CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 240	Date: January 19, 2018
	Change Request 10366

SUBJECT: Internet Only Manual (IOM) Update to Pub. 100-02, Chapter 11 - End Stage Renal Disease (ESRD), Section 100

I. SUMMARY OF CHANGES: Update to Section 100 of Chapter 11 of the Benefit Policy Manual.

EFFECTIVE DATE: January 1, 2017

*Unless otherwise specified, the effective date is the date of service.

IMPLEMENTATION DATE: February 20, 2018

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE				
R	11/100/Payment for Renal Dialysis Services Furnished to Individuals With Acute				
	Kidney Injury (AKI)				

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements Manual Instruction

Attachment - Business Requirements

Pub. 100-02 Transmittal: 240 Date: January 19, 2018 Change Request: 10366

SUBJECT: Internet Only Manual (IOM) Update to Pub. 100-02, Chapter 11 - End Stage Renal Disease (ESRD), Section 100

EFFECTIVE DATE: January 1, 2017

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IMPLEMENTATION DATE: February 20, 2018

I. GENERAL INFORMATION

- **A. Background:** On June 29, 2015, the Trade Preferences Extension Act of 2015 was enacted in which section 808 amended Section 1861(s)(2)(F) of the Social Security Act (42 U.S.C. 1395x(s)(2)(F)) by extending renal dialysis services paid under section 1881(b)(14) to beneficiaries with acute kidney injury, effective January 1, 2017.
- **B. Policy:** This CR contains no policy changes. Contractors shall note the updates to the manual section.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
·		A/B		D	Shared-				Other	
		N	MA(\mathbb{C}	M	System				
					Е	M	Maintainers			
		A	В	Н		F	M	V	C	
				Н	M	I	C	M	W	
				Н	A	S	S	S	F	
					C	S				
10366.1	Contractors shall be in compliance with the updates to	X								
	CMS Internet Only Manual (IOM) Publication 100-									
	02, Chapter 11-End Stage Renal Disease (ESRD),									
	section 100.									
10366.2	Contractors shall continue to follow instructions	X								
	provided in change requests 9598, 9987 and others									
	until manual instructions are implemented.									

III. PROVIDER EDUCATION TABLE

Number	Responsi Responsi		nsib	ibility		
			A/B		D	С
		1	MA(7)	M	Е
					Е	D
		A	В	Н		I
				Н	M	
				Н	A	
					C	
10366.3	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will	X				

receive notification of the article release via the established "MLN Matters"

Number	per Requirement		Responsibility				
			A/B		D	C	
		1	MA(2	M	E	
		_	Ъ	TT	E	ען	
		A	В	H H	M	1	
				H	A		
					C		
	listserv. Contractors shall post this article, or a direct link to this article, on their						
	Web sites and include information about it in a listsery message within 5						
	business days after receipt of the notification from CMS announcing the						
	availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are						
	free to supplement MLN Matters articles with localized information that would						
	benefit their provider community in billing and administering the Medicare						
	program correctly.						

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A *"Should" denotes a recommendation.*

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Janae James, janae.james@cms.hhs.gov.

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

Medicare Benefit Policy Manual Chapter 11 - End Stage Renal Disease (ESRD)

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(Rev.240, Issued: 01-19-18)

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100 - Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

(Rev. 240, Issued: 01-19-18, Effective: 01-01-17, Implementation: 02-20-18)

On June 29, 2015, the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114-27) was enacted. In the TPEA, Congress amended the Act to include coverage and provide for payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Social Security Act (the Act by including coverage for renal dialysis services furnished on or after January 1, 2017 by a renal dialysis facility or provider of services currently paid under section 1881(b)(14) of the Act to an individual with AKI. In addition, section 808(b) of TPEA amended section 1834 of the Act by adding a new subsection (r). Subsection (r)(1) of section 1834 of the Act provides that in the case of renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or a provider of services paid under such section during a year (beginning with 2017) to an individual with AKI, the amount of payment under Part B for such services shall be the base rate for renal dialysis services determined for such year under such section, as adjusted by any applicable geographic adjustment applied under subparagraph (D)(iv)(II) of such section and may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act.

100.1 Definition of AKI

(Rev. 240, Issued: 01-19-18, Effective: 01-01-17, Implementation: 02-20-18)

Section 1834(r)(2) of the Act defines "individual with acute kidney injury" to mean an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14) of the Act.

100.2 Payment Rate for AKI Dialysis

(Rev. 240, Issued: 01-19-18, Effective: 01-01-17, Implementation: 02-20-18)

The payment rate for AKI Dialysis is the ESRD PPS per treatment base rate updated annually by the market basket, less the productivity adjustment and adjusted by any other adjustment factor applied to the ESRD PPS base rate.

100.3 Geographic Adjustment Factor

(Rev. 240, Issued: 01-19-18, Effective: 01-01-17, Implementation: 02-20-18)

The payment rate for AKI dialysis is adjusted by the geographic adjustment factor that is applied to the ESRD PPS base rate for a particular facility, which is the same wage index applied under the ESRD PPS.

100.4 Other Adjustments to the AKI Payment Rate

(Rev. 240, Issued: 01-19-18, Effective: 01-01-17, Implementation: 02-20-18)

There are currently no other adjustments applied to the AKI Payment Rate

A. ESRD Network Fee

The ESRD Network Fee reduction is not applicable to claims for beneficiaries with AKI.

B. ESRD Quality Incentive Program (QIP)

The ESRD QIP is not applicable for beneficiaries with AKI at this time.

C. Sequestration Adjustments

The 2 percent sequestration adjustment is applicable to claims for beneficiaries with AKI.

100.5 Renal Dialysis Services Included in the AKI Payment Rate (Rev.240, Issued: 01-19-18, Effective: 01-01-17, Implementation: 02-20-18)

Drugs, biologicals, laboratory services, and supplies that are considered to be renal dialysis services under the ESRD PPS as defined in 42 CFR 413.171, are considered to be renal dialysis services for patients with AKI. As such, no separate payment would be made for renal dialysis drugs, biologicals, laboratory services, and supplies that are included in the ESRD PPS base rate when they are furnished by an ESRD facility to an individual with AKI.

Other items and services furnished to beneficiaries with AKI that are not considered to be renal dialysis services as defined in 42 CFR 413.171, but that are related to their dialysis treatment as a result of their AKI and that an ESRD facility might furnish to a beneficiary with AKI, would be separately payable. In particular, an ESRD facility could seek separate payment for drugs, biologicals, laboratory services, and supplies that ESRD facilities are certified to furnish and that would otherwise be furnished to a beneficiary with AKI in a hospital outpatient setting. Items and services included on the consolidated billing list are not separately payable for patients with AKI.

All dialysis treatments, that is, hemodialysis and peritoneal dialysis, furnished to individuals with AKI in an ESRD facility will be paid the AKI payment rate. This includes any treatments that exceed the three times-weekly limitation applied to treatments furnished to ESRD beneficiaries. CMS expects that individuals with AKI will need renal dialysis services for a finite number of days since the intent of the dialysis for these patients is curative.

100.6 Applicability of Specific ESRD PPS Policies to AKI Dialysis (Rev. 240, Issued: 01-19-18, Effective: 01-01-17, Implementation: 02-20-18)

A. Dialysis Modality

Beneficiaries with AKI can receive their dialysis via the most clinically appropriate in-facility modality.

B. Uncompleted Dialysis Treatment

Generally, CMS only pays for one treatment per day across all settings. However, similar to the policy applied under the ESRD PPS for treatments for patients with ESRD, in the interest of fairness and in accordance with Chapter 8, section 10.2 of the Medicare Claims Processing Manual, if a dialysis treatment is started, that is, a patient is connected to the machine and a dialyzer and blood lines are used, but the treatment is not completed for some unforeseen, but valid reason, for example, a medical emergency when the patient must be rushed to an emergency room, both the ESRD facility and the hospital would be paid. This is considered to be a rare occurrence that must be fully documented to the A/B MAC's satisfaction.

C. Home and Self-Dialysis

Due to the nature of AKI, dialysis treatments at home or self-dialysis in the dialysis facility are not permitted. Specifically, these patients require supervision by qualified staff during their dialysis and close monitoring through laboratory tests to ensure that they are receiving the necessary care to improve their condition and get off of dialysis. Therefore, the home dialysis benefit does not extend to beneficiaries with AKI.

D. Vaccines and Their Administration

Section 1881(b)(14)(B) of the Act specifically excludes vaccines covered under section 1861(s)(10) of the Act from the ESRD PPS. However, ESRD facilities are identified as an entity that can bill Medicare for vaccines and their administration. Therefore, ESRD facilities may furnish vaccines to beneficiaries with AKI and bill Medicare in accordance with billing requirements in the Medicare Claims Processing Manual (Pub. 100-04, Chapter 18 Preventive and Screening Services, section 10.2). The staff time associated with vaccine administration is covered in the AKI dialysis payment rate.

E. Telehealth

Since telehealth dialysis services are limited to renal dialysis services for home dialysis patients telehealth related to renal dialysis services is not available for beneficiaries with AKI.

F. ESRD Conditions for Coverage (CfCs)

The ESRD CfCs at 42 CFR part 494 are health and safety standards that all Medicare participating dialysis facilities must meet. These standards set baseline requirements for patient safety, infection control, care planning, staff qualifications, record keeping, and other matters to ensure that all patients, including ESRD and AKI patients, receive safe and appropriate care.

G. Payment for Erythropoietin Stimulating Agents (ESAs) and the ESA Monitoring Policy for AKI Patients

ESAs are included in the bundled payment amount for treatments administered to patients with AKI. The Non-ESRD HCPCS codes should be used (J0881, J0885, J0887). The revenue codes for reporting Epoetin Alfa are 0634 and 0635. All other ESAs are reported using revenue code 0636.

The ESA monitoring policy has not yet been extended to AKI patients receiving treatment in an ESRD facility. Since this policy is not applicable to these treatments, the value codes used to report hemoglobin and hematocrit levels are not required when billing for ESAs.

100.7 Billing for Physicians' Services for Individuals with AKI (Rev.240, Issued: 01-19-18, Effective: 01-01-17, Implementation: 02-20-18)

Physicians are able to bill separately for services provided to individuals with AKI. CMS expects providers to follow correct coding guidelines and use the appropriate HCPCS or CPT codes for the items and services provided to the patient.

The following CPT codes are available for ESRD facilities and physician's offices to use when billing for physicians' services provided in either an ESRD facility (place of service 65) or a physician's office (place of service 11):

- 90935 Hemodialysis procedure with single evaluation by a physician or other qualified health care professional;
- 90937 Hemodialysis procedure requiring repeated evaluation(s) with or without substantial revision of dialysis prescription;
- 90945 Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous replacement therapies), with single evaluation by a physician or other qualified health care professional;
- 90947 Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies) requiring repeated evaluations by a physician or

other qualified health care professional, with or without substantial revision of dialysis prescription.

Please note: this is not an exhaustive list – as indicated above, CMS expects facilities and physician's offices to bill the appropriate codes.