizations and rates of ED visits and hospitalizations (overall and ambulatory-care-sensitive condition) per 100 beneficiaries before and after patient-centered medical home recognition, using a difference-in-differences regression model comparing patient-centered medical homes and propensity-matched non-patient-centered medical homes.

   RESULTS: Comparing patient-centered medical home with non-patient-centered medical home practices, the rate of growth in ED payments per beneficiary was $54 less for 2009 patient-centered medical homes and $48 less for 2010 patient-centered medical homes relative to non-patient-centered medical home practices. The rate of growth in all-cause and ambulatory-care-sensitive condition ED visits per 100 beneficiaries was 13 and 8 visits fewer for 2009 patient-centered medical homes and 12 and 7 visits fewer for 2010 patient-centered medical homes, respectively. There was no hospitalization effect.
   CONCLUSION: From 2008 to 2010, outpatient ED visits increased more slowly for Medicare patients being treated by patient-centered medical home practices than comparison non-patient-centered medical homes. The reduction was in visits for both ambulatory-care-sensitive and non-ambulatory-care-sensitive conditions, suggesting that steps taken by practices to attain patient-centered medical home recognition such as improving care access may decrease some of the demand for outpatient ED care.

7. Green, J. A.;Mor, M. K.;Shields, A. M.;Sevick, M. A.;Arnold, R. M.;Palevsky, P. M.;Fine, M. J.;Weisbord, S. D. Associations of health literacy with dialysis adherence and health resource utilization in patients receiving maintenance hemodialysis. *Am J Kidney Dis.* 2013 62(1):73-80 doi:10.1053/j.ajkd.2012.12.014

BACKGROUND: Although limited health literacy is common in hemodialysis patients, its effects on clinical outcomes are not well understood.
STUDY DESIGN: Observational study.

SETTING & PARTICIPANTS: 260 maintenance hemodialysis patients enrolled in a randomized clinical trial of symptom management strategies from January 2009 through April 2011.
PREDICTOR: Limited health literacy.

OUTCOMES: Dialysis adherence (missed and abbreviated treatments) and health resource utilization (emergency department visits and end-stage renal disease [ESRD]-related hospitalizations).

MEASUREMENTS: We assessed health literacy using the Rapid Estimate of Adult Literacy in Medicine (REALM) and used negative binomial regression to analyze the independent associations of limited health literacy with dialysis adherence and health resource utilization over 12-24 months.

RESULTS: 41 of 260 (16%) patients showed limited health literacy (REALM score, </=60). There were 1,152 missed treatments, 5,127 abbreviated treatments, 552 emergency department visits, and 463 ESRD-related hospitalizations. Limited health literacy was associated independently with an increased incidence of missed dialysis treatments (missed, 0.6% vs 0.3%; adjusted incidence rate ratio [IRR], 2.14; 95% CI, 1.10-4.17), emergency department visits (annual visits, 1.7 vs 1.0; adjusted IRR, 1.37; 95% CI, 1.01-1.86), and hospitalizations related to ESRD (annual hospitalizations, 0.9 vs 0.5; adjusted IRR, 1.55; 95% CI, 1.03-2.34).
LIMITATIONS: Generalizability and potential for residual confounding.

CONCLUSIONS: Patients receiving maintenance hemodialysis who have limited health literacy are more likely to miss dialysis treatments, use emergency care, and be hospitalized related to their kidney disease. These findings have important clinical practice and cost implications.

8. Morgan, S. R.;Chang, A. M.;Alqatari, M.;Pines, J. M. Non-emergency department interventions to reduce ED utilization: a systematic review. *Acad Emerg Med.* 2013 20(10):969-85 doi:10.1111/acem.12219

OBJECTIVES: Recent health policy changes have focused efforts on reducing emergency department (ED) visits as a way to reduce costs and improve quality of care. This was a systematic review of interventions based outside the ED aimed at reducing ED use.

METHODS: This study was designed as a systematic review. We reviewed the literature on interventions in five categories: patient education, creation of additional non-ED capacity, managed care, prehospital diversion, and patient financial incentives. Studies written in English, with interventions administered outside of the ED, and a comparison group where ED use was an outcome, were included. Two independent reviewers screened search results using

MEDLINE, Cochrane, OAIster, or Scopus. The following data were abstracted from included studies: type of intervention, study design, population, details of intervention, effect on ED use, effect on non-ED health care use, and other health and financial outcomes. Quality of individual articles was assessed using Grading of Recommendations Assessment, Development, and Evaluation (GRADE) guidelines.

RESULTS: Of 39 included studies, 34 were observational and five were randomized controlled trials. Two of five studies on patient education found reductions in ED use ranging from 21% to 80%. Out of 10 studies of additional non-ED capacity, four showed decreases of 9% to 54%, and one a 21% increase. Both studies on prehospital diversion found reductions of 3% to 7%. Of 12 studies on managed care, 10 had decreases ranging from 1% to 46%. Nine out of 10 studies on patient financial incentives found decreases of 3% to 50%, and one a 34% increase. Nineteen studies reported effect on non-ED use with mixed results. Seventeen studies included data on health outcomes, but 13 of these only included data on hospitalizations rather than morbidity and mortality. Seven studies included data on cost outcomes. According to the GRADE guidelines, all studies had at least some risk of bias, with four moderate quality, one low quality, and 34 very low quality studies.

CONCLUSIONS: Many studies have explored interventions based outside the ED to reduce ED use in various populations, with mixed evidence. Approximately two-thirds identified here showed reductions in ED use. The interventions with the greatest number of studies showing reductions in ED use include patient financial incentives and managed care, while the greatest magnitude of reductions were found in patient education. These findings have implications for insurers and policymakers seeking to reduce ED use.

1a.3.—Linkage

N/A

1a.3.1. Source of Systematic Review

1a.4.—Clinical Practice Guideline Recommendation

1a.4.1. Guideline Citation

1a.4.2. Specific Guideline

1a.4.3. Grade

1a.4.4. Grades and Associated Definitions

1a.4.5. Methodology Citation

1a.4.6. Quantity, Quality, and Consistency

1a.5.—United States Preventative Services Task Force Recommendation

1a.5.1. Recommendation Citation

1a.5.2. Specific Recommendation

1a.5.3. Grade

1a.5.4. Grades and Associated Definitions1a.5.5. Methodology Citation

1a.6.—Other Systematic Review of the Body of Evidence

1a.6.1. Review Citation

1a.6.2. Methodology Citation

1a.7.—Findings from Systematic Review of Body of the Evidence Supporting the Measure

1a.7.1. Specifics Addressed in Evidence Review
1a.7.2. Grade
1a.7.3. Grades and Associated Definitions
1a.7.4. Time Period
1a.7.5. Number and Type of Study Designs
1a.7.6. Overall Quality of Evidence
1a.7.7. Estimates of Benefit
1a.7.8. Benefits Over Harms
1a.7.9. Provide for Each New Study
1a.8.—Other Source of Evidence
1a.8.1. Process Used 1a.8.2. Citation

1b.—Evidence to Support Measure Focus

1b.1. Rationale

Emergency department encounters are an important indicator of care coordination and quality of life. More than half (55.0%) of all patients with end-stage renal disease (ESRD) visit the ED during their first year of dialysis, and patients with ESRD have a mean of 2.7 ED visits per patient-year (Lovasik et al., 2016). This rate is 6-fold higher than the national mean rates for US adults in the general population (CDC, 2011). Furthermore, the Lovasik study notes that among Medicare beneficiaries, 30% of hospital admissions that originate in the ED are for diagnoses that are often dialysis related such as complications of vascular access, congestive heart failure/fluid overload, septicemia, and hyperkalemia.

Measures of the frequency of ED use may help dialysis facility level efforts to prevent emergent unscheduled care and control escalating medical costs.

References:
Centers for Disease Control and Prevention. National hospital ambulatory medical care survey: 2011 emergency department summary tables. http://www.cdc.gov/nchs/fastats/injury.htm 2011 [cited 2017 January 9].

Lovasik BP, Zhang R, Hockenberry JM, Schrager JD, Pastan SO, Mohan S, Patzer RE.Emergency Department Use and Hospital Admissions Among Patients With End-Stage Renal Disease in the United States. JAMA Intern Med. 2016 Oct 1; 176(10):1563-1565.

1b.2. Performance Scores

We calculated the measure for each year 2012-2015 (below). We included all Medicare-certified dialysis facilities with eligible time at risk for the measure. We excluded transplant-only facilities and Veteran Affairs (VA) facilities. The distribution of the SEDR for each year is shown below (restricted to facilities with at least 5 patient years at risk). Standardized ED Visit rates vary widely across facilities. For example, for the 6,256 facilities included in 2015, the SEDR varied from 0.00 to 6.49. The mean value was 1.00 and the SD was 0.36. A table showing the deciles of the SEDR for 2015 is included in the appendix.

2012
N (facilities)=5,663, N (patients)=394,778, Mean=1.01, Std Dev=0.37, Min=0.0, Max=3.44, IQR=0.45

2013
N (facilities)=5,842, N (patients) =404,353, Mean=1.01, Std Dev=0.36, Min=0.0, Max=3.83, IQR=0.42

2014
N (facilities)=6,059, N (patients) =413,602, Mean=1.00, Std Dev=0.36, Min=0.0, Max=3.85, IQR=0.42

2015
N (facilities)=6,256, N (patients) =421,570, Mean=1.00, Std Dev=0.36, Min=0.0, Max=6.49, IQR=0.42

1b.3. Summary of Data Indicating Opportunity
N/A

1b.4. and 1b.5. Disparities
Race, female sex, insurance status, younger age, and SES have been shown to be predictors of differential emergency department utilization in the general population (Capp et al., 2015; Colligan et al., 2016; LaCalle et al., 2010; Zuckerman and Shen 2004). In the ESRD population, low health literacy (a proxy of SES) was found to be a predictor of ED use in one study (Green et al., 2013), as well as SDS/SES factors of younger age, female sex, black race, and public insurance (Medicaid) while lower ED use was associated with private insurance (Lovasik et al., 2016).

Age:
For the 18-24 age group, Hazard Ratio =1.81, p<0.0001.
For the 25-44 age group, Hazard Ratio = 1.41, p<0.0001.
For the 45-59 age group, Hazard Ratio = 1.13, p<0.0001.
The 60-74 age group was used as the reference group.
For the 75+ age group, Hazard Ratio = 1.02, p<0.0001.

Sex:
For Female: Hazard Ratio = 1.05, p<0.0001.
Male was used as the reference group.

Race:
White was used as the reference group.
For Black: Hazard Ratio =1.17, p<0.0001.
For Native Americans: Hazard Ratio =1.05, p<0.0001.
For Asian/PI: Hazard Ratio =0.83, p<0.0001.
For Other race: Hazard Ratio = 1.04, p-value =0.008

Ethnicity:
Non-Hispanic was used as the reference group.
For Hispanic: Hazard Ratio = 1.04, p-value =<0.0001.
For Unknown ethnicity: Hazard Ratio =1.02, p-value=0.204.

Employment Status:
Unemployed was used as the reference group.
For Employed: Hazard Ratio =0.88, p<0.0001.
For Other/Unknown*: Hazard Ratio =0.96, and the p<0.0001.
* Other/Unknown group includes Homemaker, Retired due to age/preference, retired due to disability, Medical leave of absence, or missing employment status.

Medicare Coverage:
Medicare as primary w/o Medicaid was used as the reference group.
Medicare as primary with Medicaid: Hazard Ratio = 1.21, and the p-value <0.0001.
Medicare as secondary/Medicare HMO: Hazard Ratio = 0.40, and the p-value <0.0001.

Our results indicate potential disparities in emergency department utilization. Differences are observed by age (younger age), sex (females), race (blacks, Native Americans, and other), dual Medicare-Medicaid status, and employment status (unemployed).

For example, compared to the reference group, younger age groups had higher risk of an emergency department encounter. This was highest for 18-24 year olds, with a negative gradient for the 25-44 age group, the 45-59 age group, and the 75+ age group. Females had higher risk of an emergency department encounter compared to males (5% higher). Black patients also had a higher risk (17% higher) of an emergency department visit compared to whites, as do Native Americans (5% higher) and patients of other race (4% higher). However, Asian/Pacific Islander patients had a lower risk (17% lower). Hispanic patients had a higher risk (4%) of an emergency department encounter compared to non-Hispanic patients. Patients who were employed (at ESRD incidence) had a 12% lower risk of an emergency department encounter, compared to unemployed patients (unemployed at ESRD incidence). Finally, patients dually covered by Medicare and Medicaid had a 21% higher risk of an emergency department encounter compared to patient with Medicare as their primary insurance, while those with MSP/Medicare HMO had 60% lower risk of an ED encounter.

While there are notable differences by younger age, race, sex and insurance status, it is unclear if these disparities in emergency department encounters are based on different clinical risk factors for these subgroups or differences in care quality.

Refer to Risk Adjustment section (2b4) for further analyses on race, ethnicity, sex and socioeconomic status.

References:
Capp R, West DR, Doran K, Sauaia A, Wiler J, Coolman T, Ginde AA. Characteristics of Medicaid-Covered Emergency Department Visits Made by Nonelderly Adults: A National Study. J Emerg Med. 2015 Dec; 49(6):984-9.

Colligan EM, Pines JM, Colantuoni E, Howell B, Wolff JL. Risk Factors for Persistent Frequent Emergency Department Use in Medicare Beneficiaries. Ann Emerg Med. 2016 Jun; 67(6):721-9.

Green JA, Mor MK, Shields AM, Sevick MA, Arnold RM, Palevsky PM, Fine MJ, Weisbord SD. Associations of health literacy with dialysis adherence and health resource utilization in patients receiving maintenance hemodialysis. Am J Kidney Dis. 2013 Jul; 62(1):73-80.

LaCalle E, Rabin E. Frequent users of emergency departments: the myths, the data, and the policy implications. Ann Emerg Med. 2010 Jul; 56(1):42-8.

Lovasik BP, Zhang R, Hockenberry JM, Schrager JD, Pastan SO, Mohan S, Patzer RE.Emergency Department Use and Hospital Admissions Among Patients With End-Stage Renal Disease in the United States.JAMA Intern Med. 2016 Oct 1;176(10):1563-1565.

Zuckerman S, Shen YC. Characteristics of occasional and frequent emergency department users: do insurance coverage and access to care matter? Med Care. 2004 Feb; 42(2):176-82.

Scientific Acceptability

1.—Data Sample Description

1.1 What Type of Data was Used for Testing?
Medicare claims, Registry

1.2 Identify the Specific Dataset
Data are derived from an extensive national ESRD patient database, which is primarily based on the CMS Consolidated Renal Operations in a Web-enabled Network (CROWN) system. The CROWN data include the Renal Management Information System (REMIS), CROWNWeb facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form, CMS-2746 Death Notification Form, and CMS-2744 Annual Facility Survey Form data), the historical Standard Information Management System (SIMS) database (formerly maintained by the 18 ESRD Networks until replaced by CROWNWeb in May 2012), the National Vascular Access Improvement Initiative's Fistula First Catheter Last project (in CROWNWeb since May 2012), Medicare dialysis and hospital payment records, transplant data from the Organ Procurement and Transplant Network (OPTN), the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Workbench, which includes data from the Certification and Survey Provider Enhanced Report System (CASPER), the Dialysis Facility Compare (DFC) and the Social Security Death Master File. The database is comprehensive for Medicare patients. Non-Medicare patients are included in all sources except for the Medicare payment records. CROWNWeb provides tracking by dialysis provider and treatment modality for non-Medicare patients. Information on emergency department visits is obtained from Medicare Outpatient Claims Standard Analysis Files (SAFs). Medicare Inpatient Claims SAFs are used to determine if emergency department visits resulted in an admission. Prevalent comorbidities are obtained using Medicare Physician Supplier, Inpatient, Outpatient, Skilled Nursing, Home Health, and Hospice claims.

1.3 What are the Dates of the Data Used in Testing? January 1, 2013- December 31, 2015

1.4 What Levels of Analysis Were Tested?
Hospital/facility/agency

1.5 How Many and Which Measured Entities Were Included in the Testing and Analysis?

Table 1. Number of facilities and median facility size by year

Year	Number of Facilities	Median Facility Size (as of 12/31)
2012	5,663	60
2013	5,842	61
2014	6,059	61
2015	6,256	61

1.6 How Many and Which Patients Were Included in the Testing and Analysis?
Medicare dialysis patients were included in the testing and analysis for each of the four years from 2012-2015 of which there were 394,778; 404,353; 413,602 and 421,570 patients respectively.

Table 2. Descriptives of Patient Characteristics Included in the Measure

Patient Demographics	Percent
Age	
Patient Age: 18-24	0.6
Patient Age: 25-44	10.6
Patient Age: 45-59	25.6
Patient Age: 60-74	39.9
Patient Age: 75+	23.3
Sex (% female)	44.5
ESRD due to Diabetes (%)	46.7
Medicare coverage(%)	
Medicare primary + Medicaid	40.2
Medicare primary + no Medicaid	46.7
Medicare secondary/HMO	13.1
Time since Start of ESRD	
91 days-6 months	11.6
6 months-1 year	13.6
1-2 years	17.1
2-3 years	14.8
3-5 years	18.2
5+ years	24.8
Employment status 6 months prior to ESRD (%)	
Unemployed	22.1
Employed	19.0
Other/Unknown *	59.0
Race (%)	
White	59.7
Black	34.0
Native American/Alaskan Native	1.2
Asian/Pacific Islander	4.8
Other/Unknown	0.3
Ethnicity (%)	
Hispanic	15.8
Non-Hispanic	83.6
Unknown	0.6

* Other/Unknown groups includes Homemaker, Retired due to age/preference, retired due to disability, Medical leave of absence, or missing employment status. Note: Some categories (Time since start of ESRD and Employment) sum to 100.1% due to rounding.

1.7 Sample Differences, if Applicable

N/A

1.8 What were the social risk factors that were available and analyzed? For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

Patient level:

- Employment status 6 months prior to ESRD
- Sex
- Race
- Ethnicity
- Medicare coverage*

**Assessed at the start of time at risk based on calendar year and facility assignment. Medicare coverage in the model was defined as:*
1. Medicare as primary and Medicaid
2. Medicare as primary and NO Medicaid
3. Medicare as secondary or Medicare HMO

Data on patient level SDS/SES factors obtained from Medicare claims and administrative data.
Proxy/Area level: ZIP code level – Area Deprivation Index (ADI) elements from 2014 Census data:

- Unemployment rate (%)
- Median family income (rescaled as (income-60,000)/10,000)
- Income disparity
- Families below the poverty level (%)
- Single-parent households w/ children <18 (%)
- Home ownership rate (%)
- Median home value (rescaled as (homevalue-200,000)/100,000)
- Median monthly mortgage (rescaled as (mortgage-1,500)/1,000)
- Median gross rent (rescaled as (rent-900)/1,000)
- Population (aged 25+) with <9 years of education (%)
- Population (aged 25+) without high school diploma (%)

2a.2—Reliability Testing

2a2.1. Level of Reliability Testing

Performance measure score

2a2.2. Method of Reliability Testing

The reliability of the Standardized Emergency Department Encounter Ratio (SEDR) was assessed using data among Medicare ESRD dialysis patients during 2012-2015. If the measure were a simple average across individuals in the facility, the usual approach for determining measure reliability would be a one-way analysis of variance (ANOVA), in which the between and within facility variation in the measure is determined. The inter-unit reliability (IUR) measures the proportion of the total variation of a measure that is attributable to the between-facility variation. The SEDR, however, is not a simple average and we instead estimate the IUR using a bootstrap approach, which uses a resampling scheme to estimate the within facility variation that cannot be directly estimated by ANOVA.

A small IUR (near 0) reveals that most of the variation of the measures between facilities is driven by random noise, indicating the measure would not be a good characterization of the differences among

facilities, whereas a large IUR (near 1) indicates that most of the variation between facilities is due to the real difference between facilities.

Here we describe our approach to calculating IUR. Let T1,…,TN be the SEDR for these facilities. Within each facility, select at random and with replacement B bootstrap samples. Our numerical experiments reveal that B=100 is sufficient. That is, if the ith facility has ni subjects, randomly draw with replacement ni subjects from those in the same facility, find their corresponding SEDRi and repeat the process B (say, 100) times. Thus, for the ith facility, we have bootstrapped SEDRs of T_i1^*,…, T_i200^*. Let S_i^* be the sample variance of this bootstrap sample. From this it can be seen that

$$s_{t,w}^2 = \frac{\sum_{i=1}^{N}[(n_i - 1)S_i^{*2}]}{\sum_{i=1}^{N}(n_i - 1)}$$

is a bootstrap estimate of the within-facility variance in the SEDR, namely, $\sigma_{t,w}^2$. Calling on formulas from the one way analysis of variance, an estimate of the overall variance of T_i is

$$s_t^2 = \frac{1}{n'(N-1)} \sum_{i=1}^{N} n_i (T_i - \bar{T})^2$$

where

$$\bar{T} = \sum n_i T_i / \sum n_i$$

is the weighted mean of the observed SEDR and

$$n' = \frac{1}{N-1} \left(\sum n_i - \sum n_i^2 \Big/ \sum n_i \right)$$

is approximately the average facility size (number of patients per facility). Note that s_t^2 is the total variation of SEDR and is an estimate of $\sigma_b^2 + \sigma_{t,w}^2$, where σ_b^2 is the between-facility variance, the true signal reflecting the differences across facilities. Thus, the estimated IUR, which is defined by

$$IUR = \frac{\sigma_b^2}{\sigma_b^2 + \sigma_{t,w}^2}$$

can be estimated with $(s_t^2 - s_{t,w}^2)/s_t^2$.

The measure calculation is only reported for facilities with at least 5 patient years at risk.

2a2.3. Statistical Results from Reliability Testing

Overall, as presented in Table 3, we found that IURs for the one-year SEDRs have a range of 0.65 - 0.72 across the years 2012, 2013, 2014 and 2015, which indicates that approximately 65% to 72% of the variation in the one-year SEDR can be attributed to the between-facility differences and about 28% to 35% to within-facility variation.

Table 3: IUR for one-year SEDR, 2012-2015

	2012		2013		2014		2015	
	IUR	**Facilities**	**IUR**	**Facilities**	**IUR**	**Facilities**	**IUR**	**Facilities**
Overall	**0.69**	5675	**0.72**	5851	**0.64**	6070	**0.65**	6267

2a2.4. Interpretation

The IUR value is considered strong. As described in section 2b5.3 the measure demonstrates it is effective at detecting outlier facilities and statistically meaningful differences in performance scores across measured entities.

2b2—Validity Testing

2b2.1. Level of Validity Testing

Empirical validity testing

Systematic assessment of face validity of performance measure score

2b2.2. Method of Validity Testing

Face Validity: In May 2016, we presented a preliminary version of the SEDR measure to a CMS Technical Expert Panel (TEP) for clinical validity. The nine member TEP was composed of clinical nephrologists, ED physicians, a renal nurse, and ESRD patients. The TEP discussions were informed by a review of relevant literature and related ED and hospital measures as part of the environmental scan we prepared for the TEP. Potential measures were evaluated using the criteria for clinical performance measures adopted by the National Quality Forum (NQF) and CMS (importance, scientific acceptability, feasibility, and usability). During the discussion, the TEP considered:

- Relevant measures endorsed by the National Quality Forum (NQF), or reported in the Dialysis Facility Reports (DFRs)
- Components of a potential ED measure, such as the location of the patient prior to the ED encounter, the method by which the patient was directed to the ED, presenting complaint, severity of illness, and outcome of the ED encounter
- The degree to which performance on a measure is under control of the dialysis facility
- The potential need for exclusion criteria and/or risk adjustment
- Data availability and additional analyses

The TEP discussed different ED outcomes and recommended limiting an ED encounter measure to visits that do not result in an inpatient admission because ED visits resulting in hospitalization are already captured through the respective NQF endorsed Standardized Hospitalization Ratio (SHR) for Admissions and the Standardized Readmission Ratio (SRR) for dialysis facilities measures. In addition, the TEP agreed that observation stays should be included in an ED measure. Ultimately, the TEP indicated that

ED encounters that do not result in admission are not well monitored as a quality indicator and panelists believed this measure would provide facilities with a more complete picture of their performance on key clinical outcomes of mortality, hospitalization, readmission, and ED usage. The TEP consensus supported the clinical validity of the measure. Finally, in June 2017 a final model that included extensive risk adjustment for prevalent comorbidities was presented to the TEP for review. The TEP voted unanimously in support of the final fully risk adjusted SEDR measure. See the section on risk adjustment for further detail on prevalent comorbidity risk adjustment.

Empirical validity testing - validation of performance measure scores: We assessed empirical validity of the measure by calculating Spearman correlations. Spearman correlation was selected because the data are rank-ordered (non-parametric data). Correlations were calculated to assess the association of SEDR with clinical and intermediate outcome quality measures expected to be markers of quality care. The measures selected are fully developed and NQF endorsed, and represent an important subset of core clinical quality measures for this patient population. The measures used are vascular access type (fistula use and catheter $\geq$ 90 days), dialysis adequacy (Kt/V $\geq$1.2), mortality (Standardized Mortality Ratio - SMR), and hospitalization (SHR). We also included the Emergency Department use within 30-days of Discharge (ED30) which is currently being submitted for endorsement as a companion measure to SEDR. We expected the following correlations of SEDR to the above quality measures:

- Vascular Access: Fistula – We anticipated this would be a negative correlation since successfully creating an AVF is generally seen as representing a robust process to coordinate care outside of the dialysis facility, and potentially reduces the likelihood of patients at such facilities going to the ED for an acute condition. Therefore higher rates of facility level AVF would be inversely related to outpatient ED visits.
- Vascular Access: Catheter – We were agnostic about the direction of the correlation. A high vascular catheter rate could represent lack of facility care processes needed to create an AVF in which case the relationship to SEDR would be positive. A high catheter rate could also represent a higher burden of comorbidity at the facility level such that AVF placement is more challenging. In this scenario, sicker patients who have a long-term catheter may be more likely to be admitted to the hospital versus have an outpatient only ED encounter, in which case the relationship with SEDR would be a negative correlation.
- Kt/V $\geq$ 1.2: We anticipated this would be a negative correlation with SEDR. Facilities that have a high proportion of patients with adequate small solute clearance may also have processes of care in place that would likely avoid ED encounters. In addition, patients who are unable to achieve a Kt/V of 1.2 may be morbidly obese, use a catheter for vascular access, or be non-adherent to treatment recommendations such that they may be at higher risk for ED use.
- SMR: We anticipated a positive correlation with mortality since patients who require acute medical care in the ED may have conditions that put them at higher risk for death. However, we anticipate the strength of the association to be weak since patients who go to the ED and are not admitted are likely to be less sick than those admitted.
- SHR: We were agnostic about the direction of the correlation since SEDR and SHR target different subpopulations of dialysis patients that experience acute care. For facilities that have a higher burden of comorbidities, patients may be more likely to be admitted versus have an outpatient only ED encounter, thus the correlation with SHR would be negative. However if facilities do not have processes in place to assist with comorbidity management, it is possible both SEDR and SHR would increase together, and yield a positive correlation.
- ED30: We anticipated this would be a positive correlation since both measures are a reflection of outpatient ED use.

2b2.3. Statistical Results from Validity Testing

Results of the Spearman correlations testing the association between SEDR and vascular access type, Kt/V ≥1.2, Standardized Mortality Ratio (SMR), Standardized Hospitalization Ratio (SHR), and the Standardized Ratio of Emergency Department Encounters Occurring Within 30 Days of Hospital Discharge for Dialysis Facilities (ED30), which is currently being submitted for endorsement as a companion measure to SEDR measure, are presented in Table 4. The correlations below were calculated for each of the calendar years 2012-2015.

Table 4. Spearman Correlation of SEDR and Related Measures (2012-2015)

	2012		**2013**		**2014**		**2015**	
	Corr.	P-value	Corr.	P-value	Corr.	P-value	Corr.	P-value
Vascular Access: Catheter>90 days	-0.04	0.0058	-0.04	0.0017	-0.04	0.0034	-0.02	0.0868
Vascular Access: Fistula	-0.07	<.0001	-0.06	<.0001	-0.05	<.0001	-0.05	<.0001
Kt/V≥1.2	-0.07	<.0001	-0.04	0.0018	-0.05	<.0001	-0.09	<.0001
SHR	-0.09	<.0001	-0.06	<.0001	-0.08	<.0001	-0.1	<.0001
SMR	0.07	<.0001	0.09	<.0001	0.09	<.0001	0.08	<.0001
ED30	---	---	---	---	---	---	0.51	<0.0001

2b2.4. Interpretation

As expected the SEDR correlates with dialysis facility processes and outcomes that are commonly thought to be related to quality of care. Higher rates of emergency department visits are associated with suboptimal dialysis adequacy as well as lower rates of arteriovenous fistula use as indicated by the negative association. This suggests that facilities with processes of care to provide optimal small solute clearance and optimal vascular access may have other processes of care to help their patients avoid needing the ED for unscheduled acute care. We found a negative but very weak association between SEDR and having a catheter >90 days for vascular access; the observed association was weakest for 2015 and did not achieve statistical significance ($p>0.05$). It may be that patients with longer term catheter use are more likely to be admitted (e.g., for catheter associated infections) rather than experience an outpatient ED encounter. This would attenuate the relationship between long-term catheter-based vascular access and outpatient ED utilization.

Higher ED utilization was also associated with lower facility hospitalization rates and higher mortality rates. The correlation with SHR was relatively low, as might be expected, since SEDR focuses on outpatient use of ED services whereas SHR captures ED use that results in hospitalization. Thus, SEDR likely captures dialysis patients that have a lower acuity of illness than the SHR. Higher ED utilization was associated with higher mortality but the correlation was weak.

Lastly, we assessed the correlation between the SEDR and the companion ED30 measure (also being submitted for consideration of NQF endorsement). Since ED encounters that are measured in the ED30 are also captured in the SEDR, these two measures demonstrate a strong degree of correlation while assessing complementary elements of care.

2b3—Exclusion Analysis

2b3.1. Method of Testing Exclusion

We calculated a Pearson correlation to assess the association between the SEDR measure with and without the hospice exclusion. Additionally, we calculated the number and percentage of patient years at risk, and ED visits excluded for patients actively enrolled in Hospice.

Exclusions that are implicit in the denominator definition include patient time at risk in which the patient:

- Has had ESRD for 90 days or less
- Is less than 18 years of age

We also exclude patient time at risk where the patient was:

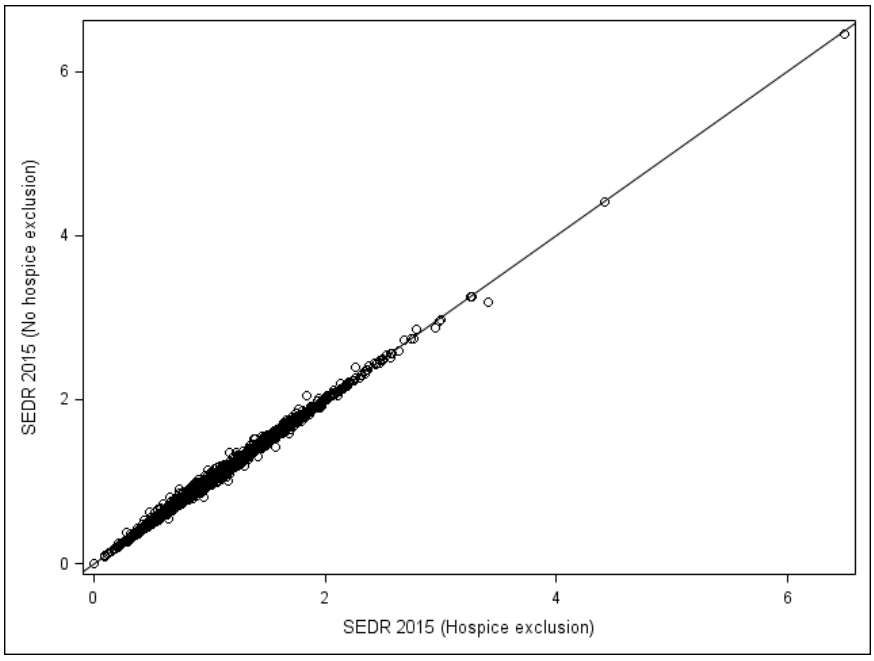
- Actively enrolled in hospice during the calendar month of the ED encounter

2b3.2. Statistical Results From Testing Exclusion

There were 2,062 patient years at risk excluded due to active enrollment in hospice, which represents 0.67% of total years in the analysis. This excludes 4,111 (0.90%) ED visits during this time period (2015).

As shown in Figure 1, we compared each facility's SEDR with and without the hospice exclusion and found the two measures to be highly correlated (overall Pearson correlation coefficient [r] =0.99875, p<0.0001).

Figure 1. Correlation between SEDR with and without the hospice exclusion (2015)



2b3.3. Interpretation

The measure with and without the exclusion criteria is highly correlated suggesting the overall impact on the measure's validity in not substantial. However, this exclusion is necessary to account for any differences in the proportion of hospice patients between facilities.

2b4—Risk Adjustment or Stratification

2b4.1. Method of controlling for differences

Statistical risk model with 86 risk factors

2b4.2. Rationale why Risk Adjustment is not Needed

N/A

2b4.3. Conceptual, Clinical, and Statistical Methods

Consideration of clinical risk factors: The risk adjustment is based on a Cox (relative risk) model. The adjustment is made for patient age, sex, diabetes as cause of ESRD, duration of ESRD, nursing home status, BMI at incidence, comorbidities at incidence, prevalent comorbidities, and calendar year. In this model for SEDR, covariates are taken to act multiplicatively on the ED rate and the adjustment model is fitted with facility defining strata so as to provide valid estimates even if the distribution of adjustment variables differs across facilities. Relevant references are Cox (1972), Kalbfleisch and Prentice (2002), Lawless and Nadeau (1995), Cook and Lawless (2007) and Liu, Schaubel and Kalbfleisch (2010). All analyses are done using SAS.

In general, adjustment factors for the SEDR were selected based on several considerations. Our starting point was the Standardized Hospitalization Ratio (SHR) (NQF 1463) which is the model on which we developed SEDR. We began with a large set of patient characteristics (listed above), which were first evaluated for face validity by the 2016 TEP. Factors considered appropriate were then investigated with statistical models to determine if they were related to ED encounters.

Methodology for prevalent comorbidity selection: We began the selection process with the 283 AHRQ CCS groupers for calendar year 2015. We eliminated the following 32 groupers either due to a possible association with facility care, a reflection of underlying kidney disease, or because they were not appropriate adjusters for our analysis.

AHRQ CCS Groupers Excluded	Description
2	Septicemia
123	Influenza
156	Nephritis / Nephrosis
157	Acute Kidney Failure
158	Chronic Kidney Disease
254	Rehabilitation care; fitting of prostheses; and adjustment of devices
255	Administrative/social admission
256	Medical examination/evaluation
257	Other aftercare
258	Other screening for suspected conditions
259	Residual codes; unclassified
E-Codes	21 Groupers total

Next, five categories of specific ICD-9 codes were removed from the remaining 251 AHRQ CCS groupers. These codes, listed in the Appendix, may be associated with dialysis facility care and include diagnoses such as secondary hyperparathyroidism, fluid overload, hyperkalemia, and vascular access infections. Once these specific ICD-9 codes were excluded, the 251 CCS groupers were consolidated down to 130 groupers by combining similar categories that had specificity beyond what was needed for our risk adjustment.

The selection of prevalent comorbidities was derived using a boosting variable selection method that was applied to the 130 AHRQ CCS groupers to identify a subset of prevalent comorbidities based on their ability to predict outpatient ED encounters. This process is more selective than traditional forward step-wise model building in selecting covariates. The boosting method [1] included the following steps:

1. Use forward stage-wise regression to iteratively detect comorbidities. That is, given the inclusion of some comorbidities, this method identifies additional comorbidity predictors to add to the analysis model.

2. Randomly draw bootstrapped samples and repeatedly apply the boosting procedure on each bootstrapped sample. The variables are ranked based on their selection frequencies.

3. Apply an empirical Bayes false discovery rate (FDR) controlling procedure [2,3] to effectively control the fraction of false discoveries. This procedure is able to control the FDR at a preselected level $0 < q < 1$ (FDR-controlling parameter). For instance, if $q = 0{:}1$ and 10 variables are selected with an estimated FDR less than q, at most 1 of these 10 variables would be expected to be a false positive. This is an equivalent process to assessing the statistical significance of the association between the predictor variable and an emergency department encounter.

The boosting method resulted in a set of 67 CCS groupers that were predictive of an ED encounter. This list of prevalent comorbidities was presented to the ED TEP in June 2017 and received unanimous support for inclusion in the SEDR and ED30 measures.

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1. Friedman, J.H. (2001). Greedy function approximation: A gradient boosting machine. Annals of Statistics, 29(5), 1189-1232.

2. Benjamini, Y., and Hochberg, Y. (1995). Controlling the false discovery rate: A practical and powerful approach to multiple testing. Journal of the Royal Statistical Society. Series B (Methodological), 57, 289-300.

3. Efron, B. (2012). Large-Scale Inference: Empirical Bayes Methods for Estimation, Testing, and Prediction Institute of Mathematical Statistics Monographs, Cambridge University Press.

Consideration of SDS/SES risk factors: SDS/SES factors were evaluated based on appropriateness (whether related to differences in outcomes), empirical association with the outcome, and as supported in published literature.

The relationship among patient-level SDS, socioeconomic disadvantage, access to care, and acute care utilization such as hospitalization and emergency department use is well-established in studies in the general population and has received considerable attention over the years (AHRQ Reports, 2011; 2012;

2013; 2014; 2015). There is also overlap between patient-level SDS factors such as race, and area-level SES. For example, blacks and other minority races, compared to whites, disproportionately tend to have lower income, experience more neighborhood poverty, residential segregation, levels of educational attainment, and unemployment levels. Together these jointly influence key health outcomes related to morbidity and acute care use (Williams 2006; Williams and Collins, 2001).

Race, insurance status, younger age, and SES have been shown to be predictors of emergency department utilization in the general population (Capp et al., 2015; Colligan et al., 2016; LaCalle et al., 2010; Zuckerman and Shen 2004; Hastings et al., 2008). For example, a study by Zuckerman and Shen (2004) reported that black adults had higher odds than whites of being occasional users compared to non-ED users. This difference between blacks and whites was larger when comparing frequent-users to non-users (Zuckerman and Shen, 2004, pg. 178). However, they also found few differences in the likelihood of frequent ED use when comparing patients that have private insurance versus those who are uninsured, while frequent ED use was more likely among those with public insurance (i.e., Medicaid) (Zuckerman and Shen 2004). Those with lower income also had higher odds of being occasional and frequent ED users, while individuals with some college had lower odds of being an occasional or frequent user of the ED, compared to those with no high school diploma. An analysis by Cunningham et. al., (2016) of frequent ED use at two urban hospitals found that frequent ED use was associated with younger age, and that frequent users were more likely to be black. However, there was no significant difference in primary care access between infrequent and frequent users, suggesting that access to care did not explain variation in ED utilization. In addition to younger age, another study reported that those who were single/divorced, single-parents, had high school education or less, or had lower income were more likely to be frequent users of the ED (Sun et al., 2003). Among dual-eligible patients that receive care from a Federally Qualified Health Center (FQHC), relative rates of ED use were lower compared to dual-eligibles that did not receive care from an FQHC (Wright et al., 2015), suggesting the importance of access to primary care. Finally, trends in ED use show differences by sex (female), age (45-64), and geography (the Midwest) and in large central metropolitan areas (Skinner et al., 2014, pg 2-3).

In the ESRD population, low health literacy (a proxy of SES) was found to be a predictor of ED use in one study (Green et al., 2013), as well as SDS/SES factors of younger age, female sex, black race, and public insurance (Medicaid) while lower ED use was associated with private insurance (Lovasik et al., 2016). ESRD patients discharged from a skilled nursing facility that had a subsequent emergency department encounter within 30 days were more likely to be of black race, have dual Medicare-Medicaid status, and higher comorbidity (Hall et al., 2015). In ESRD patients that received a transplant, higher risk of ED use was associated with younger age, female sex, black race, Hispanic ethnicity, and public insurance (Medicaid) (Schold et al., 2016). Treatment adherence was also found to be a risk factor for emergency department visits (Chan et al., 2014). This suggests that there may be related SDS/SES or community level factors that adversely impact patient treatment adherence.
Area-level factors, typically operating as proxies of patient level factors, have also been found to influence acute care use, such as readmission (Herrin et al., 2015; Kind et al, 2014) as well as ED use (Skinner et al., 2014, pg 2-3). Additionally, area-level SES has been observed to be associated with poor outcomes in ESRD patients (e.g., Almachraki et al 2016).

Given these observed linkages we tested available patient- and area-level SDS/SES variables based on the conceptual relationships described above and demonstrated in the literature, as well as the availability of data for analysis.

In our analyses we use the publicly available Area Deprivation Index (ADI) developed by Singh and colleagues at the University of Wisconsin. The ADI reflects a full set of SES characteristics, including measures of income, education, and employment status, measured at the ZIP code level. Singh (2003) has applied the index in a variety of contexts, including analysis of county-level mortality rates. Singh found area differences in mortality associated with low SDS. Over the period studied, mortality differences widened because of slower mortality reductions in more deprived areas. More recently, the ADI has been applied to the calculation of risk-adjusted rates of hospital readmission (Kind et al 2014).

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2b4.4. Statistical Results

Table 5. SEDR Model Coefficients, Data Years 2012–2015.

Covariate	Coefficient	P-value
Comorbidities at start of ESRD		
At least one of the comorbidities listed below	0.00	0.51
Atherosclerotic heart disease	0.02	<.0001
Other cardiac disease	0.00	0.61
Diabetes*	0.03	<.0001
Congestive heart failure	0.03	<.0001
Inability to ambulate	-0.02	0.00
Chronic obstructive pulmonary disease	0.02	<.0001
Inability to transfer	-0.03	0.00
Malignant neoplasm, cancer	-0.03	<.0001
Peripheral vascular disease	-0.01	0.00
Cerebrovascular disease, CVA, TIA	0.03	<.0001
Tobacco use (current smoker)	0.08	<.0001
Alcohol dependence	0.01	0.05
Drug dependence	0.16	<.0001
No Medical Evidence (CMS-2728) Form	0.02	0.01
Cause of ESRD		
Diabetes	0.03	<.001
Sex: Female	0.08	<.0001
Age		
18-24	0.69	<.0001
25-44	0.43	<.0001
45-59	0.19	<.0001
60-74	Reference	
75+	-0.02	<.0001
BMI		
Underweight	0.01	0.04
Normal weight	Reference	
Overweight	-0.02	<.0001
Obese	-0.04	<.0001
Calendar year		
2012	Reference	
2013	0.02	<.0001
2014	0.06	<.0001
2015	0.07	<.0001
In nursing home the previous year	-0.09	<.0001
Diabetes as cause of ESRD X time on ESRD interaction term		
91 days-6 months	Reference	
6 months-1 year	0.03	0.00
1-2 years	0.00	0.95

Covariate	Coefficient	P-value
2-3 years	-0.02	0.01
3-5 years	-0.03	<.0001
5+ years	-0.04	<.0001
Cause of ESRD: diabetes X sex: female interaction term	0.02	<.0001
Age X diabetes as cause of ESRD interaction term		
18-24	0.03	0.37
25-44	0.03	<.0001
45-59	0.03	<.0001
60-74	Reference	
75+	-0.02	<.0001
Age X female sex interaction term		
18-24	0.14	<.0001
25-44	0.06	<.0001
45-59	-0.04	<.0001
60-74	Reference	
75+	0.01	0.26
Prevalent comorbidity groupers		
HIV infection	0.08	<.0001
Hepatitis	0.04	<.0001
Viral infection	0.04	<.0001
Other infections; including parasitic; Sexually transmitted infections (not HIV or hepatitis)	0.04	<.0001
Melanomas of skin; Other non-epithelial cancer of skin	-0.09	<.0001
Benign neoplasm of uterus; Other and unspecified benign neoplasm	-0.05	<.0001
Diabetes mellitus with or without complications	0.04	<.0001
Fluid and electrolyte disorders	0.10	<.0001
Encephalitis, Meningitis and other CNS infections	-0.13	<.0001
Epilepsy; convulsions	0.06	<.0001
Headache; including migraine	0.19	<.0001
Otitis, Dizziness, and other ear and sense organ disorders	0.09	<.0001
Neuropathy, pain syndromes, and other neurologic disorders	0.06	<.0001
Essential hypertension	0.10	<.0001
Secondary hypertension and hypertensive complications	0.08	<.0001
Acute myocardial infarction and atherosclerotic heart disease	0.03	<.0001
Nonspecific chest pain	0.20	<.0001
Pulmonary embolism and other pulmonary heart disease	0.01	<.0001
Other and ill-defined heart disease	0.05	<.0001
Conduction disorders; Cardiac dysrhythmias	0.05	<.0001
Other circulatory disease	0.02	<.0001
Phlebitis; thrombophlebitis and thromboembolism	0.02	<.0001
Acute and chronic tonsillitis; Acute bronchitis; Other upper respiratory infections	0.09	<.0001
Chronic obstructive pulmonary disease and bronchiectasis; Asthma	0.06	<.0001
Other lower respiratory disease	0.11	<.0001
Other upper respiratory disease	0.02	<.0001
Disorders of teeth, jaw and mouth	0.12	<.0001
Esophageal disorders	0.01	<.0001

Covariate	Coefficient	P-value
Digestive track disorders (gastritis, gastric ulcers, and other disorders of stomach; appendicitis)	0.05	<.0001
Anal and rectal conditions	0.05	<.0001
Peritonitis and intestinal abscess	-0.10	<.0001
Pancreatic disorders (not diabetes)	0.13	<.0001
Gastrointestinal hemorrhage	0.02	<.0001
Noninfectious gastroenteritis	0.10	<.0001
Other gastrointestinal disorders	0.01	<.0001
Urinary tract infections	0.02	<.0001
Calculus of urinary tract	0.05	<.0001
Other diseases of kidney and ureters (e.g ureteral stricture or reflux; excludes renal calculus)	0.01	<.0001
Prostate hyperplasia, prostatitis and other male genital disorders	0.03	<.0001
Skin disorders: cellulitis, ulcers, inflammatory and others	0.04	<.0001
Infective arthritis and osteomyelitis	-0.07	<.0001
Other non-traumatic joint disorders	0.05	<.0001
Spondylosis; intervertebral disc disorders; other back problems	0.10	<.0001
Osteoporosis	-0.08	<.0001
Other connective tissue disease; Other bone disease and musculoskeletal deformities	0.07	<.0001
Sprains and strains	0.17	<.0001
Complication of device; implant or graft	0.03	<.0001
Superficial injury; contusion	0.11	<.0001
Poisoning by medications or nonmedicinal substances	0.02	<.0001
Other injuries and conditions due to external causes	0.04	<.0001
Syncope	0.05	<.0001
Gangrene	-0.07	<.0001
Shock	-0.16	<.0001
Nausea and vomiting	0.15	<.0001
Abdominal pain	0.17	<.0001
Malaise and fatigue	0.07	<.0001
Allergic reactions	0.08	<.0001
Anxiety disorders	0.10	<.0001
Attention-deficit, conduct, and disruptive behavior disorders	0.09	<.0001
Developmental disorders	0.09	<.0001
Mood disorders	0.01	<.0001
Personality disorders	0.17	<.0001
Schizophrenia and other psychotic disorders	0.02	<.0001
Alcohol-related disorders	0.20	<.0001
Suicide and intentional self-inflicted injury	0.15	<.0001
Screening and history of mental health and substance abuse codes	0.09	<.0001
Miscellaneous mental health disorders	0.05	<.0001
Missing comorbidity flag	0.82	<.0001

*The diabetes indicator includes all diabetes comorbidities on CMS-2728 and diabetes as cause of ESRD

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors *(e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.)* **Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.**

Table 6 below shows the parameter estimates from the respective Cox models for the original baseline SEDR and one with patient- and area-level SDS/SES variables added.

Table 6. Coefficients for baseline model and model with additional SDS/SES adjustors, 2012-2015

	Baseline SEDR		SDS/SES-adjusted SEDR	
Covariate	**Coefficient**	**P-value**	**Coefficient**	**P-value**
Medicare coverage*				
Medicare primary + Medicaid	NA	NA	0.19	<.0001
Medicare primary + no Medicaid	NA	NA	Reference	-
Medicare secondary/HMO	NA	NA	-0.91	<.0001
Employment status 6 months prior to ESRD				
Unemployed	NA	NA	Reference	-
Employed	NA	NA	-0.13	<.0001
Other/Unknown **	NA	NA	-0.04	<.0001
Race				
White	NA	NA	Reference	-
Native American/Alaskan Native	NA	NA	0.05	<.0001
Asian/Pacific Islander	NA	NA	-0.19	<.0001
Black	NA	NA	0.15	<.0001
Other/Unknown	NA	NA	0.04	0.01
Ethnicity				
Hispanic	NA	NA	0.04	<.0001
Non-Hispanic	NA	NA	Reference	-
Unknown	NA	NA	0.02	0.20
ADI Index	NA	NA	0.00	<.0001
Comorbidities at start of ESRD				
At least one of the comorbidities listed below	0.00	0.51	0.00	0.32
Atherosclerotic heart disease	0.02	<.0001	0.03	<.0001
Other cardiac disease	0.00	0.61	0.01	<.0001
Diabetes***	0.03	<.0001	0.03	<.0001
Congestive heart failure	0.03	<.0001	0.02	<.0001
Inability to ambulate	-0.02	0.00	-0.03	<.0001
Chronic obstructive pulmonary disease	0.02	<.0001	0.03	<.0001
Inability to transfer	-0.03	0.00	-0.03	<.0001
Malignant neoplasm, cancer	-0.03	<.0001	0.00	0.23
Peripheral vascular disease	-0.01	0.00	-0.01	0.03
Cerebrovascular disease, CVA, TIA	0.03	<.0001	0.02	<.0001
Tobacco use (current smoker)	0.08	<.0001	0.07	<.0001
Alcohol dependence	0.01	0.05	-0.01	0.39
Drug dependence	0.16	<.0001	0.11	<.0001

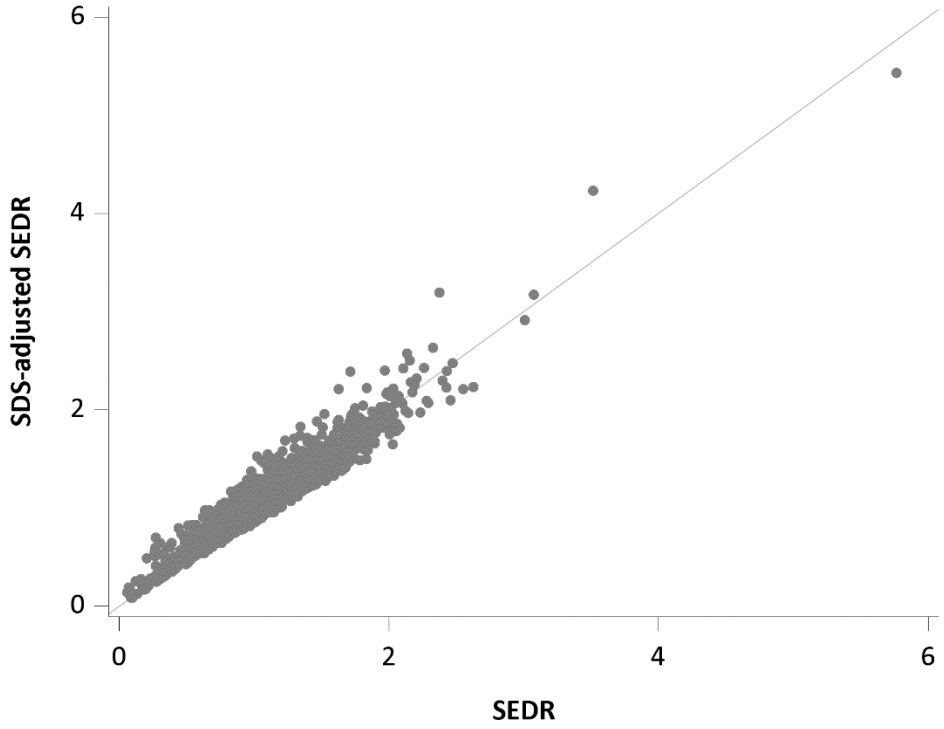
Covariate	Baseline SEDR Coefficient	Baseline SEDR P-value	SDS/SES-adjusted SEDR Coefficient	SDS/SES-adjusted SEDR P-value
No Medical Evidence (CMS-2728) Form	0.02	0.01	-0.02	0.00
Cause of ESRD				
Diabetes	0.03	<.001	0.04	<.0001
Sex: Female	0.08	<.0001	0.05	<.0001
Age				
18-24	0.69	<.0001	0.59	<.0001
25-44	0.43	<.0001	0.34	<.0001
45-59	0.19	<.0001	0.13	<.0001
60-74	Reference	-	Reference	-
75+	-0.02	<.0001	0.02	<.0001
BMI				
Underweight	0.01	0.04	0.01	0.00
Normal weight	Reference	-	Reference	-
Overweight	-0.02	<.0001	-0.02	<.0001
Obese	-0.04	<.0001	-0.04	<.0001
Calendar year				
2012	Reference	-	Reference	-
2013	0.02	<.0001	0.02	<.0001
2014	0.06	<.0001	0.06	<.0001
2015	0.07	<.0001	0.08	<.0001
In nursing home the previous year	-0.09	<.0001	-0.11	<.0001
Diabetes as cause of ESRD X time on ESRD interaction term				
91 days-6 months	Reference	-	Reference	-
6 months-1 year	0.03	0.00	0.03	0.00
1-2 years	0.00	0.95	0.00	0.99
2-3 years	-0.02	0.01	-0.02	0.00
3-5 years	-0.03	<.0001	-0.04	<.0001
5+ years	-0.04	<.0001	-0.05	<.0001
Cause of ESRD: diabetes X sex: female interaction term	0.02	<.0001	0.00	0.23
Age X diabetes as cause of ESRD interaction term				
18-24	0.03	0.37	-0.04	0.32
25-44	0.03	<.0001	0.02	<.0001
45-59	0.03	<.0001	0.03	<.0001
60-74	Reference	-	Reference	-
75+	-0.02	<.0001	-0.04	<.0001
Age X female sex interaction term				
18-24	0.14	<.0001	0.17	<.0001
25-44	0.06	<.0001	0.07	<.0001
45-59	-0.04	<.0001	-0.03	<.0001
60-74	Reference	-	Reference	-
75+	0.01	0.26	0.00	0.73
Prevalent comorbidity groupers				
HIV infection	0.08	<.0001	0.05	<.0001

Covariate	Baseline SEDR Coefficient	Baseline SEDR P-value	SDS/SES-adjusted SEDR Coefficient	SDS/SES-adjusted SEDR P-value
Hepatitis	0.04	<.0001	0.01	<.0001
Viral infection	0.04	<.0001	0.05	<.0001
Other infections; including parasitic; Sexually transmitted infections (not HIV or hepatitis)	0.04	<.0001	0.04	<.0001
Melanomas of skin; Other non-epithelial cancer of skin	-0.09	<.0001	-0.04	<.0001
Benign neoplasm of uterus; Other and unspecified benign neoplasm	-0.05	<.0001	-0.05	<.0001
Diabetes mellitus with or without complications	0.04	<.0001	0.03	<.0001
Fluid and electrolyte disorders	0.10	<.0001	0.09	<.0001
Encephalitis, Meningitis and other CNS infections	-0.13	<.0001	-0.13	<.0001
Epilepsy; convulsions	0.06	<.0001	0.05	<.0001
Headache; including migraine	0.19	<.0001	0.18	<.0001
Otitis, Dizziness, and other ear and sense organ disorders	0.09	<.0001	0.08	<.0001
Neuropathy, pain syndromes, and other neurologic disorders	0.06	<.0001	0.06	<.0001
Essential hypertension	0.10	<.0001	0.05	<.0001
Secondary hypertension and hypertensive complications	0.08	<.0001	0.10	<.0001
Acute myocardial infarction and atherosclerotic heart disease	0.03	<.0001	0.04	<.0001
Nonspecific chest pain	0.20	<.0001	0.18	<.0001
Pulmonary embolism and other pulmonary heart disease	0.01	<.0001	0.02	<.0001
Other and ill-defined heart disease	0.05	<.0001	0.05	<.0001
Conduction disorders; Cardiac dysrhythmias	0.05	<.0001	0.06	<.0001
Other circulatory disease	0.02	<.0001	0.02	<.0001
Phlebitis; thrombophlebitis and thromboembolism	0.02	<.0001	0.02	<.0001
Acute and chronic tonsillitis; Acute bronchitis; Other upper respiratory infections	0.09	<.0001	0.09	<.0001
Chronic obstructive pulmonary disease and bronchiectasis; Asthma	0.06	<.0001	0.06	<.0001
Other lower respiratory disease	0.11	<.0001	0.10	<.0001
Other upper respiratory disease	0.02	<.0001	0.02	<.0001
Disorders of teeth, jaw and mouth	0.12	<.0001	0.11	<.0001
Esophageal disorders	0.01	<.0001	0.01	<.0001
Digestive track disorders (gastritis, gastric ulcers, and other disorders of stomach; appendicitis)	0.05	<.0001	0.05	<.0001
Anal and rectal conditions	0.05	<.0001	0.05	<.0001
Peritonitis and intestinal abscess	-0.10	<.0001	-0.07	<.0001
Pancreatic disorders (not diabetes)	0.13	<.0001	0.13	<.0001

Covariate	Baseline SEDR Coefficient	Baseline SEDR P-value	SDS/SES-adjusted SEDR Coefficient	SDS/SES-adjusted SEDR P-value
Gastrointestinal hemorrhage	0.02	<.0001	0.02	<.0001
Noninfectious gastroenteritis	0.10	<.0001	0.10	<.0001
Other gastrointestinal disorders	0.01	<.0001	0.02	<.0001
Urinary tract infections	0.02	<.0001	0.03	<.0001
Calculus of urinary tract	0.05	<.0001	0.05	<.0001
Other diseases of kidney and ureters (e.g ureteral stricture or reflux; excludes renal calculus)	0.01	<.0001	0.02	<.0001
Prostate hyperplasia, prostatitis and other male genital disorders	0.03	<.0001	0.03	<.0001
Skin disorders: cellulitis, ulcers, inflammatory and others	0.04	<.0001	0.04	<.0001
Infective arthritis and osteomyelitis	-0.07	<.0001	-0.06	<.0001
Other non-traumatic joint disorders	0.05	<.0001	0.03	<.0001
Spondylosis; intervertebral disc disorders; other back problems	0.10	<.0001	0.09	<.0001
Osteoporosis	-0.08	<.0001	-0.07	<.0001
Other connective tissue disease; Other bone disease and musculoskeletal deformities	0.07	<.0001	0.06	<.0001
Sprains and strains	0.17	<.0001	0.16	<.0001
Complication of device; implant or graft	0.03	<.0001	0.01	<.0001
Superficial injury; contusion	0.11	<.0001	0.12	<.0001
Poisoning by medications or nonmedicinal substances	0.02	<.0001	0.02	<.0001
Other injuries and conditions due to external causes	0.04	<.0001	0.04	<.0001
Syncope	0.05	<.0001	0.05	<.0001
Gangrene	-0.07	<.0001	-0.07	<.0001
Shock	-0.16	<.0001	-0.15	<.0001
Nausea and vomiting	0.15	<.0001	0.14	<.0001
Abdominal pain	0.17	<.0001	0.15	<.0001
Malaise and fatigue	0.07	<.0001	0.07	<.0001
Allergic reactions	0.08	<.0001	0.09	<.0001
Anxiety disorders	0.10	<.0001	0.11	<.0001
Attention-deficit, conduct, and disruptive behavior disorders	0.09	<.0001	0.10	<.0001
Developmental disorders	0.09	<.0001	0.07	<.0001
Mood disorders	0.01	<.0001	0.02	<.0001
Personality disorders	0.17	<.0001	0.17	<.0001
Schizophrenia and other psychotic disorders	0.02	<.0001	0.01	0.03
Alcohol-related disorders	0.20	<.0001	0.18	<.0001
Suicide and intentional self-inflicted injury	0.15	<.0001	0.15	<.0001
Screening and history of mental health and substance abuse codes	0.09	<.0001	0.09	<.0001
Miscellaneous mental health disorders	0.05	<.0001	0.05	<.0001
Missing comorbidity flag	0.82	<.0001	0.92	<.0001

*Patients without Medicare coverage or with unknown coverage type were excluded from the model.
** Other/Unknown includes patients who are on medical leave of absence, retired due to age or disability, homemakers, or those with no employment status information available.
***The diabetes indicator includes all diabetes comorbidities on CMS-2728 and diabetes as cause of ESRD.

Figure 2. Correlation between SEDR without and with SDS adjustment, 2012-2015



Pearson correlation coefficient rho = 0.96 (p<0.0001)

Patient-level SDS: Compared with males, females were 5% more likely to experience an emergency department encounter (HR=1.05; p <0.0001). Hispanics had a slightly higher risk of having an emergency department encounter (HR=1.04; p<0.0001) than non- Hispanics. Compared with white patients, Asian/PI (HR=0.83, p<0.0001) patients were almost 20% less likely to have an emergency department encounter, while Native Americans were slightly more likely (HR=1.05, p<0.0001). Notably, compared to whites, black patients had a 17% higher risk (HR=1.17, p<0.0001) of having an emergency department encounter. Patients in the youngest age group (18-24) had almost two-times higher risk of an emergency department encounter (HR=1.81*; p<0.0001) compared with the reference group (60-74). The effect shows a negative gradient moving from younger to older age categories. The results for these SDS factors are consistent with prior studies both in the respective chronic dialysis setting and general population indicating younger age, black race and female sex as potential SDS risk factors for ED use.

**4/9/2018 update: our original submission said the hazard ratio was 1.18; the last two digits were transposed, so we have corrected the HR to be 1.81.*

Patient-level SES: Compared with Medicare-only patients, dually-eligible patients with both Medicare and Medicaid (HR=1.21; p <0.0001) were around 20% more likely to have an emergency department

encounter. However, patients with Medicare as secondary payer/Medicare HMO (HR=0.40, p <0.0001) were 60% less likely to visit the emergency department. The result for dually-eligible patients having higher risk of an emergency department encounter is consistent with prior studies demonstrating that this insurance category, on average, represents an at-risk group.

Patients who were employed prior to ESRD incidence were 11% less likely to have an emergency department encounter (HR=0.88; p<0.0001) compared to unemployed patients. This difference could reflect that patients still able to work may have potentially lower comorbidity burden and have fewer acute care encounters. However, employment information is obtained only at ESRD incidence, therefore we are unable to capture changes to patients' employment status over time and whether that corresponds with changes in emergency department use. Note that for employment categories, the "Other/Unknown" category also had a slightly lower risk of having an emergency department encounter (about 4%). We note this likely represents a diverse mix of patients with regard to SES, such as homemakers and those who are retired. The lower risk of emergency department visits may be associated with unmeasured characteristics of this heterogeneous group.

Area-level SES: The Area Deprivation Index had no impact on the risk of emergency department encounters (HR = 1.00; p<0.0001), suggesting the level of area-SES is not predictive of outpatient ED utilization.

Table 7. Flagging rates, baseline SEDR and SEDR adjusted for SDS/SES: 2012-2015

	SEDR with SDS/SES			
Baseline SEDR	Better than Expected	As Expected	Worse than Expected	**Total**
Better than Expected	56	16	0	**72 (1.11%)**
As Expected	18	6041	58	**6117 (94.15%)**
Worse than Expected	0	61	305	**308 (4.74%)**
Total	**74 (1.14%)**	**6118 (94.17%)**	**305 (4.69%)**	6,497

Several patient-level SDS/SES factors were predictive of higher emergency department encounter use, however when comparing the baseline SEDR measure with one that includes adjustment for patient and area-level SDS/SES, we observed very small differences in flagging of facility performance (Figure 2 and Table 7). For example, in the baseline SEDR, 308 facilities are flagged as worse than expected while 305 are flagged as worse than expected in the SEDR adjusted for SDS/SES, resulting in a negligible decrease in the number of facilities flagged for worse than expected performance. Additionally, both the baseline SEDR and SEDR adjusted for SDS/SES are highly correlated (rho = 0.96 (p<0.0001). For these reasons and the lack of definitive evidence indicating that differences are primarily attributable to patient or area-level SDS/SES factors versus facility practices, no additional risk adjustment is made for patient race, ethnicity, or patient and area-level SES.

2b4.5. Method Used to Develop the Statistical Model or Stratification Approach

Risk factors were selected for the final model based on the magnitude of the coefficients, evaluation of their statistical significance, and the model C-statistic. The C-statistic measures the discriminative power of the regression model with considered risk factors.

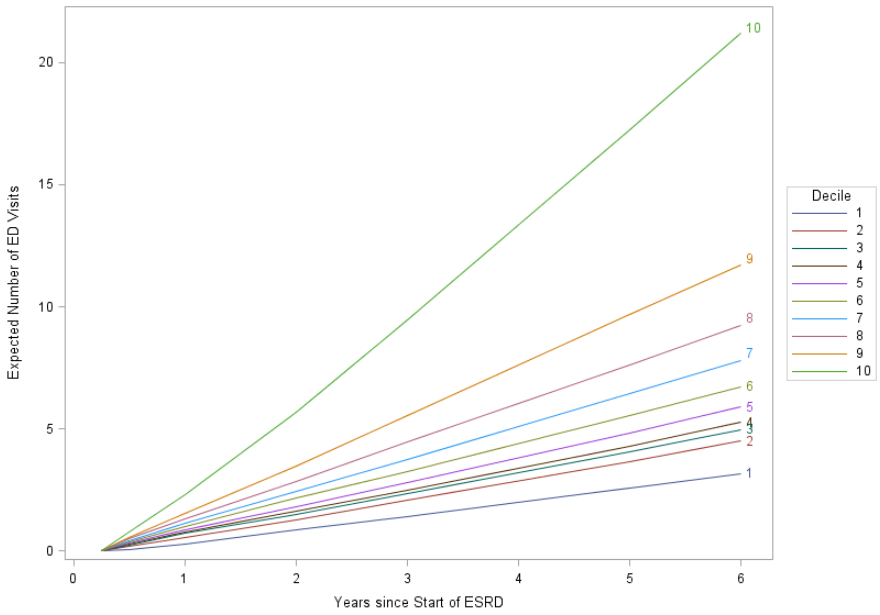
2b4.6. Statistical Risk Model Discrimination Statistics (e.g., c-statistic, R^2)

The estimate of the C-statistic for the SEDR is 0.67.

2b4.7. Statistical Risk Model Calibration Statistics (e.g., Hosmer-Lemeshow statistic)
N/A

2b4.8. Statistical Risk Model Calibration—Risk decile plots or calibration curves
Decile plots showing piecewise linear estimates of the cumulative rates by years since start of ESRD are plotted in Figure 3. This plot creates deciles based on the value of xbeta from the stage 1 model. For each decile we then fit a model with no covariates and pull out the baseline survival curve.

Figure 3. Decile Plot for SEDR (2012-2015 data)



2b4.9. Results of Risk stratification Analysis
N/A

2b4.10. Interpretation
The decile plot (Figure 3) shows that the risk factors in the model are discriminating well between patients. There is good separation among all 10 groups, and the ordering is as predicted by the model (i.e. patients predicted to be at lower risk have lower emergency department rates). The absolute differences between the groups is also large, with patients predicted to have the highest emergency department rates (line 10) having about 7 times higher emergency department rates than those predicted to have the lowest rates (line 1). This means that the model fit is good and therefore adequately adjusts for patient characteristics (case mix).

2b4.11. Optional Additional Testing for Risk Adjustment
N/A

2b5—Identification of statistically significant and clinically meaningful differences
2b5.1. Method for determining
To adjust for over-dispersion of the data, we compute the p-value for our estimates using the empirical null distribution, a robust approach that takes account of the natural random variation among facilities

that is not accounted for in the model (Efron, 2004; Kalbfleisch and Wolfe, 2013). Our algorithm consists of the following concrete steps. First, we fit an over-dispersed Poisson model (e.g., SAS PROC GENMOD with link=log, dist=poisson and scale=dscale) for the number of hospital admissions

$$\log(E[\mathbf{n}_{ik}]) = \log(\mathbf{E}_{ik}) + \boldsymbol{\theta}_k,$$

where $\mathbf{n}_{ik}$ is the observed number of events for patient *i* in facility *k*, $\mathbf{E}_{ik}$ is the expected number of events for patient *i* in facility *k* and $\boldsymbol{\theta}_k$ is the facility-specific intercept. Here, i ranges over the number of patients $\underline{N_k}$ who are treated in the *k*th facility. The natural log of the SEDR for the *k*th facility is then given by the corresponding estimate of $\boldsymbol{\theta}_k$. The standard error of $\boldsymbol{\theta}_k$ is obtained from the robust estimate of variance arising from the overdispersed Poisson model.

Second, we obtain a z-score for each facility by dividing the natural log of its SEDR by the standard error from the general linear model described above. These z-scores are then grouped into quartiles based on the number of patient years at risk for Medicare patients in each facility. Finally, using robust estimates of location and scale based on the normal curve fitted to the center of the z-scores for the SEDR, we derive the mean and variance of a normal empirical null distribution for each quartile. This empirical null distribution is then used to calculate the p-value for a facility's SEDR.

References:

Efron B. Large-scale simultaneous hypothesis testing: the choice of a null hypothesis. J Am Stat Assoc. 2004; 99:96–104

Kalbfleisch, J.D. & Wolfe, R.A. On Monitoring Outcomes of Medical Providers. Stat Biosci 2013; 5(2):286-302

2b5.2. Statistical Results

Table 8. Number and percentage of facilities by classification of SEDR, 2015.

Better than expected	As expected	Worse than expected	Total
0.64% (40)	93.86% (5,872)	5.50% (344)	6,256

2b5.3. Interpretation

Without empirical null methods, a large number of facilities will be flagged. In contrast, the methods based on the empirical null, used here, make appropriate adjustments for overdispersion. Using this method, facilities are flagged if they have outcomes (excessive emergency department encounters) that are extreme when compared to the variation in outcomes for other facilities of a similar size. Overall, most are flagged as expected (about 94%), while <1% are better than expected, and approximately 6% are flagged as worse than expected.

2b6—Comparability of performance scores

2b6.1. Method of testing conducted to demonstrate comparability

N/A

2b6.2. Statistical Results

N/A

2b6.3. Interpretation
N/A

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)
Since many data elements can be obtained from multiple sources, missing data occurs only rarely. However, if the patient's age or sex is missing, then they are excluded from analysis. If the reported BMI value on the 2728 medical evidence form is missing, we impute the value by using the corresponding average BMI of the patients of the same age, sex, race, and diabetes status. If race or diabetes status is missing, then just age and sex are used. Patients with less than 6 months of Medicare eligible claims in the prior year were considered as having incomplete prevalent comorbidity information but were not excluded from the model.

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (*e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each*)
N/A

2b6.3. What is your interpretation of the results in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias**?** (i*.e., what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis, provide rationale for the selected approach for missing data*)
N/A

Feasibility

3a.1. How are the data elements needed to compute measure scores generated
Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

3b.1. Are the data elements needed for the measure as specified available electronically
ALL data elements are in defined fields in a combination of electronic sources

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment
N/A

3c.1. Describe what you have learned or modified as a result of testing
N/A

3c.2. Describe any fees, licensing, or other requirements
N/A

Usability and Use

4a.1. Program, sponsor, purpose, geographic area, accountable entities, patients
N/A

4a.2. If not publicly reported or used for accountability, reasons
Development of the measure was recently completed so there has not been an opportunity for public reporting or use in another accountability application.

4a.3. If not, provide a credible plan for implementation
CMS will consider implementing the SEDR measure as part of CMS' Dialysis Facility Compare (DFC) public reporting program, whose purpose is to help dialysis patients and their caregivers understand the quality of care provided by dialysis facilities and to be able to compare selected aspects of care between dialysis facilities. All Medicare-certified dialysis facilities that treat dialysis patients in the U.S. are reported on DFC.

4b.1. Progress on improvement
N/A

4b.2. If no improvement was demonstrated, what are the reasons
The measure is not yet implemented in a public report program, so improvement could not be evaluated. CMS anticipates future implementation of the ED30 (SEDR) measures into a public reporting program. Once implemented, facility performance on the measure can be evaluated to determine if the measure has supported and detected quality improvement in reducing emergency department visits

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.
How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.
N/A

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.
N/A

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.
Describe how feedback was obtained.
N/A

4a2.2.2. Summarize the feedback obtained from those being measured.
N/A

4a2.2.3. Summarize the feedback obtained from other users
N/A

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.
N/A

Related and Competing Measures

5—Relation to Other NQF-Endorsed Measures

5.1a. The measure titles and NQF numbers are listed here
1463 : Standardized Hospitalization Ratio for Dialysis Facilities

2505 : Emergency Department Use without Hospital Readmission During the First 30 Days of Home Health

5.1b. If the measures are not NQF-endorsed, indicate the measure title 5a—
Emergency Department Encounters Occurring Within 30 Days of Hospital Discharge (ED30) (currently undergoing endorsement review with SEDR).

Harmonization
5a.1. Are the measure specifications completely harmonized
No

5a.2. If not completely harmonized, identify the differences rationale, and impact
These measures are not completely harmonized. Each measure assesses different outcomes as reflected in certain differences across the measure specifications. The proposed Standardized Emergency Department Encounter Ratio (SEDR) for Dialysis Facilities and Standardized Ratio of Emergency Department Encounters Occurring Within 30 Days of Hospital Discharge (ED30) for Dialysis Facilities measures both focus on dialysis facilities' ED use, but they measure different aspects of ED use. The SEDR measures the overall rate of ED use while the ED30 focuses on ED use closely following a hospitalization. Both SEDR and ED30 apply to the same target population - adult Medicare-covered dialysis patients who have had ESRD for more than 90 days. The SEDR and SHR are both intended to encourage appropriate management of acute conditions but measure two different acute care outcomes. SEDR measures outpatient acute care services while SHR measure inpatient acute care services. SEDR is harmonized with SHR and ED30 in several aspects. All are harmonized to the population they measure (Medicare-covered ESRD patients); however SHR also includes pediatric patients. All three measures have risk adjustment for prevalent comorbidities while only SEDR and SHR also adjust for incident comorbidities taken from CMS form 2728. Exclusions: 1) Only SEDR and ED30 exclude hospice patients; 2) ED30 includes additional exclusions based on discharge type, that are not part of SEDR or SHR; 3) ED30 adjusts for discharging hospital, acknowledging that for ED encounters after a hospital discharge, that hospitals also bear accountability for properly coordinating care with the dialysis facility. SEDR and NQF measure 2505: Emergency Department Use without Hospital Readmission During the First 30 Days of Home Health have the same focus (emergency department encounters). Differences: 1) Home Health is focused on emergency department use within the first 30 days of home health; 2) each measure has distinct target populations; 3) risk adjustment factors; and 4) model type (2-stage Cox model vs multinomial logistic model). For example, the Home Health 30 measure adjusts for over 400 covariates that were statistically significantly predictive of acute care hospitalization or emergency use (without

admission). SEDR currently adjusts for a set of comorbidities present at ESRD incidence and for a set of prevalent comorbidities. Because of the different care settings and comorbidity profile of Home Health patients, different risk adjustment approaches are justified.

5b—Competing measures
N/A

5b.1 Describe why this measure is superior to competing measures
N/A

Co.1 Measure Steward (Intellectual Property Owner): Centers for Medicare and Medicaid Services

Co.2 Point of Contact: Sophia, Chan, sophia.chan@cms.hhs.gov

Co.3 Measure Developer if different from Measure Steward: University of Michigan Kidney Epidemiology and Cost Center

Co.4 Point of Contact: Jennifer, Sardone, jmsto@med.umich.edu, 734-936-5711-

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

According to the CMS Measure Management System Blueprint, TEPs are advisory to the measure contractor. In this advisory role, the primary duty of the TEP is to suggest candidate measures and related specifications, review any existing measures, and determine if there is sufficient evidence to support the proposed candidate measures.

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Forum of ESRD Networks

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Vice President/Chair of Public Policy
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New Carrollton, MD

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2018

Ad.3 Month and Year of most recent revision: 04, 2018

Ad.4 What is your frequency for review/update of this measure? Annually

Ad.5 When is the next scheduled review/update for this measure? 04, 2019

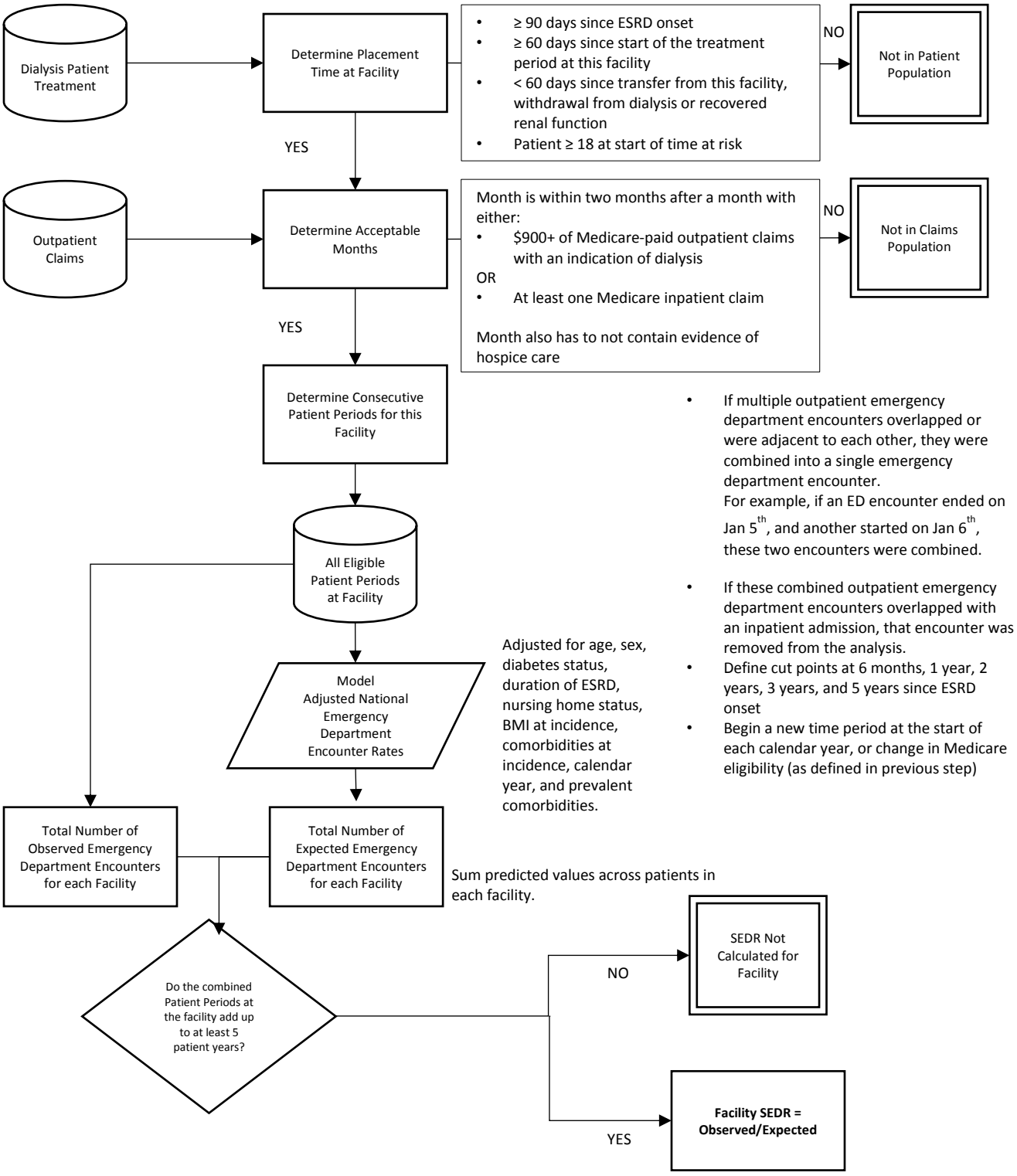
Ad.6 Copyright statement:

Ad.7 Disclaimers:

Ad.8 Additional Information/Comments:

Appendix for SEDR (#3404)

S.14. Calculation Algorithm/Measure Logic



*Multiple data sources include CMS Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Dialysis Facility Compare (DFC) and the Social Security Death Master File.

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.

Table 1 shows the deciles of performance for the SEDR for CY2015.

Table 1. Deciles of Standardized ED Visit Ratio, 2015

Deciles	N	Minimum	Maximum
1	625	0.00	0.60
2	626	0.60	0.72
3	626	0.72	0.81
4	625	0.81	0.88
5	626	0.88	0.96
6	626	0.96	1.04
7	625	1.04	1.13
8	626	1.13	1.25
9	626	1.25	1.46
10	625	1.46	6.49

2b3.1.1 If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

Below we list the groupers used for identification of prevalent comorbidities in the SEDR risk adjustment model (Table 2), along with the list of ICD-9 codes that were excluded from specific groupers because may be associated with dialysis facility care and include diagnoses such as secondary hyperparathyroidism, fluid overload, hyperkalemia, and vascular access infections (Table 3).

Table 2: Prevalent Comorbidity Adjustment Definitions

Prevalent Comorbidity	AHRQ CCS Grouper(s)
HIV infection	5
Hepatitis	6*
Viral infection	7
Other infections including parasitic and sexually transmitted infections (not HIV or hepatitis)	8-9
Melanomas of skin; Other non-epithelial cancer of skin	22-23
Benign neoplasm of uterus; Other and unspecified benign neoplasm	46-47
Diabetes mellitus with or without complications	49-50
Fluid and electrolyte disorders	55*
Encephalitis, Meningitis and other CNS infections	76-78
Epilepsy; convulsions	83
Headache; including migraine	84
Otitis, Dizziness, and other ear and sense organ disorders	92-94
Neuropathy, pain syndromes, and other neurologic disorders	95
Essential hypertension	98
Secondary hypertension and hypertensive complications	99
Acute myocardial infarction and atherosclerotic heart disease	100-101
Nonspecific chest pain	102
Pulmonary embolism and other pulmonary heart disease	103
Other and ill-defined heart disease	104
Conduction disorders; Cardiac dysrhythmias	105-106
Other circulatory disease	117
Phlebitis; thrombophlebitis and thromboembolism	118,119,121
Acute and chronic tonsillitis; Acute bronchitis; Other upper respiratory infections	124-126
Chronic obstructive pulmonary disease and bronchiectasis; Asthma	127-128
Other lower respiratory disease	133*
Other upper respiratory disease	134
Disorders of teeth, jaw and mouth	136-137
Esophageal disorders	138
Digestive track disorders (gastritis, gastric ulcers, and other disorders of stomach; appendicitis)	139-142

Prevalent Comorbidity	AHRQ CCS Grouper(s)
Anal and rectal conditions	147
Peritonitis and intestinal abscess	148
Pancreatic disorders (not diabetes)	152
Gastrointestinal hemorrhage	153
Noninfectious gastroenteritis	154
Other gastrointestinal disorders	155
Urinary tract infections	159
Calculus of urinary tract	160
Other diseases of kidney and ureters (e.g. ureteral stricture or reflux; excludes renal calculus)	161*
Prostate hyperplasia, prostatitis and other male genital disorders	164-166
Skin disorders: cellulitis, ulcers, inflammatory and others	197-200
Infective arthritis and osteomyelitis	201
Other non-traumatic joint disorders	204
Spondylosis; intervertebral disc disorders; other back problems	205
Osteoporosis	206
Other connective tissue disease; Other bone disease and musculoskeletal deformities	211-212
Sprains and strains	232
Complication of device; implant or graft	237*
Superficial injury; contusion	239
Poisoning by medications or nonmedicinal substances	241-243
Other injuries and conditions due to external causes	244
Syncope	245
Gangrene	248
Shock	249
Nausea and vomiting	250
Abdominal pain	251
Malaise and fatigue	252
Allergic reactions	253
Anxiety disorders	651
Attention-deficit, conduct, and disruptive behavior disorders	652
Developmental disorders	654
Mood disorders	657
Personality disorders	658
Schizophrenia and other psychotic disorders	659
Alcohol-related disorders	660
Suicide and intentional self-inflicted injury	662
Screening and history of mental health and substance abuse codes	663
Miscellaneous mental health disorders	670

* Not all ICD-9 codes associated with the grouper(s) were included. See table of exclusions below.

Table 3: ICD-9 Code Exclusions for Prevalent Comorbidities

Prevalent Comorbidity	ICD-9 Codes Excluded	
Hepatitis (CCS 6)	0702	HEPATITIS B WITH COMA (Begin 1980 End 1991)
	07020	VRL HEPAT B CM W/O DELTA (Begin 1991)
	07021	VRL HEPAT B CM W DELTA (Begin 1991)
	07022	CHR HEPAT COMA W/O DELTA (Begin 1994)
	07023	CHR HEPAT COMA W/ DELTA (Begin 1994)
	0703	HEPATITIS B W/O COMA (Begin 1980 End 1991)
	07030	VRL HPT B W/O CM W/O DLT (Begin 1991)
	07031	VRL HPT B W/O CM W DELTA (Begin 1991)
	07032	CHR HEPAT W/O COMA W/O DELTA (Begin 1994)
	07033	CHR HEPAT W/O COMA W/ DELTA (Begin 1994)
Fluid and electrolyte disorders (CCS 55)	2760	HYPEROSMOLALITY
	2761	HYPOSMOLALITY
	2762	ACIDOSIS
	2763	ALKALOSIS
	2764	MIXED ACID-BASE BAL DIS
	2765	HYPOVOLEMIA (End 2005)
	27650	VOLUME DEPLETION NOS (Begin 2005)
	27651	DEHYDRATION (Begin 2005)
	27652	HYPOVOLEMIA (Begin 2005)
	2766	FLUID OVERLOAD (end 2010)
	27669	FLUID OVERLOAD NEC (Begin 2010)
	2767	HYPERPOTASSEMIA
	2768	HYPOPOTASSEMIA
	2769	ELECTROLYT/FLUID DIS NEC
Other lower respiratory disease (CCS 133)	5184	ACUTE LUNG EDEMA NOS
Other diseases of kidney and ureters (CCS (161)	58881	SEC HYPERPARATHYRD-RENAL (Begin 2004)
Complication of device; implant or graft (CCS 237)	99668	INFXN PERITON DIALY CATHET (Begin 1998)
	99931	INFECT d/t CENT VEN CATH (Begin 2007)
	99932	BLOOD INFECTION d/t CEN VEN CATH
	99933	LOCAL INFECTION d/t CEN VEN CATH