



## The Difference Between Billing Assigned and Billing Non-Assigned

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- The DME industry has been in existence since the 1970s.
- The industry primarily serves the elderly, meaning that DME suppliers have largely been dependent on Medicare.
- DME suppliers have primarily billed Medicare on an assignment basis. That is, (i) the supplier provides the product to the Medicare beneficiary, (ii) the supplier takes assignment from the beneficiary and bills Medicare, (iii) Medicare pays the supplier 80% of the allowable, and (iv) the supplier collects the other 20% from the beneficiary.



- Under this "assignment" model, the successful DME supplier had to be proficient at billing and collecting from Medicare.
- While the assignment model will remain with us, we are witnessing a transition to a non-assignment model.
- Under the non-assignment model, a non-participating supplier will (i) collect money up front from the beneficiary and (ii) submit a claim to Medicare on behalf of the beneficiary in order for the beneficiary to receive reimbursement from Medicare.



- There are several factors behind this transition:
  - Subject to certain restrictions, the supplier can charge the beneficiary whatever the supplier wants to.
  - The supplier receives its money up-front.
  - Many Baby Boomers are willing to pay cash for Cadillac products rather than be relegated to a "Cavalier" product paid for by Medicare.







#### Avoiding Discrimination





#### Anti-Discrimination Rule

• CMS has an anti-discrimination rule that states that it can terminate a DME supplier's PTAN for a number of reasons, including if the supplier "places restrictions on the persons it will accept for treatment and it fails either to exempt Medicare beneficiaries from those restrictions or to apply them to Medicare beneficiaries the same as to all other persons seeking care." 42 C.F.R. 489.53.



#### **Avoiding Discrimination**

- A supplier can set up any pricing it wants as long as it is the same for all.
- Suppliers can make decisions on what to take assignment on based on any algorithm as long as it is the same for all payers.









# Participating vs. Non-Participating





#### Participating Supplier

- A DME supplier elects to become a "participating supplier" by completing the Medicare Participating Physician or Supplier Agreement.
- When a DME supplier elects to become a participating supplier, it agrees to accept assignment on all claims for Medicare products and services and agrees to be paid the Medicare-allowed amount as full payment, less any unmet deductible and coinsurance.





#### Non-Participating Supplier

- When a DME supplier is a "non-participating supplier," it may accept assignment on a claim-by-claim basis.
- If a non-participating supplier does not accept assignment, it can collect directly from the patient for Medicare covered products and services and charge more than the Medicare allowable in such cases.
- The supplier is required to file the claim with Medicare on a nonassigned basis on behalf of the patient, and any Medicare reimbursement is sent directly to the patient.



## Switching From Participating Supplier to Non-Participating Supplier

- To terminate an existing Medicare participating supplier agreement and become non-participating, the supplier must notify the National Supplier Clearinghouse ("NSC") in writing during the enrollment period.
- The annual participation enrollment period begins on November 15 and concludes on December 31 of each year.







#### Billing Nonassigned





#### Competitive Bid Items

- If a non-participating supplier without a competitive bid ("CB") contract sells or rents an item (that falls within a product category covered by CB) on a nonassigned basis to a patient residing in a CBA, the item is not covered and the patient will not be reimbursed by Medicare.
- The noncontract supplier is required to notify the beneficiary that it is not a contract supplier for the CB item in the CBA, and the supplier must obtain a signed ABN indicating that the beneficiary was informed in writing prior to receiving the competitively bid item or service that there would be no payment by Medicare due to the supplier's noncontract status.



#### Renting a Capped Rental Item

- Assume that an item is reimbursable by Medicare as a "capped rental item."
- Assume that the non-participating, noncontract supplier rents the item, on a nonassigned basis, to a patient not residing in a CBA.
- In this situation, the supplier can collect a rental amount from the patient that is higher than the Medicare fee schedule, and Medicare will pay 80% of the Medicare fee schedule rental payment to the patient on a monthly basis.



#### Payment Authorization Form

 The DME supplier must have the beneficiary complete a signature authorization for the claim form every month for items rented on a nonassigned basis.





#### Supplies and Accessories

- For supplies and accessories used with beneficiary-owned equipment (equipment that is owned by the beneficiary, but was not paid for by Medicare FFS), Medicare will pay for them; however, all of the following information must be submitted with the initial claim in Item 19 on the CMS-1500 claim form or in the NTE segment for electronic claims:
  - HCPCS code of base equipment
  - A notation that this equipment is beneficiary-owned
  - Date the patient obtained the equipment



#### Supplies and Accessories

- Medicare requires that supplies and accessories only be provided for equipment that meets the existing coverage criteria for the base item.
- In the event of a documentation request from a CMS contractor, the supplier must provide information justifying the medical necessity for the base item and the supplies and/or accessories.
- Note: drugs and biologicals (e.g., nebulizer drugs) are mandatory assignment items.





### Repairs

- Repairs to equipment that a beneficiary owns are covered when necessary to make the equipment serviceable.
- If the expense for repairs exceeds the estimated expense of purchasing (or renting another item of equipment for the remaining period of medical need), no payment can be made for the amount of the excess.
- When billing for repairs, include the HCPCS code and date of purchase of the item being repaired, the manufacturer's name, product name, model number, MSRP of the repair item provided, and the justification for the repair.



#### Commercial Insurance Mandates Assignment

- Under the anti-discrimination provision, the supplier can adopt a policy in which (i) it bills nonassigned for Products A, B, and C and/or (ii) it bills nonassigned for all products in which third party reimbursement is \$100 or less.
- This policy does not discriminate against Medicare patients because this policy applies across the board.



#### Commercial Insurance Mandates Assignment

- The following question arises: If the insurance company requires the supplier to bill on an assigned basis for all products, including "Product A," then does the supplier have the right (under the anti-discrimination provision) to sell/rent "Product A" to the Medicare patient on a nonassigned basis?
  - The answer is "yes." Rather than saying it will only take assignment on claims based on a certain dollar figure, the supplier can adopt a policy that a particular item will be available to a patient if the reimbursement received meets a certain dollar threshold.



#### Commercial Insurance Mandates Assignment

- The supplier can always make that item available to a Medicare patient on a nonassigned basis.
- If the commercial insurance does not allow nonassigned claims, the item is only available to the patient if the insurance reimbursement meets the threshold dollar amount.



#### Switching to Medicare Advantage

- A Medicare beneficiary may switch from Medicare FFS to a Medicare Advantage plan.
- The question is: "Do Medicare Advantage plans allow the DME supplier to bill nonassigned or do Medicare Advantage plans require the supplier to take assignment?"
- The supplier will need to look to the specific Medicare Advantage plan to see if the plan requires the supplier to take assignment or allows the supplier to bill nonassigned. If the answer is that the specific plan requires assignment, then the supplier can make the item available to the patient only if the insurance reimbursement meets the threshold dollar amount.



#### Payment Authorization

- A request for payment signed by the beneficiary must be obtained for each claim and kept on file by the supplier.
- Generally, suppliers may obtain and retain in their files a one-time payment authorization.
- Except as specified below, once the supplier has obtained the beneficiary's onetime authorization, later claims can be filed without obtaining an additional signature from the beneficiary.
- These claims may be on an assigned or nonassigned basis with the exception of DME rentals. The one-time authorization for DME rental claims is limited to assigned claims.
- For items rented on a nonassigned basis, the supplier will have to get a beneficiary authorization signature each month.



#### What the Supplier Can Charge

- The supplier can charge the patient an amount higher than the Medicare fee schedule. While the supplier can charge the patient an amount lower than the Medicare fee schedule, the supplier needs to be aware of the federal statute that says that a supplier is prohibited from charging Medicare substantially in excess of the supplier's usual and customary charges, unless there is good cause shown.
- In addition, the supplier needs to also be aware of (i) Medicaid statutes that say that the supplier must bill Medicaid its "usual and customary," and (ii) provisions in commercial insurance contracts that state that the supplier must give its "best price" to the insurer.



#### Limiting Charge

- According to CMS: "The provider may bill the beneficiary no more than the "limiting charge" for covered services.
- The "limiting charge" applies only to certain Medicare-covered services and does not apply to DME.



#### Selling Capped Rental Items

 Since Medicare will not pay anything for the sale of a capped rental item, an approach may be to allow the beneficiary to rent on a nonassigned basis so that the supplier receives higher reimbursement, but the beneficiary still receives paid 80% of the Medicare allowable.



#### Billing for Items on Same Day

 A supplier cannot submit some items assigned and others nonassigned on the same date of service.



## Changing from Assigned to Nonassigned

- If the supplier is non-participating, then it can change to nonassigned during the rental period.
- The supplier should give the patient at least 30 days advance notice, so the patient can look for another supplier that will accept assignment.
- Also, if the supplier changes to nonassigned for rental equipment, the supplier will have to obtain a beneficiary payment authorization signature for each month's rental.



## Changing from Assigned to Nonassigned

- In the past, the DME MACs have stated that a supplier cannot change from assigned to nonassigned during the course of the 36 month oxygen rental.
- B&F disagrees. Language from the Federal Register makes it clear that the supplier's notice regarding acceptance of assignment is not binding.



#### Oxygen Contents

 A non-participating supplier can bill oxygen contents nonassigned after the 36-month rental period.



#### Stationary and Portable

 If an oxygen patient has both a concentrator and a portable that are being billed on two different anniversary dates, one claim can be assigned and the other claim can be nonassigned.



#### **Contents Charge**

 The Oxygen Policy Article makes clear that a supplier can adopt either flat rate for contents or a charge that varies based on the quantity of contents provided.



#### Self-Fill Cylinders

- A supplier can use conserving devices, portable oxygen concentrators, etc.
- A supplier can technically use a self-fill unit for the individual patients as long as each patient has his/her own equipment and self-fill cylinders.
- The supplier can have the patient, nurse, or other caregiver fill the cylinder for the patient.
- The supplier cannot have one self-fill unit with a number of cylinders to fill for unnamed individuals.



#### **Number of Cylinders**

- Unless it is a safety issue to have multiple cylinders in a residence, there
  is not a limit to what should be provided to meet that patient's needs.
- The supplier is required to provide all contents that the patient needs during the month and cannot limit the number of cylinders.



#### Post-Payment Audits

- Because relatively few DME claims have historically been billed nonassigned, there is no significant track record of CMS pursuing recoupments of nonassigned claims.
- Having said this, nonassigned claims are equally as vulnerable to audits as assigned claims.
- If a nonassigned claim is audited, the supplier will be responsible to produce the documents justifying medical necessity.



# Nebulizer Drugs

• The nebulizer medications should be covered if the patient meets Medicare medical necessity coverage criteria for the nebulizer and all of the following information is submitted with the initial claim in Item 19 on the CMS-1500 claim form or in the NTE segment for electronic claims: HCPCS code of base equipment, a notation that this equipment is beneficiary-owned, and the date the patient obtained the equipment.



# Secondary Insurer

- If the supplier does not accept assignment on an item, the billed amount will be whatever amount the supplier sets.
- The secondary insurer will not typically pay the difference between the billed and allowed charge. This is typically disallowed by secondary payers.



# ABN

- The intake process should be the same for assigned and nonassigned items.
- If the patient does not meet medical necessity criteria and the supplier chooses to provide and bill nonassigned, an ABN should be issued and assuming the ABN is valid, the supplier should have no repayment obligation. The supplier should not routinely be obtaining an ABN for all nonassigned claims.
- An ABN should be issued only when the supplier reasonably believes that the claim will be denied. In the instance that a nonassigned claim is reviewed and payment denied, the supplier will usually be required to refund the amount collected back to the Medicare beneficiary unless a valid ABN was obtained.



## Required Documentation

- A supplier should evaluate all patients against the LCD and policy article requirements.
- If a patient meets all Medicare requirements, an ABN cannot be used.
- A nonassigned claim can be filed with appropriate notification to the patient.



### Rental Copayments

- The supplier cannot collect all rental "copayments" up front because a copayment is tied to the monthly rental charge.
- A supplier can charge its regular charge for the equipment and collect the full amount from the patient on a nonassigned basis for the first month, and then take assignment for all subsequent month rentals.
- A one-time claim authorization is effective for future month rentals when assignment is accepted.
- A separate authorization is required for each month rental billed on a nonassigned basis.



### Medicare Advantage Plans and ABNs

- ABNs are specific to Medicare FFS.
- Whether a Medicare Advantage plan requires an ABN, or something equivalent to an ABN to hold the patient responsible if the plan denies coverage for the claim, is dependent on the particular plan.





#### **Prior Authorization**

- The supplier can bill nonassigned on an item that requires prior approval.
- Obtaining prior approval does not mean that the supplier has to take assignment.
- A supplier is required to follow Medicare guidelines for coverage regardless of assignment of claim.



## Prescription Items

- Any item labeled as a prescription device or supply requires a prescription prior to dispensing, regardless of whether it is being sold by a Medicare supplier, "retail" company or online company with no PTAN.
- State licensing requirements govern who can/cannot sell prescription items. The seller of a prescription-only item should retain the prescription in its records.





# Electronic Signature

 Medicare should accept an electronic signature that meets the requirements of the Uniform Electronic Transactions Act ("UETA").



# Denial of Nonassigned Claim

 Applicable reasons for denial of a nonassigned claim are lack of medical necessity, failure to have a Medicare supplier number, violation of telephone solicitation prohibition, denial of an Advanced Determination of Medicare Coverage (ADMC) request, and non-contracted suppliers for competitive bid items in a CBA.



## Billing Secondary Insurance

 A supplier is not required to bill secondary insurance on a nonassigned claim.



### Hospital-Owned Supplier

 If the supplier and the hospital are under the same Tax ID number (i.e., the supplier is a "department" of the hospital), and if the hospital is participating, then the supplier must be participating as well.







#### Retail





#### Retail and Billing Nonassigned

- A supplier is engaged in "retail" when it sells an item for cash.
- If the patient is a Medicare beneficiary and if the item sold is covered by Medicare and if the patient pays cash to the supplier for the item, then the supplier will be deemed to have provided the item on a nonassigned basis.
- If the patient is a Medicare beneficiary and if the item sold is not covered by Medicare, then the transaction will be a retail cash sale.
- If the patient is not a Medicare beneficiary, then it does not matter either way if the item is covered by Medicare. The transaction will be a retail cash sale.



## **Baby Boomers**

- There are 78 million "Baby Boomers." They are retiring at the rate of 10,000 per day.
- While the 23 million of the "Greatest Generation" expected Medicare to pay for everything, Boomers understand that they will be required to pay out-of-pocket for a portion of their health care expenses...including DME.
- From a Boomer's standpoint, the most important asset he has is time.
   Many 70 year old Boomers will not want to wait around for Medicare approval.
- Rather, the Boomers will simply pay cash and move on with their lives.



# Separate Legal Entity

 Assume that ABC Medical Equipment, Inc. has a PTAN and is located on Main Street. Assume that John Smith is the sole stockholder of ABC. Although it is not legally required, it makes good business sense for Smith to set up a new corporation with its own Tax ID #, called "ABC Retail Sales, Inc."



- ABC Retail will not have a PTAN
- ABC Retail will be located on Elm Street. Or it can be located on Main Street next to ABC Medical, with ABC Medical being in Suite A and ABC Retail being in Suite B. The bottom line is that ABC Medical and ABC Retail will be physically separated from each other.
- Each corporation will have its own employees, own bank account, etc.
   In short, each corporation will be operated as a distinct entity.





- When a customer wants the Cadillac product and services, then he can pay cash for the product at ABC Retail. If a customer wants Medicare to pay for the product, then he can obtain the product from ABC Medical.
- ABC Retail will stock only "Cadillac" products. ABC Medical will stock a variety of products, including "Cavalier" products.



• If a customer walks into ABC Retail and says that he wants Medicare to pay for the product, then ABC Retail can refer the customer to ABC Medical. Conversely, if a customer walks into ABC Medical, does not like the product selection, and is willing to pay cash for a higher end product, then ABC Medical can refer the customer to ABC Retail. Even though the two companies will have the same owner (John Smith), the companies are nevertheless separate legal entities (each with its own Tax ID #). And so the relationship between the two companies needs to be the same as if they were not owned by the same person. Therefore, there can be no money going back and forth between the two companies that is tied to referrals.



• It will be important for ABC Medical and ABC Retail to truly operate as separate legal entities (e.g., no commingling of money). This way, someone suing one of the companies will not be able to "pierce the corporate veil" and sue the other company as well.



 ABC Retail needs to be aware of 42 U.S.C. 1395m(j)(4)(A), which states that if a supplier furnishes DME to a Medicare beneficiary, for which no payment may be made because the supplier does not have a Medicare supplier number, then any expenses incurred for the DME will be the responsibility of the supplier. This means that the ABC Retail customer will have no financial responsibility for the product, and ABC Retail will be required to refund the customer, unless before the product was furnished, (i) the customer was informed that Medicare would not reimburse the customer for the product and (ii) the customer agreed to pay cash knowing that he would not be reimbursed. In order to meet this requirement, when a customer walks into ABC Retail and if the employee suspects that the customer is covered by Medicare, then the employee may want the customer to sign an ABN.



 Alternatively, ABC Retail may want to make the calculated decision that having suspected Medicare customers sign an ABN will have a "chilling" effect on the retail experience for the customer. Therefore, ABC Retail might decide not to require a suspected Medicare customer to sign an ABN; and then in those few instances when a Medicare customer subsequently complains that he was unaware that Medicare would not reimburse him, ABC Retail will reimburse the customer. From a practical standpoint, this will not occur very often. ABC Retail should also post signs that are conspicuous to the public, that say that ABC Retail is not a Medicare supplier. Now let us assume that ABC Retail desires to sell items for cash over the internet. ABC Retail's web page should have the following in large bold type appear as soon as the customer clicks on a link to view DME, as well as immediately prior to check-out:





 Notice to Medicare Beneficiaries. Medicare will pay for medical equipment and supplies only if a supplier has a Medicare supplier number. We do not have a Medicare supplier number. Medicare will not pay for any medical equipment and supplies we sell or rent to you. You will be personally and fully responsible for payment.



#### Reasons for a Separate Legal Entity

- There are two fundamental reasons behind setting up ABC Retail as a separate legal entity:
  - Exposure to Audits ABC Medical is at risk for recoupment liability in the
    event of an aggressive audit. If ABC Retail is only a "division" or "DBA" of ABC
    Medical, and if ABC Medical does get hit with a large recoupment, then it will
    also adversely affect the financial condition of the retail "division." On the other
    hand, if ABC Retail is a separate legal entity, then generally speaking, any
    recoupment liability imposed against ABC Medical will not spill over to ABC
    Retail.



#### Reasons for a Separate Legal Entity

• Future Sale of Retail Business – If ABC Retail is a "division" of ABC Medical, and if John Smith desires in the future to sell his retail business, but retain his Part B Business, then Smith has no choice but to have ABC Medical enter into an asset sale of its retail business. Smith will not have the option of selling his stock in ABC Medical. On the other hand, if ABC Retail is a separate legal entity, and if Smith decides in the future to sell the retail business, then he has the option of engaging in either an asset sale or a stock sale. Additionally, if ABC Retail is a separate legal entity, then it can bring in additional investors.







## Questions?









# Thank you

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