DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 414 and 494

[CMS–1651–CN]

Medicare Program; End-Stage Renal Disease Quality Incentive Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure, and Appeals Process for Breach of Contract Actions; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correction.

SUMMARY: This document corrects technical and typographical errors that appeared in the final rule published in the **Federal Register** on November 4, 2016, entitled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model.''

DATES: This correction is effective on January 1, 2017.

FOR FURTHER INFORMATION CONTACT: Julia Howard, (410) 786–8645, for issues related to DMEPOS CBP and bid surety bonds, state licensure, and the appeals process for breach of DMEPOS CBP contract actions. Stephanie Frilling, (410) 786–4507, for issues related to the ESRD QIP.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2016–26152 of November 4, 2016 (81 FR 77834) (hereinafter referred to as the CY 2017 ESRD PPS final rule) there are technical and typographical errors that are discussed in the ''Summary of Errors,'' and further identified and corrected in the ''Correction of Errors'' section below. The provisions in this correction notice are effective as if they had been included in the CY 2017 ESRD PPS final rule published in the **Federal Register** on November 4, 2016.

II. Summary of Errors

On page 77874, we inadvertently made technical errors with respect to the calculation of the performance standard values in Table 2, ''Improvement of Performance Standards Over Time.''

On page 77886, we inadvertently made technical errors with respect to the calculation based on the most recently available data of the Achievement Threshold and Performance Standard values that apply to the Kt/V Composite, Standardized Transfusion Ratio and Hypercalcemia measures, and the calculation based on the most recently available data of the Achievement Threshold, Benchmark and Performance Standard values that apply to the ICH CAHPS measure in Table 6, ''Finalized Numerical Values for the Performance Standards for the PY 2019 ESRD QIP Clinical Measures Using the Most Recently Available Data.'' We also inadvertently included values for the Achievement Threshold, Benchmark and Performance Standard for the Standardized Hospitalization Ratio Clinical Measure, which is not a measure that we have adopted for the PY 2019 program.

On page 77897, we inadvertently included values for the Standardized Hospitalization Ratio Clinical Measure, which is not a finalized PY 2019 ESRD QIP measure, in Table 12, ''PY 2020 Clinical Measure Including Facilities With at Least 11 Eligible Patients Per Measure.''

On page 77932 we made a technical error in our response to the first comment under ''1. Bid Surety Bond Requirement''. In our response, we stated ''While we acknowledge that there will be a number of entities that are required to make large expenditures in order to obtain a bid surety bond for each CBA in which they are submitting a bid, we anticipate that this revision on the bid surety bond amount from $100,000 to $50,000 will reduce that overall burden on all suppliers.'' We inadvertently included the term ''suppliers'' at the end of the sentence but the term should read ''bidders.''

On page 77933 in our response to the comment on why the bid surety bond was only required until January 1, 2019, we inadvertently included a ''1'' in the reference to the round of competition in 2019 in which the bid surety bond requirement commences. The reference should read ''Round 2019'' and not ''Round 1 2019.''

At the top of page 77934 in our discussion on ''Appeals Process for a DMEPOS Competitive Bidding Breach of Contract Action'' we repeated a typographical error from the proposed rule (81 FR 42849) by stating that we proposed removing ''§ 414.423(g)(2)(i)'' from the regulation. The correct citation in this discussion should read ''§ 414.422(g)(2)(i)'', consistent with the proposal to remove corrective action plan from the list of actions for a breach of contract in the regulation, as described in the preamble and regulation text of the proposed and final rules (81 FR 42849, 42878, and 81 FR 77934, 77967).

III. Waiver of Proposed Rulemaking, 60-Day Comment Period, and Delay of Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 553(d) of the APA, and section 1871(e)(1)(B)(i) of the Act mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the notice and comment and delay in effective date. APA requirements; in cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act provide exceptions from the notice and 60-day comment period and delay in effective date requirements as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process are impracticable, unnecessary, or contrary to the public interest. In addition, both section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) of the Act allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and an agency includes a statement of support.

In our view, this correcting document does not constitute rulemaking that would be subject to these requirements. This correcting document is simply correcting technical errors in the preamble and does not make substantive changes to the policies or payment methodologies that were adopted in the final rule, and therefore, it is unnecessary to follow the notice and comment procedure in this instance.

Even if this were a rulemaking to which the notice and comment and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the CY 2017 ESRD PPS final rule or delaying the effective date would be contrary to the public interest because it is in the public's interest for dialysis facilities to receive appropriate payments in as timely a manner as possible, and to ensure that the CY 2017 ESRD PPS final rule accurately reflects our policies as of the date they take effect and are applicable. Further, such procedures would be unnecessary, because we are not altering the payment methodologies or policies. For these reasons, we believe we have good cause to waive the notice and comment and effective date requirements.

IV. Correction of Errors

In FR Doc. 2016–26152 of November 4, 2016 (81 FR 77834), we make the following corrections:

1. On page 77874, Table 2 is corrected to read as follows:

TABLE 2—IMPROVEMENT OF PERFORMANCE STANDARDS OVER TIME

Measure	PY 2015	PY 2016	PY 2017	PY 2018	PY 2019
Hemoglobin >12 g/dL	1%	0%	.....	.....	.....
Vascular Access Type:					
% Fistula	60%	62.3%	64.46%	65.94%	65.93%
% Catheter	13%	10.6%	9.92%	8.80%	9.19%
Kt/V:					
Adult Hemodialysis	93%	93.4%	96.89%	97.24%	.....
Adult Peritoneal Dialysis	84%	85.7%	87.10%	89.47%	.....
Pediatric Hemodialysis	93%	93%	94.44%	93.94%	.....
Pediatric Peritoneal Dialysis	.....	.....	.....	72.60%	.....
Hypercalcemia	.....	1.70%	1.30%	1.19%	1.85%
NHSN Bloodstream Infection SIR	.....	.....	.....	0.861	0.797
Standardized Readmission Ratio	.....	.....	0.998	0.998	0.998
Standardized Transfusion Ratio	.....	.....	.....	0.923	0.894

2. On page 77886, Table 6 is corrected to read as follows:

TABLE 6—FINALIZED NUMERICAL VALUES FOR THE PERFORMANCE STANDARDS FOR THE PY 2019 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

Measure	Achievement threshold	Benchmark	Performance standard
Vascular Access Type:			
%Fistula	53.66%	79.62%	65.93%
%Catheter	17.20%	2.95%	9.19%
Kt/V Composite	86.99%	97.74%	93.08%
Hypercalcemia	4.24%	0.32%	1.85%
Standardized Transfusion Ratio	1.488	0.421	0.901
Standardized Readmission Ratio	1.289	0.624	0.998
NHSN Bloodstream Infection	1.738	0	0.797
ICH CAHPS: Nephrologists' Communication and Caring	56.41%	77.06%	65.89%
ICH CAHPS: Quality of Dialysis Center Care and Operations	52.88%	71.21%	60.75%
ICH CAHPS: Providing Information to Patients	72.09%	85.55%	78.59%
ICH CAHPS: Overall Rating of Nephrologists	49.33%	76.57%	62.22%
ICH CAHPS: Overall Rating of Dialysis Center Staff	48.84%	77.42%	62.26%
ICH CAHPS: Overall Rating of the Dialysis Facility	51.18%	80.58%	65.13%

Data Sources: VAT measures: 2015 Medicare claims; SRR, STrR: 2015 Medicare claims; Kt/V: 2015 Medicare claims and 2015 CROWNWEB; Hypercalcemia: 2015 CROWNWeb; NHSN: CDC; CAHPS: 2015 ICH CAHPS surveys.

3. On page 77897, Table 12 is corrected to read as follows:

TABLE 12—PY 2020 CLINICAL MEASURES INCLUDING FACILITIES WITH AT LEAST 11 ELIGIBLE PATIENTS PER MEASURE

Measure	N	75th/25th Percentile	90th/10th Percentile	Std error	Statistically Indistinguishable	Truncated mean	Truncated SD	TCV	TCV's 0.10
Kt/V Delivered Dose above minimum ..	6210	96.0	98.0	0.093	No	92.5	4.20	0.05	Yes.
Fistula Use	5906	73.2	79.6	0.148	No	65.7	8.88	0.14	No.
Catheter Use	5921	5.43	2.89	0.093	No	[1] 90.1	5.16	<0.01	Yes.
Serum Calcium >10.2	6257	0.91	0.32	0.049	No	[1] 97.8	1.48	<0.01	Yes.
NHSN—SIR	5781	0.41	0.00	0.011	No	0.963	0.57	<0.01	Yes.
SRR	5739	0.82	0.64	0.004	No	0.995	0.21	<0.01	Yes.
STrR	5650	0.64	0.43	0.008	No	0.965	0.37	<0.01	Yes.
ICH CAHPS:									
Nephrologists communication and caring.	3349	71.8	77.1	0.159	No	65.7	7.11	0.11	No.
Quality of dialysis center care and operations.	3349	66.2	71.2	0.134	No	60.9	6.20	0.10	No.
Providing information to patients	3349	82.4	85.6	0.101	No	78.4	4.61	0.06	Yes.
Rating of Nephrologist	3349	69.9	76.6	0.204	No	62.0	9.29	0.15	No.
Rating of dialysis facility staff	3349	70.9	77.4	0.215	No	62.0	9.92	0.16	No.
Rating of dialysis center	3349	73.8	80.6	0.221	No	64.8	10.18	0.16	No.

[1] Truncated mean for percentage is reversed (100 percent – truncated mean) for measures where lower score = better performance.

4. On page 77932, third column, line 17, the word ''suppliers'' is corrected to read as ''bidders''.

5. On page 77933, first column, line 30, remove the number ''1'' before ''2019''.

6. On page 77934, first column, line 3, the citation ''§ 414.423(g)(2)(i)'' is corrected to read ''§ 414.422(g)(2)(i)''.

Dated: December 19, 2016.

Madhura Valverde,

Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2016–31019 Filed 12–22–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 219

[Docket No. FRA–2001–11213, Notice No. 21]

Drug and Alcohol Testing: Determination of Minimum Random Testing Rates for 2017

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of determination.

SUMMARY: This notice of determination provides the FRA Administrator's minimum annual random drug and alcohol testing rates for calendar year 2017.

DATES: Effective December 23, 2016.

FOR FURTHER INFORMATION CONTACT: Jerry Powers, FRA Drug and Alcohol Program Manager, W33–310, Federal Railroad Administration, 1200 New Jersey Avenue SE., Washington, DC 20590 (telephone 202–493–6313); or Sam Noe, FRA Drug and Alcohol Program Specialist (telephone 615–719–2951).

SUPPLEMENTARY INFORMATION: For the next calendar year, FRA determines the minimum annual random drug testing rate and the minimum annual random alcohol testing rate for railroad employees covered by hours of service laws and regulations (covered service employees) based on the railroad industry data available for the two previous calendar years (for this Notice, calendar years 2014 and 2015). Railroad industry data submitted to FRA's Management Information System (MIS) shows the rail industry's random drug testing positive rate for covered service employees has continued to be below 1.0 percent for the applicable two calendar years. FRA's Administrator has therefore determined the minimum annual random drug testing rate for the period January 1, 2017, through December 31, 2017, will remain at 25 percent of covered service employees under § 219.602 of FRA's drug and alcohol rule (49 CFR part 219). In addition, because the industry-wide random alcohol testing violation rate for covered service employees has continued to be below 0.5 percent for the applicable two calendar years, the Administrator has determined the minimum random alcohol testing rate will remain at 10 percent of covered service employees for the period January 1, 2017, through December 31, 2017, under § 219.608. Because these rates represent minimums, railroads may conduct FRA random testing at higher rates.

In a June 10, 2016, final rule, FRA expanded the scope of part 219 to cover maintenance-of-way (MOW) employees (81 FR 37894). MOW employees will become subject to FRA random drug and alcohol testing on June 12, 2017, when the final rule takes effect. In 1994, when FRA, in concert with the other DOT modes, established a drug MIS system (58 FR 68232, December 23, 1993), FRA set its initial minimum random drug testing rate at 50 percent for covered employees because of the lack of data to gauge the extent of the drug abuse problem at that time. FRA set its minimum random alcohol testing rate for covered employees at 25 percent for the same reason. As its MIS data continued to show consistently low industry-wide drug and alcohol positive rates among covered employees, FRA lowered its minimum annual random drug and alcohol testing rates to their current respective rates of 25 and 10 percent.

Similarly, because FRA has no MIS data for MOW employees yet, the Administrator has determined that for the period June 12, 2017, through December 31, 2017, the minimum annual random drug testing rate will be set at 50 percent of MOW employees, and the minimum annual random alcohol testing rate will be set at 25 percent of MOW employees. As with covered employees, because these rates represent minimums, railroads may conduct FRA random testing of MOW employees at higher rates.

Issued in Washington, DC, on December 20, 2016.

Sarah E. Feinberg,

Administrator.

[FR Doc. 2016–31009 Filed 12–22–16; 8:45 am]

BILLING CODE 4910–06–P