| CMS Manual System | Department of Health & Human Services (DHHS) |
|---------------------------------------|---|
| Pub 100-04 Medicare Claims Processing | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 4061 | Date: May 25, 2018 |
| | Change Request 10667 |

SUBJECT: July 2018 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

I. SUMMARY OF CHANGES: The ASP methodology is based on quarterly data submitted to CMS by manufacturers. CMS will supply contractors with the ASP and Not Otherwise Classified (NOC) drug pricing files for Medicare Part B drugs on a quarterly basis. Payment allowance limits under the Outpatient Prospective Payment System (OPPS) are incorporated into the Outpatient Code Editor (OCE) through separate instructions that can be located in chapter 4, section 50 of the Internet Only Manual (IOM).

EFFECTIVE DATE: July 1, 2018

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

IMPLEMENTATION DATE: July 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*.

| 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:

Recurring Update Notification

Attachment - Recurring Update Notification

SUBJECT: July 2018 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

EFFECTIVE DATE: July 1, 2018

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

IMPLEMENTATION DATE: July 2, 2018

I. GENERAL INFORMATION

A. Background: The ASP methodology is based on quarterly data submitted to CMS by manufacturers. The CMS will supply contractors with the ASP and the NOC drug pricing files for Medicare Part B drugs on a quarterly basis. Payment allowance limits under the OPPS are incorporated into the OCE through separate instructions that can be located in chapter 4, section 50 of the IOM.

B. Policy: This Recurring Update addresses the following pricing files:

File: July 2018 ASP and ASP NOC -- Effective Dates of Service: July 1, 2018, through September 30, 2018

File: April 2018 ASP and ASP NOC -- Effective Dates of Service: April 1, 2018, through June 30, 2018

File: January 2018 ASP and ASP NOC -- Effective Dates of Service: January 1, 2018, through March 31, 2018

File: October 2017 ASP and ASP NOC -- Effective Dates of Service: October 1, 2017, through December 31, 2017

File: July 2017 ASP and ASP NOC -- Effective Dates of Service: July 1, 2017, through September 30, 2017

II. BUSINESS REQUIREMENTS TABLE

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

| ment | Responsibility | | | | | | | | | | | | |
|---|--|---|--|--|--|---|--|---|--|-----|-----|--|--|
| | | A/B | 3 | D | | Sha | red- | | Other | | | | |
| | MAC | | MAC | | MAC | | MAC | | | Sys | tem | | |
| | | | | | Е | M | aint | aine | ers | | | | |
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| | | | Н | | _ | | | | | | | | |
| | | | Н | A | | S | S | F | | | | | |
| | | | | C | S | | | | | | | | |
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| | | | | | | | | | | | | | |
| via the CMS Virtual Data Center (VDC). | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | X | X | X | X | | | | | VDC | | | | |
| ing file through the VDC on or after June 15, | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| 1 | 2018 and, if released, the revised April 2018, 2018, October 2017, and July 2017, ASP drug iles for Medicare Part B drugs shall be via the CMS Virtual Data Center (VDC). ractors shall download the July 2018 ASP ring file through the VDC on or after June 15, | 2018 and, if released, the revised April 2018, 2018, October 2017, and July 2017, ASP drug iles for Medicare Part B drugs shall be via the CMS Virtual Data Center (VDC). Tractors shall download the July 2018 ASP X | A/E MAGE A/E MA | A/B MAC A B H H H H 2018 and, if released, the revised April 2018, 2018, October 2017, and July 2017, ASP drug illes for Medicare Part B drugs shall be evia the CMS Virtual Data Center (VDC). Tractors shall download the July 2018 ASP X X X | A/B MAC M E A B H H M A C 2018 and, if released, the revised April 2018, 2018, October 2017, and July 2017, ASP drug iles for Medicare Part B drugs shall be evia the CMS Virtual Data Center (VDC). | A/B D MAC M E M A B H H M I H A S C S 2018 and, if released, the revised April 2018, 2018, October 2017, and July 2017, ASP drug iles for Medicare Part B drugs shall be a via the CMS Virtual Data Center (VDC). | A/B D Sha Sys E Maint A B H H M I C H A S S 2018 and, if released, the revised April 2018, 2018, October 2017, and July 2017, ASP drug iles for Medicare Part B drugs shall be evia the CMS Virtual Data Center (VDC). | A/B D Shared-System H A/B D System MAC M B H F M V H A S S S C S 2018 and, if released, the revised April 2018, 2018, October 2017, and July 2017, ASP drug iles for Medicare Part B drugs shall be e via the CMS Virtual Data Center (VDC). | A/B MAC M System E Maintainers A B H M I C M W H A S S S F 2018 and, if released, the revised April 2018, 2018, October 2017, and July 2017, ASP drug iles for Medicare Part B drugs shall be via the CMS Virtual Data Center (VDC). | | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|-----------------|--|----------------|------------|-------------|-------------|---|-------------|-------------|---|-------|
| | | | A/B MA(| } | D M E | | Sha Sys | tem | | Other |
| | | A | В | H H H | M A C | F | M C S | V M S | С | |
| 10667.1.1 .1 | The contractors shall retrieve the July 2018 final file: MU00.@BF12390.ASP.R2.CY18.JUL.S.V0615 | | X | | X | | | | | VDC |
| 10667.1.1 .2 | The contractors shall retrieve July 2018 final file: MU00.@BF12390.ASP.R2.CY18.JUL.S.V0615.FISS | X | | X | | | | | | VDC |
| 10667.1.1 .3 | The contractors shall retrieve the July 2018 ASP NOC pricing file from the CMS ASP webpage on or after June 15, 2018. | X | X | X | X | | | | | |
| 10667.1.1 .4 | The contractors shall use the July 2018 ASP and NOC drug pricing files to determine the payment limit for separately payable Medicare Part B drug claims processed or reprocessed on or after July 2, 2018 with dates of service July 1, 2018, through September 30, 2018. | X | X | X | X | | | | | |
| 10667.1.1 | The contractors shall use the July 2018 ASP drug pricing file to update the drug payment limits for infusion drugs furnished through a covered item on DME processed or reprocessed claims on or after July 2, 2018, with dates of service on or after July 1, 2018. | | X | | X | | | | | |
| 10667.1.2 | If released by CMS, the contractors shall download the revised April 2018 ASP drug pricing file through the VDC on or after June 15, 2018. | X | X | X | X | | | | | VDC |
| 10667.1.2 .1 | The contractors shall retrieve the April 2018 final file: MU00.@BF12390.ASP.R2.CY18.APR.S.V0615 | | X | | X | | | | | VDC |
| 10667.1.2 .2 | The contractors shall retrieve the April 2018 final file: MU00.@BF12390.ASP.R2.CY18.APR.S.V0615.FISS | X | | X | | | | | | VDC |
| 10667.1.2 .3 | If released by CMS, the contractors shall overlay or manually update the previous April 2018 file with the new April 2018 ASP drug pricing file. | X | X | X | X | | | | | |
| 10667.1.2 .4 | If released by CMS, the contractors shall use the revised April 2018 ASP drug pricing file to determine the payment limit for separately payable Medicare Part B drug claims processed or reprocessed on or after July 2, 2018 with dates of service April 1, 2018, through June 30, 2018. | X | X | X | X | | | | | |
| 10667.1.2 .5 | If released by CMS, the contractors shall retrieve the revised April 2018 ASP NOC pricing file from the CMS ASP webpage on or after June 15, 2018. | X | X | X | X | | | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|-----------------|---|----------------|------------|-------------|-------------|---|---|-----------------------|---|-------|
| | | 1 | A/B MAC | 3 | D M E | | | red- stem taine | 1 | Other |
| | | A | В | H H H | 1 | F | M | ι ι | С | |
| 10667.1.2 | If released by CMS, the contractors shall use the revised April 2018 ASP NOC pricing file to determine the payment limit for separately payable Medicare Part B drug claims processed or reprocessed on or after July 2, 2018 with dates of service April 1, 2018, through June 30, 2018. | X | X | X | X | | | | | |
| 10667.1.3 | If released by CMS, the contractors shall download the revised January 2018 ASP drug pricing file through the VDC on or after June 15, 2018. | X | X | X | X | | | | | VDC |
| 10667.1.3 .1 | The contractors shall retrieve the January 2018 final file: MU00.@BF12390.ASP.R2.CY18.JAN.S.V0615 | | X | | X | | | | | VDC |
| 10667.1.3 .2 | The contractors shall retrieve the January 2018 final file: MU00.@BF12390.ASP.R2.CY18.JAN.S.V0615.FISS | X | | X | | | | | | VDC |
| 10667.1.3 | If released by CMS, the contractors shall overlay or manually update the previous January 2018 file with the new January 2018 ASP drug pricing file. | X | X | X | X | | | | | |
| 10667.1.3 | If released by CMS, the contractors shall use the revised January 2018 ASP drug pricing file to determine the payment limit for separately payable Medicare Part B drug claims processed or reprocessed on or after July 2, 2018 with dates of service January 1, 2018, through March 31, 2018. | X | X | X | X | | | | | |
| 10667.1.3 | If released by CMS, the contractors shall retrieve the revised January 2018 ASP NOC pricing file from the CMS ASP webpage on or after June 15, 2018. | X | X | X | X | | | | | |
| 10667.1.3 | If released by CMS, the contractors shall use the revised January 2018 ASP NOC pricing file to determine the payment limit for separately payable Medicare Part B drug claims processed or reprocessed on or after July 2, 2018 with dates of service January 1, 2018, through March 31, 2018. | X | X | X | X | | | | | |
| 10667.1.4 | If released by CMS, the contractors shall download the revised October 2017 ASP drug pricing file through the VDC on or after June 15, 2018. | X | X | X | X | | | | | VDC |
| 10667.1.4 .1 | The contractors shall retrieve the October 2017 final file: MU00.@BF12390.ASP.R2.CY17.OCT.S.V0615 | | X | | X | | | | | VDC |

| Number | Requirement | Responsibility | | | | | | | | |
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| | | | А/В ИА(| | D M | | Other | | | |
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| | | A | В | H H | M | F I | M C | V M | C W | |
| | | | | Н | A | S | S | S | F | |
| | | | | | С | S | | | | |
| 10667.1.4 | The contractors shall retrieve the October 2017 final | X | | X | | | | | | VDC |
| .2 | file: MU00.@BF12390.ASP.R2.CY17.OCT.S.V0615.FISS | | | | | | | | | |
| 10667.1.4 .3 | If released by CMS, the contractors shall overlay or manually update the previous October 2017 file with the new October 2017 ASP drug pricing file. | X | X | X | X | | | | | |
| 10667.1.4 .4 | If released by CMS, the contractors shall use the revised October 2017 ASP drug pricing file to | X | X | X | X | | | | | |
| | determine the payment limit for separately payable Medicare Part B drug claims processed or reprocessed on or after July 2, 2018 with dates of service October 1, 2017, through December 31, 2017. | | | | | | | | | |
| 10667.1.4 | If released by CMS, the contractors shall retrieve the | X | X | X | X | | | | | |
| .5 | revised October 2017 ASP NOC pricing file from the CMS ASP webpage on or after June 15, 2018. | | | | | | | | | |
| 10667.1.4 .6 | If released by CMS, the contractors shall use the revised October 2017 ASP NOC pricing file to determine the payment limit for separately payable Medicare Part B drug claims processed or reprocessed on or after July 2, 2018 with dates of service October 1, 2017, through December 31, 2017. | X | X | X | X | | | | | |
| 10667.1.5 | If released by CMS, the contractors shall download the revised July 2017 ASP drug pricing file through the VDC on or after June 15, 2018. | X | X | X | X | | | | | VDC |
| 10667.1.5 | The contractors shall retrieve the July 2017 final file: MU00.@BF12390.ASP.R2.CY17.JUL.S.V0615 | | X | | X | | | | | VDC |
| 10667.1.5 .2 | The Contractors shall retrieve the July 2017 final file: MU00.@BF12390.ASP.R2.CY17.JUL.S.V0615.FISS | X | | X | | | | | | VDC |
| 10667.1.5 | If released by CMS, the contractors shall overlay or manually update the previous July 2017 file with the new July 2017 ASP drug pricing file. | X | X | X | X | | | | | |
| 10667.1.5 | If released by CMS, the contractors shall use the revised July 2017 ASP drug pricing file to determine the payment limit for separately payable Medicare Part B drug claims processed or reprocessed on or after July 2, 2018 with dates of service July 1, 2017, through September 30, 2017. | X | X | X | X | | | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|-----------------|--|----------------|------------|-------------|-------------|---|--------------------|--|-------|-----|
| | | | A/B MA(| } | D M E | | Sha Sys aint | | Other | |
| | | A | В | H H H | M A C | F | M C S | | С | |
| 10667.1.5 .5 | If released by CMS, the contractors shall retrieve the revised July 2017 ASP NOC pricing file from the CMS ASP webpage on or after June 15, 2018. | X | X | X | X | | | | | |
| 10667.1.5 .6 | If released by CMS, the contractors shall use the revised July 2017 ASP NOC pricing file to determine the payment limit for separately payable Medicare Part B drug claims processed or reprocessed on or after July 2, 2018 with dates of service July 1, 2017, through September 30, 2017. | X | X | X | X | | | | | |
| 10667.2 | The contractors shall not search and adjust claims that have already been processed unless brought to their attention. | X | X | X | X | | | | | |
| 10667.3 | The contractors shall notify CMS of successful receipt via email to price_file_receipt@cms.hhs.gov stating the name of the file received, (e.g., CLAB, ASP, etc.) and the entity for which it was received (i.e., include states, carrier numbers, quarter, and if Part A, Part B, or both). | | X | | X | | | | | VDC |
| 10667.4 | The ASP and NOC drug pricing files shall contain the applicable payment allowance limits (i.e., 106% ASP, 106% Wholesale Acquisition Cost (WAC), or 95% Average Wholesale Price (AWP)); therefore, Medicare contractors shall not make any additional payment calculations. | X | X | X | X | | | | | |
| 10667.5 | For any drug or biological not listed in the ASP or NOC drug pricing files, the contractors shall determine the payment allowance limits in accordance with the policy described in the Medicare Claims Processing Manual, Chapter 17, Section 20.1.3. | X | X | X | X | | | | | |
| 10667.5.1 | For any drug or biological not listed in the ASP or NOC drug pricing files that is billed with the KD modifier, the contractors shall determine the payment allowance limits in accordance with instructions for pricing and payment changes for infusion drugs furnished through an item of durable medical equipment on or after January 1, 2017, associated with the passage of the 21st Century Cures Act. | X | X | X | X | | | | | |
| 10667.5.2 | The A/B MACs Part A and Part HHH shall seek payment allowances not on the ASP file from their | X | | X | | | | | | |

| Number | Requirement | Re | espo | nsi | bilit | V | | | | |
|-----------|---|-------------------------------|----------|------------|------------|---|--------|---|-------|--|
| 1100000 | Tregul vinon | Responsibility A/B D Shared- | | | | | | | Other | |
| | | | ЛA(| | M | | System | | | |
| | | | | | Е | | aint | | | |
| | | A | В | Н | | F | M | V | С | |
| | | | | Н | M | I | C | M | W | |
| | | | | Н | A | S | S | S | F | |
| | | | | | С | S | | | | |
| | A/B MAC Part B contractor for drugs and biologicals. | | | | | | | | | |
| 10667.6 | The contractors shall use the most current version | X | X | X | X | | | | | |
| | available of the Medicare Contractor Reporting | | | | | | | | | |
| | Template for Part B drugs to report information on | | | | | | | | | |
| | Medicare Part B drugs not paid on a cost or | | | | | | | | | |
| | prospective payment basis when payment limits are | | | | | | | | | |
| | not listed in the quarterly drug pricing ASP, NOC | | | | | | | | | |
| | files, or in the OPPS Pricer. | | | | | | | | | |
| 10667.6.1 | The contractors shall use the template to report pricing | X | X | X | X | | | | | |
| | information for: | | | | | | | | | |
| | NOC days and included on the Medican Day | | | | | | | | | |
| | NOC drugs not included on the Medicare Part B NOC pricing file, | | | | | | | | | |
| | B NOC pricing me, | | | | | | | | | |
| | | | | | | | | | | |
| | any Healthcare Common Procedure Coding | | | | | | | | | |
| | System (HCPCS) drug codes not on the ASP | | | | | | | | | |
| | file, and | | | | | | | | | |
| | | | | | | | | | | |
| | oppg t | | | | | | | | | |
| | OPPS drugs not in the OPPS Pricer. | | | | | | | | | |
| | | | | | | | | | | |
| 10667.6.2 | The contractors shall list all drugs that were priced | X | X | X | X | | | | | |
| | since the last submitted report. | | | | | | | | | |
| 10667.6.3 | The contractors shall list each drug priced on the | X | X | X | X | | | | | |
| 10007.0.3 | report only once. | 1 | 1 | / X | 4 1 | | | | | |
| | | | | | | | | | | |
| 10667.6.4 | For compounded drugs, the contractors shall report the | X | X | X | X | | | | | |
| | name of each drug in the compounded product. | | | | | | | | | |
| 10007.05 | The continue to the little of | ** | 17 | 17 | 17 | | | | | |
| 10667.6.5 | The contractors shall prepare and submit the reports so | X | X | X | X | | | | | |
| | that each report covers approximately 30 days of pricing activity. | | | | | | | | | |
| | pricing activity. | | | | | | | | | |
| 10667.6.6 | The contractors shall report drugs omitted from | X | X | X | X | | | | | |
| | previous reports in the next report. | | | | | | | | | |
| 1025 | | | | | | | | | | |
| 10667.6.7 | The contractors shall complete the report in its | X | X | X | X | | | | | |
| | entirety. | | | | | | | | | |
| 10667.6.8 | The contractors shall not report radiopharmaceuticals. | | X | | | | | | | |
| | 1 | | | | | | | | | |
| | | | _ | | | | | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|-----------|---|----------------|------------|-------------|-------------|------------------|--------------------|-------------|-------------|-------|
| | | | A/B MA(| } | D M E | | Sha Sys aint | tem | | Other |
| | | A | В | H H H | M A C | F I S S | M C S | V M S | C W F | |
| 10667.6.9 | The A/B MACs Part A and Part HHH shall report pricing information for drugs, biologicals, and radiopharmaceuticals that are billed using C9399. | X | | X | | | | | | |
| 10667.6.1 | The contractors shall download the most current version available of the template from the CMS website at http://www.cms.gov/McrPartBDrugAvgSalesPrice/. | X | X | X | X | | | | | |
| 10667.6.1 | The contractors shall complete the template on a monthly basis. | X | X | X | X | | | | | |
| 10667.6.1 | The contractors shall ensure that the format of the template is Microsoft Excel. | X | X | X | | | | | | |
| 10667.6.1 | The contractors shall send the completed template to sec303aspdata@cms.hhs.gov on the first business day of the month. | X | X | X | X | | | | | |
| 10667.6.1 | If the contractor has not priced any drugs since the last submitted report, in lieu of using the template, the contractor shall send an email to Sec303aspdata@cms.hhs.gov stating that the contractor has no drug pricing to report. | X | X | X | X | | | | | |

III. PROVIDER EDUCATION TABLE

| Number | Requirement | Re | spoi | nsib | ility | |
|---------|---|----|------|--------------|-------|---|
| | | | | | | |
| | | | A/B | | D | C |
| | | ľ | MA(| \mathbf{C} | M | Е |
| | | | | | E | D |
| | | A | В | Н | | I |
| | | | | Н | M | |
| | | | | Н | A | |
| | | | | | C | |
| 10667.7 | MLN Article: A provider education article related to this instruction will be | X | X | X | X | |
| | 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 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 | | | | | |

| Number | Requirement | Re | spoi | nsib | ility | |
|--------|--|----|------|------|-------|---|
| | | | | | | |
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| | | | | | Е | D |
| | | Α | В | Н | | I |
| | | | | Н | M | |
| | | | | Н | Α | |
| | | | | | C | |
| | 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

[&]quot;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): Glenn McGuirk, 410-786-5723 or Glenn.McGuirk@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: 0