

<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 1722</b>	<b>Date: September 29, 2016</b>
	<b>Change Request 9479</b>

**Transmittal 1616, dated February 4, 2016, is being rescinded and replaced by Transmittal 1722, dated, Month Day, Year to update Business Requirement 5. All other information remains the same.**

**SUBJECT: Updating the Fiscal Intermediary Shared System (FISS) to Make Payment for Drugs and Biologicals Services for Outpatient Prospective Payment System (OPPS) Providers**

**I. SUMMARY OF CHANGES:** This CR implements system changes necessary to the Fiscal Intermediary Shared System (FISS) and Integrated Outpatient Code Editor (IOCE) necessary to make payment for drugs and biologicals to Outpatient Prospective Payment System (OPPS) providers.

**EFFECTIVE DATE: July 1, 2016**

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

**IMPLEMENTATION DATE: July 5, 2016**

*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/revise 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: 1722	Date: September 29, 2016	Change Request: 9479
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## **I. GENERAL INFORMATION**

**A. Background:** The Centers for Medicare & Medicaid Services (CMS) pays for all outpatient drugs using the Average Sales Price (ASP) methodology. The schedule for submission of all ASP pricing is statutory per Section 621(a) of the Medicare Modernization Act. Drug manufacturers are required to submit drug ASPs within 30 days of the close of their fiscal quarter. Given the complexity, volume of data, and the number of drugs affected, approximately 6 weeks are required to process, validate, and issue final ASPs for a given quarter. The ASP rates for drugs furnished on or after January 1, 2016, will not be available until mid-December 2015. The ASP rates for drugs furnished on or after April 1, 2016, will not be available until mid-March 2016. The ASP rates for drugs furnished on or after July 1, 2016, will not be available until mid-June 2016 and the ASP rates for drugs furnished on or after October 1, 2016, will not be available until mid-September 2016 respectively.

Previously, CMS supplied contractors with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis and this file was used for payment to most institutional providers by FISS. OPPS claims were an exception to this process. Payment for OPPS claims were based on tables provided to the OPPS Pricer to account for some of the special processing rules that are unique to OPPS providers (i.e., pass-through status necessary and drugs provided solely in the hospital setting).

Certain drug Healthcare Common Procedure Coding System (HCPCS) codes that will be updated quarterly, will not have the new drug prices included for the reasons explained above. Claims for dates of service falling under the quarterly ASP drug pricing file that include one or more drug HCPCS codes from the file, found at the address specified in the Business Requirements, are to be held by the A/B Medicare Administrative Contractor (MAC) until a revised ASP drug pricing file is installed in their production region. Refer to the ASP drug pricing schedule in the attachment A for the revised ASP drug pricing file installation deadlines.

**B. Policy:** Transmittal 875, Change Request (CR) 4371 issued on February 24, 2006, instructed Fiscal Intermediary Standard System (FISS) to “hook” and hold claims with bill types 12x, 13x, or 76x, with dates of service on or after the first day of each quarter, that include one or more drug HCPCS codes from the list that will be provided quarterly. The current “hook” program should be maintained and updated each quarter based as prior instructions found in CR 9319. This process should continue until further notice.

Starting on July 1, 2016, drug HCPCS on OPPS claims will no longer be priced by the Outpatient PPS Pricer. The fee schedule amount from the ASP drug file or any future drug fee schedule amount will be used by FISS to price covered outpatient drugs, and drugs and biologicals with pass-through status under the OPPS.

This will necessitate a downloading of a second ASP drug file approximately 2 week prior to each quarterly release that will continue to utilize the “hook” process until that second ASP drug file is loaded into the

FISS.

**II. BUSINESS REQUIREMENTS TABLE**

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

Number	Requirement	Responsibility									
		A/B MAC			D M E M A C	Shared- System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
9479.1	The July 2016 OPSS Hospital update ASP drug pricing files for Medicare Part B drugs will be available via the CMS Data Center (CDC).										CDC
9479.1.1	Contractors shall download the OPSS Hospital update July 2016 ASP drug pricing file through the CDC on or after June 13, 2016.  Final File: <u>MU00.@BF12390.ASP.CY16.JUL.V0613</u>	X				X					VDC
9479.2	The IOCE shall identify drugs that will be priced by the Shared System Maintainer with a SI of "G" and "K" utilizing the Payment Indicator flag "2".										IOCE
9479.3	The IOCE shall identify drug lines that require a payment offset for Pass-Through drugs utilizing the Payment Adjustment Flags (PAF) 18-20 on the line(s).										IOCE
9479.4	The IOCE shall identify offset amounts paired with drug lines in the above requirement utilizing the payer only value code set QR-QT.										IOCE
9479.5	The system maintainer shall price drugs with a SI of "G" and "K" utilizing the Payment Indicator flag "2", Payment Method Flag "2", and APC equal to '00000' based on the ASP fee amount.	X				X					
9479.6	The system maintainer shall wage adjust the offset amounts using the provider's wage index times the labor portion of the unadjusted offset amount added to the non-labor portion of the unadjusted offset amount for calendar year of OPSS.					X					
9479.7	The system maintainer shall apply the wage-adjusted offset amount from the payer only value codes QR-QT to its paired line item(s).  <b>PAF Payer only</b>					X					

Number	Requirement	Responsibility									
		A/B MAC			D M E M A C	Shared- System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
	<u>Lines(s)</u> <u>VC</u>										
	18 QR										
	19 QS										
	20 QT										
9479.8	If more than 1 service line pairs with a payer only value code, the Shared System Maintainer shall prorate the wage-adjusted offset based on the ratio of the covered charges for each line in comparison to the total covered charges of all the paired lines. (See “example of proration of multiple lines pairing to an offset amount” below in IV Section B)					X					
9479.9	If the offset amount for any Pass-Through drug line is greater than the payment amount, the system maintainer shall set the payment amount to zero. Do not allow a negative payment to apply to the line.					X					
9479.10	Medicare Shared System Maintainer shall ensure that coinsurance amounts are not applied to the drugs lines that have an offset amount as identified by PAF 18-20.					X					

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	C E D I	C E D I	C E D I		
		A	B	H H H						
	None									

### IV. SUPPORTING INFORMATION

#### Section A: Recommendations and supporting information associated with listed requirements:

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
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**Section B: All other recommendations and supporting information: Example of proration of multiple lines pairing to an offset amount:**

Line A has a covered charge of \$400.00.

Line B has a covered charge of \$100.00.

Total of covered charges paired to the same offset is \$500.00.

Both lines A and B have PAF 18 and pair with the payer only value code of “QR” \$100.00.

Apply 80% of the wage adjusted payer only value code “QR” to line A and 20% of the wage adjusted payer only value code “QR” to line B.

**V. CONTACTS**

**Pre-Implementation Contact(s):** Fred Rooke, fred.rooke@cms.hhs.gov , Yvonne Young, YVONNE.YOUNG@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: 1**

### 2016 Revised ASP File Schedule

<b>Update</b>	<b>Drug HCPCS codes available to FISS, FIs and A/B MACs</b>	<b>Revised ASP File Updated/Sent to FISS</b>	<b>FISS Release Revised ASP to Data Centers</b>	<b>Latest Test Installation Date</b>	<b>Latest Production Installation Date</b>	<b>FIs and A/B MACs Begin to Release Claims</b>
July 1, 2016	05/02/2016	06/13/2016	06/16/2016	06/20/2016	07/05/2016	07/06/2016
October 1, 2016	08/01/2016	09/12/2016	09/15/2016	09/19/2016	10/03/2016	10/04/2016