Jurisdictions B, C and D Councils Combined A-Team Questions
August 2016 – Final Copy to Council Chairs

Enteral/Parenteral/IV Therapy

1. The YouTube CMS Provider Minute: Enteral Nutrition Infusion Pumps states that both the order and form (referring to the DIF) need to be signed and dated by the physician. The January 2015 Joint DME MAC Publication titled; "*DME Information Forms (DIFs) Usage for Enteral and Parenteral Nutrition and External Infusion Pumps – Revised*", clearly states, "DIFs are completed entirely by the supplier and do not need to be signed by the treating physician. DIFs are required to be signed and dated by the supplier." Please confirm that the Joint Publication statement quoted above is accurate and retract or modify the video to ensure suppliers are provided clear and accurate guidance.

DME MAC response: The DME Information forms (DIFs) CMS-10125, CMS-10126 contain completion instructions and state the supplier's signature certifies that the information on the form is an accurate representation of the situation(s) under which the item or service is billed. After completion, supplier must sign and date the DME Information Form, verifying the attestation. The DME MAC Supplier Manuals include DIF completion instructions, and indicate the DIFs can be completed in their entirety by the DME supplier. The video referred to in the question was created and published by CMS, and not the DME MACs. Therefore, we are unable to modify but will inform CMS so that the video may be updated.

2. DME MAC Joint Publication entitled "Billing Guidance - Billing for External Infusion Pumps and Drugs When Treatment Was Initiated Somewhere Other Than the Beneficiary Home" represents a reversal of a clear, longstanding policy on how suppliers should bill for external infusion pumps, drugs and related supplies.

The DME MAC Joint Publication incorrectly specifies that "only when external infusion pumps, drugs and related supplies are initiated and administered in the beneficiary's home may claims be billed to the DME MAC under the Durable Medical Equipment benefit." The Joint Statement indicates that any infusion not initiated in the home is only billable to the A/B MAC. However, this policy interpretation is a major deviation from CMS' recently issued MLN Matters® Number 1609 as well as CMS' established policy regarding suppliers' ability to bill DME MACs for drugs infused through external infusion pumps.

On April 25, 2016, CMS released MLN Matters® Number 1609, "Medicare Policy for Prolonged Drug and Biological Infusions Started Incident to a Physician's Service Using an External Pump," which appears to be the impetus for the DME MAC Joint Publication. Importantly, CMS' article was limited to "prolonged drug and biological infusions **started as** incident to a physician's service using an external pump." CMS explained that prolonged drug and biological infusions started as incident

to a physician's service using an external pump should be treated as an incident to service and cannot be billed on suppliers' claims to DME MACs.

([1] DME MAC Joint Publication, "Billing Guidance – Billing for External Infusion Pumps and Drugs When Treatment Was Initiated Somewhere Other Than the Beneficiary Home," May 5, 2016.)

CMS specifies that the article **"does not apply to suppliers' claims submitted to Durable Medical Equipment MACs (DME MACs)."** 2 In contrast to the DME MAC Joint Publication, the MLN Matters article does **not** limit the ability of suppliers to bill DME MACs for infusion pumps, drugs and supplies to equipment and supplies to those items that are initiated and administered in the beneficiary's home.

The current policy article associated with the local coverage determination (LCD) for external infusion pumps provides that "Injectable drugs administered in a physician's office, whether with or without a pump, must be billed to the local carrier and not the DME MAC. **Drugs put into an infusion pump in the physician's office for use in the beneficiary's home must be billed to the DME MAC if the pump is billed to the DME MAC."** 3 The current LCD provides that "charges for drugs administered by a DME infusion pump **may only be billed by the entity that actually dispenses the drug to the Medicare beneficiary** and that entity must be permitted under all applicable federal, state, and local laws and regulations to dispense drugs…." 4

Consistent with the policy article and LCD, CMS' MLN Matters Number MM7397, entitled "Pharmacy Billing for Drugs Provided 'Incident to a Physician Service," (revised on April 10, 2012 and effective on January 1, 2013) explains the following:

Pharmacies may bill Medicare Part B for certain classes of drugs, including immunosuppressive drugs, oral anti-emetic drugs, oral anti-cancer drugs and drugs self-administered through any piece of durable medical equipment.

- Claims for these drugs are generally submitted to the Durable Medical Equipment Medicare Administrative Contractor (DME MAC). The carrier or A/B MAC will reject these claims as they need to be sent to the DME MAC.

- In the rare situation where a pharmacy dispenses a drug that will be administered through implanted DME and a physician's service will not be utilized to fill the pump with the drug, the claim is submitted to the A/B MAC or carrier.

MM7397 describes situations when pharmacies may **not** bill Medicare Part B for drugs, including (1) when the drugs are "dispensed directly to a beneficiary for administration 'incident to' a physician service, such as refilling an implanted drug pump" and (2) "for drugs <u>furnished to a physician</u> for administration to a Medicare beneficiary. When these drugs are administered in

the physician's office to a beneficiary, these drugs can be billed to Medicare only if the physician purchases the drugs from the pharmacy. In the case, the drugs are being administered 'incident to' a physician's service and pharmacies may not bill Medicare Part B under the 'incident to' provision."

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[2]CMS MLN Matters® Number SE 1609, available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1609.pdf.

[3] NHIC, Corp., External Infusion Pumps – Policy Article (A52507), Revision Effective Date: 01/01/2016.

[4] NHIC, Corp., External Infusion Pumps (L33794), Revision Effective Date: 01/01/2016.

[5] Pharmacy Billing for Drugs Provided "Incident To" a Physician Service, MLN Matters® Number MM7397, available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7397.pdf (last visited June 16, 2016).

Similarly, in a previous communication with CMS regarding billing for drugs inserted into an implanted pump, the agency explained that the insertion of drugs into the implanted pump is performed by the physician, and thus the drugs and the pump are incidental to that physician service. CMS contrasted this with the provision of drugs for an **external infusion pump**, which CMS recognized does not require a physician's actions and thus the pump, drugs and supplies can be billed by a home infusion therapy provider under the DME benefit even when the therapy is initiated in the physician's office.

The LCD and policy article are consistent with guidance in CMS' manuals. For instance, Appendix C of Chapter 6 of the Medicare Prescription Drug Benefit Manual (CMS 100-18) clarifies that:

Drugs infused in the home using an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare DME MAC.

Question regarding "Billing Guidance - Billing for External Infusion Pumps and Drugs When Treatment Was Initiated Somewhere Other Than the Beneficiary Home".

Some chemotherapy protocols call for a 46-72-hour continuous maintenance dose of Fluorouracil (5-FU) be started immediately following the load dose, which is administered in a clinical setting.

a. Is it proper to bill the DME MAC if the home infusion supplier delivers the drug, equipment and supplies to the beneficiary in the clinic setting, they start the continuous maintenance dose in the clinic, and the patient then leaves the facility to complete the 46 – 72 hour infusion in the home?

DME MAC Response: In the event that the facility bills for the administration of the drug and/or the cost of the drug itself, it would not be billable to the DME MAC.

b. Is the answer to A predicated on whether or not the physician is billing for the CPT administration code for the infusion?

DME MAC Response: Yes.

c. If the physician is not providing the drug there is no "incident to billing", correct?

DME MAC Response: That would not be correct. In this scenario, the physician may still bill for 'incident to' services including supplies, pump, etc. as part of the infusion administration CPT code.

d. Must all four of the following criteria, listed in both SE1609 and the DME MAC Joint Publication, be met in order for drug, pump and supplies to not be billable to the DME MAC
   - Purchase a drug for a medically reasonable and necessary prolonged drug infusion; and,
   - Begin the drug infusion in the physician's office or hospital outpatient setting using an external pump; and,
   - Send the patient home for a portion of the infusion; and,
   - Have the patient return at the end of the infusion period

DME MAC Response: Yes, as long as the physician bills 'incident to' services for supervision, billing for these services would apply to the DME benefit. Note that these are not criteria for billing but rather represent an example scenario for billing.

In some situations, the patient is on infusion medication that is continuously delivered (Inotropic, pain management) and the infusion cannot be interrupted even for a short time. When the patient is about to leave the acute care or skilled facility, the home infusion provider may be required to initiate the infusion therapy and provide the drug, pump and supplies in order to ensure a safe transition home.

The following language in the DME MAC Joint Publication would essentially eliminate a beneficiary's access to the Part B DME infusion benefit by prohibiting a DME home infusion provider from billing for infusion pumps, drugs and supplies that are not initiated in the home setting - "Only when external infusion pumps, drugs and related supplies are initiated and administered in the beneficiary's home may claims be billed to the DME MAC under the Durable Medical Equipment benefit." This appears to directly contradict the MLN Learning Matters article as discussed in the introduction to these questions.

e. Was this an intentional policy change, or would the transfer of a patient to home for home infusion under the care of a home infusion provider remain billable to the DME MAC? Does this vary based on the type of facility the patient is leaving? The safe transition of care to

the home environment is an important factor. Most hospital and clinics do not allow their medical equipment to leave the premises, nor do they have the support services to manage patient's infusion needs in the home environment. The direction provided by CMS is clear. If a patient is started on the infusion in the home setting under the care of a home infusion provider, and is completed therein, this is considered as a DME benefit and should be billed as such.

DME MAC Response: This is not a policy change. CMS and the contractors became aware of improper billing by some providers of infusion services. Consequently, CMS provided instructions to the MAC contractors restating the rules that if a patient is started on the infusion in the home setting under the care of a home infusion provider, and is completed therein, the claim should be billed to the DME MAC.

f. Some patients travel long distances to receive care from a facility to obtain specialized treatments and cannot be safely disconnected from the infused medication for the duration of travel. If this interpretation is followed as stated, these patients will no longer have access to home infusion under the DME benefit. Is that the intent?

DME MAC Response: As stated above, CMS' intent was to reiterate program guidance due to non-compliance with billing rules. In this the scenario described above, patients return home to complete their infusion, and the facility bills for all services, including the drug, to the provider's A/B MAC contractor.

g. Is this policy specific to a single infusion, or does it extend to subsequent infusions given in different sites of care?

DME MAC Response: The instruction in this policy clarifies billing in this jurisdiction. The MAC jurisdictional billing may change if the continuing provision of infusion services is assumed by the infusion company and ongoing physician 'incident to' services are no longer being provided. Examples of this may occur with longer-term infusions such as 5-FU and epoprostenol.

h. Are the DME MACs coordinating with the A/B MACs to ensure that beneficiaries continue to have access to prolonged infusions, that are an important component of the many chemotherapy protocols?

DME MAC Response: There have been collaborative calls and discussions involving the medical directors from A, B and DME MACs to ensure consistent interpretation of CMS guidelines.

3. JW Modifier Clarification:

Fluorouracil is prescribed by a physician as part of the chemotherapy regimen, to be given via IV continuous infusion. Prior to compounding this sterile product, the pharmacist calculates an overfill

amount of drug (Fluorouracil) and accompanying diluent. The total compounded amount of drug in mg will be slightly higher than the prescribed dose.

For purposes of this discussion: The total compounded amount of drug in mg = the prescribed dose in mg + required overfill amount of drug in mg.

When compounding the product, the pharmacy compounds the overfill amount of drug and diluent in the infusion container (which is either a disposable elastomeric pump or an infusion bag with attached administration set.) The prescribed dose is indicated on the prescription label.

a. Is the pharmacy required to bill for this overfill amount by using the JW modifier?

DME MAC Response: This is dependent upon how the drug is supplied (container size) and the units of service in the HCPCS code narrative. Refer to the scenarios discussed in the article cited below for information on the various combinations of HCPCS code units of service and drug container sizes.

b. If a supplier identifies that they submitted a claim without the JW modifier what are the steps to correct the claim?

DME MAC response: In the event that the supplier has utilized drug dosage formulations and/or unit does sizes which minimize drug wastage, and there is an amount of drug which has been discarded, then the amount of wastage is reported on a separate claim line along with the JW modifier. If this was not done at the time the claim was initially billed, the provider may submit a request for a reopening.

Claims for drugs billed to Medicare must use drug dosage formulations and/or unit dose sizes that minimize wastage. Providers and suppliers are expected to use drugs or biologicals most efficiently, in a clinically appropriate manner. Only when the most efficient combination of dosage forms are used and there is drug remaining may a supplier bill the discarded amount using the JW modifier on the claim line for the UOS not administered to the patient.

Please refer to Joint DME MAC publication “Correct Coding-JW Modifier Use-Revised- Effective for Claims with Dates of Service On or After January 1, 2017.”

4. NOC DIF Revisions:

a. In response to the recent joint notification regarding revised DIFs for HyQvia, if the DIF was sent with J7799 states the drug name (e.g. HyQvia) are we required to consistently uploaded DIFs when a HCPCS code has been assigned?

DME MAC Response: A Revised DIF is required when there has been a change in any of the information recorded on the DIF. If a drug previously billed under the J7799 NOC code is assigned a HCPCS code a revised DIF is required.

b. Would it be appropriate to have the revised DIF created, and kept on-file upon request only? Simply because a HCPCS code has been assigned the miscellaneous NOC HCPCS DIF does specify the drug name and the claim includes this information.

DME MAC Response: No, the revised DIF must be submitted with the first claim submitted after the change.

c. What is the DME MAC guidance on claims that have processed for payment in full without the loading of the revised DIF for the new J-code assignment aft 1/1/16?

DME MAC Response: The DME MACs have provided some flexibility during the code transition in applying the new policy. Going forward the correct code must be applied.

d. Would this be applicable to other NOC drugs?

DME MAC Response: Yes.

e. Is there an edit that has been put in place with an effective date?

DME MAC Response: This question is unclear. Is Council asking if the system has been updated to require that when HyQvia is billed that it is billed with the new J-code or is Council asking if the system has been updated to require a revised DIF?

5. The new Medicare LCD criteria for home inotrope therapy state a patient must be American College of Cardiology Foundation/American heart Association (ACCF/AHA) Stage D heart failure OR New York heart Association (NYHA) Class IV heart failure. NYHA criteria are more subjective symptom based while ACCF/AHA are more objective based. Therefore, there are situations when a patient medical record will note a patient is Stage D Class III heart failure OR Stage C Class IV heart failure. Will these statements meet Medicare LCD criteria since the LCD text states one or the other?

The new Medicare LCD (L33794) states the therapy must be:

I. Prescribed following an evaluation by a cardiologist with training in the management of advanced heart failure;
II. For parenteral inotropic drugs, the cardiologist with training in the management of advanced heart failure who performs the initial evaluation does not need to be the prescriber for the parenteral inotropic drug. However, the prescribing practitioner must: verify that an initial evaluation was performed by a cardiologist with training in the management of advanced heart failure; and have documentation of the evaluation; and provide a copy of the initial evaluation and the prescription for the item(s) to the DMEPOS supplier.

Questions:

a. In either situation, is it acceptable to have the medical necessity documentation including staging, past GDMT, presenting symptoms, improvement on inotropes and plan of care to

be dictated by a resident, fellow, PA or NP if the cardiologist with training in the management of advanced heart failure provides an attestation co-signature below the note detailing they evaluated the patient with the resident, fellow, PA or NP, agree with the findings, etc. and provide a signature complying with Medicare signature guidelines?

b. In many major teaching hospitals where advanced cardiac care is provided, this is the standard documentation methodology. Would the above scenario meet the criteria pertaining to "prescribed following an evaluation by a cardiologist with training in the management of advanced heart failure"?

DME MAC Response: The DME MACs recognize that there are common medical education scenarios where a physician in training may provide and document care to a beneficiary. The supervising physician is expected to provide and document their oversight and acceptance of the care provided. As long as this is documented and the supervising physician meets the LCD requirements, in the event of a claim review, such records would meet the "heart failure specialist requirements".

6. PN Homemix: The NCD coverage policy for PN states that there needs to be a "statement from the attending physician that establishes that the beneficiary, due to his/her physical or mental state, is unable to safely or effectively (home) mix the (tpn) solution and there is not family member or other person who can do so."

Since the practice of mixing TPN at home are long gone (the above NCD is from 8-11-1984) and the pharmacy regulations/USP 797 demand compounded sterile preparation (CSP) of TPN AND the Medical Policy and LCD do not mention this criteria, is this something that can be expected from the Medicare Carriers or any auditing body, pre or post pay? Can this requirement be removed since it is no longer an acceptable practice? The new Medicare LCD criteria for home inotrope therapy state a patient must be American College of Cardiology Foundation/American heart Association (ACCF/AHA) Stage D heart failure OR New York heart Association (NYHA) Class IV heart failure. NYHA criteria are more subjective symptom based while ACCF/AHA are more objective based. Therefore, there are situations when a patient medical record will note a patient is Stage D Class III heart failure OR Stage C Class IV heart failure. Will these statements meet Medicare LCD criteria since the LCD text states one or the other?

DME MAC Response: Potentially, it remains conceivable that an audit could be developed which would edit for parameters and documentation as defined in NCD 180.2 The DME MACs do not have the authority to modify NCDs. CMS has described a process to request changes on the coverage pages of the CMS website. The DME MAC medical directors have also made CMS aware of this question and response.

(Language from NCD 180.2: Nutrient solutions for parenteral therapy are routinely covered. However, Medicare pays for no more than one month's supply of nutrients at any one time. Payment for the nutrients is based on the reasonable charge for the solution components unless the medical record, including a signed statement from the attending physician, establishes that the beneficiary, due to his/her physical or mental state, is unable to safely or effectively mix the solution and there is no family member or other person who can do so. Payment will be on the basis of the reasonable charge for more expensive premixed solutions only under the latter circumstances.).

7. On Medicare CMN's one of the options listed in some areas is 'D' for Does Not Apply. Is D still a valid code to use? One company was told it has been changed to N but the actual CMN still states D as the option.

   DME MAC Response: The instructions on the second page of the CMN (using the Oxygen CMN – CMS-484 as an example, state: "This section is used to gather clinical information to help Medicare determine the medical necessity for the item(s) being ordered. Answer each question which applies to the items ordered, checking "Y" for yes, "N" for no, or "D" for does not apply."

Respiratory Care Equipment/Oxygen/PAP/Other

8. This is a follow up question to the response given on question #11 from the April 2016 Q & A. The question and answers were:

   If a supplier has all required elements in the WOPD, with a non-specific modality order for "portability" for the portable oxygen system:

   a. Does the order have to be specific to compressed gas, portable concentrator, etc. or will "portability" suffice?
   b. If the physician documents via an attestation statement that their standard protocol for ordering portability shall be compressed gas portables unless otherwise specified would Medicare accept the attestation in lieu of a modified order?

   DME MAC response: See response to Question 2 above for information about what is required for a detailed written order. Generally speaking, detailed written orders must contain a detailed description of the item ordered. Simply stating "portability" is not specific and a general blanket attestation for all patients is not acceptable.

The response in this question referenced the response in Question #2 which is referring to the DWO needed for billing and not the WOPD. The answer to #11 on the April 2016 Q&A seems to contradict the attached DME MAC Joint Publication updated April 28, 2016.

DME MAC response: See response to Question 2 above for information about what is required for a detailed written order. Generally speaking, detailed written orders must contain a detailed description of the item ordered. Simply stating "portability" is not specific and a general blanket attestation for all patients is not acceptable.

The DME MAC Joint Publication states the description of the item can be "general or may be more specific" which leads Providers to believe portability would be a sufficient general description for oxygen portable (E0431 or E0434). The answer received in the April 2016 Q&A contradicts the Joint Publication and states portability is not a sufficient description. Can we please get further clarification?

DME MAC response: The revisions to the ACA 6407 were published on April 28, 2016, which was after the April council questions were finalized and sent to the respective councils. If a supplier is going to provide portable oxygen based on a 5-element order, the description can be general or more specific. Based on the example provided above, "portability" on a 5-element order would be acceptable, but does not meet the descriptive element for a detailed written order.

9. The patient was tested on room air at rest with an O2 SAT of 85%, the physician initially prescribed Oxygen continuously at 2-LPM. However, at the time of recertification or at a sooner face to face exam, the patient states they are only using the oxygen at night and the physician documents such in the progress notes; he also changes his order to Nocturnal Oxygen at 2-LPM.

a. For a patient who initially qualified for continuous oxygen; can the physician change his order from continuous O2 to nocturnal O2 without performing nocturnal testing?

DME MAC Response: Yes.

b. If so, would the supplier need a new written order for nocturnal O2 at 2-LPM and a Recert CMN 484 with the nocturnal orders?

DME MAC Response: No.

c. If this type change occurs prior to the 12-month recertification; would the provider be required to get a new order and a Revised CMN 484?

DME MAC Response: No.

d. If no, will a qualifying overnight oximetry test and face to face exam suffice to qualify the patient moving from continuous O2 to nocturnal O2?

DME MAC Response: This would not be needed.

10. Medicare released the clarifications to the Vent Policy on May 5, 2016. The release does not address the life sustaining or life threatening that was present in the prior release. However, the RAD LCD still says that for the NIV the records should show that without use of a vent the pts condition would be life threating or would lead to serious harm or death.

a. Is the RAD LCD being amended to remove that part or are we still expected to provide that documentation in the medical records for NIV vents?
b. When there is an update to the NCD such as the clarification on the Vent Policy that was released on May 5, 2016 and the LCDs have not been updated, what policies will providers be held accountable to for documentation?

DME MAC Response: The DME MAC medical directors are aware of the CMS clarifications to the interpretation of the Frequent and Substantial Servicing statutory payment rules. An update to the LCD and associated Policy Article will be forthcoming.

11. This is a follow up question to the response given on question #12 from the April 2016 Q & The question and answer were:

We're seeing a CO-234 denial code when providing disposable and non-disposable nebulizer kits. In Jurisdiction C, when calling about these denials, we are being referred to CR 9345; however, we have been unable to locate any such Change Request. Where can we access this CR, and what guidance does this provide to explain the denial?

DMD response: The CO-234 denials are the result of CMS-mandated "same or similar" edits. These claims are coded as rejections and do not have appeal rights.

a. The response to the question did not provide us with the information on where the CR 9345 was posted and how were suppliers notified. Can you please clarify this?
b. Some patients may require a 2nd kit as a back-up to use during cleaning. Are there any exceptions to this?

DME MAC Response: This is a CMS change request that was not publicly posted. The DME MACs do not have discretion to discuss this.

12. The patient is currently using a CPAP compliantly for OSA. They have recently been diagnosed with Chronic Respiratory Failure in addition to their OSA and WILL require an E0466 Trilogy Ventilator during the day and at night.

The CPAP and Trilogy Ventilator cannot be used at the same time; therefore, the CPAP will be picked-up.

If the patient comes off the E0466 Vent in the future and needs to return to the CPAP for their OSA, can the pulmonologist document such and the patient return to CPAP for OSA without a repeat sleep study?

DME MAC Response: When the use of an item of rental DME is discontinued and later restarted, CMS requires that contractors assess the circumstances to determine whether a new capped rental should begin or the original rental should resume at the point it was discontinued. The assessment is required when there is a break-in-service of 60 or more days (excluding the days left in the rental month that the item was discontinued) have passed. If the original medical need for the item continues, the capped rental would resume at the point it was discontinued. For new episodes of care, a new rental would be started. It is recommended that the supplier be prepared to provide sufficient detailed documentation to justify the circumstance of each beneficiary's use.

As a reminder,DME MAC supplier manuals state "A period of continuous use allows for temporary interruptions in the use of equipment. Interruptions may last up to 60 consecutive days plus the

days remaining in the rental month (this does not mean calendar month, but the 30-day rental period) in which use ceases, regardless of the reason the interruption occurs. Thus, if the interruption is less than 60 consecutive days plus the days remaining in the rental month in which use ceases, contractors will not begin a new 13-month rental period. Also, when an interruption continues beyond the end of the rental month in which the use ceases, contractors will not make payment for additional rental until use of the item resumes. Contractors will establish a new date of service when use resumes. Unpaid months of interruption do not count toward the 13-month limit." This reflects the language in the Claims Processing Manual Chapter 20, Section 30.5.4, which was amended to reflect the 13 month rental period from the previously referenced 15 months contained in the CPM.

Rehab Equipment

13. Is there any update from CMS on the proposed Prior Authorization program? On an Open Door call on 05/04/2016, it was stated that two PWC codes, K0856 and K0861, has been selected. Is there any additional information - on a timeline, whether this will be national or more limited, or any other updates?

DME MAC Response: CMS has not provided any additional information to the DME MACs.

The final rule for prior authorization for durable medical equipment, prosthetics, orthotics and supplies was published on December 30, 2015. While the final rule itself is effective February 29, 2016, the regulation does not include implementation dates for prior authorization of items. Advance notice through a Federal Register notice will occur at least 60 days prior to an implementation date of prior authorization for any specific item.

Under the final rule, CMS will publish a notification of the items on the Required Prior Authorization List in the Federal Register 60 days before implementation. In addition, CMS will conduct education for beneficiaries and industry before implementation.

14. CR9579/MM9579 issued 04/28/16 with an effective date of 10/01/2016: Are these statements correct?

a. Replacement parts billed as part of a repair to a bid-base wheelchair:
   - If the beneficiary lives in a CBA, can be provided by any supplier. The parts need to be billed as ExxxxNURB or KxxxxNURB (without KE or KY), and will be paid at the SPA for that CBA.

     True or False

     DME MAC Response: True

b. Replacement parts billed as part of a repair to a NON-bid-base wheelchair.
   - If the beneficiary lives in a CBA, can be provided by any supplier. The parts need to be billed as ExxxxNURB or KxxxxNURB (without KE or KY), and will be paid at the SPA for that CBA.

True or False

DME MAC Response: True

c. Replacement parts billed as part of a repair to a bid-base wheelchair.
   - If the bene does not live in a CBA; need to be billed as ExxxxNURB or KxxxxNURB (without KE or KY), and will be paid at the RSPA (rural or non-rural) for that state.
     True or False

     DME MAC Response: True

d. Replacement parts billed as part of a repair to a NON-bid-base wheelchair.
   - If the bene does not live in a CBA; need to be billed as ExxxxNURB or KxxxxNURB (without KE or KY), and will be paid at the RSPA (rural or non-rural) for that state.
     True or False

     DME MAC Response: True

DME MAC Response: According to the instructions provided in MLN9579 effective October 1, 2016, all repair parts that are described by HCPCS codes for competitive bidding items, billed with the RB modifier, whether within or outside a CBA, will be paid on a lump sum basis. If the beneficiary resides within a CBA and the repair part is described by HCPCS codes for competitive bidding items, and billed with the RB it will be paid at the single payment amount. If the beneficiary resides outside of a CBA and the repair part is described by HCPCS codes for competitive bidding items and billed with the RB modifier it will be paid at the adjusted fee schedule (rural or non-rural) for the state.

15. Additional questions regarding CR9579/MM9579:

a. It is our understanding that if a part is classified as a capped rental code, when provided as a repair and billed with the RB modifier, it can only be billed and paid as a purchase (NU, or possibly UE).

   True or False

   DME MAC Response: True. Any part provided as part of a repair and submitted with the RB modifier must be billed with RB NU modifier combination. If a repair is billed RB RR modifier combination it will be returned as unprocessable.

b. Certain replacement codes are classified as capped rental codes – including several new codes changing to the capped rental category on 7/1/2016 (i.e., E2369 PWC gearbox). Since the effective date of this CR is 10/1/2016, how will these parts be billed if delivered in July, August or September (as repairs to non-CRT bases)? Must they be delivered and billed as rentals for any months prior to October?

DME MAC Response: This change does not take effect until 10/1/2016.Until then when billing for repairs you must follow the previous instructions. If the item falls within the capped rental category then it must be billed as a rental with the RR modifier and monthly capped rental modifiers.

c. For any parts that are on rental (delivered prior to the effective date of CR9579), and have not paid out 13 months prior to 10/1/2016, must these rentals be converted and billed as purchases for the October service date? Billed with the NU modifier, assuming the part was new when it was replaced on the wheelchair?

DME MAC Response: That is correct.

d. How will payment be determined?

DME MAC Response: Any rental payments previously allowed will be subtracted from the purchase price and the remainder will be paid in a lump sum.

e. For replacement/repair parts delivered to bene's who live in a CBA, but the parts were for use with Group 3 PWCs; for dates of service prior to 10/01/2016 (going back to 07/01/2013), will any of the MACs use their discretion to pay at the 'full' fee schedule allowable rather than the CBA SPAs?

DME MAC Response: No.

16. CR9520 implementation of PAMPA regs re CRT bases and accessories; new fee schedule amounts and new KU modifier.

This is effective July 1, 2016 for claims submitted with dates of service January 1, 2016 and after. Group 3 PWC bases, cushions used with the bases, and accessory codes on the PAMPA list will be paid at the new fee schedule amounts when billed with the KU modifier.

a. Do we continue to use the KE and KY modifiers?

DME MAC Response: The instructions included in CR9520 indicate that billing KE, KU modifier combination is considered invalid and any claim submitted with this combination after July 1, 2016 will be returned as unprocessable. The instructions provided in CR9520 do not change the instructions for use of the KY modifier.

In addition, CR9642 states that the KE modifier for dates of service on or after July 1, 2016 is an invalid modifier for any use.

b. Many of the codes on the PAMPA list are used as replacement parts when provided as part of a repair to the CRT base chair. Is the KU modifier used with RB to appropriately pay these claims at the correct fee schedule amount?

DME MAC Response: Yes. However, with the implementation of CR9579 this is subject to change. See response provided in question 14.

c. Many of the codes on the PAMPA list are used when provided as part of a modification (some time after the initial wheelchair sale) to the CRT base chair. Is the KU modifier used (without RB) to appropriately pay these claims at the correct fee schedule amount?

DME MAC Response: Insufficient information provided to answer this question. It is unclear what is meant by modification.

d. For those claims for dates of service January 1, 2016 and after that have already been processed & paid at the incorrect RSPA, how should adjustments be submitted? Many providers will have a substantial number of claims that will need to be submitted for adjustments. Will each of the MACs please explain the process for adjusting these claims, and is each MAC willing or able to process adjustments from a spreadsheet rather than individual claim/line re-submission, as was done for prior 'fixes'?

DME MAC Response: All four of the DME MACs have agreed to accept spreadsheets for reopening of these claims requested by suppliers and have published instructions for submission.

CGS – Jurisdiction B, C published an article on July 5, 2016. The article is titled; "Requesting a Reopening Based on the Implementation of Section 2 of the Patient Access and Medicare Protection Act (PAMPA)".

Noridian – Jurisdiction A, D published an article on July 21, 2016. The article is titled; "Group 3 Complex Rehabilitative Power Wheelchair Accessories Reopening Guidance".i

17. Will the KE modifier be used in any circumstances for dates of service July 1 2016 and after?

DME MAC Response: No. CR9642, indicates the KE modifier for dates of service July 1, 2016 is no longer valid for any use.

Medical Supplies/Ostomy/Urological

18. We understand orders which only state "PRN" or "as needed" as utilization estimates for replacement, frequency, use, or consumption are not deemed acceptable by Medicare. Often, disposable supplies are requested with the frequency stated as a range.

Fpr example, an order for a surgical dressing might specify that a 4 x 4 hydrocolloid dressing requires changing 1-2 times per week for 1 month or until the ulcer heals. This is specific because it specifies a range of supplies which are to be utilized (e.g. minimum and maximum) for a specific amount of time. There are varying factors to determine when the minimum/maximum is to be used.

Would a range in these types of circumstances not suffice the requirement?

DME MAC Response: In the event of an audit, the medical record must provide sufficient information to justify the beneficiary's actual utilization and must contain specific enough documentation to establish the number of supplies used and the timeframe of usage.

Documentation/Education/Miscellaneous

19. The Medicare Claims processing manual indicates that the one-time authorization is not valid for non-assigned DME rental claims. When a non-participating provider decides not to accept assignment on Medicare covered DME rental item(s), is the supplier required to obtain a signature from the beneficiary prior to billing each rental month for the DME item(s)? How does this work if the beneficiary does not provide the authorization each month; does that relieve the supplier from filing the courtesy non-assigned claim to Medicare until the authorization is received?With the effective date of the new Prior Authorization rule being February 29, 2016, can you offer a status update on implementation of the program?

DME MAC Response: The jurisdiction Supplier Manuals answer this question – for non-assigned capped rental claims, an authorization must be received each month. Proof of delivery documentation is only required upon delivery. In translation, suppliers do not have to obtain a new delivery slip for capped rental items every month if the item(s) has been in continuous possession of the beneficiary. If for some reason the equipment was picked up and then redelivered, the supplier would need to obtain new proof of delivery once the item(s) is redelivered.

Capped rental items billed as non-assigned require beneficiary authorization each month. A one-time authorization does not apply to DME capped rental items billed on a non-assigned basis. One reference for this information is in the Jurisdiction C Supplier Manual (Chapters 3 & 6).

20. In an insurance change scenario, if a beneficiary is Medicare eligible, but only has Part A and picks up part B at a later date, but meets the Face to Face requirement while eligible for Part A, since the policy does not stipulate they have to be eligible for Part B, it just says Medicare, is this acceptable?

Would i the face to face that was conducted while the patient was only covered under part A benefits be used to qualify the patient once he/she transitions to part B?

DME MAC Response: Yes, for both questions.