



News Flash - Test Your Medicare Claims Now! After you have submitted claims containing both National Provider Identifiers (NPIs) and legacy identifiers and those claims have been paid, Medicare urges you to send a small batch of claims now with only the NPI in the primary provider fields. If the results are positive, begin increasing the number of claims in the batch. (Reminder: For institutional claims, the primary provider fields are the Billing and Pay-to Provider fields. For professional claims, the primary provider fields are the Billing, Pay-to, and Rendering Provider fields. If the Pay-to Provider is the same as the Billing Provider, the Pay-to Provider does not need to be identified.)

MLN Matters Number: MM5946

Related Change Request (CR) #: 5946

Related CR Release Date: February 8, 2008

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Related CR Transmittal #: R1445CP and R82BP

Implementation Date: March 10, 2008

January 2008 Update of the Hospital Outpatient Prospective Payment System (OPPS) - Manualization

Provider Types Affected

Providers submitting claims to Medicare contractors (Fiscal Intermediaries (FIs), Part A/B Medicare Administrative Contractors (A/B MACs), and/or Regional Home Health Intermediaries (RHHIs)) for services paid under the OPPS provided to Medicare beneficiaries

Provider Action Needed

This article is based on Change Request (CR) 5946 which describes updates to both the Medicare Claims Processing Manual and the Medicare Benefits Policy Manual in order to clarify existing Centers for Medicare & Medicaid Services (CMS) OPPS policy. Much of this information has been conveyed previously by CR5912, which is discussed in MLN Matters article MM5912 at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5912.pdf> on the CMS website.

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Background

This article is based on CR 5946 which is quite lengthy and includes important changes regarding certain OPPS issues. Those details will not be repeated in this article, but they are available in CR 5946 at

<http://www.cms.hhs.gov/Transmittals/downloads/R82BP.pdf> and

<http://www.cms.hhs.gov/Transmittals/downloads/R1445CP.pdf> on the CMS

website. Many of the changes to the Medicare Claims Processing Manual are being made simply to manualize changes already conveyed by CR5912, which is summarized by MLN Matters article MM5912 at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5912.pdf> on the

CMS website. The changes to both manuals are summarized in the remainder of this article.

Medicare Claims Processing Manual Updates

Key changes to this manual are summarized as follows:

Chapter 4 (Part B Hospital (Including Inpatient Hospital Part B and OPPS)), Section 10

This section was modified to identify the five (5) composite APCs that are effective for services furnished on or after January 1, 2008 in the following table:

<i>Composite APC</i>	<i>Composite APC Title</i>	<i>Criteria for Composite Payment</i>
8000	<i>Cardiac Electrophysiologic Evaluation and Ablation Composite</i>	<i>At least one unit of CPT code 93619 or 93620 and at least one unit of CPT code 93650, 93651 or 93652 on the same date of service</i>
8001	<i>Low Dose Rate Prostate Brachytherapy Composite</i>	<i>One or more units of CPT codes 55875 and 77778 on the same date of service</i>
8002	<i>Level I Extended Assessment and Management Composite</i>	<i>1) eight or more units of Healthcare Common Procedure Coding System (HCPCS) code G0378 are billed-- <ul style="list-style-type: none"> ● On the same day as HCPCS code G0379*; or ● On the same day or the day after CPT codes 99205 or 99215; and 2) There is no service with SI=T on the claim on the same date of service or 1 day earlier than G0378</i>

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<i>Composite APC</i>	<i>Composite APC Title</i>	<i>Criteria for Composite Payment</i>
8003	<i>Level II Extended Assessment and Management Composite</i>	<i>1) eight or more units of HCPCS code G0378** are billed on the same date of service or the date of service after 99284, 99285 or 99291; and 2) There is no service with SI=T on the claim on the same date of service or 1 day earlier</i>
0034	<i>Mental Health Services Composite</i>	<i>Payment for any combination of mental health services with the same date of service exceeds the payment for APC 0033. For the list of mental health services to which this composite applies, see the IOCE supporting files for the pertinent period.</i>

**Payment for direct admission to observation care (HCPCS code G0379) is made either under APC 604 (Level 1 Hospital Clinic Visits) or APC 8002 (Level I Extended Management and Assessment Composite) or is packaged into payment for other separately payable services. See section 290.5.2 for additional information and the criteria for payment of HCPCS code G0379.*

*** For additional reporting requirements for observation services reported with HCPCS code G0378, see section 290.5.1 of this chapter.*

Note: See Addendum A at <http://www.cms.hhs.gov/HospitalOutpatientPPS/> on the CMS website for the national unadjusted payment rates for these composite APCs.

Other changes were made to Chapter 4, Section 10, to:

- Further explain the calculation of APC payment rates;
- Emphasize the importance of reporting all HCPCS codes and all charges for all services because of the packaging of certain items and services under the OPSS;
- Explain the combinations of packaged services of different types that are furnished on the same date of service; and
- Further clarify outlier adjustments.

Chapter 4, Section 20.5.1.1 - Packaged Revenue Codes

The following revenue codes when billed under OPSS without HCPCS codes are packaged services for which no separate payment is made. However, the cost of these services is included in the transitional outpatient payment (TOP) and outlier calculations. The revenue codes for packaged services (with new revenue codes bolded and italicized) are: 0250, 0251, 0252, 0254, 0255, 0257, 0258, 0259, 0260, 0262, 0263, 0264, 0269, 0270, 0271, 0272, ***0273***, 0275, 0276, 0278, 0279, 0280, 0289, ***0343, 0344***, 0370, 0371, 0372, 0379, 0390, 0399, 0560, 0569, 0621, 0622, 0624, 0630, 0631, 0632, 0633, , 0681, 0682, 0683, 0684, 0689, 0700, ***0709***, 0710, ***0719***, 0720, 0721, ***0732***, 0762, ***0801, 0802, 0803, 0804, 0809***, 0810, 0819, ***0821, 0824, 0825, 0829***, and 0942.

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Chapter 4, Section 20.5.1.4 - Revenue Codes for "Sometimes Therapy" Services

This section was added to show that certain wound care services described by CPT codes are classified as "sometimes therapy" services that may be appropriately provided under either a certified therapy plan of care or without a certified therapy plan of care.

Hospitals receive separate payment under the OPSS when they bill for certain wound care services that are furnished to hospital outpatients independent of a certified therapy plan of care.

When billing for wound care services under the OPSS that are furnished independent of a certified plan of care, providers should neither attach a therapy modifier (that is, GP for physical therapy, GO for occupational therapy, and GN for speech language pathology) to the wound care CPT codes nor report their charges under a therapy revenue code (that is, 042x, 043x, or 044x), to receive payment under the OPSS.

Chapter 4, Section 61.4 - Billing and Payment for Brachytherapy Sources

This new section contains information regarding billing for brachytherapy sources (e.g. brachytherapy devices or seeds, solutions), which are paid separately from services to administer and deliver brachytherapy in the OPSS, per section 1833 T)(2)(H) of the Social Security Act. This payment for brachytherapy sources reflects the number, isotope, and radioactive intensity of devices furnished, as well as stranded versus non-stranded configuration of sources.

The list of separately payable sources is found in Addendum B of the most recent OPSS annual update published in the Federal Register, as well as in the recurring update notifications of the current year for billing purposes. (See Addendum B at <http://www.cms.hhs.gov/HospitalOutpatientPPS/> on the CMS website) New sources meeting the OPSS definition of a brachytherapy source may be added for payment beginning any quarter, and the new source codes and descriptors are announced in the recurring update notifications.

Each unit of a billable source is identified by the unit measurement in the respective source's long descriptor. Seed-like sources are generally billed and paid "per source" based on the number of units of the source HCPCS code reported, including the billing of the number of sources within a stranded configuration of sources. Providers therefore must bill the number of units of a source used with the brachytherapy service rendered.

Brachytherapy sources eligible for separate billing and payment must be radioactive sources, meaning that the source contains a radioactive isotope. Separate brachytherapy source payments reflect the number, isotope, and radioactive intensity of sources furnished to patients, as well as stranded and non-stranded configurations.

A hospital may report and charge Medicare and the Medicare beneficiary for all brachytherapy sources that are ordered by the physician for a specific patient, acquired by the hospital, and used in the care of the patient. Specifically, brachytherapy sources prescribed by the physician in accordance with high quality clinical care, acquired by the hospital, and actually implanted in the patient may be reported and charged. In the case where most, but not all, prescribed sources are implanted in the patient, CMS will consider the

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relatively few brachytherapy sources that were ordered but not implanted due to specific clinical considerations to be used in the care of the patient and billable to Medicare under the following circumstances. The hospital may charge for all sources if they were specifically acquired by the hospital for the particular patient according to a physician's prescription for the sources that was consistent with standard clinical practice and high quality brachytherapy treatment, in order to ensure that the clinically appropriate number of sources was available for the implantation procedure, and they were not implanted in any other patient. Those sources that were not implanted must have been disposed of in accordance with all appropriate requirements for their handling. In general, the number of sources used in the care of the patient but not implanted would not be expected to constitute more than a small fraction of the sources actually implanted in the patient. Under these circumstances, the beneficiary is liable for the copayment for all the sources billed to Medicare.

Providers should report charges related to supervision, handling, and loading of radiation sources, including brachytherapy sources, in one of two ways:

- Report the charge separately using CPT code 77790 (Supervision, handling, loading of radiation source), in addition to reporting the associated HCPCS procedure code(s) for application of the radiation source; or
- Include the supervision, handling, and/or loading charges as part of the charge reported with the HCPCS procedure code(s) for application of the radiation source.

Do not bill a separate charge for brachytherapy source storage costs. These costs are treated as part of the department's overhead costs.

Chapter 4, Section 200.4 Billing for Amniotic Membrane

This section was added to show that hospitals should report HCPCS code V2790 (Amniotic membrane for surgical reconstruction, per procedure) to report amniotic membrane tissue when the tissue is used. A specific procedure code associated with use of amniotic membrane tissue is CPT code 65780 (Ocular surface reconstruction; amniotic membrane transplantation). Payment for the amniotic membrane tissue is packaged into payment for CPT code 65780 or other procedures with which the amniotic membrane is used.

Chapter 4, Section 200.5 – Billing and Payment for Cardiac Rehabilitation Services

This section was added to reflect the National Coverage Determination for cardiac rehabilitation programs, which requires that programs must be comprehensive and to be comprehensive they must include a medical evaluation, a program to modify cardiac risk factors (e.g., nutritional counseling), prescribed exercise, education, and counseling. See the National Coverage Determination (NCD) Manual, Section 20.10, for more information. (This manual is available at <http://www.cms.gov/Manuals/IOM/list.asp> on the CMS website.) A cardiac rehabilitation session may include more than one aspect of the comprehensive program. For CY 2008, hospitals will continue to use CPT code 93797 (Physician services for outpatient cardiac rehabilitation, without continuous ECG monitoring (per session)) and CPT code 93798 (Physician services for outpatient cardiac rehabilitation, with continuous ECG monitoring

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(per session)) to report cardiac rehabilitation services. However, effective for dates of service on or after January 1, 2008, hospitals may report more than one unit of HCPCS code 93797 or 97398 for a date of service if more than one cardiac rehabilitation session lasting at least 1 hour each is provided on the same day. In order to report more than one session for a given date of service, each session must last a minimum of 60 minutes. For example, if the cardiac rehabilitation services provided on a given day total 1 hour and 50 minutes, then only one session should be billed to report the cardiac rehabilitation services provided on that day.

Chapter 4, Section 200.6 - Billing and Payment for Alcohol and/or Substance Abuse Assessment and Intervention Services

For CY 2008, the CPT Editorial Panel has created two new Category I CPT codes for reporting alcohol and/or substance abuse screening and intervention services. They are CPT code 99408 (Alcohol and/or substance (other than tobacco) abuse structured screening (e.g., AUDIT, DAST), and brief intervention (SBI) services; 15 to 30 minutes); and CPT code 99409 (Alcohol and/or substance (other than tobacco) abuse structured screening (e.g., AUDIT, DAST), and brief intervention (SBI) services; greater than 30 minutes). However, screening services are not covered by Medicare without specific statutory authority, such as has been provided for mammography, diabetes, and colorectal cancer screening. Therefore, beginning January 1, 2008, the OPSS recognizes two parallel G-codes (HCPCS codes G0396 and G0397) to allow for appropriate reporting and payment of alcohol and substance abuse structured assessment and intervention services that are not provided as screening services, but that are performed in the context of the diagnosis or treatment of illness or injury.

Contractors shall make payment under the OPSS for HCPCS code G0396 (Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., AUDIT, DAST) and brief intervention, 15 to 30 minutes) and HCPCS code G0397, (Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., AUDIT, DAST) and intervention greater than 30 minutes), only when reasonable and necessary (i.e., when the service is provided to evaluate patients with signs/symptoms of illness or injury) as per section 1862(a)(1)(A) of the Act.

HCPCS codes G0396 and G0397 are to be used for structured alcohol and/or substance (other than tobacco) abuse assessment and intervention services that are distinct from other clinic and emergency department visit services performed during the same encounter. Hospital resources expended performing services described by HCPCS codes G0396 and G0397 may not be counted as resources for determining the level of a visit service and vice versa (i.e., hospitals may not double count the same facility resources in order to reach a higher level clinic or emergency department visit). However, alcohol and/or substance structured assessment or intervention services lasting less than 15 minutes should not be reported using these HCPCS codes, but the hospital resources expended should be included in determining the level of the visit service reported.

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Chapter 4, Section 200.7.1 Cardiac Echocardiography Without Contrast

This section instructs hospitals to bill for echocardiograms without contrast in accordance with the CPT code descriptors and guidelines associated with the applicable Level I CPT code(s) (93303-93350).

Chapter 4, Section 200.7.2 Cardiac Echocardiography With Contrast

This section instructs hospitals to bill for echocardiograms with contrast using the applicable HCPCS code(s) included in Table 200.7.2 below. Hospitals should also report the appropriate units of the HCPCS codes for the contrast agents used in the performance of the echocardiograms.

Table 200.7.2 – HCPCS Codes For Echocardiograms With Contrast

HCPCS	Long Descriptor
C8921	Transthoracic echocardiography with contrast for congenital cardiac anomalies; complete
C8922	Transthoracic echocardiography with contrast for congenital cardiac anomalies; follow-up or limited study
C8923	Transthoracic echocardiography with contrast, real-time with image documentation (2D) with or without M-mode recording; complete
C8924	Transthoracic echocardiography with contrast, real-time with image documentation (2D) with or without M-mode recording; follow-up or limited study
C8925	Transesophageal echocardiography (TEE) with contrast, real time with image documentation (2D) (with or without M-mode recording); including probe placement, image acquisition, interpretation and report
C8926	Transesophageal echocardiography (TEE) with contrast for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report
C8927	Transesophageal echocardiography (TEE) with contrast for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis
C8928	Transthoracic echocardiography with contrast, real-time with image documentation (2D), with or without M-mode recording, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report

Chapter 4, Section 200.8 – Billing for Nuclear Medicine Procedures

Effective January 1, 2008, the I/OCE will begin editing for the presence of a diagnostic radiopharmaceutical HCPCS code when a separately payable nuclear medicine procedure is present on a claim. Hospitals

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should begin including diagnostic radiopharmaceutical HCPCS codes on the same claim as a nuclear medicine procedure beginning on January 1, 2008. Hospitals are also instructed to submit the claim so that the services on the claim each reflect the date the particular service was provided. Therefore, if the nuclear medicine procedure is provided on a different date of service from the diagnostic radiopharmaceutical, the claim will contain more than one date of service. More information regarding these edits is available at <http://www.cms.hhs.gov/HospitalOutpatientPPS/> on the CMS website.

Chapter 4, Section 290, subsections dealing with Observation Services

These sections have been revised to add clarifications and updates related to the reporting hours of observation and billing and payment for observation. Note that general standing orders for observation services following all outpatient surgery are not recognized. Hospitals should not report as observation care, services that are part of another Part B service, such as postoperative monitoring during a standard recovery period (e.g., 4-6 hours), which should be billed as recovery room services. Similarly, in the case of patients who undergo diagnostic testing in a hospital outpatient department, routine preparation services furnished prior to the testing and recovery afterwards are included in the payments for those diagnostic services. Observation services should not be billed concurrently with diagnostic or therapeutic services for which active monitoring is a part of the procedure (e.g., colonoscopy, chemotherapy). In situations where such a procedure interrupts observation services, hospitals would record for each period of observation services the beginning and ending times during the hospital outpatient encounter and add the length of time for the periods of observation services together to reach the total number of units reported on the claim for the hourly observation services HCPCS code G0378 (Hospital observation service, per hour). Observation time ends when all medically necessary services related to observation care are completed. For example, this could be before discharge when the need for observation has ended, but other medically necessary services not meeting the definition of observation care are provided (in which case, the additional medically necessary services would be billed separately or included as part of the emergency department or clinic visit). Alternatively, the end time of observation services may coincide with the time the patient is actually discharged from the hospital or admitted as an inpatient. Observation time may include medically necessary services and follow-up care provided after the time that the physician writes the discharge order, but before the patient is discharged. However, reported observation time would not include the time patients remain in the observation area after treatment is finished for reasons such as waiting for transportation home.

If a period of observation spans more than 1 calendar day, all of the hours for the entire period of observation must be included on a single line and the date of service for that line is the date that observation care begins.

Also, observation services are reported using HCPCS code G0378 (Hospital observation service, per hour). Beginning January 1, 2008, HCPCS code G0378 for hourly observation services is assigned status indicator N, signifying that its payment is always packaged. No separate payment is made for observation services reported with HCPCS code G0378, and APC 0339 is deleted as of January 1, 2008. In most circumstances, observation services are supportive and ancillary to the other services provided to a patient. In certain circumstances when observation care is billed in conjunction with a high level clinic visit (Level 5), high level emergency department visit (Level 4 or 5), critical care services, or direct admission as

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an integral part of a patient's extended encounter of care, payment may be made for the entire extended care encounter through one of two composite APCs when certain criteria are met. For information about payment for extended assessment and management composite APCs, see Chapter 4, Section 10.2.1 (Composite APCs) of the Medicare Claims Processing Manual.

APC 8002 (Level I Extended Assessment and Management Composite) describes an encounter for care provided to a patient that includes a high level (Level 5) clinic visit or direct admission to observation in conjunction with observation services of substantial duration (8 or more hours). APC 8003 (Level II Extended Assessment and Management Composite) describes an encounter for care provided to a patient that includes a high level (Level 4 or 5) emergency department visit or critical care services in conjunction with observation services of substantial duration. There is no limitation on diagnosis for payment of these composite APCs; however, composite APC payment will not be made when observation services are reported in association with a surgical procedure (T status procedure) or the hours of observation care reported are less than 8. The Integrated Outpatient Code Editor (I/OCE) evaluates every claim received to determine if payment through a composite APC is appropriate. If payment through a composite APC is inappropriate, the I/OCE, in conjunction with the Pricer, determines the appropriate status indicator, APC, and payment for every code on a claim.

All of the following requirements must be met in order for a hospital to receive an APC payment for an extended assessment and management composite APC:

1. Observation Time

- a. Observation time must be documented in the medical record.
- b. A beneficiary's time in observation (and hospital billing) begins with the beneficiary's admission to an observation bed.
- c. A beneficiary's time in observation (and hospital billing) ends when all clinical or medical interventions have been completed, including follow-up care furnished by hospital staff and physicians that may take place after a physician has ordered the patient be released or admitted as an inpatient.
- d. The number of units reported with HCPCS code G0378 must equal or exceed 8 hours.

2. Additional Hospital Services

- a. The claim for observation services must include one of the following services in addition to the reported observation services. The additional services listed below must have a line item date of service on the same day or the day before the date reported for observation:
 - An emergency department visit (CPT code 99284 or 99285) or
 - A clinic visit (CPT code 99205 or 99215); or
 - Critical care (CPT code 99291); or
 - Direct admission to observation reported with HCPCS code G0379 (APC 0604) must be reported on the same date of service as the date reported for observation services.

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- b. No procedure with a T status indicator can be reported on the same day or day before observation care is provided.

3. Physician Evaluation

- a. The beneficiary must be in the care of a physician during the period of observation, as documented in the medical record by admission, discharge, and other appropriate progress notes that are timed, written, and signed by the physician.
- b. The medical record must include documentation that the physician explicitly assessed patient risk to determine that the beneficiary would benefit from observation care.

Criteria 1 and 3 related to observation care beginning and ending time and physician evaluation apply regardless of whether the hospital believes that observation services will be packaged or will meet the criteria for extended assessment and management composite payment.

Only observation services that are billed on a 13X bill type may be considered for a composite APC payment.

Non-repetitive services provided on the same day as either direct admission to observation care or observation services must be reported on the same claim because the OCE claim-by-claim logic cannot function properly unless all services related to the episode of observation care, including hospital clinic visits, emergency department visits, critical care services, and T status procedures, are reported on the same claim. Additional guidance can be found in CR4047, Transmittal 763, issued on November 25, 2005. The MLN Matters article related to that CR is available at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM4047.pdf> on the CMS website.

If a claim for services providing during an extended assessment and management encounter including observation care does not meet all of the requirements listed above, then the usual APC logic will apply to separately payable items and services on the claim; the special logic for direct admission will apply, and payment for the observation care will be packaged into payments for other separately payable services provided to the beneficiary in the same encounter.

Direct admission to observation care continues to be reported using HCPCS code G0379 (Direct admission of patient for hospital observation care). Hospitals should report G0379 when observation services are the result of a direct admission to observation care without an associated emergency room visit, hospital outpatient clinic visit, or critical care service on the day of initiation of observation services. Hospitals should only report HCPCS code G0379 when a patient is admitted directly to observation care after being seen by a physician in the community.

Payment for direct admission to observation will be made either separately as a low level hospital clinic visit under APC 0604 or packaged into payment for composite APC 8002 (Level I Prolonged Assessment and Management Composite) or packaged into the payment for other separately payable services provided in the same encounter. The criteria for payment of HCPCS code G0379 under either APC 0604 or APC 8002 include:

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- Both HCPCS codes G0378 (Hospital observation services, per hr) and G0379 (Direct admission of patient for hospital observation care) are reported with the same date of service; and.
- No service with a status indicator of T or V or Critical Care (APC 0617) is provided on the same day of service as HCPCS code G0379.

If either of the above criteria is not met, HCPCS code G0379 will be assigned status indicator N and will be packaged into payment for other separately payable services provided in the same encounter.

Only direct admission to observation services billed on a 13X bill type may be considered for a composite APC payment.

When services are not covered as observation services, hospitals must not bill beneficiaries directly for reasonable and necessary observation services for which the OPSS packages payment for observation as part of the payment for the separately payable items and services on the claim. Hospitals should not confuse packaged payment with non-coverage or nonpayment. See the Medicare Benefit Policy Manual, Chapter 6, Section 20.6 for further explanation of non-covered services and notification of the beneficiary in relation to observation care. That manual is available at <http://www.cms.hhs.gov/Manuals/IOM/list.asp> on the CMS website.

Chapter 16, Section 40.3 - Hospital Billing Under Part B

This section was updated to include information related to billing certain Part B services. Specifically, if a hospital bills claims for both *hospital outpatient and non-patient* laboratory tests *on different dates of service*, it should prepare two bills: one for the outpatient (13X type of bill) laboratory test *and* the other for the non-patient laboratory specimen (14X type of bill) tests. The hospital includes laboratory tests *provided to hospital outpatients* on the same bill with other *hospital outpatient* services to the same beneficiary, unless it is billing for non-patient laboratory specimen tests *provided on a different day from the other hospital outpatient services*, in which case it submits a separate bill for the non-patient laboratory specimen tests.

For all hospitals except CAHs and Maryland waiver hospitals, if a patient receives hospital outpatient services on the same day as a specimen collection and laboratory test, then the patient is considered to be a registered hospital outpatient and cannot be considered to be a non-patient on that day for purposes of the specimen collection and laboratory test. However if the non-CAH or Maryland waiver hospital only collects or draws a specimen from the beneficiary and the beneficiary does not also receive hospital outpatient services on that day, the hospital may choose to register the beneficiary as an outpatient for the specimen collection or bill for these services as non-patient on the 14x bill type.

For CAHs, payment for clinical diagnostic laboratory tests is made at 101 percent of reasonable cost only if the individuals are outpatients of the CAH (85X type of bill), as defined in 42 CFR 410.2, and are physically present in the CAH at the time the specimens are collected. Clinical diagnostic laboratory tests performed for persons who are not physically present at the CAH (non-patients 14X type of bill) when the specimens are collected are made in accordance with the provisions of sections 1833(a)(1)(D) and 1833(a)(2)(D) of the Social Security Act. See also 42 CFR 413.70(b)(iii). Similarly, for Maryland waiver hospitals, the waiver is limited to services to inpatients and registered outpatients as defined in 42 CFR 410.2. Therefore

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payment for non-patients (specimen only, TOB 14X) who are not registered outpatients at the time of specimen collection will be made on the clinical diagnostic laboratory fee schedule.

Chapter 17, Section, 90.2 - Drugs, Biologicals, and Radiopharmaceuticals

This chapter was revised to include the following:

A. General Billing and Coding for Hospital Outpatient Drugs, Biologicals, and Radiopharmaceuticals

Hospitals should report charges for all drugs, biologicals, and radiopharmaceuticals, regardless of whether the items are paid separately or packaged, using the correct HCPCS codes for the items used. It is also of great importance that hospitals billing for these products make certain that the reported units of service of the reported HCPCS code are consistent with the quantity of a drug, biological, or radiopharmaceutical that was used in the care of the patient.

Payment for drugs, biologicals, and radiopharmaceuticals under the OPSS is inclusive of both the acquisition cost and the associated pharmacy overhead or nuclear medicine handling cost. Hospitals should include these costs in their line-item charges for drugs, biologicals, and radiopharmaceuticals.

Under the OPSS, if commercially available products are being mixed together to facilitate their concurrent administration, the hospital should report the quantity of each product (reported by HCPCS code) used in the care of the patient. Alternatively, if the hospital is compounding drugs that are not a mixture of commercially available products, but are a different product that has no applicable HCPCS code, then the hospital should report an appropriate unlisted drug code (J9999 or J3490). In these situations, it is not appropriate to bill HCPCS code C9399. HCPCS code C9399, Unclassified drug or biological, is for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which a specific HCPCS code has not been assigned.

The HCPCS code list of retired codes and new HCPCS codes reported under the hospital OPSS is published quarterly via CRs that are known as Recurring Update Notifications. The latest payment rates associated with each APC and HCPCS code may be found in the most current Addendum A and Addendum B, respectively, which can be found under the CMS quarterly provider updates on the CMS Web site at: <http://www.cms.hhs.gov/HospitalOutpatientPPS/AU/list.asp>

B. Pass-Through Drugs, Biologicals, and Radiopharmaceuticals

Payment for drugs, biologicals, and radiopharmaceuticals may be made under the pass-through provision which provides additional payments for drugs, biologicals, and radiopharmaceuticals that meet certain requirements relating to newness and relative costs. According to section 1833(t) of the Social Security Act, transitional pass-through payments can be made for at least 2 years, but no more than 3 years. For the process and information required to apply for transitional pass-through payment status for drugs, biologicals, and radiopharmaceuticals, go to the main OPSS Web page, currently at <http://www.cms.hhs.gov/HospitalOutpatientPPS/> on the CMS website to see the latest instructions.

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Payment rates for pass-through drugs, biologicals, and radiopharmaceuticals are updated quarterly. The all-inclusive list of billable drugs, biologicals, and radiopharmaceuticals for pass-through payment is included in the current quarterly Addendum B. The most current Addendum B can be found under the CMS quarterly provider updates at <http://www.cms.hhs.gov/HospitalOutpatientPPS/AU/list.asp> on the CMS website.

C. Non Pass-Through Drugs and Biologicals

Under the OPSS, drugs and biologicals that are not granted pass-through status receive either packaged payment or separate payment. Payment for drugs and biologicals with estimated per day costs equal to or below the applicable drug packaging threshold is packaged into the payment for the associated procedure, commonly a drug administration procedure. Drugs and biologicals with per day costs above the applicable drug packaging threshold are paid separately through their own APCs.

D. Radiopharmaceuticals

1. General

Beginning in CY 2008, the OPSS divides radiopharmaceuticals into two groups for payment purposes: diagnostic and therapeutic. Diagnostic radiopharmaceuticals function effectively as products that enable the provision of an independent service, specifically, a diagnostic nuclear medicine scan. Therapeutic radiopharmaceuticals are themselves the primary therapeutic modality.

2. Diagnostic Radiopharmaceuticals

Beginning in CY 2008, payment for non pass-through diagnostic radiopharmaceuticals is packaged into the payment for the associated nuclear medicine procedure.

Beginning January 1, 2008, the I/OCE will begin requiring claims with separately payable nuclear medicine procedures to include a diagnostic radiopharmaceutical. Hospitals are required to submit the diagnostic radiopharmaceutical on the same claim as the nuclear medicine procedure. Hospitals are also instructed to submit the claim so that the services on the claim each reflect the date the particular service was provided. Therefore, if the nuclear medicine procedure is provided on a different date of service from the diagnostic radiopharmaceutical, the claim will contain more than one date of service. More information regarding these edits is available at <http://www.cms.hhs.gov/HospitalOutpatientPPS/> on the CMS website.

3. Therapeutic Radiopharmaceuticals

The OPSS will continue to pay for non pass-through therapeutic radiopharmaceuticals at charges adjusted to cost From January 1, 2008 through June 30, 2008. Beginning July 1, 2008, payment for separately payable therapeutic radiopharmaceuticals under the OPSS will be made on a

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prospective basis with payment rates based upon mean costs from hospital claims data, unless otherwise required by law.

Medicare Benefit Policy Updates

The key new/revised sections of the **Medicare Benefit Policy Manual** that are conveyed by in CR5946 are intended to clarify existing policy regarding the OPPTS. Basically, these clarifications are in the following areas:

- Chapter 6 (Hospital Services Covered under Part B), Section 20 (Outpatient Hospitals Services). The subsections that are new or revised include discussions on:
 - Limitations of coverage of certain services to hospital outpatients and an exception to the limitation;
 - Definitions of outpatient, encounter, and diagnostic services;
 - Outpatient diagnostic services;
 - Outpatient Therapeutic Services; and Outpatient observation services.
- Chapter 6, Section 70.5, which clarifies policy regarding laboratory services furnished to non-hospital patients by the hospital laboratory.

The actual revisions to this manual are available as an attachment to the CR5946, Transmittal R82BP, which is at <http://www.cms.hhs.gov/Transmittals/downloads/R82BP.pdf> on the CMS website

Additional Information

The official instruction, 5946, issued to your FI, RHHI, and A/B MAC regarding this change may be viewed by looking at two transmittals. The first transmittal has the changes to the Medicare Claims Processing Manual and is at <http://www.cms.hhs.gov/Transmittals/downloads/R1445CP.pdf> on the CMS website. The second transmittal contains the changes to the Medicare Benefit Policy Manual and it is at <http://www.cms.hhs.gov/Transmittals/downloads/R82BP.pdf> on the same site

If you have any questions, please contact your FI, RHHI, or A/B MAC at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

News Flash - It's Not Too Late to Give and Get the Flu Shot! In the U.S., the peak of flu season typically occurs anywhere from late December through March; however, flu season can last as late as May. Each office visit presents an opportunity for you to talk with your patients about the importance of getting an annual flu shot and a one time pneumococcal vaccination. Protect yourself, your patients, and your family and friends by getting and giving the flu shot. **Don't Get the Flu. Don't Give the Flu. Get Vaccinated!** Remember - Influenza and pneumococcal vaccinations and their administration are covered Part B benefits. Note that influenza and pneumococcal vaccines are NOT Part D covered drugs. You and your staff can learn more about Medicare's coverage of adult immunizations and related provider education resources, by reviewing Special Edition MLN Matters article SE0748 at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0748.pdf> on the CMS website.

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