

Medicare Jurisdiction A DME MAC and Region A Council

Meeting Notes

August 6, 2008

8:30 am EST

Teleconference

DISCLAIMER:

THE NOTES FROM THE MEETING ARE NOT OFFICIAL FROM THE PSC. THE NOTES ARE ONLY THE REGION A & B COUNCIL'S INTERPRETATION OF THE INFORMATION DISCUSSED AND THE COUNCIL SHALL NOT BE HELD RESPONSIBLE FOR PROVIDERS USE. INTERPRETATIONS CAN NOT BE USED TO PROTECT THE PROVIDER IN THE CASE OF AN AUDIT DISCREPANCY.

Present: Dr. Hughes, Karen Grasso, Laraine Forry, Georgie Blackburn, Asela Cuervo, Carol Napierski, Herb Langsam, Jackie McClure, Jim Cooke, John Shirvinsky, Karyn Estrella, Kathleen Sheehan, Kelly Brussell, Gerry Francisco for Kimberlie Rogers-Bowers, Paul Komishock, Paula Finamore-Galluci, Terri Maggio, Robbin Boardman, and Rose Schafhauser.

Meeting started at 8:31 EST.

Meeting notes typed by Rose Schafhauser.

1. Medlearn Matters CR 5971 Clarification – on Signature Requirements is unclear: The program integrity manual (PIM) has 2 sections that talk about signatures. Chapter 5 is on detailed written orders but doesn't get specific. There were changes in March that escaped him that we will want to review. Main point is in chapter 3.4.1.1. for information on signature requirements. In the CMN section – section D has to be signed, clear and legible – either hand signed, electronically signed, or stamped. Then it tells the contractors when they do an audit – they should never deny the CMN on the nature of the signature. Section 3.4.1.1. says we cannot use stamped signature on orders/prescription or in the medical record – it wouldn't be considered a valid medical record. It doesn't say they can't allow stamped signatures on CMN. Problem is when the CMN is used as an order – then the stamped signature is a problem. From Dr Hughes' point of view – just using CMN as a CMN – then a stamped signature is ok. If a provider uses CMN as a substitute as a prescription than don't use a stamped signature. The PIM should be used as a guide not the Medlearn Matters article. Dr Hughes suggested that before going out and changing your process, talk to program integrity at CMS to have them clarify.
2. Oxygen CMN has been published for paperwork reduction act review – are you aware of any changes? The Medical Directors have not been contacted regarding changes. All CMNs maybe under review for comment. He understands CMS is not making any major changes.
3. Review the PAP LCD:
 - a. Why was on sleepiness scale picked? Settled on Epworth Scale because of general consensus of the sleep industry was that it is the most widely known one.
 - b. Define treating physician? It is the term that everyone in Medicare uses. It is self defining that a treating physician is someone who is treating the patient in some shape or form. Excluded from treating physicians are doctors for hire, internet interviews, etc. The doctor must legitimately be involved in the ongoing care of the patient. It is ok to use a consulting physician/specialist in sleep medicine. Follow-up visits can be either/or. Assuming that family doctor has the information, they do not care who they use. Would not accept a one time visit to improve on sleep symptoms. Dr. Hughes recommending thinking about the medical records – if Medicare is going to audit – evidence that the patient is being taking care of for the ongoing condition.
 - c. Sleep studies done in a sleep lab of a hospital that also has a DME company that is affiliated with the hospital system, can they provide the equipment? Hospital arrangements usually get a pass. Dr Hughes suggests that if you are concerned with relationship with the hospitals sleep lab, get with your hospital attorneys to get a legal opinion if affiliation with the sleep lab is independent.
 - d. ICD.9 code 327.23 now must be used instead of the 780.53 miscellaneous code – how does that work of having an effective date of 3/13/08 – can we just change the code or get new

documentation? Providers must now use 327.23, for you may start getting denials for the 780.53. In regards to the ICD.9 code going back to 3/13/08 – Medicare will not be denying yet for they may have not turned on the edit yet. Dr. Hughes suggests talking to the customer service folks at the DME MAC on how to handle claims currently in their system.

- i. If you confirm with the physician that they have in their records the 327.23 – this can be documented in your records with a phone call. It is not that critical of an issue for there is only one code.
- e. Reference to specific CPAP supplies on an order, it used to be that the physician could be generic in ordering CPAP supplies, has that changed? Have to specifically make a list of the common supplies – tubing, mask, etc. If you have repeat orders, you do not need to have another order done unless they change frequency in replacement, then a new order would be needed.
- f. After 91st day, the treating physician has to have documentation of adherence to the use of the PAP device – does the provider have to provide a downloadable PAP? The treating physician must have objective data, some kind of download or information that they are using the PAP. In the new policy, the Medical Directors somewhat paralleled how they do oxygen certification. They are still looking at this area.
- g. On sleep study interpretation, does this mean a facility that is a non-accredited sleep lab, they must have the sleep study interpreted by a certified or accredited? Yes – must be read by certified sleep certification specialist. The American Board of Internal Medicine represents pulmonologist, and all professionals in the sleep business. No specialty is excluded by the board requirement. There are lots of unaccredited sleep labs and physicians not qualified to do the interpretations. Must have an accredited lab or physician.
- h. Significant changes when you restrict something in a policy, why did this policy not go out for public comment? This is an expansion policy – not a total new one – so therefore not required to go out for comment. They are not prohibited from adding specific details.
- i. Memory cards – not all units have them – it appears they must have 30 days of history. The policy seems to dictate that the beneficiary receive a unit that has that capability – but nothing in the policy that dictates the type of machine and there is no additional allowable for the more expensive machine. So how does a provider provide the history? This can be done in one shot or throughout time. Can use hour meters and logs are acceptable.

4. Meeting will be continued on Tuesday, August 12 at 8:00 am EST.

Additional meeting notes Tuesday, August 12

Present: Dr. Hughes, Laraine Forry, Georgie Blackburn, Carol Napierski, Gloria Murray, Jackie McClure, Jim Cooke, John Shirvinsky, Karyn Estrella, Kelly Brussell, Gerry Francisco and Jim Dudley for Kimberlie Rogers-Bowers, Melissa Watson and Rose Schafhauser

1. Updates from Dr. Hughes:
 - a. Stamped signature issue are NOT acceptable on CMNs and DIFFs. It has been the wording on the CMN and CMS will adjust chapter 5 to indicate that stamped signatures are not ok. Fax and use of electronic CMN mechanisms to sign those documents would be acceptable in an audit. Electronic would be a verified signature. There should be something out from CMS that states this. Amy Capece at NHIC will have CMS make the affective date going forward. Do not publicize this yet.
 - i. The providers will have to work with the physician community to notify them that stamped signatures are not acceptable.
 - b. Draft policies will be coming out on specific equipment in the next week or 2. 4 are in the pipeline. Hoping for the 15th for the first 2 and the other 2 next month.

Additional PAP Questions and Answers:

2. Does the DME MAC have advice on continued usage? There are 2 elements to continued use. The 1st is a compliance meter piece. The policy makes reference to “downloadable”. The Medical Directors realize it is too narrow of the term. The policy will be adjusted to address that. Someone has to take care of the compliance and that somehow ends up with the physician. The 2nd piece is that the physician has to make an assessment that there is some improvement. Each one of the elements has to be met, then

payment will continue past the 3rd month. This is not a supplier only record. The 2 changes in the policy are big: 1st is the addition of clinical improvement piece and 2nd that the physician has to make that assessment.

- a. Who is the physician? The referring physician or sleep doctor can make the assessment. Doctor House Calls for hire is not acceptable. There will be additional clarification on this in the policy in the next couple of weeks.
 - b. Will there be a delay in implementation? The compliance check and lab criteria physician credential for facility based testing, will be delayed, but the rest of the policy may not be. The home sleep testing piece will not be delayed.
 - c. How do we make sure the second appointment is set up for the patient, because many do not come back? Somebody has to follow-up on the patient.
3. Is there a web site (s) that we can access to verify that a physician is a diplomat of ABSM or ABMS? Yes. Go the American Board of Sleep Medicine (ABSM) or American Board of Medical Specialties (ABMS) websites. Sleep certification is a secondary certification, not primary. Folks affiliated with sleep labs are employees and owners, if not certified, are still ok. Do not have to be direct employees. The physician bills separately for the reading of the study.
4. How are providers able to identify that the physician interpreting the test meets the criteria? Ask them or see the answer to 3.
5. The policy specifically states “supplier-generated form is not a substitute for the comprehensive medical record”. Are they expecting providers to obtain these chart notes at the time of order to document coverage? It is up to the provider.
6. For orders on or after 9/1/08 the requirement states that the patient have a face to face with the ordering physician and that specific items, including an Epworth Sleepiness Scale be documented in their medical record. Many of the patient’s we will receive an order for on or after 9/1/08 have already had that initial visit to the physician and there has been no time to educate the physician community as to the requirements. How does Medicare suggest we handle these patients? Do they need to start from scratch so that these items can be documented in their chart? That is why there is a 45 day notice. 31 day notice in this case. He understands the time is tight. But there are accommodations for folks put them on the side to work on. Should have been telling them that.
- a. Is the Epworth scale being questioned? No. Because it is in a local policy, however, it could be reviewed on a case by case basis. You as a supplier could accept it, when it gets denied, then make the argument on an appeal and that there should be an acceptance on the policy.
 - b. If the Berlin scale had been used, it would include sleepiness scale – is that ok? That is not what the policy says. Must use the Epworth, not the Berlin. The minimum is the Epworth, and that is what they will be looking for it in the medical record. This will not change.
7. Please clarify the change to a RAD within the initial 3 month period. For example: if a patient is using a CPAP for 30 days and is not improving so the doctor switches them to a RAD. Is a new face to face required for follow up along with a new download to meet the continued coverage beyond 90 days for the RAD? No, a new face to face is not required. Yes, you have show compliance with the RAD. The initial visit that justifies the equipment is not. If they are not compliant on the equipment, then they may need to have a new face to face. As long as they can show compliance in the usage. If compliant but not improvement, may need to have another visit to have to show clinical improvement. Must have clinical improvement for payment.
- a. It patient is on a CPAP – on the 65th day they change to RAD device, they will not have 30 days for compliance on the RAD – what is the rule that? Should have a compliance test that they are using the equipment, if they aren’t compliant, should be a different issue. According to the physicians, they have indicated that most can figure out if the patient shows improvement in the first few weeks.
8. Are providers required to maintain a copy of the face to face instruction given by the entity providing the HST equipment? No, providers should have anything to do with the testing. Do not get involved.

9. If on the first follow up visit to the physician, the patient doesn't meet the 70% compliance threshold, however going forward they begin to use consistently and meet the criteria after an additional 7 days use, do they then have to go back to the doctor to show compliance, or is a downloaded report sufficient? Answered in 7 – nothing limits the number of visits. Have to have at least one visit. The download report is not sufficient, you need both and have to go together in order to have payment continued.
10. How is the provider to assess and document if the patient has had a "Face-to-Face" clinical evaluation (a) which appears to include a dozen different elements and (b) which must occur PRIOR to the sleep test? The face to face documents that the patient is appropriate for sleep test. Same way you assess any clinical test that you document any part of medical necessity. The DME MAC does not require you to get this prior to submission of the claim. That is your discretion.
11. Must the provider have on file a copy of the physician's clinical record to reflect criteria enumerated in the clinical evaluation? Same response as number 10.
12. Please define a "focused cardiopulmonary and upper airway system evaluation"? It is what it is. Those are the relevant body parts that are important to document the evaluation of obstructive sleep apnea.
13. We sometimes do not know how the clinicians have defined apnea or hypopnea events in their test results; must they now document how they are defining these parameters for us? The definitions are standard medical definitions based on standard medicine. If there are funky things, the physician doesn't get to define what hypopnea is, the test would be ruled invalid. Must use standard definitions.
14. Please define "has received instruction in the use of...." Does that mean a face-to-face encounter with the patient or written instructions sent by mail, or DVD? The definition is on the use of the equipment from the provider on how to use the equipment. This falls under same umbrella of other equipment instructions – you must document – doesn't matter how, just be consistent. There must be an appropriate note. If a narrative note on review of instructions is signed and dated, should be fine. Check off form, probably not. If they provide a DVD/instruction sheet, if you document that they understand how to use the equipment, should be fine.
15. Re: "If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep...": How does Medicare define "sleep"? Is this both REM and Non-REM? This is for the labs to do. Sleep is sleep.
16. Please differentiate between a "Sleep Center" and a "Sleep Lab". Both these terms are used in the policy? These terms are used interchangeably, as anyone else's terms of where you go to get sleep tests.
17. The policy alludes to a RAD being covered for patients w/OSA who's CPAP has been tried and failed based on a "trial conducted in a facility or in a home setting. How does Medicare define a "facility" and who decides that the trial has failed in the home setting? These are clinical decisions, answer to number 16. During a split night study, patient didn't tolerate CPAP, and then used bi-level device. This can be done in one night as a split study.
18. How does a provider document that a sleep test has been done by a qualified Medicare provider of sleep tests? There is no central entity that certifies the labs. Some labs get JCAHO certification but that is not what they are talking about. If you have some type of certification, should be ok. Generally in an audit, is that when they look at the test that was provided at the lab, is which part the lab has to bill, Part A or B, to provide that test. It is the standards to bill Medicare for the tests that they are interested in during an audit. There is no consistent licensure for those kinds of labs.
 - a. Is there any type of documentation? Can ask the lab – you should know your labs. There is nothing in the policy that requires you to document or assess. It is up to the provider.

- b. What is the view on hotel based sleep lab? Depends on who is doing the study. If they are credentialed and do not have space, it is fine. If a person is a fly by night – probably not. Use common sense.
19. What is the rationalism for the requirement for providers to use only more expensive PAP devices with utilization information download capability in order to document adherence to PAP therapy when the reimbursement is fixed and disregards which type of equipment used? This was discussed already and this based on their focusing on high technology products. This language will be adjusted to be broader in order to document compliance. There is a number of ways to read the machine.
20. Are the operational hurdles created when making continued reimbursement to us for the patient's equipment dependent upon the physician's compliance with the re-evaluation requirement? Yes. It is contingent upon the 2 elements. CMS wants to take the control out of the supplier's hands and into the physician's hands. This is a deliberate change based on 15 years of audits. Will continue to take away control from the provider. Dr Hughes believes we will see other policies move into this direction.
- a. If provider gets an ABN initially about the compliance portion of having to have a follow-up visit and if not seen by their physician, that this equipment would be non-covered? Dr Hughes is not an expert on ABNs. The ABN must be unique to the individual patient, and must tell the beneficiary the specific details as to the possible denial. To the extent of that, the reevaluation falls into that category, depending how you word the ABN (written uniquely for that patient) should be covered. Talk to Amy Capece at NHIC.
 - b. Nothing in policy precludes that the visit can be done anytime during that 90 days? No, has not gone that far.
21. If a patient hasn't reached 70% compliance by day 90, but is trying to improve, can we continue treatment? This gets into if day on 90 they are not compliant, will probably never be compliant. There are exceptions, but reality is that these decisions are made in the first couple of weeks. If you have any unusual scenario, do on a case by case basis.
22. Are DME's expected to have copies of the initial face-to-face physician notes? If they ask for them in an audit, yes, you are going to need the sleep study, follow-up visit, etc. It is between you and the referring physician. Dr Hughes cannot mandate that we get this at the front end, it would be a paperwork reduction violation. The physician does not have to give the provider the information unless they are doing an audit.
23. Do we need copies of the medical follow up notes? Same as 22, yes, in audit you would.
24. In regards to the lab affiliation: if a physician has worked with the lab for years, the physician should be fine. The only group it leaves out is the folks doing on their own and is not part of a lab.

Meeting concluded at 9:28am EST.