

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-20 One-Time Notification</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 1941</b>	<b>Date: October 27, 2017</b>
	<b>Change Request 10281</b>

**SUBJECT: Transitional Drug Add-on Payment Adjustment (TDAPA) for patients with Acute Kidney Injury (AKI)**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to update the Acute Kidney Injury (AKI) payment policy.

**EFFECTIVE DATE: April 1, 2018**

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

**IMPLEMENTATION DATE: April 2, 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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
N/A	N/A

**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:**

**One Time Notification**

# Attachment - One-Time Notification

Pub. 100-20	Transmittal: 1941	Date: October 27, 2017	Change Request: 10281
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## **I. GENERAL INFORMATION**

**A. Background:** On June 29, 2015, the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114-27) was enacted. Section 808(a) of TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017 by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with Acute Kidney Injury (AKI). Section 808(b) of TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) base rate beginning January 1, 2017.

Thus, beginning January 1, 2017, ESRD facilities are able to furnish dialysis to AKI patients. The AKI provision is provided at the following link: <https://www.congress.gov/bill/114th-congress/house-bill/1295/text#tocHEE69B51CC87340E2B2AB6A4FA73D2A82>.

The provision provides Medicare payment to ESRD facilities, that is, hospital-based and freestanding, for renal dialysis services furnished to beneficiaries with AKI (both adult and pediatric). Medicare will pay ESRD facilities for the dialysis treatment using the ESRD PPS base rate adjusted by the applicable geographic adjustment factor, that is, the ESRD PPS wage index. In addition to the dialysis treatment, the ESRD PPS base rate pays ESRD facilities for other items and services considered to be renal dialysis services as defined in 42 CFR §413.171 and there will be no separate payment for those services.

Renal dialysis services, 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 that are furnished to beneficiaries with AKI that are not considered to be renal dialysis services but are related to their dialysis as a result of their AKI, would be separately payable, that is, 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.

In Change Request (CR) 9598, CMS implemented the initial payment policy decisions related to AKI. These policies include the identification of services considered to be AKI using revenue codes, Healthcare Common Procedure Coding System (HCPCS) and CPT codes, and ICD-10 codes, treatment settings, treatment limits, and rules for separately billable items and services. CR 9814 excluded AKI claims from receiving the ESRD network fee reduction, and CR 9987 updated the claims submission policies for Erythropoietin Stimulating Agents (ESAs) for AKI patients.

Under ESRD PPS the drug designation process, CMS provides payment using a Transitional Drug Add-on Payment Adjustment (TDAPA) for new injectable or intravenous drugs and biologicals that qualify under 42 CFR 413.234(c)(1).



Number	Requirement	Responsibility							
		A/B MAC		D M E	Shared-System Maintainers				Other
		A	B		H H H	M A C	F I S S	M C S	
10281.2	Contractors shall create a reason code to RTP any AKI claims billed with HCPCS J0604 or J0606.					X			
10281.2.1	Contractors shall RTP the claim.	X							

**III. PROVIDER EDUCATION TABLE**

Number	Requirement	Responsibility					
		A/B MAC			D M E	C E D I	M A C
		A	B	H H H			
10281.3	MLN Article: A provider education article related to this instruction will be available at <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv 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.	X					

**IV. SUPPORTING INFORMATION**

**Section A: Recommendations and supporting information associated with listed requirements: N/A**

*"Should" denotes a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

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

**V. CONTACTS**

**Pre-Implementation Contact(s):** Michelle Cruse, michelle.cruse@cms.hhs.gov , 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):**

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**ATTACHMENTS: 0**