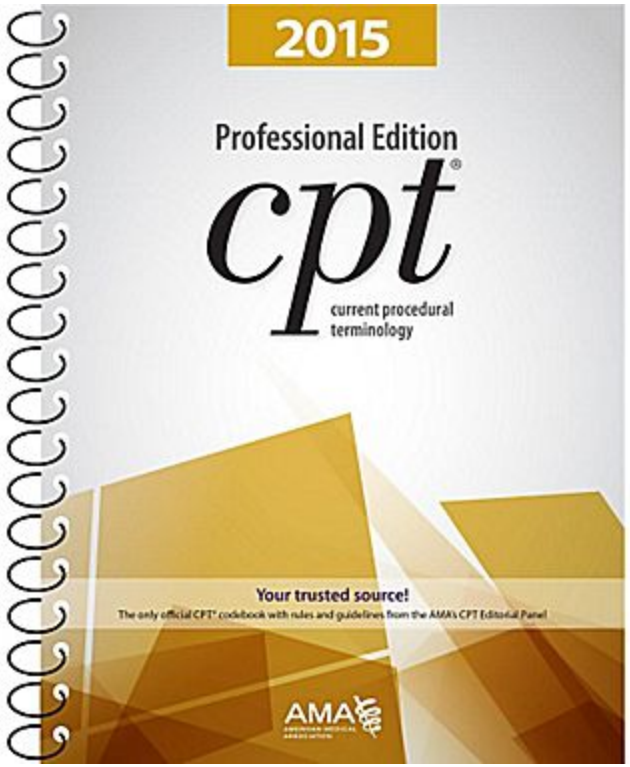
Office of Billing Compliance 2015 Coding, Billing and Documentation Program

Diagnostic Radiology

Radiology Helpful Hints

- Always document the numbers of views personally reviewed!
  - Don't assume because the technical services included 3 views that your professional billing does not need to specifically mention the # of views
- Always include ALL organs reviewed so services are not downcoded on an audit
- Always ensure an order is received for all services performed and billed. If there is a "protocol" to perform certain services together, there still must be an order for that patient.
  - If no order on an audit, it is the radiology who has the financial payback liability not the sending physician.
- ALWAYS DOCUMENT CONTRAST; BOTH WITH AND W/O!
- Common coding issues and new codes on the following slides

2015 Code Changes



Breast Ultrasound Imaging

The current breast ultrasound code (76645) has been deleted, and two new codes (76641-76642) have been created, one each for complete and limited exams.

- Procedure code 76641 represents a complete examination of all four quadrants of the breast and the retroareolar region.
- The limited code, 76642, is for a focused exam of the breast that is limited to one or more of the elements included in 76641.
  - There is a new note in the CPT® Manual that directs the assignment of the limited extremity code 76882 if only the axilla is evaluated using ultrasound.
- Both code definitions also include an examination of the axilla, if performed.
- **76641** Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete
- **76642** Ultrasound, breast, ; limited
- **Deleted 76645** Ultrasound, breast(s) (unilateral or bilateral), real time with image documentation

As with all ultrasound examinations, there must be a thorough evaluation of the anatomic area, image documentation, and a final written report to ensure that it is separately reportable. However, this is generally not an area of concern for radiology practices and/or departments.

Digital Breast Tomosynthesis (DBT)

- Additionally, three new codes have been created for digital breast tomosynthesis (DBT) to address both screening and diagnostic studies.
- The screening DBT code +77063 is an add-on code that will be reported together with the screening mammogram code 77057.

  - **77061** Digital breast tomosynthesis; unilateral
  - **77062** Digital breast tomosynthesis; bilateral
  - **77063** Screening digital breast tomosynthesis, bilateral
    - (List separately in addition to code for primary procedure 77057 Screening mammography, bilateral (2-view film study of each breast))

Digital Breast Tomosynthesis (DBT)

- CMS announced that the codes for diagnostic tomosynthesis (77061 and 77062) will not be valid for Medicare billing.
- Instead, providers must report DBT to Medicare using a new HCPCS code, +G0279 [Diagnostic digital breast tomosynthesis, unilateral or bilateral (List separately in addition to G0204 or G0206)].
  - G0204 Diagnostic mammography, producing direct 2D digital image, bilateral, all views
  - G0206 Diagnostic mammography, producing direct 2D digital image, unilateral, all views
- Note that unlike 77061 and 77062, G0279 is an add-on code, meaning that it cannot be reported as a stand-alone service.
- For those payors that do accept codes 77061 and 77062, these codes may not be reported with the regular screening mammography code 77057. This may create some challenges when appropriately reporting screening and diagnostic studies on the same date of service. It is important to note that while new procedure codes have been created for this technology, there is no guarantee that all payers will provide separate payment.

New DXA Codes

- **77085** Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine), including vertebral fracture assessment.

- **77086** Vertebral fracture assessment via dual energy X-ray absorptiometry (DXA)

- 77085 represents vertebral fracture assessment done as part of a bone density study and 77086 is for vertebral fracture assessment alone.

General Principals of Documentation

- **All documentation must be legible to all readers**. Illegible documents are considered not medically necessary if it is useless to provide a continuum of care to a patient by all providers. Documentation is for the all individuals not just the author of the note.
- Per the Centers for Medicare and Medicaid services (CMS) practitioners are expected to complete the documentation of services "during or as soon as practicable after it is provided in order to maintain an accurate medical record."
  - CMS does not provide any specific period, but a reasonable expectation would be no more than a couple of days away from the date of service.
  - Until the practitioner completes the documentation for a service, **including signature**, the practitioner cannot submit the service to Medicare. Medicare states if the service was not documented, then it was not done, and this includes a signature.
- An addendum to a note should be dated and timed the day the information is **added** to the medical record and only contain information the practitioner has direct knowledge is true and accurate.

Teaching Physicians (TP) Guidelines

Billing Services When Working With Residents Fellows and **Interns**

All Types of Services Involving a resident with a TP Requires Appropriate Attestations In EHR or Paper Charts To Bill

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Diagnostic Procedures

- **RADIOLOGY AND OTHER DIAGNOSTIC TESTS**
- **General Rule:** The Teaching Physician may bill for the interpretation of diagnostic Radiology and other diagnostic tests if the interpretation is performed or reviewed by the Teaching Physician with modifier 26 in the hospital setting.

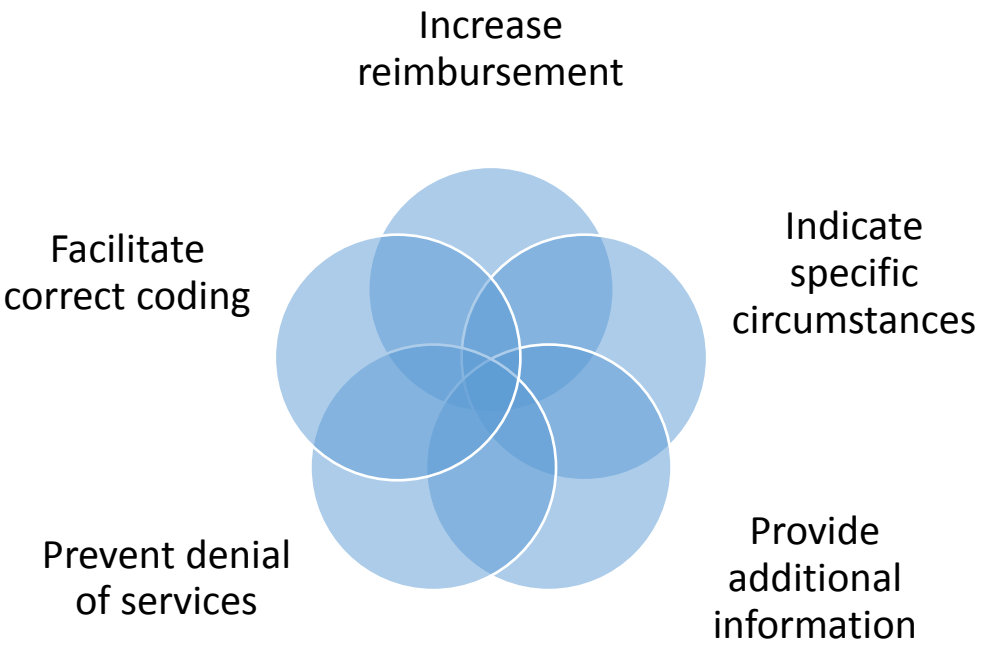
- **Teaching Physician Documentation Requirements:**
- Teaching Physician prepares and documents the interpretation report.
- OR
- Resident prepares and documents the interpretation report
- The Teaching Physician must document/dictate: "I personally reviewed the film/recording/specimen/images and the resident's findings and agree with the final report".

- **A countersignature by the Teaching Physician to the resident's interpretation is not sufficient documentation.**

Modifiers: Provider Documentation MUST Support the Use of All Modifiers

A billing code **modifier** allows you to indicate that a procedure or service has been altered by some specific circumstance but has not changed in its definition.

Modifiers allow to:



Modifier GC

CMS Manual Part 3 - Claims Process - Transmittal 1723

- Teaching Physician Services That Meet the Requirement for Presence During the Key Portion of the Service when working with a resident or fellow

- Teaching Physician Services that are billed using this modifier are certifying that they have been present during the key portion of the service.

Repeat Procedures

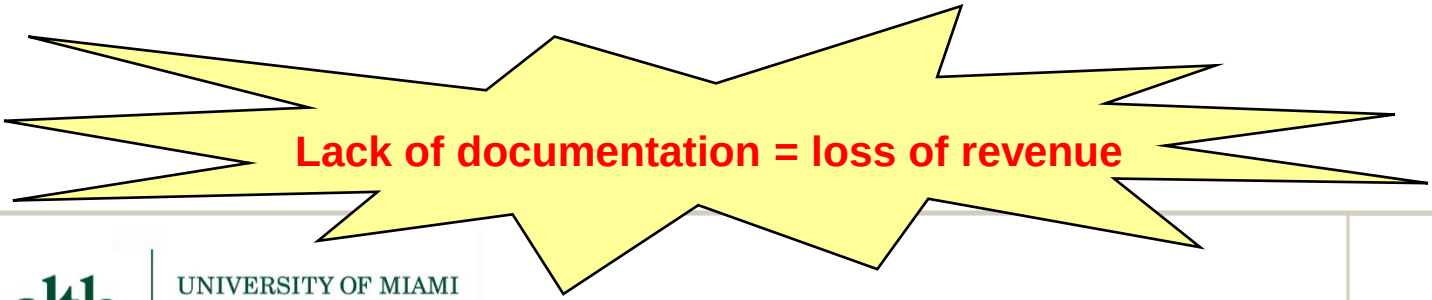
- In cases when the same or mutually exclusive procedure was performed multiple times on the same day
  - Document TIME of each procedure
  - Document separate paragraphs describing each procedure
- Appropriate documentation:
  - Allows to avoid denials upon a review
  - Supports the charges
  - Accurately reflects rendered services
- Append appropriate modifier to the “second charge” for the day:
  - Modifier – 76 “Repeat Procedure by the Same Physician”
  - Modifier – 77 “Repeat procedure by Another Physician”

Example:

- **7 AM – Chest X-Ray 2 views CPT 71020**
- **3 PM – Chest X-Ray 2 views CPT 71020 – 76 or CPT 71020 – 77**

Documentation Tips for Multiple Procedures

- List all of the radiological tests reviewed/performed
  - Indicate pertinent history of present illness
  - Specify anatomical site(s)
  - Include number of views if applicable
  - Indicate if contrast has been used
- Assure that test-specific interpretation is documented within the body of the report for all reviewed tests
- E.g. : Chest CT scan w/o contrast and Abdominal CT with and w/o contrast



Modifier 59: Distinct Procedural Service

- Designates instances when *distinct* and *separate multiple services* are provided to a patient on a single date of service and should be paid separately.
- Modifier-59 is defined for use in a wide variety of circumstances to identify:
  - Different encounters Different anatomic sites (Different services (Most commonly used and frequently incorrect).
- **4 new modifiers to define subsets of Modifier-59**:
  - **XE - Separate Encounter**, a service that is distinct because it occurred during a separate encounter. Used infrequently and usually correct.
  - **XS - Separate Structure,** a service that is distinct because it was performed on a separate organ/structure. Less commonly used and can be problematic.
    - Biopsy on one lesion and excision on another. Biopsy is "bundled" into excision, therefore must properly bill biopsy CPT with a 59 modifier to indicate separate structure.
  - **XP – Separate Practitioner**, a service that is distinct because it was performed by a different practitioner.
  - **XU – Unusual non-overlapping service**, the use of a service that is distinct because it does not overlap usual components of the main service.

Only a practitioner or coder should designate a modifier 59 to a claim (not a biller) based exclusively on the procedure note details – not OP report headers.

99144 Moderate Sedation

- Provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; age 5 years or older, first 30 minutes intra-service time.
- Moderate sedation is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. It does not include minimal sedation, deep sedation or monitored anesthesia care.
- If the physician performing the procedure also provides moderate sedation for the procedure, payment may be made for conscious sedation consistent with CPT guidelines; however, if the physician performing the procedure provides local or minimal sedation for the procedure, no separate payment is made.

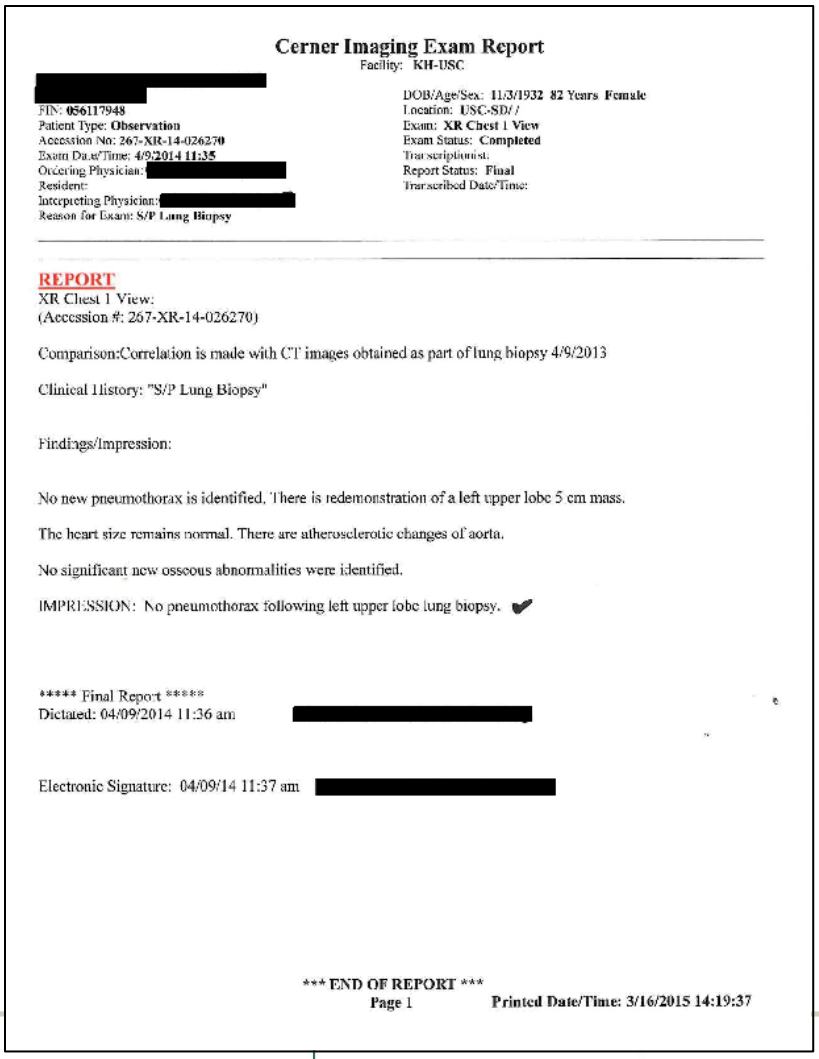
99144 Moderate Sedation

- **DEFINING START AND STOP TIME**
  - "Intra-service time starts with the administration of the sedation agent(s), requires continuous face-to-face attendance, and ends at the conclusion of personal contact by the physician providing the sedation." (Per CPT)
    - Thus, anesthesia services and time are considered completed when the patient may be safely left under the observation of a trained anesthesia assistant, and the doctor may safely leave the room to attend to other duties.
  - Per AMA clarification, in order to bill the threshold of 16 minutes must be met (15 minutes or < is not billable.
  - The AMA in 2012—asserted that "recovery . . . is not reported separately and is not included in the intra-service time."
- All providers should document sedation for every procedure if performed.

F/U Chest X-Ray After Lung Biopsy

- A follow-up x-ray after a lung biopsy performed for the sole reason of biopsy F/U is bundled into the biopsy and not separately billable (diagnosis for biopsy and x-ray are the same.)
- A follow-up x-ray after a lung biopsy performed with a different diagnosis and additional reason than the biopsy F/U only is billable.

F/U Chest X-Ray After Lung Biopsy



Cerner Imaging Exam Report
Facility: KH-USC

[redacted]
FIN: 056117948
Patient Type: Observation
Accession No: 267-XR-14-026270
Exam Date/Time: 4/9/2014 11:35
Ordering Physician: [redacted]
Resident:
Interpreting Physician: [redacted]
Reason for Exam: S/P Lung Biopsy

DOB/Age/Sex: 11/3/1932 82 Years Female
Location: USC-SD/ /
Exam: XR Chest 1 View
Exam Status: Completed
Transcriptionist:
Report Status: Final
Transcribed Date/Time:

REPORT
XR Chest 1 View:
(Accession #: 267-XR-14-026270)

Comparison:Correlation is made with CT images obtained as part of lung biopsy 4/9/2013

Clinical History: "S/P Lung Biopsy"

Findings/Impression:

No new pneumothorax is identified. There is redemonstration of a left upper lobe 5 cm mass.

The heart size remains normal. There are atherosclerotic changes of aorta.

No significant new osseous abnormalities were identified.

IMPRESSION: No pneumothorax following left upper lobe lung biopsy.

***** Final Report *****
Dictated: 04/09/2014 11:36 am [redacted]

Electronic Signature: 04/09/14 11:37 am [redacted]

*** END OF REPORT ***
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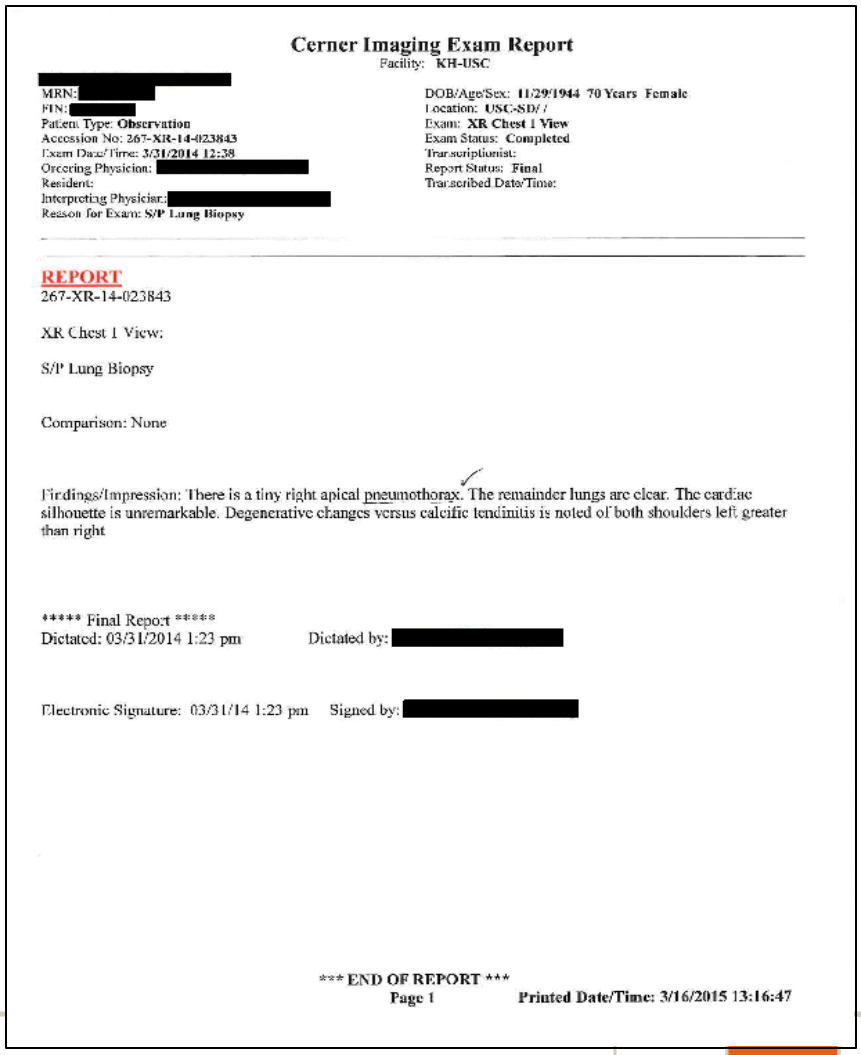

Cerner Imaging Exam Report
Facility: KH-USC

MRN: [redacted]
FIN: [redacted]
Patient Type: Observation
Accession No: 267-XR-14-023843
Exam Date/Time: 3/31/2014 12:38
Ordering Physician: [redacted]
Resident:
Interpreting Physician: [redacted]
Reason for Exam: S/P Lung Biopsy

DOB/Age/Sex: 11/29/1944 70 Years Female
Location: USC-SD/ /
Exam: XR Chest 1 View
Exam Status: Completed
Transcriptionist:
Report Status: Final
Transcribed Date/Time:

REPORT
267-XR-14-023843

XR Chest 1 View:

S/P Lung Biopsy

Comparison: None

Findings/Impression: There is a tiny right apical pneumothorax. The remainder lungs are clear. The cardiac silhouette is unremarkable. Degenerative changes versus calcific tendinitis is noted of both shoulders left greater than right

***** Final Report *****
Dictated: 03/31/2014 1:23 pm Dictated by: [redacted]

Electronic Signature: 03/31/14 1:23 pm Signed by: [redacted]

*** END OF REPORT ***
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Referring/Treating Physician and Orders

- Orders must be specific to the diagnostic test requested.
- Diagnostic tests require documentation of the name of the referring/ordering provider.
  - Absent a valid ordering provider the claim will be denied.
  - Notations such as " Chest X-ray requested by Cardiology Service" are not acceptable – must be "person" specific

Treating Practitioner to Order all Tests

- Limited exceptions:
  - Allows additional testing to be done by the radiologist prior to or without contacting the treating physician/practitioner, when the radiologist determines that based on the result of an ordered diagnostic test, an additional diagnostic test should be performed. All of the following criteria must be met:
    - The diagnostic test ordered by the treating practitioner is performed;
    - Radiologist determines and documents that, because of the abnormal result of the diagnostic test performed, an additional diagnostic test is medically necessary;
    - A delay in additional diagnostic testing would have an adverse effect on the care of the patient;
    - The result of the test is communicated to and is used by the treating practitioner in the treatment of the patient; and
    - The radiologist documents in his/her report why additional testing was done.

The Interpreting Physician May:

- Determine the test design, **unless specified in the order**.
  - The interpreting physician may determine, without notifying the treating physician/practitioner, the parameters of the diagnostic test (e.g., number of radiographic views obtained, thickness of tomographic sections acquired, use or non-use of contrast media).
  - An order for "MRI of orbit" without a specific contrast component would allow the interpreting physician to determine if contrast was medically appropriate for that specific patient without obtaining an updated order.
- Modify, without notifying the treating physician/practitioner, an order with clear and obvious errors that would be apparent to a reasonable layperson, such as the patient receiving the test (e.g., x-ray of wrong foot ordered).

Conditional Orders

- CMS has approved the use of conditional orders as long as they are limited to a specific patient.
  - Example: a patient-specific order reads: “Diagnostic mammogram of right breast with ultrasound, **as indicated**,” the radiologist may add the ultrasound to characterize the mass.
- A standing order for all patients of a given treating physician/practitioner (e.g., “if gallbladder ultrasound for Dr. Smith is negative, do UGI”) is not acceptable. The conditional order process can be replicated across diagnostic testing modalities (i.e., CT; MRI; Ultrasound; etc) with the understanding that such conditional orders MUST BE patient-specific.

Components of Diagnostic Services

- Professional Component (-26)
  - Physician's Interpretation of the test
- Appended to all codes for services rendered
- Technical Component (-TC)
  - Expense related to the cost and utilization of the equipment and technical staff.
  - Not reimbursable to physicians if place of service is inpatient or outpatient hospital setting
- Only when the equipment is owned by the Department of Radiology are entitled to reimbursement for both technical and professional component

Physician Supervision Of Diagnostic Tests

- Levels of Supervision when a technician is utilized:
  - Personal – Physician in the room
    - e.g. myelography, cisternography, dacryocystography
  - Direct – Physician in the suite (available)
    - administration of contrast media
  - General – Physician provides overall supervision
    - films

Supervision requirements apply to charges for global or technical component – It does not apply if Radiologist bills for interpretation and report only

Radiological Reports

- Elements of the report
  - Clinical Information must include
    - Referring/ordering Physician
    - Patient Demographics
    - Clinical signs or symptoms or personal history of disease
  - Body of the report should include
    - Description of the procedure including anatomical area, modality, and use of contrast.
    - Describes if and why additional testing was done.
  - Impression
    - Revises or confirms initial diagnosis
    - If findings are negative – coding is based on signs or symptoms
- All coding must be abstracted from the Body of the report and not from headers.

This becomes crucial in cases with negative or inconclusive findings!

Required Documentation - Catheter Placements

The access site

The route of the cath & the end position

Where & when injections were done

What images were taken

Any intervention performed

Medical Necessity For Procedures

- What is Medical Necessity?
  - It is a concept of justification of medical services rendered to a patient
  - services deemed “not medically necessary” – ARE NOT reimbursable
- How does Insurance Carrier know if services were Medically Necessary?
  - ICD-9-CM diagnosis codes indicate the reason for the visit

- Providers should choose only the diagnosis representing clinical conditions they are treating the patient for on a given date of service
- Use most accurate dx code

Example:

- patient with thoracic spondylosis– ICD-9 code 721.41
- patient with lumbar region spondylosis – ICD-9 code 721.42

Diagnosis Coding & Medical Necessity

- Justification of medical services rendered to a patient - Diagnosis codes indicate the reason for the encounter
  - Document the most accurate diagnosis or signs /symptoms representing clinical conditions rendering treatment / services on a given DOS to the highest specificity
  - Physician claims require diagnosis codes and are often utilized on reviews to support medical necessity thru LCDs and NCDs, especially for radiology
- If the clinical findings of the test are inconclusive or negative – code Signs or Symptoms which prompted the encounter
- Do not choose diagnoses codes – if condition is described as "probable", "possible" or "rule out"
- All requests for diagnostic testing must be documented in the reports and specify:
  - diagnosis (if confirmed) or signs or symptoms

3D Rendering with I & R

- 76376 –of CT, MRI, US, or other tomographic modality; with image postprocessing under concurrent supervision;
  - not requiring image postprocessing on an independent workstation
- 76377 –
  - ;requiring image postprocessing on an independent workstation

The codes “require concurrent physician supervision of image postprocessing 3D manipulation of volumetric data set and image rendering.”

3D Concurrent Physician Supervision

- Concurrent means active participation in and monitoring of the reconstruction process that includes:
  - design of the anatomic region that is to be reconstructed;
  - determination of the tissue types and actual structures to be displayed (e.g., bone, organs, and vessels);
  - determination of the images or cine loops that are to be archived; and
  - monitoring and adjustment of the 3D work product.
- Concurrent does not relate to the definitions for general, direct, and personal supervision established by CMS which relate to the physical location of the physician with respect to the patient and would apply to the CT acquisition base procedure code.
- ACR states that for both codes, the presence of a physician is required for supervision of image post-processing, 3-D manipulation of volumetric data set and image rendering.

Billing-Coding/Coding-Source Mar-Apr-2012/QA acr.org

Q&A

- **How does concurrent supervision apply to the radiologist that is performing the interpretation only for 3D reconstruction of images? If the 3D acquisition is the result of a computer program which generates the images, may the radiologist report the interpretation using one of the 3D codes, 76376 or 76377? How should the "concurrent supervision" be documented in the dictated report?**
  - It is not appropriate to CPT codes 76376 *or when the reconstruction of images is performed without concurrent physician supervision.*

- 76376 3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation
- 76377 ; requiring image postprocessing on an independent workstation

As stated in the Q&A published in the 11-12/06 issue of the *ACR Radiology Coding Source™* , concurrent physician supervision is required for the reporting of the three-dimensional (3D) codes 76376 and 76377.

- *It is not required to document physician involvement; however, the College recommends that it is best to document the physician's supervision or participation in the 3D reconstruction of images in case of an audit, and to from those cases where the physician is not involved.*
- Per the *AMA/ACR Clinical Examples in Radiology,* 3D codes 76376 and 76377, defines a temporal relationship to creating the 3D volume rendered images. *Concurrent* means active participation in and monitoring of the reconstruction process that includes:
  - Design of the anatomic region that is to be reconstructed;
  - Determination of the tissue types and actual structures to be displayed (eg, bone, organs, and vessels);
  - Determination of the images or cine loops that are to be archived; and
  - Monitoring and adjustment of the 3D work product.

Concurrent does not relate to the *definitions for general, direct, and personal supervision* that have been established by the CMS which relate to the physical location of the physician with respect to the patient and would apply to the computed tomography acquisition base procedure code

ICD-10

Looks like a go!

Diagnosis Coding
International Classification of Disease (ICD-10)

- ICD-10 is scheduled to replace ICD-9 coding system on October 1, 2015.
- ICD-10 was developed because ICD-9, first published in 1977, was outdated and did not allow for additional specificity required for enhanced documentation, reimbursement and quality reporting.
- ICD-10 CM will have 68,000 diagnosis codes and ICD-10 PCS will contain 76,000 procedure codes.
- This significant expansion in the number of diagnosis and procedure codes will result in major improvements including but not limited to:
  - Greater specificity including **laterality, severity of illness**
  - Significant improvement in coding for primary care encounters, external causes of injury, mental disorders, neoplasms, diabetes, injuries and preventative medicine.
  - Allow better capture of socio-economic conditions, family relationships, and lifestyle
  - Will better reflect current medical terminology and devices
  - Provide detailed descriptions of body parts
  - Provide detailed descriptions of methodology and approaches for procedures

ICD-10 Examples for Radiologists

- **ICD-9 code**: 820.8 – Fracture of neck of femur; unspecified part of neck of femur, closed
- **ICD-10 code**: S72.009A – Fracture of unspecified part of neck of unspecified femur, ***initial encounter for closed fracture***
  - For coding of fractures the "A" in the ICD-10 code is the indicator of the "episode of care" with "A" meaning it is the initial encounter for a closed fracture. With ICD-10, it will now be necessary for the radiologist to document the encounter type. The choices for fracture encounter types are:
  - A – Initial encounter for closed fracture
  - B – Initial encounter for open fracture
  - D – Subsequent encounter, fracture, with routine healing
  - G – Subsequent encounter, fracture, with delayed healing
  - J – Subsequent encounter for fracture with non-union
  - Q – Sequela (late effect)

ICD-10 Examples for Radiologists

- **ICD-9 code:** 729.5 – Pain in limb
- Best way to dictate and code "pain in limb" under ICD-10 is to report one of the 38 available ICD-10 codes (including unspecified codes) for that condition, as follows:
- M79.6 – Pain in limb, hand, foot, fingers and toes (not billable – only a title)
  - M79.60 – M79.609 – arm or leg and left or right
  - M79.62 – M79.639 – upper arm or forearm, left or right
  - M79.64 – M79.646 – hand or fingers, left or right
  - M79.65 – M79.669 – thigh or lower leg, left or right
  - M79.67 – M79.676 – foot and toes, left or right

842.00	Sprains and strains of wrist, unspecified site	S63.501A	Unspecified sprain of right wrist, initial encounter
		S63.501D	Unspecified sprain of right wrist, subsequent encounter
		S63.502A	Unspecified sprain of left wrist, initial encounter
		S63.502D	Unspecified sprain of left wrist, subsequent encounter
		S63.509A	Unspecified sprain of unspecified wrist, initial encounter
		S63.509D	Unspecified sprain of unspecified wrist, subsequent encounter
		S66.911A	Strain of unspecified muscle, fascia and tendon at right wrist and hand level, initial encounter
		S66.911D	Strain of unspecified muscle, fascia and tendon at wrist and hand level, right hand, subsequent encounter
		S66.912A	Strain of unspecified muscle, fascia and tendon at left wrist and hand level, initial encounter
		S66.912D	Strain of unspecified muscle, fascia and tendon at wrist and hand level, left hand, subsequent encounter
		S66.919A	Strain of unspecified muscle, fascia and tendon at wrist and hand level of unspecified side, initial encounter
		S66.919D	Strain of unspecified muscle, fascia and tendon at wrist and hand level, unspecified hand, subsequent encounter

Clinical Trials

Requirements for Billing Routine Costs for Clinical Trials

Effective for claims with dates of service on or after January 1, 2014 it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED.

Professional

- For professional claims, the 8-digit clinical trial number preceded by the 2 alpha characters of CT (use CT only on paper claims) must be placed in Field 19 of the paper claim Form CMS-1500 (e.g., CT12345678) or the electronic equivalent 837P in Loop 2300 REF02(REF01=P4) (**do not use CT on the electronic claim, e.g., 12345678)** when a clinical trial claim includes:
- ICD-9 code of V70.7/ICD-10 code Z00.6 (in either the primary or secondary positions) and
- **Modifier Q0** (investigational clinical service provided in a clinical research study that is in an approved clinical research study) and/or
- **Modifier Q1** (routine clinical service performed in a clinical research study that is in an approved clinical research study), as appropriate (outpatient claims only).

Hospital

- For hospital claims that are submitted on the electronic claim 837I, the 8-digit number should be placed in Loop 2300 REF02 (REF01=P4) when a clinical trial claim includes:
- Condition code 30;
- ICD-9 code of V70.7/ICD-10 code Z00.6 (in either the primary or secondary positions) and
- Modifier Q0 and/or Q1, as appropriate (outpatient claims only).

Items or services covered and paid by the sponsor may not be billed to the patient or patient's insurance, this is double billing.

WHO IS RESPONSIBLE FOR OBTAINING APPROVAL FROM THE MAC(S) FOR AN INVESTIGATIONAL DEVICE EXEMPTION (IDE) CLINICAL TRIAL?

- The principal investigator (PI) is responsible for assuring that all required approvals are obtained prior to the initiation of the clinical trial. For any clinical study involving an IDE, the PI must obtain approval for the IDE clinical trial from the Medicare Administrative Contractor (MAC) for Part A / Hospital.
- Additionally, for clinical studies involving an IDE, the PI is responsible for communicating about the trial and the IDE to the Medicare Part B (physician) MAC.
- Once approval has been received by the MAC, the following needs to take

place:

  - The Study must be entered in the Velos System within 48 hours.
  - The PI is responsible for ensuring that the IDE or the no charge device is properly set up in the facility charge master to allow accurate and compliant charging for that device before any billing will occur.

Investigational Device Exemption (IDE)

Hospital Inpatient Billing for Items and Services in Category B IDE Studies

- Payment for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved.

Routine Care Items and Services

- Hospital providers shall submit claims for the routine care items and services in Category B IDE studies approved by CMS (or its designated entity) and listed on the CMS Coverage Website, by billing according to the clinical trial billing instructions found in §69.6 of this chapter http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c32.pdf, and as described under subsection D ("General Billing Requirements").

Investigational Device Exemption (IDE)

Category B Device. On a 0624 revenue code line, **institutional providers must bill the following for Category B IDE devices for which they incur a cost:**

- Category B IDE device HCPCS code, if applicable
- Appropriate HCPCS modifier
- Category B IDE number
- **Charges for the device billed as covered charges**
- If the Category B IDE device is provided at no cost, outpatient prospective payment system (OPPS) providers must report a token charge in the covered charge field along with the applicable HCPCS modifier (i.e., modifier – FB) appended to the procedure code that reports the service to furnish the device, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing 'no cost items' under the OPPS, refer to chapter 4, §§20.6.9 and 61.3.1 of this manual.

WHEN THE TRIAL ENDS OR REACHES FULL ENROLLMENT?

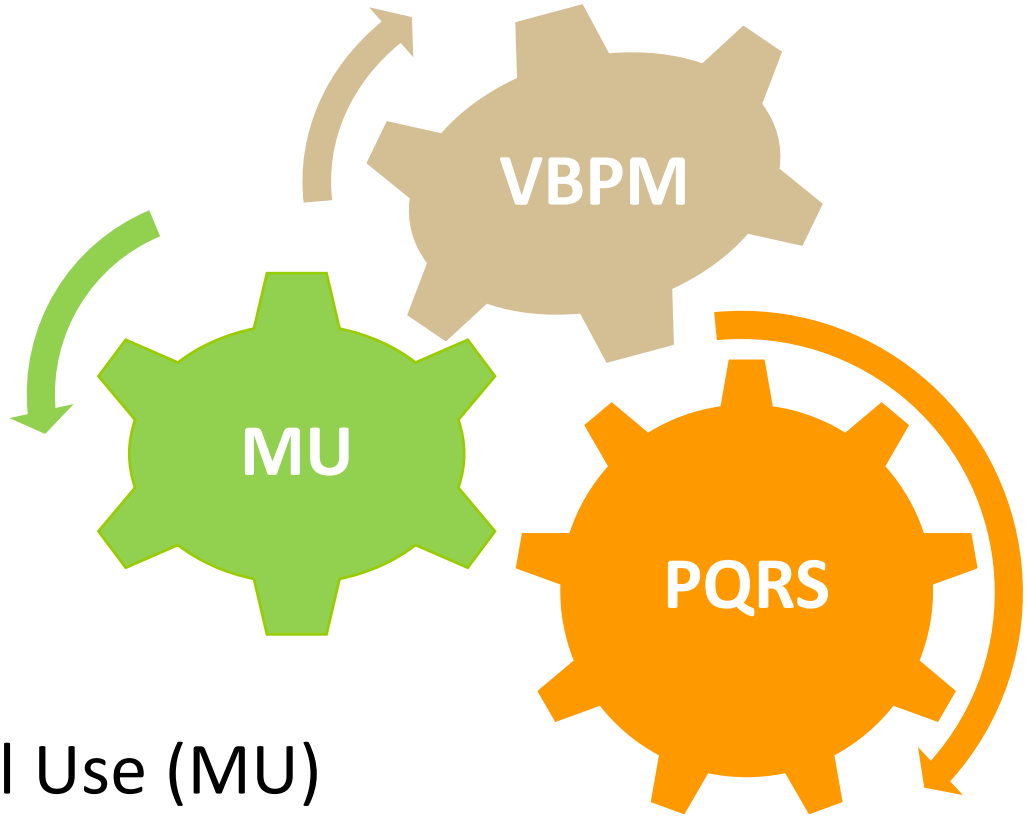
When the trial ends, whether due to reaching full enrollment or for any other reason, the PI must work with their department resource and/or the relevant Revenue Integrity Office (s) to inactivate the item in the charge master so that it may no longer be used.

If the device is approved by the FDA and is no longer considered investigational or a Humanitarian Device Exemption (HDE) and will continue to be used at UHealth, the PI must work with their department resource and/or the relevant Revenue Integrity Office (s) to inactivate the investigational device in the charge master and to ensure that a new charge code is built for the approved device. At this point, ongoing maintenance responsibility would transfer to the relevant Revenue Integrity Office (s).

UHealth/UMMG
2015 PQRS

Patient Safety and Quality Office

CMS Quality Improvement Programs



- ✓Meaningful Use (MU)
- ✓Physician Quality Reporting System (PQRS)
- ✓Value Based Payment Modifier (VBPM)

CMS Quality Programs
Medicare Part B Payment Reductions

PROGRAM	POTENTIAL MEDICARE PAYMENT REDUCTION					
	2015	2016	2017	2018	2019	2020
Meaningful Use	1%	2%	3%	4%	5%	5%
PQRS	1.5%	2%	2%	2%	2%	2%
VBPM		4%	4%	4%	4%	4%
TOTAL PENALTIES	**2.5%**	**8%**	**9%**	**10%**	**11%**	**11%**

2015 PQRS Eligible Providers

Physicians	Practitioners	Therapists
MD	Physician Assistant	Physical Therapist
DO	Nurse Practitioner	Occupational Therapist
Doctor of Podiatric	Clinical Nurse Specialist*	Qualified Speech-Language Therapist
Doctor of Optometry	CRNA	
DDS	Certified Nurse Midwife	
DMD	Clinical Social Worker	
Doctor of Chiropractic	Clinical Psychologist	
	Registered Dietician	
	Nutrition Professional	
	Audiologists	

PQRS

- Reporting Requirements:
  - ✓Reporting Period= Full CY
  - ✓Report **9** Measures from **3** National Quality Strategy Domains

- Reporting Options:
  - Claims, EHR, **Registry**
    - Individual or GPRO

NATIONAL STRATEGY DOMAINS					
Communication & Care Coordination	Effective Clinical Care	Efficiency & Cost Reduction	Patient Safety	Person & Caregiver-Centered Experience & Outcomes	Community/ Population Health

Physician Impact

Workflow and documentation changes

TO DO:

✓Study Measure Specifications

✓Ensure documentation meets measure requirements

✓Bill PQRS quality code when required in MCSL/UChart

✓Document chronic conditions/secondary diagnoses

✓Use UChart Smart Phrases

✓Ensure medical support staff completes required documentation

HIPAA, HITECH, PRIVACY AND SECURITY

- **HIPAA, HITECH, Privacy & Security Health Insurance Portability and Accountability Act – HIPAA**
  - Protect the privacy of a patient's personal health information
  - Access information for business purposes only and only the records you need to complete your work.
  - Notify Office of HIPAA Privacy and Security at 305-243-5000 if you become aware of a potential or actual inappropriate use or disclosure of PHI, including the sharing of user names or passwords.
  - **PHI is protected even after a patient's death!!!**

- **Never share your password with anyone and no one use someone else's password for any reason, ever –even if instructed to do so.**

✓If asked to share a password, report immediately.
✓If you haven't completed the HIPAA Privacy & Security Awareness on-line CBL
✓module, please do so as soon as possible by going to:

http://www.miami.edu/index.php/professional_development__training_office/learning/ulearn/

HIPAA, HITECH, PRIVACY AND SECURITY

- **HIPAA, HITECH, Privacy & Security**
- Several breaches were discovered at the University of Miami, one of which has resulted in
- a class action suit. As a result, **"Fair Warning"** was implemented.
- **What is Fair Warning?**
- • **Fair Warning** is a system that protects patient privacy in the Electronic Health Record
- by detecting patterns of violations of HIPAA rules, based on pre-determined analytics.
- • **Fair Warning** protects against identity theft, fraud and other crimes that compromise
- patient confidentiality and protects the institution against legal actions.
- • **Fair Warning** is an initiative intended to reduce the cost and complexity of HIPAA
- auditing.
- UHealth has policies and procedures that serve to protect patient information (PHI) in
- oral, written, and electronic form. These are available on the Office of HIPAA Privacy &
- Security website: http://www.med.miami.edu/hipaa

Available Resources at University of Miami, UHealth and the Miller School of Medicine

- If you have any questions or concern regarding coding, billing, documentation, and regulatory requirements issues, please contact:
  - ***Gemma Romillo, Assistant Vice President of Clinical Billing Compliance and HIPAA Privacy; or***
  - ***Iliana De La Cruz, RMC, Director Office of Billing Compliance***
    - ***Phone: (305) 243-5842***
    - **Officeofbillingcompliance@med.miami.edu**

- Also available is The University's fraud and compliance hotline via the web at www.canewatch.ethicspoint.com or toll-free at 877-415-4357 (24hours a day, seven days a week).
- Office of billing Compliance website: **www.obc.med.miami.edu**

QUESTIONS