Government Pitfalls and Mitigating Risks
“CMS, OIG High-Risk Targets”

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Disclaimer

The information contained within this presentation is accurate at the time of this session but due to constant and ongoing changes in billing, coding, documentation requirements and regulatory compliance, it is the users responsibility to ensure any content used in the future is validated using authoritative sources (CMS, AMA, Peer Review Data, etc.) prior to submitting claims for payment.

There are a larger number of slides in this deck than what will actually be presented today. Slides not covered or covered in detail are meant as referential material.

BEFORE WE GET STARTED

- Amnio Fluid for treatment of MSK
  - A multi-jurisdictional contractor advisory committee (CAC) meeting was hosted by Noridian Healthcare Solutions in the afternoon of May 12, 2021
  - Sales representatives have been providing physicians with a variety of documents, one being the HCPCS Committee (May, 2019) approval of code Q4206.
  - The problem is, the reps were telling physicians that the service was approved by Medicare for payment based on this HCPCS Code approval.
  - The truth is, the approval of a HCPCS Code in no way suggests a service is covered. Only an LCD/NCD (Policy) sets payment eligibility and the fact that there had to be a CAC meeting to discuss this was further proof that Amnio Fluid for non-wound care or limited ophthalmic applications was in fact not an approved use.
  - The absence of an LCD/NCD, contrary to what many believe and what I have heard many say over the years, actually means that a service is not covered and it is only a matter of time before the MAC catches up with you and claws-back monies paid for services.
  - Here is another interesting fact regarding Amnio Fluid… not one, single solitary commercial payer, pays for these services… Amniotic fluid is only covered for a handful or Ophthalmology and Neurosurgery diagnosis outside of wound care and as stated, there is no coverage for ortho-pain diagnosis. Again, one of the main codes being used is Q4206…

MULTI-JURISDICTIONAL CONTRACTOR ADVISORY COMMITTEE (CAC) MEETING

Clinical literature list

- **Amniotic injections sources of information**

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11. Farr J, Gomoll AH, Yanke AB, Strauss EJ, Mowry KC; ASA Study Group. A Randomized Controlled Single-Blind Study Demonstrating Superiority of Amniotic Suspension Allograft Injection Over Hyaluronic Acid and Saline Control for Modification of Knee Osteoarthritis Symptoms. J Knee Surg. 2019 Nov;32(11):1143-1154. PMID: 31533151

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13. Hannon CP, Yanke AB, Farr J. Amniotic Tissue Modulation of Knee Pain-A Focus on Osteoarthritis. J Knee Surg. 2019 Jan;32(1):26-36. doi: 10.1055/s-0038-1676370. PMID: 30544274

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15. Huddleston HP, Cohn MR, Haunschild ED, Wong SE, Farr J, Yanke AB. Amniotic Product Treatments: Clinical and Basic Science Evidence. Curr Rev Musculoskelet Med. 2020 Apr;13(2):148-154. PMID: 32076938

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The focus of the CAC is to discuss Proposed Local Coverage Determinations (LCDs), issues presented in each jurisdiction, and administrative policies.

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CAC MEETING KEY QUESTIONS:

Amniotic Product Injections for Musculoskeletal Indications – Non-Wound

- For each voting question, please use the following scale identifying your level of confidence in the clinical evidence.
  - Rating Options: 1 — 2 — 3 — 4 — 5
  - Rating Scale: 1 = Low Confidence, 3 = Intermediate, 5 = High Confidence
- All polling questions refer to a musculoskeletal condition in the Medicare-eligible population only.
- Each polling question will be completed for each of the musculoskeletal conditions listed below.
- Where "CONDITION" is listed in the polling, insert the condition under discussion.
- Timeframe Key
  - Short term *(*less than 4 weeks*)//Intermediate (4 weeks but less than 6 months)*
  - Long term – longer duration (6 months or more)

Musculoskeletal Conditions

- Condition 1 – Osteoarthritis (knee, hip, other)
- Condition 2 – Plantar Fasciitis/Achilles Tendinopathies
- Condition 3 – Rotator Cuff, Patellar, Lateral Epicondylitis, Carpel Tunnel, Trigger Finger
- Condition 4 – Low Back Pain, Cervical Facet Joints

Polling Questions

Question Number	Question
1	How confident are you in the evidence that amniotic product injections to treat the "CONDITION" demonstrates short/intermediate term safety?
2	How confident are you in the evidence that amniotic product injections to treat the "CONDITION" demonstrates long term safety?
3	How confident are you in the evidence that amniotic product injections to treat the "CONDITION" demonstrates short/intermediate term efficacy?

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Question Number	Question
4	How confident are you in the evidence that amniotic product injections to treat the "CONDITION" demonstrates long term efficacy?
5	How confident are you in the evidence that amniotic product injections/placement intra-operatively improve short/intermediate term post-operative outcomes?
6	How confident are you in the evidence that amniotic product injections/placement intra-operatively improve long term post-operative outcomes?

CQ AND CO MODIFIERS

CMS has established two modifiers, CQ and CO, to indicate services furnished in whole or in part by a PTA or OTA, respectively.

- The modifiers are defined as follows:
  - CQ modifier: Outpatient physical therapy services furnished in whole or in part by a physical therapist assistant
  - CO modifier: Outpatient occupational therapy services furnished in whole or in part by an occupational therapy assistant
    - Effective for claims with dates of service on and after January 1, 2020, the CQ and CO modifiers are required to be used, when applicable, for services furnished in whole or in part by a PTA or OTA on the claim line of the service, along with the respective GP or GO therapy modifier, to identify those services furnished in whole or in part by a PTA or OTA under a PT or OT plan of care.
    - For those practitioners submitting professional claims who are paid under the PFS, the CQ/CO modifiers apply to services of physical and occupational therapists in private practice (PTPPs and OTPPs).
    - The CQ and CO modifiers must be used when applicable for all outpatient therapy services for which payment is made under section 1848 (the physician fee schedule (PFS)) or section 1834(k) of the Social Security Act (the Act). As such, the modifiers are required to be used for therapy services furnished by providers that submit institutional claims, including the following provider types: outpatient hospitals, rehabilitation agencies, skilled nursing facilities, home health agencies and comprehensive outpatient rehabilitation facilities (CORFs). However, the CQ and CO modifiers are not applicable to claims from critical access hospitals or other providers that are not paid for outpatient therapy services under the PFS or section 1834(k).
    - The CQ modifier must be reported with the GP therapy modifier and the CO modifier with the GO therapy modifier. Claims with modifiers not so paired will be rejected/returned as unprocessable.

THE REGULATIONS FOR DETERMINING WHEN THE PTA/OTA MODIFIERS APPLY ARE LOCATED AT §§ 410.59(A)(4) AND 410.60(A)(4)

For occupational therapy services and physical therapy services, respectively. The regulations require that claims for services furnished in whole or in part by a PTA or an OTA, respectively, must include the CQ or CO modifier when:

- the PTA/OTA furnishes all of the minutes of a service independent of the PT/OT; or
- the PTA/OTA furnishes a portion of a service separately from the part that is furnished by the PT/OT such that the minutes for that portion of a service furnished by the PTA/OTA exceed 10 percent of the total minutes for that service. This 10 percent standard is also known as the de minimis standard that was finalized during CY 2020 PFS rulemaking.

Billing Examples/Scenarios:

- For purposes of the below examples, assume the following:
- The therapist (PT/OT) and assistant (PTA/OTA) furnish services or minutes/portions of services independently.
- Services furnished by the PT together with the PTA or by the OT together with the OTA are considered to be performed by the PT/OT.
- Services or minutes/portions of services performed by the PTA/OTA are independent of those performed by the PT/OT.
- In the below examples (except #9) all services are for those HCPCS codes that are described by 15-minute increments (also referenced as “timed” HCPCS codes).

GENERAL POLICY RULES

To determine how many 15-minute units can be billed in a single treatment day for a beneficiary:

- Apply the usual method used by your clinic/office as this policy has not changed, and
- Check the chart in section 20.2.C, Chapter 5, MCPM. The chart describes how to count minutes for timed codes defined by 15-minute units.

To determine whether the CQ/CO modifier applies:

- **Step 1. Identify the Timed HCPCS Codes Furnished for 15 Minutes or More.** List the code numbers of each of the services furnished along with the number of minutes in total done by the PT, PTA, OT, or OTA. When a PT, PTA, OT, or OTA provides at least 15 minutes and less than 30 minutes of a service on a single treatment day, assign 1 unit; when multiples of 15 minutes are furnished, e.g., 30 minutes (assign 2 units) and 45 minutes (assign 3 units), etc. This needs to be the first step whenever it is applicable to the billing scenario. When any of these services, i.e., full 15 minute increments, are provided by PTAs/OTAs, the CQ/CO modifiers apply. (See Example #7 for discussion when Step 1 is not taken and it results in incorrect billing.)
- **Step 2. Identify Services for Which the PT/OT and PTA/OTA Provide Minutes of the Same HCPCS Code.** After applying Step 1 where it is applicable, identify any minutes (including remaining minutes from Step 1) performed by a PT/OT and PTA/OTA for the same service/code. Add the minutes furnished by the PT/OT and the PTA/OTA together, then divide the total by 10 and round to the nearest integer – this is the ten percent de minimis time standard. Then add 1 minute to get the fewest number of minutes performed by the PTA/OTA that would exceed the 10 percent time standard for that service – if the PTA/OTA minutes meet or exceed this number, the CQ/CO modifier would be appended. This is the “simple” method for calculating the de minimis. See below for more information about the percentage method. (See Examples #1, #3, #5, #7, and #8.)
- **Step 3. Identify Services Where the PT/OT and PTA/OTA Furnish Services of Two Different Timed HCPCS Codes.** After applying Step 1 for each service, compare the remaining minutes furnished by the PT/OT for one service with the remaining minutes furnished by the PTA/OTA for a different service. Assign the CQ/CO modifier to the service provided by the PTA/OTA when the time he/she spent is greater than the time spent by the PT/OT performing the different service. The CQ/CO modifier does not apply when the minutes spent delivering a service by the PT/OT are greater than the minutes spent by the PTA/OTA delivering a different service. (See Examples #2, #4 below.)
- **Step 4. Identify the Different HCPCS Codes Where the PT/OT and the PTA/OTA Each Independently Furnish the Same Number of Minutes.** Once Step 1 is completed for each service (when applicable), and the remaining minutes for each service – one provided by the PT/OT and the other provided by the PTA/OTA ─ are the same, either service may be billed. If the service provided by the PT/OT is billed, the CQ/CO modifier does not apply. However, if the service provided by the PTA/OTA is billed, the CQ/CO modifier does apply. (See Example #6 below.)

MORE ABOUT CALCULATING THE *DE MINIMIS*:

- There are two methods for calculating the de minimis: the "*simple*" method and the "*percentage*" method. The *simple method* is used to determine when the CQ/CO modifier applies in all the examples below. The *percentage method* is also illustrated in many examples, as well as for the final billing example for group therapy (CPT 97150).
  - ***Simple Method*:** Once **Step 1** is applied for each service, where there are remaining minutes for the same service provided by the PTA/OTA and the PT/OT, add these together; divide that total by 10, then round to the nearest integer to get the 10 percent de minimis standard for that service. Then, add 1 minute to get the PTA/OTA minute floor. The CQ/CO modifier applies when the PTA/OTA minutes meet or exceed this floor.
  - ***Percentage Method*:** After **Step 1** is applied, determine if there are remaining minutes provided by the PTA/OTA and the PT/OT for the same service. If so, divide the remaining PTA/OTA time by the total time (PTA/OTA minutes + PT/OT minutes for the same service). Then multiply by 100 to get the percentage and round to the nearest integer. Where this number is greater than 10 percent (11 percent or more), the CQ/CO modifier applies.

EXAMPLES

Example #1

- PTA - 23 minutes 97110
  PT - 13 minutes 97110
  PT - 30 minutes 97140
  Total = 66 minutes - qualifies for billing 4 units (53 minutes through 67 minutes)

Bill as follows:

- 97110 = 36 total minutes = 2 units: Bill two units with PTA modifier (CQ). The first unit is for the first 15 minutes by the PTA; then the second unit is for 8 (PTA) + 13 (PT) = 21 (see calculation below)
- 97140 = 30 minutes = 2 units: Bill 2 units of 97140 without a PTA modifier

Billing Explanation:

- **First Step:** Assign units based on those that have at least 15 minutes or codes that were provided in multiples of 15 minutes. For 97110, assign 1 unit of 97110 with the CQ modifier because the PTA furnished at least 15 minutes of 97110 (therapeutic exercise). Then, assign 2 units of 97140 without the modifier, because the PT furnished the full 30 minutes of manual therapy.
- **Second Step 2:** Determine if the PTA furnished more than 10 percent of the remaining minutes of the 97110 service. To do this via the simple method: add the PTA's 8 remaining minutes to the PT's 13 minutes for a total time of 21 minutes. Divide the total by 10 to get 2.1 minutes and round to the nearest integer, which is 2 minutes (the 10 percent time standard for this service). Add 1 minute to find the minimum number of minutes, which in this example is 3 minutes. Using the percentage method, divide the PTA's remaining 8 minutes by the total 21 minutes of the service (8 PTA + 13 PT = 21 minutes) to get 0.38, then multiply the result X 100 = 38 percent.

Final Step: Because 8 minutes meets or exceeds the 3-minute minimum, and 38 percent is greater than 10 percent, a second unit of 97110 is billed with the CQ modifier.

Example #2

- PTA - 20 minutes 97110
  PT -15 minutes 97110
  PT - 23 minutes 97140
  Total = 58 minutes - 4 units can be billed (53 minutes through 67 minutes)

Billing - First Step:

- Bill 1 unit of 97110 with the CQ modifier because the PTA performed a full 15-minute unit with 5 minutes remaining.
- Bill 1 unit 97110 without the CQ modifier because the PT furnished the entire 15-minute interval of 97110.
- Then bill 1 unit of 97140 without the CQ modifier because the PT furnished a full 15-minute unit of 97140 with 8 minutes remaining.

Billing - Second Step:

- Since the remaining minutes that allow billing for the fourth unit of service are for different codes/services, compare the PTA's 5 remaining minutes of 97110 with the PT's 8 minutes of 97140 and bill for the service with the greater number of minutes—in this case, 97140.
- Therefore, bill another unit of 97140 without the CQ modifier since the 8 minutes of 97140 (by the PT) is greater than 5 minutes of 97110 (by the PTA).
- In this example, 97110 appears on two different lines of service (LOS) on the claim: 1 unit of 97110 is reported with the CQ modifier on one LOS and 1 unit of 97110 is reported without the CQ modifier on another LOS.

Example #3

- PTA - 19 minutes of 97110
  PT - 10 minutes of 97110
  Total = 29 minutes – two units of 97110 can be billed (23 minutes through 37 minutes).

Billing Explanation:

- **First Step:** Bill one unit of 97110 with the CQ modifier because a full 15-minutes was provided by the PTA, with 4 minutes remaining.
- **Second Step:** Determine if the PTA's 4 remaining minutes exceed the 10 percent time standard. Simple method: Add together the PTA's 4 remaining minutes and the 10 PT minutes to get the total time of 14 minutes and divide by ten to get 1.4 minutes and round to the nearest integer = 1 minute to get the 10 percent de minimis time standard. Then add 1 minute to get 2 minutes that sets the floor value for PTA minutes. If the PTA minutes are at or above the floor, the CQ modifier applies. Percentage method: Divide the PTA's 4 remaining minutes by the total time of 14 to get 0.29 then multiply by 100 = 29 percent. If the resulting percentage is greater than 10 percent, the PTA modifier applies.

Final Step: Bill another unit of 97110 with the CQ modifier since 4 minutes is greater than the 2-minute floor number and 29 percent is greater than 10 percent.

Example #4

- PTA - 19 minutes of 97110
  PT - 10 minutes of 97140
  Total = 29 minutes – two units can be billed (23 minutes through 37 minutes).

Billing Explanation:

- **First Step:** Bill 1 unit of 97110 with the CQ modifier because the PTA performed a full 15 minute unit, with 4 minutes remaining.
- **Second Step:** Since the remaining minutes are for different services, bill the service with the greater number of minutes. Since the PT's 10 minutes of 97140 (manual therapy) is greater than the PTA's 4 remaining minutes of 97110 (therapeutic exercise), bill 1 unit of 97140; the CQ modifier does not apply because the PT provided the 97140 service.

Example #5

- PT - 34 minutes 97112
  PT - 12 minutes 97110
  PTA – 14 minutes 97110
  PTA – 8 minutes 97032
  Total = 68 minutes – 5 units can be billed (68 minutes through 82 minutes)
- **Billing Explanation:**
- **First Step:** Bill two units of 97112 without a CQ modifier because the PT furnished two full 15-minute units of the service (neuromuscular reeducation), with 4 minutes remaining.
- **Second Step:** Determine if the CQ modifier is applied to one or both units of 97110. Simple method: Add the PTA's (14 minutes) and PT's (12 minutes) time together to get a total of 26 minutes, divide by 10 = 2.6 and round to nearest integer = 3. Then, add 1 to get 4 minutes, which is the floor number of minutes at which the CQ modifier applies. The CQ modifier is applied to both units of 97110 if the PTA furnished 4 or more minutes. Percentage method: Add the PTA and PT minutes together to get 26 minutes (14 +12=26). Divide the PTA's 14 minutes by 26 = 0.54 X 100 = 54 percent, which is greater than the 10 percent standard above which the CQ modifier applies. The CQ modifier applies to both units of 97110.
- **Third Step:** Then bill 1 unit of 97035 with the CQ modifier for the 8 minutes of ultrasound by the PTA

Example #6

- OT - 11 minutes 97140
  OTA - 11 minutes 97110
  Total = 22 minutes ─ One (1) unit can be billed (8 minutes through 22 minutes)

Billing Explanation:

- Since two different services were furnished for an equal number of minutes – 97140 (manual therapy) by the OT and 97110 (therapeutic exercise) by the OTA ─ either one of the services can be billed. Either one unit of 97140 can be billed without the CO modifier, or one unit of 97110 can be billed with the CO modifier.

Example #7

- PTA - 5 minutes 97110
  PT - 30 minutes 97110
  Total = 35 minutes – 2 units can be billed (23 minutes through 37 minutes).

Billing Explanation:

- **First Step:** Bill two (2) units of 97110 without the CQ modifier because the PT furnished 2 complete 15-minute units of therapeutic exercise. Record the 5 minutes of service by the PTA with the total time for the treatment session, even though the time is not billable.
- In this scenario, if the PT/PTA did not follow “Step 1” of the general rule, it would result in one or both units of 97110 being mistakenly billed with a CQ modifier as described below:
  - *Simple method:* Divide the 35 total minutes by 10 = 3.5, round to 4.0 minutes, then add 1 minute = 5 – CQ modifier is billed incorrectly.
  - *Percentage method:* Divide the PTA’s 5 minutes by the total time (35 minutes) ─ 5 divided by 35 = 0.14 X 100 = 14 percent. The PTA’s 5 minutes would be incorrectly billed with the CQ modifier in this scenario.

Example #8

- PTA Independently – 3 minutes 97110
  PT + PTA Together ─ 27 minutes 97110
  Total = 30 minutes ─ 2 units of 97110 can be billed (23 minutes through 37 minutes).

Billing Explanation:

- **Step 1:** Bill 1 unit without the CQ modifier because a full 15-minute unit was furnished by the PT and PTA together at the same time (with 12 remaining minutes).
- **Step 2:** Decide whether the CQ modifier applies to the second unit. Simple method: Add the PTA's 3 minutes to the remaining 12 minutes furnished by the PT and PTA together to get the total time of 15 minutes. Then divide by 10 to get 1.5 and round to the closest integer = 2. Add 1 to get 3 minutes – the floor time at which or above which the final unit would be billed with the CQ modifier. Percentage method: Divide the PTA's 3 minutes by the total time of 15 (PT+PTA (12) + PTA (3)) = 0.2 times 100 = 20 percent, which is greater than the 10 percent time standard. Bill one unit of 97110 with the CQ modifier because the PTA provided 3 minutes of service which meets the floor, and the PTA provided 20 percent of the total minutes which exceeds the 10 percent time standard. Since the PTA delivered 3 minutes of therex, the second unit of 97110 is billed with CQ modifier.
- In this scenario, 97110 will appear on two different claim lines of service (LOS) – one unit of 97110 with the CQ modifier on one LOS and one unit 97110 without the CQ modifier on another LOS.

Example #9: Untimed code Example – 1 unit is billed for all untimed codes

- OTA – 20 minutes 97150 independent of the OT
  OT ─ 20 minutes 97150 independent of the OTA
  Total = 40 minutes of Group Therapy = I unit of 97150 is billed for each group member

Billing Explanation:

- One unit of group therapy 97150 is billed with the CO modifier because the OTA provided more than the 10 percent time standard in this example. Either method can be used to determine if the OTA's time exceeded the 10 percent time standard for this clinical scenario, see below:
- ***The simple method:*** First add the OTA's 20 minutes to the OT's 20 minutes to get 40, then divide by 10 to get 4.0 and add 1 to equal 5 minutes. The OTA's 20 minutes is equal to or greater than 5 minutes so the CO modifier is required on the claim.
- ***The percentage method:*** Divide the number of minutes that an OTA independently furnished a service by the total number of minutes the service was furnished as a whole – 20 divided by 40 equals 0.50. Then multiple by 100 to get 50 percent, which is greater than 10 percent. The CO modifier is applied to 97150.
- ***Tie breaker:*** The tie breaker does not apply in this scenario because the example does not contain two different timed codes described in 15-minute intervals. For "tie breaker" see Example #6 above.

Objectives

- Privacy and Security is a high priority for OCR in 2021
- Evaluation and Management Services 2021;
- Medical Necessity, The False Claims Act and Defensibility
  - Definition and Generally Accepted Error Rates
- Consultation vs. New / Established Patient;
- Incident-To Provisional Billing
- Sustained or High Error Rate
- Corrective Action Plan (CAP)
- OIG Areas of Focus;
  - Evaluation and Management Services
  - Medical Necessity
  - Cloning and Clinical Plagiarism
  - Incident-to Provisional Billing

2021 E/M CHANGES

- **The Changes to the 2021 E/M Codes are applicable to only Office or Other Outpatient Service Codes 99202 – 99215 (99201 has been deleted). Hospital and other E/M codes are not impacted by the changes.**
- **History and Exam**
  - Will no longer be scored (elements counted), ***but*** they still have to be present in the note and support medical necessity
- **MDM**
  - Encounter Diagnosis
    - Only diagnoses documented as active treatment during the present encounter will be considered for scoring purposes
  - Data & Complexity
    - There will be new requirements for specific combinations of different work elements to support a specific level
  - Table of Risk
    - The entire table of risk has been consolidated into one column on a new MDM grid and uses only the last column of treatment options for the patient
- **Time**
  - The visit will no longer have to be dominated by counseling/coordination of care
  - Time spent now includes the rendering providers total time spent including non-face-to-face time spent specific to the encounter and patient
  - ***Remember that medical necessity is still going to have to be reflected within the documentation of each encounter!***

Evaluation and Management Services

- Medical Necessity as it relates to coding – 30.6.1 – Evaluation and Management Services – Medical Necessity is the overarching criteria in addition to the individual elements of the CPT Codes
- History
  - Medical Necessity and how we use it to determine the level of intensity for an encounter
  - Chief Complaint
  - History – Focus on the History of Present Illness / the history should be clinically relevant
  - Exam – It needs to be clinically relevant
  - Medical-Decision Making – This has changed in 2021. Expect further guidance from the MACs and CMS in the coming months.

AMA DEFINITION OF RISK – WHEN CLINICAL AND NON-CLINICAL REVIEW DEPLOYED BY PAYER

"Definitions of risk are based upon the usual behavior and thought processes of a physician or other qualified health care professional in the same specialty (This is why we request the credentials for the physician reviewer in this case). For the purposes of medical decision making, level of risk is based upon consequences of the problem(s) addressed at the encounter when appropriately treated. Risk also includes medical decision making related to the need to initiate or forego further testing, treatment and/or hospitalization."

MEDICAL NECESSITY

"Medically Necessary" or "Medical Necessity" shall mean health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are: a) in accordance with **generally accepted standards of medical practice**; b) clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and c) not primarily for the convenience of the patient, physician or other health care provider, **and not more costly than an alternative service or sequence of services** at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community or otherwise consistent with the standards set forth in policy issues involving clinical judgment.

UNDERSTANDING HOW TO DEFEND “MEDICAL NECESSITY”

- Unless the contrary is specified, the term “Medical Necessity” must refer to what is medically necessary for a particular patient, and hence entails an individual assessment rather than a general determination of what works in the ordinary case.
  - Second Circuit Court of Appeals, cited in Kaminski, Defining Medical Necessity, http://www.cga.ct.gov/2007/rpt/2007-r-0055.htm

MEDICARE'S VIEW OF "MEDICAL NECESSITY"

- In the Medicare program, "Medical Necessity" is defined under Title XVIII of the Social Security Act, Section 1862 (a) (1) (a): "Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

  The above is a legal doctrine by which evidence-based clinical standards are used to determine whether a treatment or procedure is reasonable, necessary and/or appropriate.

How Do We Defend Medical Necessity

- Documentation within the Medical Record:
  1. **Does "Medical Necessity" exist or likely exists, but the issue is lacking documentation in the medical record?**
     - Physicians have a responsibility to provide sufficient documentation that paints a clear picture of each and encounter
     - Determining whether the procedures in question are truly clinically necessary or if the issue is documentation related is critical to the defense of the investigation
     - Make sure that all relevant medical records have been retrieved and reviewed. This means office notes, hospital notes, nursing home, rehabilitation, etc.
     - Do LCDs or NCDs exist to provide documentation requirements
     - If the allegations are that documentation is inaccurate, have we generated clinical rebuttals to further clarify the need for services and state the physician's opinion clearly

CLEAR AND BINDING MEDICAL NECESSITY STANDARD

- The Medicare statute requires that any "rule" requirement, or other statement of policy (other than a material coverage decision) that establishes or changes a substantive legal standard must be promulgated by regulation. 42 U.S.C § 1395hh.
  - Has CMS promulgated a standard for determining whether a service is reasonable and necessary?
  - Courts FROM TIME TO TIME give deference to the determination of the "Treating physician" (United States v. Prabhu, 442 F. Supp 2d 1008 (D. Nev 2006) – The Treating Physician Rule was removed from SSA Regulations Effective March 27, 2017
- Clarity of Medical Necessity issues affect whether a claim is "False" and whether the requisite "knowledge" exists.
  - "Claims are not 'false' under the FCA when reasonable persons can disagree regarding whether the service was properly billed to the Government." *Prabhu*
  - "a Defendant does not 'knowingly' submit a 'false' claim when his conduct is consistent with a reasonable interpretation of ambiguous regulatory guidance." *Prabhu*

TREATING PHYSICIAN RULE

<u>Treating Physicians</u> -- The first section of the Medicare statute is the prohibition "Nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided."

- From this, one could conclude that the beneficiary's physician should decide what services are medically necessary for the beneficiary, and a substantial line of authority in the Social Security disability benefits area holds that the treating physician's opinion is entitled to special weight and is binding upon the Secretary when not contradicted by substantial evidence.
- Some courts have applied the rationale of the "treating physician" rule in Medicare cases, and have rejected the Secretary's assertion that the treating physician rule should not be applied to Medicare determinations.

TREATING PHYSICIAN RULE CONT'D

In *Holland vs. Sullivan*, the court concluded:

- Though the considerations bearing on the weight to be accorded a treating physician's opinion are not necessarily identical in the disability and Medicare context, **we would expect the Secretary to place significant reliance on the informed opinion of a treating physician** and either to **apply the treating physician rule**, with its component of "some extra weight" to be accorded that opinion, [even if contradicted by substantial evidence], or to supply a reasoned basis, in conformity with statutory purposes, for declining to do so.

JUDGEMENT ERROR

- “If the overpayment is the result of the insurance company changing its judgment after paying the claim -- determining the service was outside the scope of the insured's coverage plan, for example -- providers may not be obligated to reimburse the insurance company.”
- Many state courts have decided insurance companies are not entitled to reimbursement if the provider made no misrepresentations to prompt the payment and had no reason to suspect the payment was in error.
- However, the provider cannot keep any payment that would be considered beyond the scope of the service.

The False Claims Act

- Under the FCA, a person is deemed to have acted "knowingly" when the person "acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information."
  - 31 U.S.C. § 3729(b).
- As the Ninth Circuit has pointed out, the FCA knowledge standard does not extend to honest mistakes, but only to "lies." "Claims are not 'false' under the FCA unless they are furnished in violation of some controlling rule, regulation or standard".
  - *See, e.g., United States ex rel. Local 342 v. Caputo Co.,* 321 F.3d 926, 933 (9th Cir.2003); *United States v. Southland Mgmt. Corp.,* 326 F.3d 669, 674-75 (5th Cir.2003) ("[W]hether a claim is valid depends on the contract, regulation, or statute that supposedly warrants it.
- It is only those claims for money or property to which a Defendant is not entitled that are 'false' for purposes of the False Claims Act") (citation omitted) (en banc);
  - *United States ex rel. Hochman v. Nackman,* 145 F.3d 1069, 1073-74 (9th Cir.1998) (no falsity when Defendants' acts conformed with Veteran Administration payment guidelines);
  - *United States ex rel. Lindenthal v. Gen. Dynamics Corp.,* 61 F.3d 1402, 1412 (9th Cir.1995) (whistleblower's FCA claims for payment based on work that satisfied contractual obligations "could not have been 'false or fraudulent' within the meaning of the [False Claims Act]");
  - *United States ex rel. Glass v. Medtronic, Inc.,* 957 F.2d 605, 608 (8th Cir.1992) (a statement cannot be "false" or "fraudulent" under FCA when the statement is consistent with regulations governing program).
  - *Additionally, a Defendant does not knowingly submit false claims when he follows Government instructions regarding the claims. See United States ex rel. Butler v. Hughes Helicopters, Inc., 71 F.3d 321 (9th Cir.1995); Wang v. FMC Corp., 975 F.2d 1412, 1421 (9th Cir.1992).*

Incident-to Provisional Billing

- I-2 Services and the specifics:
  - Direct Supervision
  - Immediately Available

SUSTAINED OR HIGH ERROR RATE

- *Determining When a Statistical Sampling May Be Used*. Under the new guidance, a contractor "shall use statistical sampling when it has been determined that a sustained or high level of payment error exists. The use of statistical sampling may be used after documented educational intervention has failed to correct the payment error." This guidance now creates a three-tier structure:
- Extrapolation *shall* be used when a sustained or high level of payment error exists.
- Extrapolation *may* be used after documented educational intervention (such as in the Targeted Probe and Educate (TPE) program).
- It follows that extrapolation should *not* be used if there is not a sustained or high level of payment error or evidence that documented educational intervention has failed.
- What is a "sustained or high level of payment error?" The PIM now specifies this can be when the sample review error rate is "greater than or equal to 50[%]." This is a significant difference from error rates Medicare auditors have previously used to justify a high error rate and may provide some relief as to the punitive effects of extrapolation.
- However, the "50% or greater" test is not the only method CMS permits to determine a sustained or high level of payment error. The TPE Program differs in that it ranges from 15 – 20% billed error rate.
- The PIM also states that the contractor may look to the provider's history of noncompliance for the same or similar billing issues, or a historical pattern of noncompliant billing practice.

United States Sentencing Guidelines (USSG) – Elements of Compliance

Organization must promote culture "that encourages commitment to compliance with the law" by minimally:

1. Establishing compliance standards and procedures to prevent and detect violations

2. Governing authority oversight: "shall"

- Be knowledgeable about content and operation of program
- Exercise reasonable oversight regarding implementation and effectiveness
- Assign specific high-level person(s) direct, overall responsibility
  - Give adequate resources
  - Give adequate authority
  - Have person report directly to governing authority or subgroup on implementation and effectiveness

Developing a Corrective Action Plan

Corrective Action Plans (CAPs) are a critical component to sending a clear message that we are committed to doing the right thing. It shows our compliance plan is a living breathing document that's ever adjusting and growing with the organization.

Most compliance professionals want to self-disclose when an error is identified but self-disclosure is not always warranted. Oftentimes, things we make mistakes on don't lead to undeserved remunerations. They could simply be a breakdown in process that needs to be better defined or clarified.

- Before a decision is made about self-disclosure you should speak with your health care attorney to determine the best course of action. However, regardless of what the final determination is; you still need to develop a CAP.

There are (5) basic aspects of a CAP:

1. Issue/ Problem Definition - Identify the potential problem and provide a lay explanation of the problem (e.g. Cloning)
2. Root Cause - Identify what led to the potential problem (e.g. The ease of cutting and pasting or carry forward within an EMR)
3. Action Steps - Identify the steps taken to correct or reverse the potential problem (e.g. Training and Education for all providers documenting within the EMR)
4. Improvement Benchmark(s) and Timeframes - How you will monitor the situation going forward to ensure compliance (e.g. Re-review of provider documentation within 30-days after training and education)
5. Certification - The compliance officer or responsible party for ensuring compliance signs off on the CAP

Creating Annual Audit Elements!

2020 Audit Elements	Description of Review	Remedies	Passing Error Rate %	Performed By
1. E&M Coding and Documentation a) Prospective Baseline Review for new providers - 220 office encounters (120 new patient encounters, and 10 established patient encounters b) Annual Prospective Review for all providers - 220 office encounters - 220 hospital encounters, an c) Accuracy of Diagnosis Coding (ICD-10CM)	All chart reviews are performed prospectively unless otherwise identified. E/M chart reviews will be performed using the 19920 E/M documentation guidelines except for those specialties and subspecialties utilizing the 1997 E/M documentation guidelines. For those providers performing in-office procedure there should be a sampling of these when they are billed in conjunction to an E/M and have a modifier applied. For those providers performing these categories of EM Service(s). For any providers not performing these services they will select additional new and established patient encounters. Diagnosis codes must be assigned to the highest level of specificity	If greater than a 20% error rate refer to the Coding and Audit Escalation Policy. If greater than a 20% error rate refer to the Coding and Audit Escalation Policy. If greater than a 20% error rate refer to the Coding and Audit Escalation Policy.	<20% error rate <20% error rate <20% error rate	
2. 99211 Medical Necessity a) In the medical group setting (Incident-To) b) When billed in the Infusion Clinic. - 20 per year per provider	Incident-To Services must be performed in the physician office setting (refer to Incident-To Guidelines Policy). In the In-Patient setting refer to Split/Shared Services policy. ** There should an extensive review of Incident-To and split/shared services for CY 2019. While Articularis Healthcare has ceased performing services in this manner; there is still a potential risk that should be assessed. Groups where issues are detected should refer to their specific Corrective Action Plan (CAP) for how to proceed in CY 2020.* Infusion Centers and or Infusion Suites whereby they are located in an address other than where the billing provider is rendering services pose a potential risk and need to be observed.	If greater than a 20% error rate refer to the Coding and Audit Escalation Policy. If greater than a 20% error rate refer to the Coding and Audit Escalation Policy.	<20% error rate <20% error rate	

Annual Audit Elements Continued

3. Medical Necessity of Patients with Frequent Visits a) More than 6 visits in 3 months	Patients who are seen on a basis more frequent than what would be considered generally accepted standards of medical practice may require you to flag their claims in the system to ensure a more focused review to ensure there is no excessive billing for patient services. Certain specialties will require patients to present for visits more frequently in certain situations than others. Discretion must be used when reviewing these encounters.	If greater than a 20% error rate refer to the Coding and Audit Escalation Policy.	<20% error rate	
4. Urine Drug Toxicology Screening As outlined and in accordance with Palmetto, GBA Local Coverage Determination (LCD L320724 – Lab: Controlled Substances Monitoring and Drugs of Abuse Testing) and Local Coverage Article (LCA – A204799 – Lab: Controlled Substances Monitoring and Drugs	As outlined in the Palmetto, GBA LCD and LCA above clearly define the proper limitations for presumptive and definitive urine drug screenings as follows: "Presumptive UDT testing is limited due to: • Primarily screens for drug classes rather than specific drugs, and	If greater than a 20% error rate refer to the Coding and Audit Escalation Policy	<20% error rate	

Why Have a Compliance Program?

- Risk Minimization
    - Financial Risks & Operational Risks
    - Health & Safety Risks
    - Reputational Risks
- Better Image, Improved Relationships, Greater Trust
    - Community
    - Regulators
- External Pressures
    - CMS (ZPIC, RAC, UPIC, PSC, Private Payors, etc.)
    - Governmental Expectations (e.g. DHHS OIG)
- (Possibly) Reduced Fines and Penalties
- Greater Efficiency and Improved Outcomes
    - Better trained workforce, better morale
    - Elimination of uncertainty and confusion about roles and responsibilities
    - Better quality operations
    - Identifying and addressing problems early
    - Reducing likelihood of government audits & investigations

Why Have a Compliance Program?

Consequences of Noncompliance

- Fines, penalties, and legal fees
- Imposed compliance “settlements”
- More regulatory and audit agency scrutiny
- Management time and effort required to perform damage control
- Management turnover
- Lower faculty and staff morale
- Increased bureaucracy and lower efficiency
- Lingering effects …….
- Guilt by association: when one of us is tarred, we all wear the feathers

Source: Steve Jung

MEDICAID AND MEDICARE 72 HOUR RULE

- **Kentucky's** Medicaid rule regarding authentication of medical records and timing requirements. 907 Kentucky Administrative Regulations (KAR) 1:102 §2(4)(b)2 states: "The individual who provided the service shall date and sign the health record within seventy-two (72) hours from the date that the individual provided the service." Kentucky implemented this rule effective on **July 6, 2015**.
- **Alaska** 72 Hour Contemporaneous Documentation FAQs
  - Q1. Please clarify the 72 hour requirement for documentation of services; is this a straight 72 hours or is its 72 business hours. The 72 hour requirement applies to the initial documentation of services. The regulation states 72 hours from the end date of service. This is a straight 72 hours from the end of date of service.
    - An example is the date of service is June 15, 2018, the 72 hour clock starts at 12:00 am June 16, 2018 and is to be documented by 11:59 pm June 18, 2018.
  - Q2. What about weekends and holidays? The 72 hour requirement does not allow an extension for weekends and holidays.
  - **Noridian** - Q3. After a service has been rendered, what amount of time is acceptable to Medicare for the doctor to sign the notes?
    - A3. In most cases, Noridian expects that the notes are signed at the time services are rendered. Further delays may require an explanation. See CMS Internet Only Manual (IOM), Publication 100-08, Medicare Program Integrity Manual, Section 3.3.2.5

SIGNATURE REQUIREMENTS

- CMS's vague guidance is found in Chapter 12 of the Manual in the following statement, "The service should be documented during, or as soon as practicable after it is provided in order to maintain an accurate medical record."
- Check with your MAC. Some give reasonable direction:
  - **WPS** which states, "A reasonable expectation would be no more than a couple of days away from the service itself."
  - **Noridian** states that they expect, "In most cases the notes would be signed at the time services are rendered."
  - **Palmetto** is a little more direct stating, "Providers should not add a late signature to the medical record, (beyond the short delay that occurs during the transcription process)." It is understood that there are circumstances, like waiting for transcription to be complete that might preclude signing the record at the time of service. In general, it is best to sign the record at the time of service, if not within a day or two at the latest.
  - You may not add late signatures to orders or medical records (beyond the short delay that occurs during the transcription process). MLN Fact Sheet – Complying with Medicare Signatures - ICN 905364 May 2018

- FCSO memo (see pages 3-6), followed by practical compliance tips that apply to each issue raised.
- **Medicare Comment No. 1**
  - *"Medicare expects the documentation to be generated at the time of service or shortly thereafter. Delayed entries within a reasonable time frame (24 to 48 hours) are acceptable for purposes of clarification, error correction, the addition of information not initially available, and if certain unusual circumstances prevented the generation of the note at the time of service."*
- **Medicare Comment No. 2**
  - *"The medical record cannot be altered. Errors must be legibly corrected so that the reviewer can draw an inference as to their origin. These corrections or additions must be dated, preferably timed, and legibly signed or initialed."*
- **Medicare Comment No. 3**
  - "*Every note must stand alone, i.e., the performed services must be documented at the outset. Delayed written explanations will be considered. They serve for clarification only and cannot be used to add and authenticate services billed and not documented at the time of service or to retrospectively substantiate medical necessity. For that, the medical record must stand on its own with the original entry corroborating that the service was rendered and was medically necessary."*
- **Medicare Comment No. 5**
  - *"Documentation is considered cloned when each entry in the medical record for a patient is worded exactly alike or similar to the previous entries. Cloning also occurs when medical documentation is exactly the same from patient to patient. It would not be expected that every patient had the exact same problem, symptoms, and required the exact same treatment."*
  - *"Cloned documentation does not meet medical necessity requirements for coverage of services rendered due to the lack of specific, individual information. All documentation in the medical record must be specific to the patient and her/his situation at the time of the encounter. Cloning of documentation is considered a misrepresentation of the medical necessity requirement for coverage of services. Identification of this type of documentation will lead to denial of services for lack of medical necessity and recoupment of all overpayments made."*

OIG Risk Areas 2021

These are in no particular order:

- Evaluation and Management Services – There is no clear definition for an acceptable error rate… OIG under Corporate Integrity Agreements indicates a 5% or less error rate is within the margin of error they are willing to accept.
  - Under Medicare's Targeted, Probe and Educate (TPE) Program – Providers scoring at or below a 20% error rate are not forced in to Tier 2 or Tier 3 of the program. However, refunds are required for those services / encounters determined to be overpayments.
- Cloning and Clinical Plagiarism –
  - The word '**cloning**' refers to **documentation** that is worded exactly like previous entries.
  - Clinical plagiarism occurs when a physician copies and pastes information from another provider and calls it his or her own. Defaulting or copying and pasting clinical information using existing documentation from other patient encounters in a different health record facilitates billing at a higher level of service than was actually provided.
- Incident-to and Split/Shared Services
- Prolonged Evaluation and Management Services – Avoid these (99354 – 99357) - Prolonged services are for additional care provided to a beneficiary after an evaluation and management (E/M) service has been performed. Physicians submit claims for prolonged services when they spend additional time beyond the time spent with a beneficiary for a usual companion E/M service. *The necessity of prolonged services are considered to be rare and unusual.* The Medicare Claims Processing Manual includes requirements that must be met in order to bill for a prolonged E/M service code (Medicare Claims Processing Manual, Pub. 100-04, Ch. 12, §30.6.15.1). Source: https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000115.asp
- "Medical Necessity"

Cloning

- The word 'cloning' refers to documentation that is worded exactly like previous entries. This may also be referred to as 'cut and paste', copy and paste, or 'carried forward.' Cloned documentation may be handwritten, but generally occurs when using a preprinted template or a Promoting Interoperability (PI) Programs electronic record.
- Promoting Interoperability (PI) Programs electronic records replace traditional paper medical records with computerized record keeping to document and store patient health information. EHRs may include patient demographics, progress notes, medications, medical history, and clinical test results from any health care encounter.
- While these methods of documenting are acceptable, it would not be expected the same patient had the same exact problem, symptoms, and required the exact same treatment or the same patient had the same problem/situation on every encounter. Authorship and documentation in an EHR must be authentic.
- Cloned documentation does not meet medical necessity requirements for coverage of services. Identification of this type of documentation will lead to denial of services for lack of medical necessity and recoupment of all overpayments made.
- Over-documentation is the practice of inserting false or irrelevant documentation to create the appearance of support for billing higher level services. Some PI Programs technologies auto-populate fields when using templates built into the system. Other systems generate extensive documentation on the basis of a single click of a checkbox, which if not appropriately edited by the provider may be inaccurate. Such features produce

POLICY NUMBER: 1.0

APPLICABLE RULE: OIG DOCUMENTATION COMPLIANCE

POLICY ON: Cloning of Medical Records

Applicable Rule: OIG Documentation Compliance

Implementation Date: 8/13/2019

Purpose:

The word 'cloning' refers to documentation that is worded exactly like previous entries. This may also be referred to as **'cut and paste'** or **'carried forward.'** Cloned documentation may be handwritten, but generally occurs when using a preprinted template or an Electronic Health Record (EHR). While these methods of documenting are acceptable, it would not be expected the same patient had the same exact problem, symptoms, and required the exact same treatment or the same patient had the same problem/situation on every encounter.

Cloned documentation does not meet medical necessity requirements for coverage of services. Identification of this type of documentation will lead to denial of services for lack of medical necessity and recoupment of all overpayments made when a payor or carrier determines the services to be cloned.

Items that could be linked to Cloning:

- Op Reports that were obviously pre-populated templates and were identical in content even down to the Estimated Blood Loss.
- Gender errors resulting from a cut and paste function. A patient is "he" in one paragraph and a "she" in another paragraph.
- Documentation in the H&P indicating body system findings are Within Normal Limits (WNL), yet the same body system is the reason for the admission and in fact, not within normal limits.
- Protocols that are being used as standard orders and in most cases have not been adapted to the patient but results in many pages of orders.
- The use of pre populated templates for H&Ps, Discharge Summaries and orders creates a huge medical record but it is often repetitive and reimbursement is not based on the quantity of documentation but upon the quality of the documentation.
- The "cut and paste" option used when templates are not pre-populated creates less credible information because errors go unnoticed within the volume of the records.

Providers will strive to ensure each encounter is unique to the current patient encounter and will only carry forward information from previous dates of service that are relevant and applicable. This information will be re-confirmed or a note will specifically state how the carried forward information is being utilized for the current encounter.

Creating a Culture of Compliance & "The Importance of a Corporate Compliance Program"

The original Filip Memo which was part of the United States Attorney's Manual (USAM), that became the Justice Manual on September 25, 2018, which focuses on specifically whether to criminally charge a corporation…

"Generally, prosecutors apply the same factors in determining whether to charge a corporation as they do with respect to individuals. *See* JM 9-27.220 et seq.

Thus, the prosecutor must weigh all of the factors normally considered in the sound exercise of prosecutorial judgment: the sufficiency of the evidence; the likelihood of success at trial; the probable deterrent, rehabilitative, and other consequences of conviction; and the adequacy of noncriminal approaches.

Creating a Culture of Compliance - Continued

However, due to the nature of the corporate "person," some additional factors are present. In conducting an investigation, determining whether to bring charges, and negotiating plea or other agreements, prosecutors should consider the following factors in reaching a decision as to the proper treatment of a corporate target:

1. the nature and seriousness of the offense, including the risk of harm to the public, and applicable policies and priorities, if any, governing the prosecution of corporations for particular categories of crime (*see* JM 9-28.400);
2. the pervasiveness of wrongdoing within the corporation, including the complicity in, or the condoning of, the wrongdoing by corporate management (*see* JM 9-28.500);
3. the corporation's history of similar misconduct, including prior criminal, civil, and regulatory enforcement actions against it (*see* JM 9-28.600);
4. the corporation's willingness to cooperate, including as to potential wrongdoing by its agents (*see* JM 9-28.700);
5. *the adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of a charging decision (see JM 9-28.800)*;

Creating a Culture of Compliance - Continued

6. the corporation's timely and voluntary disclosure of wrongdoing (*see* JM 9-28.900);

7. *the corporation's remedial actions, including, but not limited to, any efforts to implement an adequate and effective corporate compliance program or to improve an existing one, to replace responsible management, to discipline or terminate wrongdoers, or to pay restitution (see JM 9-28.1000)*;

8. collateral consequences, including whether there is disproportionate harm to shareholders, pension holders, employees, and others not proven personally culpable, as well as impact on the public arising from the prosecution (*see* JM 9-28.1100);

9. the adequacy of remedies such as civil or regulatory enforcement actions, including remedies resulting from the corporation's cooperation with relevant government agencies (*see* JM 9-28.1200); and

Creating a Culture of Compliance - Continued

10. the adequacy of the prosecution of individuals responsible for the corporation's malfeasance (*see* JM 9-28.1300)."

- * *"The factors listed in this section are intended to be illustrative of those that should be evaluated and are not an exhaustive list of potentially relevant considerations. Some of these factors may not apply to specific cases, and in some cases one factor may override all others. For example, the nature and seriousness of the offense may be such as to warrant prosecution regardless of the other factors. In most cases, however, no single factor will be dispositive. In addition, national law enforcement policies in various enforcement areas may require that more or less weight be given to certain of these factors than to others. Of course, prosecutors must exercise their thoughtful and pragmatic judgment in applying and balancing these factors, so as to achieve a fair and just outcome and promote respect for the law." [updated November 2018]*

Defining Compliance

- Health care compliance is the process of following rules, regulations, and laws that relate to healthcare practices.
- Health care organizations are held to very strict standards, regulations, and laws from the federal and state levels and violating these can result in lawsuits, significant fines, loss of licenses and exclusion.
  - Here is what bothers me and should bother you -
    THE PAYERS ARE NOT HELD TO THE SAME STANDARDS!

COMPARATIVE BILLING REPORTS (CBRs)

- “A Comparative Billing Report (CBR) provides comparative billing data to an individual health care provider.
  - CBR's contain actual data-driven tables and graphs with an explanation of findings that compare provider's billing and payment patterns to those of their peers on both a national and state level.
- Graphic presentations contained in these reports help to communicate a provider's billing pattern more clearly.
  - CBR study topic(s) are selected because they are prone to improper payments.”

WHERE DO THEY COME FROM?

The CBR is just one tool that CMS uses in its ongoing efforts to protect the integrity of the Medicare Trust Fund.

Other efforts include:

- Educating providers about Medicare's coverage, coding, and billing rules;
- Reviewing claims before they are paid to assure compliance with coverage, coding, and billing rules (called prepayment review); and
- Reviewing claims after they are paid (called postpayment review) to identify and collect overpayments made to providers.

WHAT THE CMS CBR SAYS . . .

Dear Medicare Provider:

The Centers for Medicare & Medicaid Services (CMS) strives to protect the Medicare Trust Fund and effectively manage Medicare resources. To support these goals, CMS has contracted with eGlobalTech, a professional services firm headquartered in Arlington, VA, to develop Comparative Billing Reports (CBRs). CBRs provide comparative data on how an individual health care provider's billing and payment patterns for selected topics compare to his/her peers. The CBRs give providers an opportunity to compare themselves to their peers, check their records against data in CMS' files, and review Medicare guidelines to ensure compliance. CBRs are for educational and comparison purposes and do not indicate the identification of overpayments. **Please note, no reply is necessary.**

Attached is a CBR that reflects your billing or referral patterns compared to peer providers' patterns for the same services in your state and nationwide. We recognize that practice patterns can vary by region, subspecialty, and patient acuity levels, which are elements that are not evident in the claims data reviewed for the CBR. We hope you find this CBR beneficial as an educational tool to assist you in identifying opportunities for improvement. If you have any questions regarding this CBR, or if you want to change the way you receive CBRs in the future, please contact the CBR Support Help Desk.

THEY USE MULTIPLE SOURCES FOR INCENTIVES

This CBR focuses on internists who submitted claims for established patient evaluation and management (E/M) services appended with modifier 25. The *CPT® 2014 Professional Edition* manual defines modifier 25 as indicative of a "significant, separately identifiable E/M service by the same physician or other qualified health professional on the same day of the procedure or other service." In 2005, the Office of the Inspector General (OIG) released a report on Medicare payments for E/M services billed with modifier 25. The report, "Use of Modifier 25" (OEI-07-03-00470), indicated that out of $1.96 billion paid for claims using modifier 25, as much as $538 million was paid improperly. The OIG found that many providers appended the modifier to more than 50 percent of the services they billed, while other providers used modifier 25 on their E/M services when no other services were performed on the same day. Of the 431 claims audited, 35 percent did not meet program requirements.

WHAT THE PRIVATE PAYER CBR SAYS . . .

We routinely review claims data to help ensure coding and payment accuracy. To underscore the importance of correct practices, we have implemented an evaluation and management (E&M) correct coding program. Through this program, we review available Cigna billing data to compare a health care professional's E&M coding practices with their peers within the same primary specialty and in the same community.

Enclosed is your 2015 E&M report. The report includes data for dates of service from January 2015 through December 2015. According to this data, for one or more of the Current Procedural Terminology (CPT®) codes evaluated, your E&M submission patterns differed from your peer group by at least 0.5 standard deviations. We want to remind you to follow CPT guidelines for appropriate coding so you accurately document and bill for the services you provide.

WHAT THE PRIVATE PAYER CBR REALLY MEANS . . .

We will re-evaluate your E&M coding practices on an annual basis. If your E&M submission patterns continue to deviate from your peer group, we will contact you to further discuss and may take the following additional steps:

- A follow-up meeting at your office
- A request for medical records
- A medical record audit at your office

HOW DOES THE CBR GENERATE ITS ANALYSIS?

- In general, the CBR benchmarks certain and specific utilization statistics against “peer” data
  - Doesn’t define “peer”: maybe specialty maybe category
  - Data period is supposed to match practice to benchmark
- From where do the data originate?
  - Data come from the Integrated Data Repository (IDR)
    - Available to CMS partners but not the general public or providers
  - Data are claimed to be more current that what is available to general public and providers
- Includes both E&M and non-E&M codes

WHAT DOES THE CBR REPORT?

- Utilization of Codes and modifiers
  - E&M codes
  - Non-E&M codes
  - Modifiers
  - Specialty-specific codes
  - High-risk codes and modifiers
- Time
  - Likely uses both CPT and RUC time, but nothing specific about point of origin
- Non-E&M codes are generally specialty-specific

STANDARD CBR REPORTING STATISTICS

- Average Minutes per Day (E&M only)
  - Sum of the products of minutes for each code times frequency
  - Divide by total number of days worked
  - Uses AMA CPT code minutes
- Average Allowed Services per Beneficiary
  - Total of all services billed divided by number of unique beneficiaries for whom the services were provided
  - Average Total Services per Year Rendered to Your Beneficiaries by All Practitioners
- Average Total Services per Year Rendered to Your Beneficiaries by All Practitioners
  - Same as above but for all services and all beneficiaries rather than a single NPI

ADDITIONAL CBR REPORTING STATISTICS

- **Percentage of Services with Modifier 25**
  - **Number of services with modifier 25 divided by total number of services**
- **Average Allowed Minutes per Visit with Modifier 25 and without Modifier 25**
  - **Sum of the products of minutes per E/M service with/without Mod 25 divided by total E&M services with/without modifier 25**
- **Average Allowed Charges per Beneficiary**
  - **Total allowed charges divided by total number of unique beneficiaries**

COMPARISON OUTCOMES

- Significantly Higher - Provider's value is higher than the peer value and the statistical test confirms a significance
- Higher - Provider's value is higher than the peer value but either the statistical test does not confirm a significance or there is insufficient data for comparison
- Does Not Exceed- Provider's value is not higher than the peer value
- N /A - Provider does not have data for comparison

AVERAGE TIME SUMMARY

Code	Description	Typical Time
99211	Minimal Problem/Exam	5
99212	Problem Focused/Exam	10
99213	Expanded Problem Focused/Exam	15
99214	Detailed Patient History /Exam · 25 Minutes	25
99215	Detailed Patient History /Exam · 25 Minutes	25
11720	Debridement of nail(s) by any method(s); one to five	N/A
11721	Debridement of nail(s) by any method(s); six or more	N/A

Utilization Summary

CPT Codes	Allowed Charges	Allowed Services	Beneficiary Count
99211	$ 37.10	2	2
99212	$ 151.22	5	5
99213	$ 1,706.80	63	22
99214	$ 22,922.84	226	193
99215	$ 31,889.15	160	171

CPT Codes	Allowed Charges	Allowed Services	Beneficiary Count
99201	$ 13,055.32	593	172
99202	$ 27,474.55	474	194
99203	$ 34,551.22	368	207
99204	$ 41,281.83	338	127
99205	$ 33,655.17	216	102

UTILIZATION OF E&M BILLED WITH SPECIFIC SERVICE

	Your % of Services with E/M	State's % of Services with E/M	Comparisons with State	National % of Services with E/M	Comparison with National
% with E/M	41%	26%	Significantly Higher	21%	Significantly Higher
A chi-square test was used in this analysis, alpha=0.05					

MINUTES PER DAY

	Your Average	State's Average	Comparison with State	National Average	Comparison with National
Minutes per Day	271.17	137.12	Significantly Higher	124.81	Significantly Higher
A t-test was used in this analysis, alpha=0.05					

AVERAGES PER BENEFICIARY

	Your Average per Beneficiary	State's Average per Beneficiary	Comparison with State	Natoinal Average per Beneficiary	Comparison to National
Services	2.45	3.61	Does Not Exceed	3.94	Does Not Exceed

A t-test was used in this analysis, alpha=0.05

	Your Average per Beneficiary	State's Average per Beneficiary	Comparison with State	Natoinal Average per Beneficiary	Comparison to National
Services	4.91	3.61	Significantly Higher	3.94	Significantly Higher

A t-test was used in this analysis, alpha=0.05

SEMPER PARATUS (ALWAYS PREPARED)

- Even when the audit document says “You do not have to respond”, know that you were targeted for a reason
- It is never advisable to ignore any “Official” document from a payer or one of their contracted “Bounty Hunters” unless:
  - You’re using a program (CRA) to identify risks and are confident in your providers’ distribution analysis;
  - You’re performing documentation (“Medical Necessity”) reviews and have independently validated the accuracy of your providers
- If you have performed a CRA and “Medical Necessity” review showing significant variance to what their findings suggest send a letter back to GlobalTech with a Cc to your MAC advising them of your disagreement with their assessment stating the facts of your independent analysis.

SAMPLE SIZE

- Probe Audits- Arcane and unreliable method to perform an audit.
  - 30 is the number most often used by ZPIC and RAC auditors.
  - OIG normally recommends 100 when engaging in self-disclosure audits
  - Either of these samples can be used for extrapolation. So, if you are performing one of these audits use a number lower than 30 and don't create a statistically valid random sample
  - Consider conducting internal audits under attorney/client privilege
- Educational Audits – 5-10 encounters
- Statistically valid audits – This depends on whether or not there is going to be an extrapolation. Typically you would want to see 30 encounters per CPT code in question according to The OIG
- Baseline Audit- 40 encounters – or a 10% selection of the provider's patient universe.
  - Performance of the audits prospectively vs retrospectively is a preference but both could result in expansion of the audit sample size, lead to refunds and/or self-disclosure

GATHERING INFORMATION

- Billing history for each DOS to be reviewed. (encounter form, copy of 1500 (if applicable) detailed billing history from billing information system.
- Copies of all corresponding records

HOW TO RESPOND TO PRIVATE PAYERS

To Whom it May Concern:

We are in receipt of your letter dated _____ identifying potential variance between what we have coded/billed during the time period of _____ and _____. To ensure we remain compliant with all payer and AMA coding/documentation guidelines as well as to validate the claims made in your letter, we have enlisted the services of _____ to perform various studies of our CPT and Modifier usage and a “Medical Necessity” review.

Our independent review demonstrates a significant variance from your suggested findings that our provider(s)are outliers. Additionally, the documentation review performed confirms all services in question have been performed; A) In accordance with generally accepted standards of medical practice and satisfy the overarching criteria used to determine “Medical Necessity”. B) Are clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient’s illness, injury or disease; and C) Are not primarily for the convenience of the patient or Physician, or other Physician, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.

AUDIT CHECKLIST

- Patient ID
- Provider ID
- Date of service
- **Medical reason for the encounter/evaluation**
- **Intensity of medically appropriate history**
- **Intensity of medically appropriate examination**
- **Complexity of decision making process**
- **Legibility**
- Orders for diagnostic tests/procedures
- **Accuracy of diagnosis to ICD-10CM**
- **Linking of diagnosis to each service**

WRAP UP

- CBRs lead to audits;
- CBRs are ***tools of intimidation*** to force providers who may be doing everything correctly to change how they are doing things, ultimately resulting in lower reimbursements, saving the payors money in the long-run;
- Understand your providers' coding/billing patterns;
- Perform regular documentation ("Medical Necessity") reviews to identify gaps between what is and what should be;
- KNOW YOUR RIGHTS & DON'T BE INTIMIDATED

Thank You!

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