

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-19 Demonstrations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 137	Date: February 5, 2016
	Change Request 9501

SUBJECT: Implementation of the Part B Drug Payment Model (Phase 1)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform the Centers for Medicare & Medicaid Services (CMS), Medicare shared system maintainers (VMS, FISS, MCS and CWF maintainers), the A/B Medicare Administrative Contractors (MACs) and the Durable Medical Equipment MACs to implement necessary claims processing systems changes for successful implementation of the Part B Drug Payment Model.

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.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
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:

Demonstrations

Attachment - Demonstrations

Pub. 100-19	Transmittal: 137	Date: February 5, 2016	Change Request: 9501
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SUBJECT: Implementation of the Part B Drug Payment Model (Phase 1)

EFFECTIVE DATE: July 1, 2016

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

IMPLEMENTATION DATE: July 5, 2016

I. GENERAL INFORMATION

A. Background: The purpose of the Change Request (CR) is to instruct CMS shared system maintainers to implement a mechanism that will allow the use and testing of different Average Sales Price (ASP) payment limit values in certain defined geographic areas based on ZIP code. The replacement values would be used in Part B settings such as hospital outpatient departments, physician offices, and pharmacies that currently submit claims for Part B drugs. The information in the background document of this implementation CR is to be construed as final, but this information may be modified as details regarding the implementation of this payment model are finalized.

Medicare pays for most drugs that are administered in a physician's office or the hospital outpatient department at ASP plus 6 percent by statute regardless of the price a provider pays to acquire the drug. Medicare makes an additional separate payment for administration of the drug under the physician fee schedule or the hospital outpatient prospective payment system (OPPS). The ASP is calculated quarterly using manufacturer-submitted data on sales to all purchasers; rebates, discounts and price concessions are reflected in the ASP. The statute does not identify a reason for setting the payment limit at an additional 6 percent above ASP, although physicians and others have asserted that it is needed for handling and overhead costs.

The ASP methodology does not take into account the effectiveness of a particular drug, or the cost of comparable drugs, when determining the Medicare payment amount. The ASP methodology has been criticized for encouraging the use of more expensive products because the add-on to the drug's cost is a percentage of the sales price while handling and overhead costs may not vary with the drug's price.

Medicare is developing methods to test the impact of changes to Part B drug payments. One approach that is being considered would focus on the 6 percent add-on to the ASP. This approach would be implemented via a grouping of five digit ZIP codes, grouped into MSAs or similar units. In this approach, ZIP codes not assigned to an alternative payment would continue to receive payment as ASP+6 percent; these ZIP codes may be grouped together to capture an MSA or similar units. The ZIP code groupings would be done by CMS and the pricing flag field that would be added in existing filler on the ZIP code file sent to the contractors would indicate which ASP pricing methodology applies to any specific ZIP code. Medicare could test the impacts on changes to the ASP add-on percentage for their effects on spending and prescribing patterns to determine, for example, if the changes affect the financial incentive for physicians or hospitals to choose higher cost drugs that do not offer additional clinical value.

Medicare is also developing methods to test the impact of targeted pricing changes to payments for individual Part B drugs beyond changes to the ASP-based payment. These targeted drug payments could vary across a different set of ZIP codes than those assigned to the different ASP methodologies.

CMS is targeting a July 5, 2016 implementation for the system changes to support these new pricing methods discussed above, but additional approaches that test other methods of targeted pricing would likely be phased in later. Also, since this model is going through notice and comment rulemaking, there is a possibility that the new ASP and Zip 5 and Zip 9 files that contain the new pricing values developed under rule making will be available and effective sometime between August 1 and September 15, 2016 rather than

on August 1, 2016 exactly.

B. Policy: Section 1115A of the Social Security Act (the Act) (added by Section 3021 of the Affordable Care Act) (42 U.S.C. 1315a) authorizes CMS’s Center for Medicare & Medicaid Innovation to test innovative health care payment and service delivery models that have the potential to lower Medicare, Medicaid, and Children's Health Insurance Program spending while maintaining or improving the quality of beneficiaries’ care.

Contractors shall implement necessary changes to their respective systems in order to accommodate a new Part B Drug Payment Model to test different approaches for the payment of Part B drugs. Contractors shall refer to the attachment(s) to this CR for a more detailed outline of the programmatic requirements of the Model. Contractors shall also refer to the attached proposed revised layouts for the ZIP code files and ASP file that CMS will create for this model. Please note that the new payment indicator will appear on both the Zip 5 and the Zip 9 files; the indicator is the same on both files based on the first five digits of the Zip. CMS is providing the indicator on both files in case that will help to simplify implementation logic changes.

****NOTE**** - The CMS supplied payment indicator that will be included on the revised ZIP 5 and ZIP 9 files is only based on the first 5 digits of the particular ZIP code. However, CMS is replicating the ZIP 5 payment indicator on the ZIP 9 file per FISS request.

****NOTE**** - Once the new drug pricing payment model is in effect (that is, once the one-time off-cycle ASP and ZIP Code files are installed per instructions below), there is no need for MACs to adjust (either when brought to their attention or by searching their own files) any previously adjudicated claims in order to ensure they are priced using the new model. Any claim adjustments necessitated by the normal course of claims processing operations shall be adjudicated and priced based on the “FROM” date of service on the claim.

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			
9501.1	The July 2016 ASP drug pricing files for Medicare Part B drugs will be available via the CMS Data Center (CDC) and will reflect the revised layout (see File Layout attachment). The ZIP 5 and ZIP 9 files that are released and downloaded under the July 2016 quarterly recurring CR (#9509) will also reflect the revised ZIP 5 and ZIP 9 layouts (see File Layout attachments).											CDC, CMS
9501.1.1	Sometime between August 1, 2016 and September 15, 2016, SSMs and contractors shall download and install both (1) a one time off cycle ASP drug pricing file (full replacement file) for Medicare Part B drugs that will reflect the revised layout and that will be available via the CMS Data Center (CDC), and (2) a one time off cycle ZIP 5 and ZIP 9 file that will also	X	X		X	X	X					VDCs

Number	Requirement	Responsibility								
		A/B MAC		H H H	D M E M A C	Shared- System Maintainers				Other
		A	B			F I S S	M C S	V M S	C W F	
	reflect the revised layouts. Contractors will be notified of these files via a TDL at the time they are ready. The files will both reflect the attached File layouts.									
9501.2	<p>The SSMs and contractors shall use the claim line HCPCS codes/modifiers in conjunction with the ZIP 5 from the incoming Part B drug claim that currently applies in specific claim processing logic (i.e. provider location or beneficiary address ZIP code) to pick up an ASP price bucket indicator from file position 23 on the revised ZIP 5 code layout (see File Layout attachment) or from file position 32 on the revised ZIP 9 code layout.</p> <p>NOTE: The price bucket indicator on both the ZIP 5 and the ZIP 9 is the same as it is based on the first 5 digits of the zip code (i.e. the additional 4 digits on the ZIP 9 file have no impact on the price bucket assignment). Contractors shall use the ASP price bucket indicator from either the ZIP 5 or ZIP 9 File in conjunction with the claim line HCPCS code/modifiers to locate the appropriate price for that HCPCS code/modifier/price bucket combination on the ASP file.</p>	X	X			X	X	X		
9501.3	<p>Between March 1 and March 15, contractors shall download test files reflecting the revised ASP file and ZIP 5 and ZIP 9 file layouts from the CMS mainframe named:</p> <p>MU00.@BF12390.PTBM.ZIP5TEST.MARCH16</p> <p>And</p> <p>MU00.@BF12390.PTBM.ZIP9TEST.MARCH16</p> <p>And</p> <p>MU00.@BF12390.PTBM.ASPTEST.MARCH16</p> <p>CMS will notify SSMs via email when these test files are available for downloading.</p>					X	X	X	VDCs	
9501.4	After the release of the one-time off-cycle ASP and ZIP 5 and ZIP 9 files from BR 9501.1.1, SSMs and contractors shall install quarterly full replacement files on the regular schedule (i.e. next full replacement file	X	X			X	X		VDCs	

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	
	will be for the October 2016 release).									
9501.5	SSMs and contractors shall be aware that, for claims for Part B drugs with “FROM” dates of service on or after the date that the one-time off-cycle files from BR 9501.1.1 are installed, the new drug pricing payment model is in effect. Until that time, claims for Part B drugs shall continue to be processed and priced by existing methods.	X	X			X	X	X		
9501.6	SSMs shall expand, as necessary, any and all online display screens and fields which are used by the MACs and their customer service representatives and claims processing and pricing staff and which allow for the proper processing of claims subject to the new payment model.					X	X	X		
9501.7	Contractors shall use existing remittance advice and Medicare Summary Notice (MSN) messaging associated with the adjudication of claims for Part B drugs for those claims that will be adjudicated using the new Part B drug pricing payment model. There are no new messaging requirements.	X	X		X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	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:

X-Ref Requirement Number	Recommendations or other supporting information:
9501.2	Refer to the attachment for this CR for a more detailed outline of the file layout
9501.1	Refer to the attachment for this CR for a more detailed outline of the file layouts
9501.1.1	Refer to the attachment for this CR for a more detailed outline of the file layouts

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

V. CONTACTS

Pre-Implementation Contact(s): Teira Canty, Teira.Canty@cms.hhs.gov , Eric Coulson, Eric.Coulson@cms.hhs.gov , Dennis Savedge, Dennis.Savedge@cms.hhs.gov , Tracey Mackey, Tracey.Mackey@cms.hhs.gov , Fred Rooke, Fred.Rooke@cms.hhs.gov , Erick Chuang, Erick.Chuang@cms.hhs.gov , Rasheeda Johnson, Rasheeda.Johnson1@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: 3

Here are the current and new layouts for the zip 5 and ASP files that will be needed to implement this Implementation of Part B Drug Payment Model:

Current Zip 5 Code File (Record length=80)

File Position	Var Name	Format
@1	STATE	\$CHAR2.
@3	ZIPCODE	\$CHAR5.
@8	CARRIER	\$CHAR5.
@13	LOCALITY	\$CHAR2.
@15	RURAL	\$CHAR1.
@16	CBLOC	\$CHAR2.
@18	RURALM	\$CHAR1.
@21	ZIP4_FLG	\$CHAR1.
@76	YEAR	\$CHAR4.
@80	QTR	\$CHAR1.

Revised Zip 5 Code File revisions to accommodate 1 alpha character payment indicator (neither ‘H’, ‘I’, ‘O’, ‘R’, nor ‘S’ will be used for this model per FISS request but other alphas from A-Z will be used in the 1 character payment indicator) that will identify the pricing ‘bucket’ to which a given zip is assigned. The alpha character will repeat on the ASP file and it, in conjunction with the HCPCS/Modifier code will be used to locate the price for that line item. (Note: this revised layout also accommodates the additional 5 character extension of the locality field under discussion for PAMA CA CBSA CR #9243) (Record length=80)

File Position	Var Name	Format
@1	STATE	\$CHAR2.
@3	ZIPCODE	\$CHAR5.
@8	CARRIER	\$CHAR5.
@13	LOCALITY	\$CHAR2.
@15	RURAL	\$CHAR1.
@16	CBLOC	\$CHAR2.
@18	RURALM	\$CHAR1.
@21	ZIP4_FLG	\$CHAR1.
@23	PAY_IND_PTB	\$CHAR1.
@26	CBSA_LOC_EXT	\$CHAR5.
@76	YEAR	\$CHAR4.
@80	QTR	\$CHAR1.

Current ASP File layout (Record length=160)

File Position	Var Name	Format
@1	HCPCS1	\$CHAR5.
@6	MOD1	\$CHAR2.
@8	MOD2	\$CHAR2.
@11	SHRTDESC	\$CHAR28.
@40	NESRDFEE	Z9.
@52	ESRDFEE	Z9.
@64	VACPERCA	Z3.
@71	VACFEE	Z9.
@83	DMEPERCA	Z3.
@90	DMEFEE	Z9.
@102	BLDPERCA	Z3.
@109	BLDFEE	Z9.
@119	CLOTTING	Z1.

Revised ASP File layout (Record length=160). The new 1 character alpha - PAY_IND_PTB – will correspond to the PAY_IND_PTB variable on the zip code file and should be used in conjunction with the HCPCS/Mod to locate the appropriate price for that claim line item. Neither ‘H’, ‘T’, ‘O’, ‘R’, nor ‘S’ will be used for this model for the PAY_IND_PTB values per FISS request but other alphas from A-Z will be used in as valid PAY_IND_PTB values.

File Position	Var Name	Format
@1	HCPCS1	\$CHAR5.
@6	MOD1	\$CHAR2.
@8	MOD2	\$CHAR2.
@11	SHRTDESC	\$CHAR28.
@40	NESRDFEE	Z9.
@52	ESRDFEE	Z9.
@64	VACPERCA	Z3.
@71	VACFEE	Z9.
@83	DMEPERCA	Z3.
@90	DMEFEE	Z9.
@102	BLDPERCA	Z3.
@109	BLDFEE	Z9.
@119	CLOTTING	Z1.
@121	PAY_IND_PTB	\$CHAR1.

Current Zip 9 Code File (Record length=80)

File Position	Var Name	Format
@1	STATE	\$CHAR2.
@3	ZIPCODE	\$CHAR5.
@8	CARRIER	\$CHAR5.
@13	LOCALITY	\$CHAR2.
@15	RURAL	\$CHAR1.
@16	CBLOC	\$CHAR2.
@18	RURALM	\$CHAR1.
@21	ZIP4_FLG	\$CHAR1.
@22	Plus_4	\$CHAR4.
@76	YEAR	\$CHAR4.
@80	QTR	\$CHAR1.

Revised Zip 9 Code File (Record length=80)

The Zip 9 file revisions to accommodate the FISS request that we carry the payment indicator field on the ZIP 9 file. NOTE that the payment indicator is based on the first 5 digits of the zip code only so taking the payment indicator from the ZIP 5 or the ZIP 9 file will yield the same results. Note: The additional 5 character extension of the locality field under discussion for PAMA CA CBSA CR #9243 is shown in position 26 for illustrative purposes but is not related to the CR 9501. If a variable is not deliberately specified in a position, assume that position contains filler.

File Position	Var Name	Format
@1	STATE	\$CHAR2.
@3	ZIPCODE	\$CHAR5.
@8	CARRIER	\$CHAR5.
@13	LOCALITY	\$CHAR2.
@15	RURAL	\$CHAR1.
@16	CBLOC	\$CHAR2.
@18	RURALM	\$CHAR1.
@21	ZIP4_FLG	\$CHAR1.
@22	Plus_4	\$CHAR4.
@26	CBSA_LOC_EXT	\$CHAR5.
@32	PAY_IND_PTB	\$CHAR1.
@76	YEAR	\$CHAR4.
@80	QTR	\$CHAR1.

Part B Drug Payment Model Assumptions Paper

Background

CMS is providing this document in order to assist contractors as they implement the Part B Drug payment Model. Although the model has not yet been finalized through notice and comment rulemaking, the information below can be used as interim guidance treated to the implementation CR. Updates to this information will be made available on a flow basis.

Medicare pays for most drugs that are administered in a physician's office or the hospital outpatient department at Average Sales Price (ASP) plus 6 percent, with additional separate payment for drug administration under the Medicare physician fee schedule (MPFS) or the hospital outpatient prospective payment system (OPPS). The ASP is calculated on a quarterly basis using manufacturer-submitted data. Medicare pays providers such as hospitals, physicians, Rural Health Clinics, Federally Qualified Health Centers and pharmacies for Part B drugs.

Every quarter, CMS creates a new ASP file for MCS, FISS and VMS systems with a national price listed by Healthcare Common Procedure Coding System (HCPCS) code. To our knowledge, currently, the claims system does not make any other adjustments to the payment rates listed on the ASP file. CMS restates some prices on the ASP file with retroactive pricing to a previous quarter and ASP payment amounts frequently change from quarter to quarter. CMS relies on updated pricing submissions from drug manufacturers each quarter and provides a quarterly pricing file for the Medicare Administrative Contractors (MACs) after validating and updating the manufacturer-submitted data. Because of the pricing submission schedule, the final contractor ASP file each quarter is frequently released very close to production deadlines.

CMS is considering testing different versions of ASP price files in different areas of the country across all Part B drug settings using a mandatory participation model. For example there may be two alternative ASP price files each quarter, in addition to the ASP price file that is currently released each quarter. We anticipate that the payment value determination for a given claim in a given geographic area that is participating in the model would be accomplished by overlaying payment limits that appear on the current "ASP" price file with model-derived payment limits in the geographic areas that are being evaluated. Certain model payment approaches may also require separate add-on payments; in such a situation, we may utilize a G-code in addition to a drug HCPCS code.

CMS anticipates that most Part B drugs, particularly the drugs that appear on the quarterly ASP price file, would be included in the model. However, CMS would develop a list of drugs that would be excluded from the model. CMS anticipates that drugs that are currently contractor priced would continue to be contractor priced.

Testing would include monitoring Medicare Part B spending and providers' prescribing patterns; implementation is anticipated to begin on August 1, 2016. This implementation date would require changing the ASP pricing files in the middle of a quarter for some geographic areas that are assigned to model-based payment limits. The geographic areas may be as large as an entire MAC, but would more likely be a subset of the MAC, based on ZIP codes or perhaps MSAs or similar units. In other words, the MAC may have to accommodate several versions of the ASP price file that would be used in different areas of the MAC jurisdiction. Monitoring and testing of the model would be performed by separately by CMS and its partners.