CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-20 One-Time Notification	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1649	**Date: April 28, 2016**
	Change Request 9601

SUBJECT: Phase 2 of 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 phase 2 of 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: January 1, 2016
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 3, 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/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
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: 1649	Date: April 28, 2016	Change Request: 9601

SUBJECT: Phase 2 of Updating the Fiscal Intermediary Shared System (FISS) to Make Payment for Drugs and Biologicals Services for Outpatient Prospective Payment System (OPPS) Providers

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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).

Now, all drugs that receive payment under OPPS will be included with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis. This will streamline all the Medicare Part B drugs into one (1) file that will follow the quarterly recurring process currently in place for the ASP drug pricing files for Medicare Part B drugs.

B. Policy: Transmittal 1616, Change Request (CR) 9479 issued on February 4, 2016, instructed Fiscal Intermediary Standard System (FISS) to implement phase 1 of the process of paying for drug HCPCS on OPPS claims utilizing FISS instead of the OPPS Pricer.

Starting on October 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. Phase 2 includes logic for FISS to cap the coinsurance amounts for procedures (which include blood and drug services) to the inpatient deductible amount for each calendar year and to insure that the rural floor is applied.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility

		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9601.1	Medicare Shared System Maintainer shall add each service day's drug copayment amount to the copayment of the same day's procedure (including blood service coinsurance line(s)) with the highest wage adjusted national coinsurance amount and compares that sum to the inpatient deductible limit for the calendar year. If the total copayment (drug(s), blood(s) and procedure identified) exceeds the inpatient deductible limit, each drug line's copayment amount is proportionately reduced to enforce the outpatient procedure copayment cap to the inpatient deductible limit.					X				
9601.2	Medicare Shared System Maintainer shall apply any reduced coinsurance amount back into the Medicare payment amount for the drug lines. **(See "Example 1 of inpatient deductible capped amount")**					X				
9601.3	If the total copayment (blood(s) and highest wage adjusted national coinsurance amount for a procedure line identified) exceeds the inpatient deductible limit (capped amount) prior to calculation of drug coinsurance, Medicare Shared System Maintainer shall make a 100% reduction of coinsurance amounts for drug lines and apply 100% of the reduction amount back into the Medicare payment amount for the drug lines. **(See "Example 2 of inpatient deductible capped amount")**					X				
9601.4	Medicare Shared System Maintainer shall make all logic in Change Request 9479 and this Change Request effective for claims with dates of service January 1, 2016 and forward.					X				IOCE
9601.5	Medicare Shared System Maintainer shall determine the appropriate CBSA wage index value for each claim. 1. Select the appropriate CBSA wage index (CBSA wage index 1, CBSA wage index 2, or the special wage index). If CBSA wage index 1 or CBSA wage index 2 is used, ensure the CBSA wage index effective date is on/after the claim's service from date and within the same					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	calendar year of the claim's service from date. If the special wage index is used, ensure the effective date of the outpatient specific file record is on/after the claim's service from date and within the same calendar year of the claim's service from date. If these criteria are not met, the wage index is invalid. 2. Get the wage index of the CBSA state code that matches the provider's state code preceded with three spaces. This is the provider's state rural floor wage index. (For example, if the provider's state code is 05, get the wage index of CBSA " 05".) If there is no CBSA state code that corresponds to the provider's state code, skip step 3, and use the wage index selected in step 1. 3. Compare the CBSA wage index obtained in step 1 with the state rural floor wage index obtained in step 2. Select the higher of the two to use as the provider's wage index. (Do not change the provider's original CBSA code assignment, even if the state rural floor wage index is higher.)									
9601.6	Medicare Shared System Maintainer shall ensure that the HCPC Pricing indicator is 'B' for the HCPCS on the ASP File.					X				
9601.7	Medicare Shared System Maintainer shall ensure that the zip code found in value code 78 is used when available for determining the carrier locality codes for payment of HCPCS on the ASP File.					X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9601.8	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 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): 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

Example 1 of inpatient deductible capped amount:

Drug Line A has a fee of $2,000.00, a payment of $1,600.00, and coinsurance of $400.00.
Drug Line B has a fee of $1,000.00, a payment of $800.00, and coinsurance of $200.00.
Drug Line C has a fee of $500.00, a payment of $400.00 and coinsurance of $100.00.
Drug Line D has a fee of $500.00, a payment of $400.00 and coinsurance of $100.00.

Highest wage adjusted national coinsurance amount for a procedure line is $888.00.

The Inpatient Part A deductible is $1,288.00 for 2016

$1,288.00 - $888.00 = $400.00 remaining coinsurance to be applied toward inpatient deductible cap.

Drug Lines A-D coinsurance is $800.00.

$400.00 cap remaining / $800.00 drug line(s) coinsurance = 50% reduction to coinsurance due to inpatient deductible cap

Apply 50% reduction of the coinsurance amounts for each line and add the remaining 50% back into the payment amount.

Drug Line A has a final payment of $1,800.00, and coinsurance of $200.00.
Drug Line B has a final payment of $900.00, and coinsurance of $100.00.
Drug Line C has a final payment of $450.00, and coinsurance of $50.00.
Drug Line D has a final payment of $450.00, and coinsurance of $50.00.

Example 2 of inpatient deductible capped amount:

Drug Line A has a fee of $2,000.00, a payment of $1,600.00, and coinsurance of $400.00.
Drug Line B has a fee of $1,000.00, a payment of $800.00, and coinsurance of $200.00.
Drug Line C has a fee of $500.00, a payment of $400.00 and coinsurance of $100.00.
Drug Line D has a fee of $500.00, a payment of $400.00 and coinsurance of $100.00.

Highest wage adjusted national coinsurance amount for a procedure line is $1,588.00.

The Inpatient Part A deductible is $1,288.00 for 2016

$1,588.00 is greater than $1,288.00. The OPPS Pricer will cap the coinsurance amount to be applied on the highest wage adjusted national coinsurance procedure line prior to application of the cap on the drug lines.

Drug Lines A-D coinsurance is $800.00.

$0 cap remaining / $800.00 = 100% reduction to coinsurance due to inpatient deductible cap

Drug Line A has a final payment of $2,000.00, and no coinsurance.
Drug Line B has a final payment of $1,000.00, and no coinsurance.
Drug Line C has a final payment of $500.00, and no coinsurance.
Drug Line D has a final payment of $500.00, and no coinsurance.