CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 4000	**Date: March 16, 2018**
	Change Request 10419

SUBJECT: Internet Only Manual Update to Pub 100-04, Chapter 16, Section 40.8 - Date of Service Policy

I. SUMMARY OF CHANGES: This Change Request (CR) updates the claims processing manual, Pub.100-04, Chapter 16, Section 40. 8.

EFFECTIVE DATE: January 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
R	16/40/40.8/Date of Service (DOS) for Clinical Laboratory and Pathology Specimens

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:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 4000	Date: March 16, 2018	Change Request: 10419

SUBJECT: Internet Only Manual Update to Pub 100-04, Chapter 16, Section 40.8 - Date of Service Policy

EFFECTIVE DATE: January 1, 2018
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 2, 2018

I. GENERAL INFORMATION

A. Background: The Date of Service (DOS) is a required field on all Medicare claim types. A laboratory service may take place over a period of time. That is, for a given laboratory test, the date the physician orders the test, the date the specimen is collected from the patient, the date the laboratory accesses the specimen, the date of the test, and the date results are produced may occur on different dates.

In most cases, the DOS for a laboratory test is the date the specimen was collected, unless certain conditions are met as set forth in the Code of Federal Regulation (CFR) 414.510(b). For instance, if the physician orders the test at least 14 days following a patient's discharge from the hospital, the DOS is the date the test is performed (instead of the date the specimen was collected).

Under the current DOS policy, if the test was not ordered at least 14 days following the date of the patients discharge from an outpatient hospital procedure, there is no way that the laboratory performing a molecular pathology laboratory test or Advanced Diagnostic Laboratory Test (ADLT) (which are separately payable under the Clinical Laboratory Fee Schedule (CLFS)) can avoid having to seek payment from the hospital. If the test is ordered less than 14 days from the date the patient was released from the hospital outpatient department, the laboratory cannot bill Medicare directly**.**

Recently, certain laboratory stakeholders informed CMS that the laboratory DOS policy creates unintentional operational consequences for hospitals and laboratories who perform molecular pathology tests and ADLTs performed on specimens collected during a hospital outpatient encounter that are separately paid at the CLFS rate and not under the hospital outpatient prospective payment system rate. To better understand the potential impact of the current DOS policy on billing for ADLT and molecular pathology tests excluded from the Outpatient Prospective Payment System (OPPS) packaging policy, CMS solicited public comments in the Calendar Year (CY) 2018 hospital OPPS and Ambulatory Surgical Center Payment Systems proposed rule published on July 20, 2017. Specifically, CMS requested comments on potential revisions to the current laboratory DOS policy that would allow the laboratory to bill Medicare directly for these laboratory tests instead of seeking payment from the hospital outpatient department.

After considering the comments received, CMS finalized an additional exception to the current laboratory DOS regulations in the CY 2018 OPPS/ASC final rule published December 14, 2017, so that the DOS for Advanced Diagnostic Laboratory Tests and molecular pathology tests excluded from OPPS packaging policy is the date the test was performed if certain conditions are met. This new exception to the laboratory DOS policy is effective beginning on January 1, 2018.

B. Policy: In the case of a molecular pathology test or an Advanced Diagnostic Laboratory Test that meets the criteria of section 1834A(d)(5)(A) of the Act, the date of service must be the date the test was performed only if the following conditions are met: (1) The test is performed following a hospital outpatient's discharge from the hospital outpatient department; (2) The specimen was collected from a hospital outpatient during an encounter (as both are defined 42 CFR 410.2); (3) It was medically appropriate

to have collected the sample from the hospital outpatient during the hospital outpatient encounter; (4) The results of the test do not guide treatment provided during the hospital outpatient encounter; and (5) The test was reasonable and medically necessary for the treatment of an illness.

This new exception to laboratory DOS policy will permit laboratories performing ADLTs and molecular pathology tests excluded from the Outpatient Prospective Payment System (OPPS) packaging policy to bill Medicare directly for those tests, instead of requiring them to seek payment from the hospital outpatient department.

A list of specific laboratory test Healthcare Common Procedure Coding System (HCPCS) codes subject to this new exception to laboratory DOS policy will be provided to Medicare Administrative Contractors (MACs) and posted to the Medicare Clinical Laboratory Fee Schedule website.

Attachment: Laboratory Test Codes Subject to DOS Exception

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	
10419.1	Contractors shall be aware of the new exception to the laboratory test codes subject to the new DOS policy, Pub. 100-04, Chapter 16, Section 40.8 of the claims processing manual. Note: A list of specific laboratory test HCPCS codes subject to this new exception to the laboratory DOS policy will be provided to the Parts A/B Medicare Administrative Contractors (MACs) and posted to the Medicare Laboratory Fee Schedule Website.	X	X							
10419.2	When claims are brought to their attention, MACs shall adjust January 1, 2018 and later dates of service claims for the laboratory tests subject to the new laboratory date of service policy exception, when those claims were denied because they did not, at the time of their adjudication, meet the new date of service policy exception being implemented via CR 10419.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

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): Vickie Poff, 410-786-0836 or vickie.poff1@cms.hhs.gov (claims processing questions) , Rasheeda Johnson, 410-786-3434 or rasheeda.johnson1@cms.hhs.gov (policy questions) , Craig Dobyski, 410-786-4584 or craig.dobyski@cms.hhs.gov (policy questions)

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: 1

Medicare Claims Processing Manual
Chapter 16 - Laboratory Services

40.8 - Date of Service (DOS) for Clinical Laboratory and Pathology Specimens
(Rev.4000, Issued: 03-16-18, Effective: 01-10-18, Implementation: 07-02-18)

The DOS policy for either a clinical laboratory test or the technical component of physician pathology service is as follows:

General Rule: The DOS of the test/service must be the date the specimen was collected.

Variation: If a specimen is collected over a period that spans two calendar days, then the DOS must be the date the collection ended.

Exceptions: The following three exceptions apply to the DOS policy for either a clinical laboratory test or the technical component of physician pathology service:

A. DOS for Tests/Services Performed on Stored Specimens:

In the case of a test/service performed on a stored specimen, if a specimen was stored for less than or equal to 30 calendar days from the date it was collected, the DOS of the test/service must be the date the test/service was performed only if:

- The test/service is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test/service do not guide treatment provided during the hospital stay; and
- The test/service was reasonable and medically necessary for treatment of an illness.

If the specimen was stored for more than 30 calendar days before testing, the specimen is considered to have been archived and the DOS of the test/service must be the date the specimen was obtained from storage.

B. DOS for Chemotherapy Sensitivity Tests/Services Performed on Live Tissue:

In the case of a chemotherapy sensitivity test/service performed on live tissue, the DOS of the test/service must be the date the test/service was performed only if:

- The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;

- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

- The results of the test/service do not guide treatment provided during the hospital stay; and

- The test/service was reasonable and medically necessary for treatment of an illness.

For purposes of applying the above exception, a "chemotherapy sensitivity test" is defined as a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. CMS identifies such tests through program instructions issued to the Medicare Administrative Contractors (MACs).

C. DOS for Advanced Diagnostic Laboratory Tests and Molecular Pathology Tests:

In the case of a molecular pathology test or a test designated by CMS as an ADLT under paragraph (1) of the definition of advanced diagnostic laboratory test in 42 CFR 414.502, the DOS must be the date the test was performed only if:

- The test was performed following a hospital outpatient's discharge from the hospital outpatient department;

- The specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2);

- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;

- The results of the test do not guide treatment provided during the hospital outpatient encounter; and

- The test was reasonable and medically necessary for the treatment of an illness.

Medicare Clinical Laboratory Fee Schedule

Revised Laboratory Date of Service (DOS) Policy

Effective January 1, 2018

Laboratory Tests For Which the DOS is the Date the Test is Performed

(Subject to the Conditions Specified in 42 CFR 414.510(b)(5))*

HCPCS Code	OPPS Payment Status Indicator**	Short Descriptor
81105	A	Hpa-1 genotyping
81106	A	Hpa-2 genotyping
81107	A	Hpa-3 genotyping
81108	A	Hpa-4 genotyping
81109	A	Hpa-5 genotyping
81110	A	Hpa-6 genotyping
81111	A	Hpa-9 genotyping
81112	A	Hpa-15 genotyping
81120	A	Idh1 common variants
81121	A	Idh2 common variants
81161	A	Dmd dup/delet analysis
81162	A	Brca1&2 seq & full dup/del
81170	A	Abl1 gene
81175	A	Asxl1 full gene sequence
81176	A	Asxl1 gene target seq alys
81200	A	Aspa gene
81201	A	Apc gene full sequence
81202	A	Apc gene known fam variants
81203	A	Apc gene dup/delet variants
81205	A	Bckdhb gene
81206	A	Bcr/abl1 gene major bp
81207	A	Bcr/abl1 gene minor bp
81208	A	Bcr/abl1 gene other bp
81209	A	Blm gene
81210	A	Braf gene
81211	A	Brca1&2 seq & com dup/del
81212	A	Brca1&2 185&5385&6174 var
81213	A	Brca1&2 uncom dup/del var
81214	A	Brca1 full seq & com dup/del
81215	A	Brca1 gene known fam variant
81216	A	Brca2 gene full sequence
81217	A	Brca2 gene known fam variant
81218	A	Cebpa gene full sequence
81219	A	Calr gene com variants
81220	A	Cftr gene com variants
81221	A	Cftr gene known fam variants
81222	A	Cftr gene dup/delet variants
81223	A	Cftr gene full sequence
81224	A	Cftr gene intron poly t
81225	A	Cyp2c19 gene com variants
81226	A	Cyp2d6 gene com variants
81227	A	Cyp2c9 gene com variants
81228	A	Cytogen micrarray copy nmbr
81229	A	Cytogen m array copy no&snp
81230	A	Cyp3a4 gene common variants
81231	A	Cyp3a5 gene common variants
81232	A	Dpyd gene common variants
81235	A	Egfr gene com variants
81238	A	F9 full gene sequence
81240	A	F2 gene
81241	A	F5 gene
81242	A	Fancc gene
81243	A	Fmr1 gene detection
81244	A	Fmr1 gene characterization

Medicare Clinical Laboratory Fee Schedule
Revised Laboratory Date of Service (DOS) Policy
Effective January 1, 2018
Laboratory Tests For Which the DOS is the Date the Test is Performed
(Subject to the Conditions Specified in 42 CFR 414.510(b)(5))*

HCPCS Code	OPPS Payment Status Indicator**	Short Descriptor
81245	A	Flt3 gene
81246	A	Flt3 gene analysis
81247	A	G6pd gene alys cmn variant
81248	A	G6pd known familial variant
81249	A	G6pd full gene sequence
81250	A	G6pc gene
81251	A	Gba gene
81252	A	Gjb2 gene full sequence
81253	A	Gjb2 gene known fam variants
81254	A	Gjb6 gene com variants
81255	A	Hexa gene
81256	A	Hfe gene
81257	A	Hba1/hba2 gene
81258	A	Hba1/hba2 gene fam vrnt
81259	A	Hba1/hba2 full gene sequence
81260	A	Ikbkap gene
81261	A	Igh gene rearrange amp meth
81262	A	Igh gene rearrang dir probe
81263	A	Igh vari regional mutation
81264	A	Igk rearrangeabn clonal pop
81265	A	Str markers specimen anal
81266	A	Str markers spec anal addl
81267	A	Chimerism anal no cell selec
81268	A	Chimerism anal w/cell select
81269	A	Hba1/hba2 gene dup/del vrnts
81270	A	Jak2 gene
81272	A	Kit gene targeted seq analys
81273	A	Kit gene analys d816 variant
81275	A	Kras gene variants exon 2
81276	A	Kras gene addl variants
81283	A	Ifnl3 gene
81287	A	Mgmt gene methylation anal
81288	A	Mlh1 gene
81290	A	Mcoln1 gene
81291	A	Mthfr gene
81292	A	Mlh1 gene full seq
81293	A	Mlh1 gene known variants
81294	A	Mlh1 gene dup/delete variant
81295	A	Msh2 gene full seq
81296	A	Msh2 gene known variants
81297	A	Msh2 gene dup/delete variant
81298	A	Msh6 gene full seq
81299	A	Msh6 gene known variants
81300	A	Msh6 gene dup/delete variant
81301	A	Microsatellite instability
81302	A	Mecp2 gene full seq
81303	A	Mecp2 gene known variant
81304	A	Mecp2 gene dup/delet variant
81310	A	Npm1 gene
81311	A	Nras gene variants exon 2&3
81313	A	Pca3/klk3 antigen
81314	A	Pdgfra gene
81315	A	Pml/raralpha com breakpoints
81316	A	Pml/raralpha 1 breakpoint

Medicare Clinical Laboratory Fee Schedule
Revised Laboratory Date of Service (DOS) Policy
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Laboratory Tests For Which the DOS is the Date the Test is Performed
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HCPCS Code	OPPS Payment Status Indicator**	Short Descriptor
81317	A	Pms2 gene full seq analysis
81318	A	Pms2 known familial variants
81319	A	Pms2 gene dup/delet variants
81321	A	Pten gene full sequence
81322	A	Pten gene known fam variant
81323	A	Pten gene dup/delet variant
81324	A	Pmp22 gene dup/delet
81325	A	Pmp22 gene full sequence
81326	A	Pmp22 gene known fam variant
81327	A	Sept9 methylation analysis
81328	A	Slco1b1 gene com variants
81330	A	Smpd1 gene common variants
81331	A	Snrpn/ube3a gene
81332	A	Serpina1 gene
81334	A	Runx1 gene targeted seq alys
81335	A	Tpmt gene com variants
81340	A	Trb@ gene rearrange amplify
81341	A	Trb@ gene rearrange dirprobe
81342	A	Trg gene rearrangement anal
81346	A	Tyms gene com variants
81350	A	Ugt1a1 gene
81355	A	Vkorc1 gene
81361	A	Hbb gene com variants
81362	A	Hbb gene known fam variant
81363	A	Hbb gene dup/del variants
81364	A	Hbb full gene sequence
81370	A	Hla i & ii typing lr
81371	A	Hla i & ii type verify lr
81372	A	Hla i typing complete lr
81373	A	Hla i typing 1 locus lr
81374	A	Hla i typing 1 antigen lr
81375	A	Hla ii typing ag equiv lr
81376	A	Hla ii typing 1 locus lr
81377	A	Hla ii type 1 ag equiv lr
81378	A	Hla i & ii typing hr
81379	A	Hla i typing complete hr
81380	A	Hla i typing 1 locus hr
81381	A	Hla i typing 1 allele hr
81382	A	Hla ii typing 1 loc hr
81383	A	Hla ii typing 1 allele hr
81400	A	Mopath procedure level 1
81401	A	Mopath procedure level 2
81402	A	Mopath procedure level 3
81403	A	Mopath procedure level 4
81404	A	Mopath procedure level 5
81405	A	Mopath procedure level 6
81406	A	Mopath procedure level 7
81407	A	Mopath procedure level 8
81408	A	Mopath procedure level 9
81410	A	Aortic dysfunction/dilation
81411	A	Aortic dysfunction/dilation
81412	A	Ashkenazi jewish assoc dis
81413	A	Car ion chnnlpath inc 10 gns
81414	A	Car ion chnnlpath inc 2 gns

Medicare Clinical Laboratory Fee Schedule

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(Subject to the Conditions Specified in 42 CFR 414.510(b)(5))*

HCPCS Code	OPPS Payment Status Indicator**	Short Descriptor
81415	A	Exome sequence analysis
81416	A	Exome sequence analysis
81417	A	Exome re-evaluation
81420	A	Fetal chrmoml aneuploidy
81422	A	Fetal chrmoml microdeltj
81425	A	Genome sequence analysis
81426	A	Genome sequence analysis
81427	A	Genome re-evaluation
81430	A	Hearing loss sequence analys
81431	A	Hearing loss dup/del analys
81432	A	Hrdtry brst ca-rlatd dsordrs
81433	A	Hrdtry brst ca-rlatd dsordrs
81434	A	Hereditary retinal disorders
81435	A	Hereditary colon ca dsordrs
81436	A	Hereditary colon ca dsordrs
81437	A	Heredtry nurondcrn tum dsrdr
81438	A	Heredtry nurondcrn tum dsrdr
81439	A	Hrdtry cardmypy gene panel
81440	A	Mitochondrial gene
81442	A	Noonan spectrum disorders
81445	A	Targeted genomic seq analys
81448	A	Hrdtry perph neurphy panel
81450	A	Targeted genomic seq analys
81455	A	Targeted genomic seq analys
81460	A	Whole mitochondrial genome
81465	A	Whole mitochondrial genome
81470	A	X-linked intellectual dblt
81471	A	X-linked intellectual dblt
81479	A	Unlisted molecular pathology
81493	A	Cor artery disease mrna
81504	A	Oncology tissue of origin
81507	A	Fetal aneuploidy trisom risk
81519	A	Oncology breast mrna
81520	A	Onc breast mrna 58 genes
81521	A	Onc breast mrna 70 genes
81525	A	Oncology colon mrna
81528	A	Oncology colorectal scr
81540	A	Oncology tum unknown origin
81541	A	Onc prostate mrna 46 genes
81545	A	Oncology thyroid
81551	A	Onc prostate 3 genes
81595	A	Cardiology hrt trnspl mrna
0004M	A	Scoliosis dna alys
0006M	A	Onc hep gene risk classifier
0007M	A	Onc gastro 51 gene nomogram
0008M	A	Onc breast risk score
0009M	A	Fetal aneuploidy trisom risk
0001U	A	Rbc dna hea 35 ag 11 bld grp
0004U	A	Nfct ds dna 27 resist genes
0008U	A	Hpylori detcj abx rstnc dna
0010U	A	Nfct ds strn typ whl gen seq
0012U	A	Germln do gene reargmt detcj
0013U	A	Onc sld org neo gene reargmt
0014U	A	Hem hmtlmf neo gene reargmt

Medicare Clinical Laboratory Fee Schedule Revised Laboratory Date of Service (DOS) Policy Effective January 1, 2018 Laboratory Tests For Which the DOS is the Date the Test is Performed (Subject to the Conditions Specified in 42 CFR 414.510(b)(5))*		
HCPCS Code	**OPPS Payment Status Indicator****	**Short Descriptor**
0016U	A	Onc hmtlmf neo rna bcr/abl1
0017U	A	Onc hmtlmf neo jak2 mut dna
0018U	A	Onc thyr 10 microrna seq alg
0019U	A	Onc rna tiss predict alg
0022U	A	Trgt gen seq dna&rna 23 gene
0023U	A	Onc aml dna detcj/nondetcj

Notes

*In the case of a molecular pathology test or a test designated by CMS as an ADLT under pa
definition of advanced diagnostic laboratory test in 42 CFR 414.502, the DOS must be the d
performed only if: (1)The test was performed following a hospital outpatient's discharge fr
outpatient department; (2) The specimen was collected from a hospital outpatient during a
both are defined in 42 CFR 410.2); (3) It was medically appropriate to have collected the sa
hospital outpatient during the hospital outpatient encounter; (4) The results of the test do
provided during the hospital outpatient encounter; and (5) The test was reasonable and m
the treatment of an illness.

**Tests granted ADLT status by CMS under Criterion (A) and molecular pathology tests are
payment status indicator A. Status indicator "A" is defined as: "Not paid under OPPS. Paid
fee schedule or payment system other than OPPS." Payment for ADLTs and molecular path
from OPPS packaging policy (Status A) are paid at the CLFS rate outside of the OPPS.

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date the test was
om the hospital
an encounter (as
mple from the
not guide treatment
edically necessary for

assigned OPPS
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ology tests excluded