Government Affairs Update

ESRD QIP 2015 Proposed Rule

Cathleen O'Keefe

ESRD PPS 2015 Proposed Rule

Kathleen Smith

FRAA Annual Meeting
Delray Beach, Fl

July 26, 2014

QIP

* Proposals affect the QIP in payment years (PY) 2016, 2017, and 2018.
* CMS seeks to adopt measures that "promote better, safer, and more coordinated care."
* Considers national priorities such as the HHS Strategic Plan, the National Quality Strategy, and the HHS National Action Plan to Prevent Healthcare Associated Infections.
* CMS has sought "to the extent feasible and practicable" to adopt measures that have been endorsed by a national consensus organization; recommended by multi-stakeholder organizations; and developed with the input of providers, beneficiaries, health advocacy organizations, and others.

Proposals for PY 2016 and Future Years

Clinical Measure for NHSN Bloodstream Infection in HD Outpatients

* Reliability adjustment starting with 2016.
* The NHSN Bloodstream Infection clinical measure adopted for 2016 included a risk adjustment for patients' vascular access type, but did not include any reliability adjustments that account for variation among facilities in the amount of exposure to or opportunity for healthcare-associated infections (HAIs).
* CDC provided NQF with a reliability adjustment (ARM) for volume of exposure and unmeasured variation across facilities… differences in the reliability of the infection estimates based on the # of patient months at a facility and any unmeasured variation across facilities.
* Facility scores adjusted more if fewer patient months in the denominator…. adjusted less if there are many patient months in the denominator.

Oral-Only Drugs Measures

* The Protecting Access to Medicare Act of 2014 (PAMA) required the Secretary to adopt measures that are specific to conditions treated with oral-only drugs.

* CMS believes the hyercalcemia clinical measure adopted beginning with PY 2016 meets the PAMA requirement.

* CMS considered adopting outcomes-based measures that relate to conditions treated with oral-only drugs, the Agency determined that doing so is not feasible at this time.

Proposals for the PY 2017 QIP

Revision to the ICH CAHPS Reporting Measure

* Facilities may not know if they have sufficient numbers of survey-eligible patients during the performance period to be eligible for the ICH CAHPS measure when they are making decisions about whether to contract with a vendor to administer the survey

* CMS proposes that starting in PY 2017, facilities will be eligible to receive a score on the ICH CAHPS measure if they treat 30 or more survey-eligible patients during the "eligibility period," which is defined as the CY before the performance period.

* Even if the facility may receive a score on the measure because it has treated at least 30 survey-eligible patients during the previous CY, CMS also proposes that the facility will still not receive a score for the performance period if the facility cannot collect 30 surveys completed during the performance period.

2016 Measure Being Eliminated in 2017 and Beyond

* CMS proposes to remove Hgb >12 g/dL, beginning with PY 2017… the measure is "topped out."
* Criteria: (1) performance of majority of facilities is high and unvarying such that measurement does not yield meaningful distinctions; (2) performance or improvement on a measures doesn't result in better or intended outcomes; (3) measure doesn't align with current clinical practice; (4) a more acceptable measure becomes available; (5) a measure that is more proximal in time to desired outcomes becomes available; (6) a measure that is more strongly associated with desired outcomes becomes available; or (7) collection of data or pubic reporting of a measure has unintended negative consequences.
* The pediatric hemodialysis adequacy measure meets the criteria, however, CMS is not proposing to remove this measure - few pediatric measures available

New Standardized Readmission Ratio (SRR) Clinical Measure for 2017 and Beyond

* Measures facility one-year, risk-standardized 30-day all-cause rate of unplanned hospital readmissions.
* All discharges of Medicare ESRD dialysis patients from acute care hospitals in a calendar year eligible for this measure.
* Calculated as the ratio of the number of observed unplanned readmissions to the number of expected unplanned readmissions.

SRR Exceptions

* Patient died during the index hospitalization;
* Patient dies within 30 days of the index discharge with no readmission;
* Patient is discharged against medical advice;
* Patient was admitted with a primary diagnosis of certain conditions related to cancers, mental health conditions, or rehabilitation procedures;
* Patient is discharged from a PPS-exempt cancer hospital;
* Patient is transferred to another acute care hospital; and
* Patient has already been discharged 12 times during the same calendar year.

SRR

* Case mix adjuster - age, gender, and co-morbidities, not for socioeconomic status or race.
* Hospitalizations are counted if they meet the definition of unplanned readmission: occurred within 30 days of the index discharge and not preceded by a planned readmission that also occurred within 30 days of the index discharge.
* Planned readmissions are those that occur as part of ongoing appropriate care of patients or that involve elective care.
* CMS states the measure is ready for adoption because "it achieves a moderate degree of reliability."

Industry Concerns with SRR Measure

* Measure is not limited to readmissions that are related to ESRD or actionable by a dialysis facility… 45% of readmissions

* Only a subset of the 55 percent attributable ESRD admissions are the same cause-specific readmissions. Attaining benchmarks or improving care cannot be achieved if the measure is not actionable at the facility level.

* Measure does not adequately account for hospital-specific patterns…. does not adjust at all for physician-level admitting patterns—the decision to admit/readmit is a physician decision

Industry Concerns with SRR Measure

* Local factors beyond the control of dialysis facilities, community healthcare resources (e.g. urgent care facilities), and non-nephrology physician and clinician practices impact hospital admission/readmission patterns.

* Not all discharges are to the home… patients may be readmitted to a hospital before they return to / receive care from dialysis facility.

* Measure differs from what has previously been proposed to the TEP (e.g. the one-year eligibility requirement for inclusion or the 6 vs. 12 readmissions limit/year) - TEP members believe that their comments/suggestions were not addressed.

Industry Concerns with SRR Measure

* CMS demo - stability of this measure year to year is unclear, esp. with with small number facilities... not clear if such facilities at higher risk.
* Demo - among hospitalizations >7% of admissions counted by CMS were not recorded as true admissions (e.g. <24 hours observation, day surgery, etc.)
* Lack of transparency and data from CMS … ability to verify and act on readmissions/prevention of readmissions is very limited.
* Public validation of definitions - to include the ICD-9 (ICD-10) definition for "non-acute readmissions' and "planned procedures" - is necessary so that specialists from the different medical disciplines can weigh in before the measure is approved for use as a CPM.

Monitoring Access to Dialysis

* Public comments on the proposal to adopt the Standardized Hospitalization Ratio measure in the 2014 ESRD QIP expressed concerns that "the measure may lead to 'cherry-picking' of patients based on their risk of hospitalizations, causing access to care issues for patients with more severe illness."

* Based on concerns raised about the impact of adoption of the SRR measure on access to care, CMS proposes to monitor changes in admission and discharge practices as well as changes in rates and patterns of involuntary discharges to determine whether selective admission and discharge practices are coupled with negative patient characteristics and trends.

Monitoring Access to Dialysis

* Monitoring would compare dialysis data before and after the adoption of an outcome measure, looking for changes in admission and discharge practices, as well as changes in rates and patterns of involuntary discharges.
* Would assess and analyze the characteristics of beneficiaries admitted to dialysis centers (stratified by location, size, and setting) in order to determine when and if selective admission and discharge practices are coupled with negative patient attributes and trends over time.
* Patterns may be identified that are indicative of diminished access to dialysis therapy.

2017 Measures Set Summary

Clinical measures would comprise 75 percent of the TPS:

* Vascular access type – AVF
* Vascular access type – Catheter > 90 days
* Kt/V – Adult hemodialysis
* Kt/V – Adult peritoneal dialysis
* Kt/V – Pediatric hemodialysis
* Hyercalcemia
* NHSN bloodstream infection in hemodialysis outpatients
* Standardized readmission ratio

Proposed reporting measures would comprise 25 percent of the TPS:

* ICH CAHPS patient experience of care survey
* Mineral metabolism (An ad hoc review conducted by NQF in 2013-2014 concurred with KCP's position that the serum phosphorus measure include plasma as an acceptable substrate. CMS proposes that these changes should not be adopted until PY 2018.)
* Anemia management

Weighting the Total Performance Score

* CMS proposes to continue weighting clinical measures at 75 percent of the total score and reporting measures at 25 percent.

* CMS also proposes to continue its policy that facilities must be eligible to receive a TPS and that the TPS will be rounded to the nearest integer, with half of an integer being rounded up.

Minimum Data for Scoring Measures and for Attestation Process for Patient Minimums

* Continue scoring facilities only on measures for which they have at least 11 qualifying patients during the performance period.
* Proposes to apply a small facility adjuster to facilities that treat 41 or fewer index discharges.
* For the Mineral Metabolism and Anemia Management reporting measures, CMS proposes to eliminate the option for facilities to attest that they did not meet the case minimum of one qualifying patient for these measures. Instead, CMS would require facilities that meet the case minimum of one to be scored on these measures.
* Facilities with between 2 and 11 qualifying patients would be required to report data for all but one qualifying patient. Facilities with 11 or more qualifying patients would be required to report data for all patients.

Minimum Data for Scoring Measures and for Attestation Process for Patient Minimums

* Proposes to eliminate option for facilities to attest that they did not meet the case minimum for the ICH CAHPS survey reporting measure. In lieu of the previous attestations, CMS proposes instead that the Agency will determine facility eligibility for the measures based on the data submitted.
* Proposes to continue existing policies that govern when a newly opened facility becomes eligible to be scored on measures as well as policies that a facility will not receive a TPS unless it receives a score on at least one clinical and one reporting measure. Facilities will not be eligible for a payment reduction if open date on or after July 1, 2015.

Proposed Payment Reductions for 2017

* Facility not receive a payment reduction if it achieves a minimum TPS equal to or greater than the total points it would have received if it performed at the performance standard for each clinical measure; received no points for each clinical measure that does not have a numerical value for the established performance standard; and received 10 points (50^{th} percentile of PY 2015 reporting measures) of facility performance for each reporting measure. CMS is proposing to increase # of points a facility would have to receive on each reporting measuring from 5 to 10.
* CMS estimates that a facility must meet or exceed a minimum TPS of 58 for PY 2017. For purposes of this estimate, the NHSN Bloodstream Infection clinical measure, the performance standard is set at zero.

Proposed Payment Reductions for 2017

The estimated payment reduction scale for PY 2017 based on the most recently available data from CY 2013 is as follows:

Performance score of…	Payment Reduction of…
100 – 58	0 percent
57 – 48	0.5 percent
47 – 38	1.0 percent
37 – 28	1.5 percent
27 – 0	2.0 percent

Extraordinary Circumstances Exception

* CMS proposes that in the event of extraordinary circumstances beyond the facility's control (e.g., a natural disaster), the facility will receive consideration for an exception from all QIP requirements during which the facility was closed.

* The facility would be required to submit a CMS Disaster Extension/Exception Request Form through www.qualitynet.org within 90 calendar days of the date of the disaster or extraordinary circumstance.

* This policy would not preclude the Agency from granting exceptions to facilities that have not made requests when CMS determines that an extraordinary circumstance (e.g., a hurricane) has affected an entire region.

Proposals for the 2018 QIP

Modify the Mineral Metabolism Reporting Measure

CMS proposes to modify the measure specifications for Mineral Metabolism reporting measure to allow facilities to report either serum phosphorous data or plasma phosphorous data beginning in PY 2018.

Proposed New Measures for 2018 and Beyond

* Continue to use all measures used in PY 2017, except for the ICH CAHPS reporting measure, which CMS is proposing to convert to a clinical measure

* CMS proposes adopting **five new measures**:
  - A standardized transfusion ratio clinical measure,
  - A pediatric peritoneal dialysis adequacy clinical measure,
  - A pain assessment reporting measure,
  - A clinical depression screening and follow up reporting measure, and
  - A healthcare personnel influenza vaccination reporting measure

Standardized Transfusion Ratio (STrR):

* Ratio of the number of observed eligible blood transfusions occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected from a predictive model that CMS states takes into consideration patient characteristics within the facility.

* Includes adult Medicare dialysis patients with ESRD for at least 90 days. Patients excluded for three days prior to the date they receive a transplant to avoid including transfusions related to transplant hospitalization.

* Excludes transfusion events from the measure if, during the previous 12 months, the patient had a Medicare claim for hemolytic and aplastic anemia, solid organ cancer, lymphoma, carcinoma in situ, coagulation disorders, multiple myeloma, myelodysplastic syndrome and myelofibrosis, leukemia, head and neck cancer, other cancers, metastic cancer, or sickle cell anemia.

* Adjusted for age, diabetes as a cause of ESRD, BMI at incidence of ESRD, comorbidity index, nursing home status, and duration of ESRD. No consensus organization has adopted a measure on transfusions

Pediatric Peritoneal Dialysis Adequacy Clinical Measure

* New measure of pediatric peritoneal dialysis adequacy to the Dialysis Adequacy measure topic.
* Would assess the percent of eligible pediatric peritoneal dialysis patient-months in which a Kt/V of > / = 1.8
* Qualifying patient-months are defined as months in which a peritoneal patient is under age 18 and has been receiving peritoneal dialysis for 90 days or longer.
* Performance expressed as a proportion of patient-months meeting the measure threshold of 1.8, and the measure will be scored based on Kt/V data entered on Medicare 72x claims.

ICH CAHPS Clinical Measure

* CMS proposes to replace reporting measures in PY 2018 and beyond with the NQF-endorsed (NQF #0258) measure: CAHPS In-Center Hemodialysis Survey.

* CMS is not proposing to change the semiannual survey administration and reporting requirements.

Screening for Clinical Depression and Follow-Up Reporting Measure

* CMS proposes a depression measure based on the NQF-endorsed measure (NQF #0418): Screening for Clinical Depression.

* Measure assesses the percentage of patients screened for clinical depression using an age-appropriate standardized tool and documentation of a follow-up plan where appropriate.

* For PY 2018, CMS proposes that facilities report on patients at least once per performance period for each eligible patient who has been treated in the facility for at least 90 days.

* CMS is proposing to score facilities on whether they have reported data, not on the measure results.

Pain Assessment and Follow-Up Reporting Measure

* CMS proposes to adopt a pain measure based on NQF-endorsed measure (NQF #0420) Pain Assessment and Follow-Up.

* Measure assesses the percentage of patients with documentation of a pain assessment using a standardized tool and documentation of a follow-up plan when pain is present.

* For PY 2018 and in future years, CMS proposes that facilities report every six months for qualifying patients who are 18 years or older and who have been treated in the facility for 90 days or more.

* CMS is proposing to score facilities based on whether they have reported data, not on the measure results.

NHSN Healthcare Personnel Influenza Vaccination Reporting Measure

* CMS proposes to adopt a reporting measure for PY 2018 and beyond based on the NQF-endorsed measure (NQF #0431) Influenza Vaccination Coverage Among Healthcare Personnel

* Measures the percentage of employees, licensed independent practitioners, or adult students, trainees, volunteers who work in a facility for at least one day between October 1 and March 31 and who receive a flu vaccination, were determined to have a medical contraindication, declined a vaccination, or were of unknown vaccination status.

* Facilities would be scored on whether they have reported data by May 15th of each year, not on the percent of personnel vaccinated.

Clinical measures for PY 2018

* Vascular Access Type – AVF
* Vascular Access Type – Catheter > 90 days
* Kt/V – Adult Hemodialysis
* Kt/V – Adult Peritoneal Dialysis
* Kt/V – Pediatric Hemodialysis Dialysis
* Kt/V – Pediatric Peritoneal Dialysis
* Hypercalcemia
* NHSN Bloodstream Infection in Hemodialysis Outpatients
* Standardized Readmission Ratio
* Standardized Transfusion Ratio
* ICH CAHPS Patient Experience of Care Survey

Reporting Measures for PY 2018

* Mineral Metabolism
* Anemia Management
* Clinical Depression Screening and Follow-Up
* Pain Assessment and Follow-Up
* NHSN Healthcare Personnel Influenza Vaccination

Proposed Payment Reductions for 2018

* CMS proposes that a facility would not receive a payment reduction for PY 2018 if it achieves a minimum TPS that is equal to or greater than the total points it would have received if it performed at the performance standard for each clinical measure; received the number of points for each reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2016 reporting measures.

* CMS continues to propose that for every 10 points a facility falls below the minimum TPS, the facility would receive an additional 0.5 percent reduction in payments – with a maximum reduction of 2 percent.

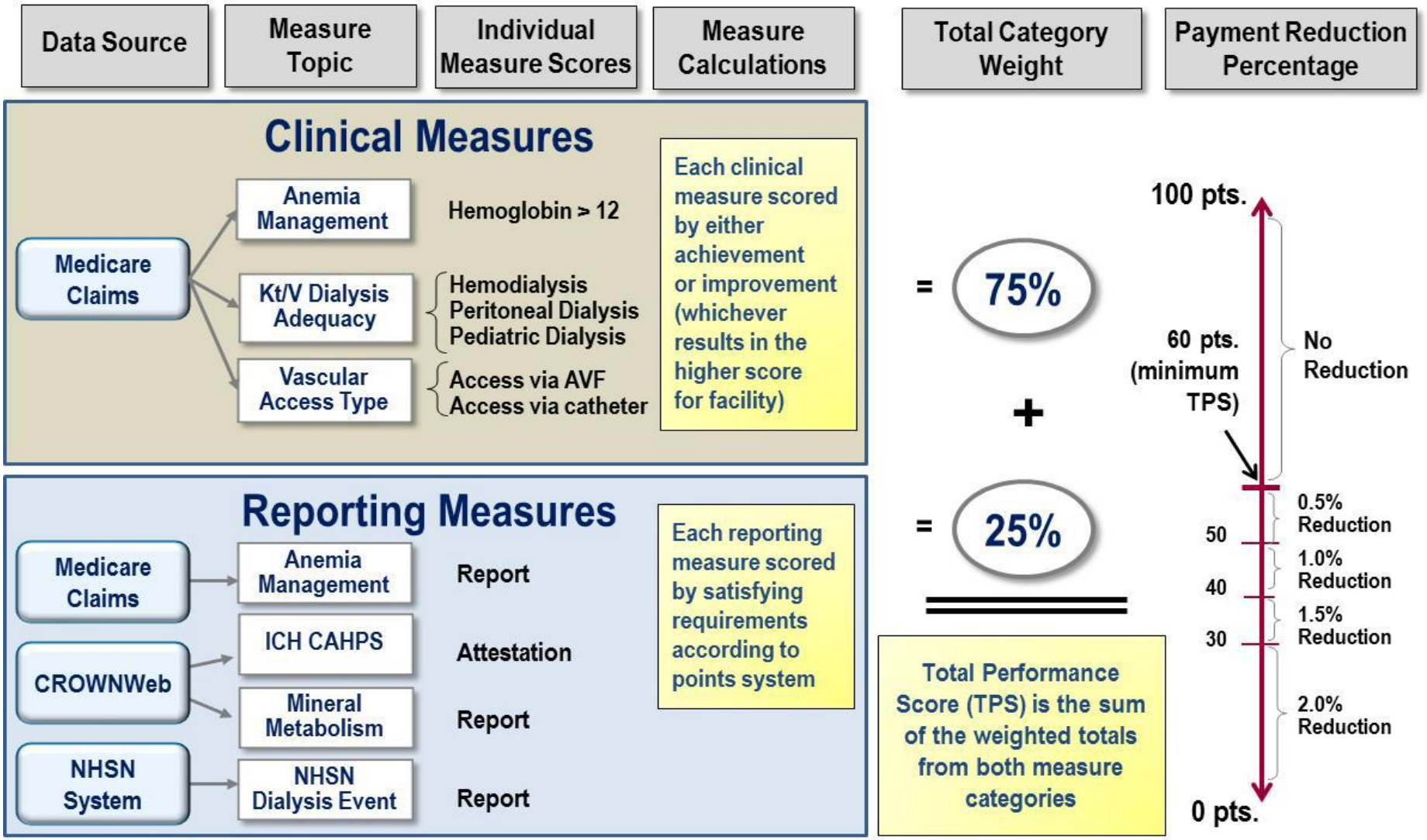
Future Considerations

* CMS is considering stratifying ESRD QIP measures for Medicare-Medicaid enrollees.

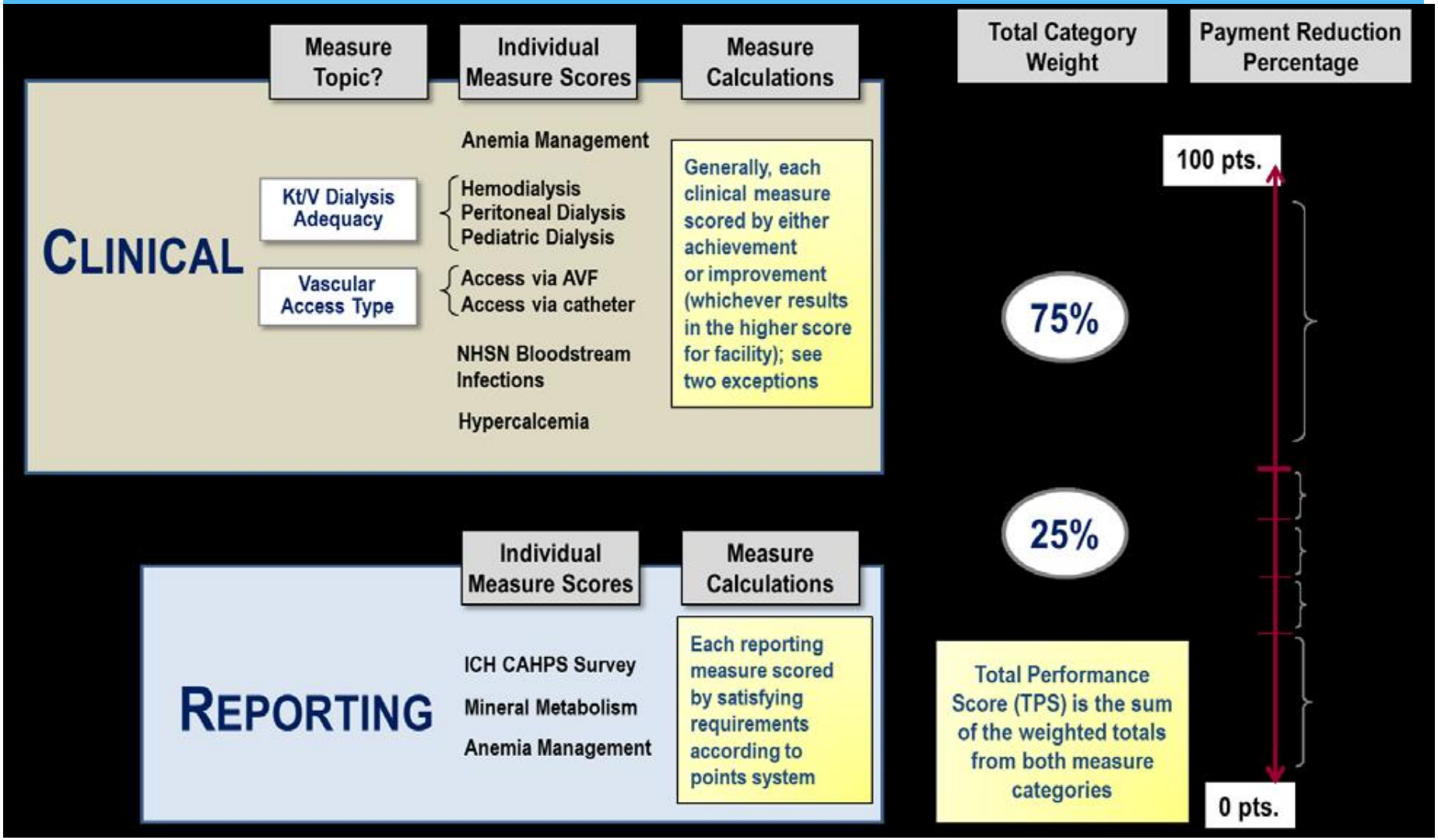
* Seeks comment on whether it would be feasible to stratify ESRD QIP measures based on whether the beneficiary is dual eligible.

* CMS is interested in whether stakeholders recommend stratifications and, if so, for what specific measures stratification would be feasible or burdensome.

ESRD QIP Payment Year 2015



ESRD QIP Payment Year 2016



Comments due September 2, 2014

1. Electronically…. http://www.regulations.gov

   Follow the "Submit a comment" instructions

2. Regular mail…

   Centers for Medicare & Medicaid Services
   Department of Health and Human Services,
   Attention: CMS-1614-P
   P.O. Box 8010,
   Baltimore, MD 21244-8010.

PPS

ESRD PPS 2015 Proposed Rule

How We Got Here

American Taxpayer Relief Act ESRD Provisions (ATRA) - Fiscal Cliff legislation 12/31/12

* **The ESRD PPS payment will be rebased effective January 2014** to reduce the payment rate to account for changes in utilization of drugs and biologicals that are included in the bundle

* **The inclusion of oral drugs in the PPS payment delayed from 2014 to 2016**

How We Got Here

2013 NPRM with ATRA Provisions

* $29.52 per treatment reduction in 2014
* 9.4% reduction from 2013
* Industry response:
  * Most aggressive ever
  * Public relations activity – LTEs, news media
  * Calls, letters, visits Members of Congress
  * Meetings with CMS, MedPAC, others
  * Significant patient advocacy

How We Got Here

2013 Final Rule with ATRA Provisions

* CMS implemented a 3- to 4-year transition of the drug utilization reduction - by offsetting the reduction by the payment update (market basket minus productivity increase factor) - **to create an overall zero percent impact for all ESRD facilities from the previous year's payment for CYs 2014 and 2015**

* For CY 2014, the ESRD PPS base rate $239.02

How We Got Here

Patient Access to Medicare Act (PAMA) – SGR Bill 3/14

Reimbursement:

* 2015 reimbursement frozen at 2014 level
* 2016 & 2017 - ATRA provision is eliminated, but Market Basket decrease of 1.25% in both years
* 2018 - Market Basket decrease of 1%
* Medicare sequester extended into 2024, but in last year, sequester will be 4% for first 6 months, and 0% in last 6 months

Non-reimbursement:

* oral only drugs will not be included in the PPS bundle until 2024
* ICD-10 postponed until October 2015
* CMS will determine when a drug is no longer an oral-only drug & include new injectable & IV products into the bundle for CY 2016
* requires audits of Medicare cost reports beginning with 2012 reports

Here We Are: 2014 NPRM

Reimbursement:

* Proposed 2015 base rate of $239.33 – net 31 cent increase over 2014 (0.3% increase overall)
  * CMS applied a wage index budget-neutrality adjustment factor of 1.001306 = $239.33

Here We Are: 2014 NPRM

* **Rebase and revise the ESRD bundled market basket**
  * Involves the input costs and the price proxies
  * Using the most recent available data (2012) compared to 2008 (basis for current market basket)
    * Major revisions to market basket
      * Changing the price measure for pharmaceuticals from a general index (**PPI pharmaceuticals for human use, Rx**) to a more specific index (**PPI vitamins, nutrients, and hematinic preparations, OTC**) that reflects drugs similar to those used in the treatment of ESRD (**NOTE:** Nothing in the bundle is OTC)
      * Updating the price measure used for compensation costs to better reflect the occupational mix in the ESRD setting
      * Cost weights change – labor weights higher, decline in drug cost share

Here We Are: 2014 NPRM

* **Outlier Policy**
  * Updated fixed-dollar loss amount for adult patients from $98.67 to $85.24 and increase the MAP amount from $51.97 to $52.61
  * CMS believes this update will increase payments for patients requiring higher resource utilization in accordance with a 1% outlier policy
  * NOTE: Industry has suggested CMS reduce or eliminate the outlier pool.

Here We Are: 2014 NPRM

* **Wage Index**
  * CMS continues gradual phase-out of the floor and reduces the wage index floor to 0.40
* **Updated the Core Based Statistical Areas (CBSA) with 2010 Census data (across all sectors, related to 2010 census)**
  * Implementing the new CBSA delineations with a transition
    * payments will be based on 50% of the CY 2014 CBSA delineations and 50% of the CY 2015 CBSA delineations in CY2015 and 100% of the proposed CY 2015 CBSA delineations in CY 2016
  * alters the labor related share calculation

Here We Are: 2014 NPRM

* **Updated labor related share**
  * from 41.737 to 50.673%
  * will have a negative impact on payments for rural facilities and Puerto Rico
  * CMS proposing a 2-year transition:
    * 50-50 in 2015 and 100% in 2016
    * Labor-related share will remain 50.673% until labor-related share value is updated

Here We Are: 2014 NPRM

* **Low Volume Payment Adjustment**
  * GAO found that the policy had not been implemented properly
  * CMS clarifying eligibility criteria

Impact Analysis

* All facilities	0.3% increase
* Free standing facilities	0.3% increase
* Hospital-based providers	0.5% increase
* Urban facilities	0.4% increase
* Rural facilities	0.5% decrease
* PR/VI	0.6% decrease

Additional Treatments

* CMS reiterated its policy that payment is limited to 3 dialysis treatments per week through the payment of 13 treatments for a 30-day month or 14 treatments for a 31-day month.
* The only time facilities should seek payment for additional dialysis sessions, including payment for shorter, more frequent modalities, is when the patient has a medical need for additional dialysis and the facility has furnished supporting medical justification for the extra treatments. **Modality choice does not constitute medical justification**.
* Contractors determine whether the additional treatments are medically necessary.

Where Are We Headed

* Rough water ahead
* Industry must remain diligent and engaged