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AN INDUSTRY IN TRANSITION: HOT BUTTON ISSUES FOR DME SUPPLIERS

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INTRODUCTION

INTRODUCTION

- The durable medical equipment ("DME") industry, as we know it today, is young. It started out in the 1970s.
- The industry "grew up unregulated." For the first three decades of its existence, hardly anyone on Capitol Hill or with CMS knew what the DME industry did.
- Well, the government appears to be trying to make up for lost time.

INTRODUCTION

- Today, the DME industry has been hit with the "perfect storm" of competitive bidding, aggressive audits, reimbursement cuts, and stringent documentation requirements.
- As a result of the confluence of these events, the industry is having to remake itself. Specifically, the industry is changing from (i) the old assignment/fee-for-service model to (ii) billing non-assigned and focusing on retail cash sales.
- As the DME industry goes through this transformation, it is facing a number of hot button issues. This webinar will focus on those issues.

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RECENT CMS GUIDANCE

REVISED: REQUIREMENTS FOR F2F AND 5EO

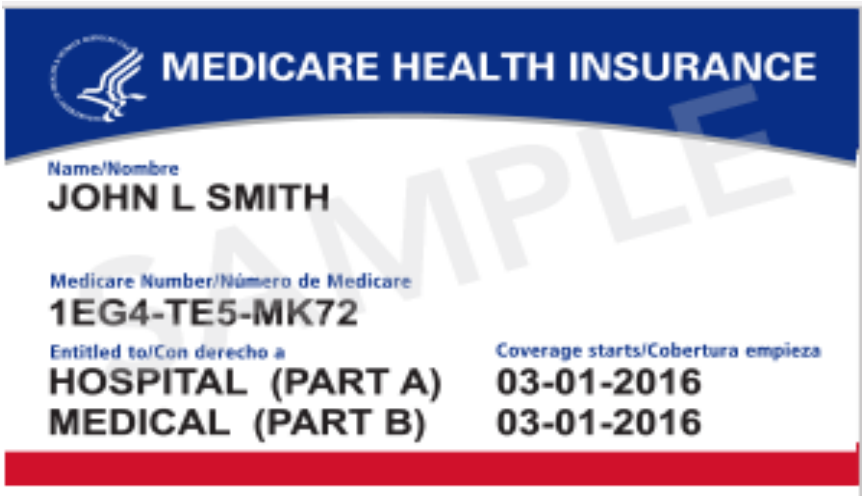
- The date stamp requirement is no longer required on the 5EO or Detailed Written Order ("DWO") for Affordable Care Act items.
- Updated Standard Policy Article removed the statement: "A date stamp or equivalent must be used by the supplier to document receipt date."
- Updated "Dear Physician" letter regarding Face-to-Face ("F2F") and 5 Element Order (5EO) requirements.
- Updated CGS Documentation Checklists.

CMS IMPLEMENTS NATIONAL PROBE & EDUCATE

- **All** DME MACs are now a part of the Targeted Probe and Educate ("TPE") program.
- TPE will fundamentally change DME MAC probe reviews and widespread service-specific audits.
- The TPE Process:
  - Up to 3 rounds of claim review
  - Direct education after each round
- Audit exemption is more possible than ever!

NEW MEDICARE CARD DESIGN RELEASED

- CMS Administrator Seema Verma published an article on September 14 regarding the new Medicare cards.
- Beneficiaries will start receiving their new Medicare cards in April 2018 through April 2019.



REMINDER: QIC TELEPHONE DEMONSTRATION

- CMS sent out a reminder on September 21 to alert providers to respond to the QIC Telephone Discussion Demonstration reopening document request letters.
- Untimely response → reopening request will not be considered and appeal will remain in its current place with the OMHA.
- C2C update: Over 300,000 reminder letters sent in July and August to suppliers that did not respond.

REMINDER: QIC TELEPHONE DEMONSTRATION

- Letters sent to the name and address on the reconsideration.
  - Contact C2C at 904-224-7349 to verify if they have pending reopening requests for your company, notify them of any changes in address, verify your billing address on file, or request a withdrawal.

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BILLING NON-ASSIGNED

ANTI-DISCRIMINATION RULE

- The Age Discrimination Act of 1975 generally prohibits age discrimination under any program receiving federal financial assistance.
- CMS has a specific anti-discrimination rule that states that CMS 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.

PARTICIPATING SUPPLIER

- When a DME supplier is a “participating supplier,” it is required to take assignment.
- The Medicare beneficiary’s obligation is to pay his/her copayment.

NON-PARTICIPATING SUPPLIER

- When a DME supplier is a “non-participating supplier,” the supplier “may accept assignment on a claim-by-claim basis.”

NON-PARTICIPATING SUPPLIER

- If a non-participating supplier does not accept assignment, the supplier can collect directly from the patient for Medicare-covered products and services and charge more than the Medicare allowable in such cases.
- In this instance, the supplier is required to file the claim with Medicare on a non-assigned basis on behalf of the patient, and any Medicare reimbursement is sent directly to the patient.

SWITCHING FROM PARTICIPATING SUPPLIER TO NON-PARTICIPATING SUPPLIER

- If a participating supplier elects to become a non-participating supplier, the supplier must terminate its existing Medicare participating supplier agreement.
- 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 [Medicare participating supplier agreement] enrollment period."

SWITCHING FROM PARTICIPATING SUPPLIER TO NON-PARTICIPATING SUPPLIER

- The annual participation enrollment period begins on November 15 and concludes on December 31 of each year.

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 non-assigned basis to a patient residing in a CB area, the item is not covered and the patient will not be reimbursed by Medicare.

COMPETITIVE BID ITEMS

- The noncontract supplier is required to notify the beneficiary that it is not a contract supplier for the competitive bidding item in the CB area, 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 non-assigned basis to a patient not residing in a CB area.
- 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.

SUPPLIES & ACCESSORIES

- For supplies and accessories used with beneficiary-owned equipment (equipment that is owned by the beneficiary, but was not paid for by the DME MAC/fee-for-service Medicare), 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

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 (if the HCPCS code is not available, include the manufacturer's name, product name, and model number of the equipment), the manufacturer's name, product name, model number, and MSRP of the repair item provided, and the justification for the repair.

COMMERCIAL INSURANCE MANDATES ASSIGNMENT

- 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 non-assigned basis?

COMMERCIAL INSURANCE MANDATES ASSIGNMENT

- The answer is “yes.” The supplier has the right to choose whether to accept Medicare assignment on a claim-by-claim basis. Rather than saying it will only take assignment on claims based on a certain dollar figure, the supplier should 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 non-assigned basis.
- If the commercial insurance does not allow non-assigned claims, the item is only available to the patient if the insurance reimbursement meets the threshold dollar amount.

SWITCHING TO MEDICARE ADVANTAGE

- Many Medicare beneficiaries are switching from Medicare fee-for-service ("FFS") to Medicare Advantage plans.
- The key question is: “Do Medicare Advantage plans allow the DME supplier to bill non-assigned or do Medicare Advantage plans require the supplier to take assignment?”

SWITCHING TO MEDICARE ADVANTAGE

- Suppliers will need to look to the specific Medicare Advantage plan to see if the specific plan requires the supplier to take assignment or allows the supplier to bill non-assigned. If the answer is that the specific Medicare Advantage plan requires assignment, then the supplier can follow the advice set out above and only make the item available to the patient if the insurance reimbursement meets the threshold dollar amount.

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) some Medicaid statutes that say that the supplier must bill Medicaid its "usual and customary" and (ii) provisions in some commercial insurance contracts that state that the supplier must give its "best price" to the insurer.

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 non-assigned basis so that the supplier receives higher reimbursement, but the beneficiary still receives paid 80% of the Medicare allowable.

CHANGING FROM ASSIGNED TO NON-ASSIGNED

- If the supplier is non-participating, then it can change to non-assigned 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 if it wants to.
- Also, if the supplier changes to non-assigned for rental equipment, the supplier will have to obtain a beneficiary claim authorization signature for each month's rental.

CHANGING FROM ASSIGNED TO NON-ASSIGNED

- In a recent webinar, the DME MACs stated that a supplier cannot change from assigned to non-assigned 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.
- B&F understands that CMS will issue a FAQ that addresses this issue.

POST-PAYMENT AUDITS

- Up to now most DME claims have been billed on an assigned basis.
- Because relatively few DME claims have historically been billed non-assigned, there is no significant track record of CMS pursuing recoupments of non-assigned claims.
- Having said this, non-assigned claims are equally as vulnerable to audits as assigned claims.

POST-PAYMENT AUDITS

- If a non-assigned claim is audited, the supplier will be responsible to produce the documents justifying medical necessity. If recovery is substantiated, the supplier will have to refund the beneficiary if an ABN was not sufficiently detailed to cover the audit finding.

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RETAIL

INTRODUCTION

- As previously discussed, most DME suppliers can no longer build their business model on Medicare FFS.
- The successful supplier needs to go outside its comfort zone and look for new sources of income.
- In particular, the DME supplier needs to look to the retail market.

INTRODUCTION

- 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.

INTRODUCTION

- 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.

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SEPARATE LEGAL ENTITY FOR RETAIL BUSINESS

INTRODUCTION

- 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. It is wise for Smith to set up a new corporation with its own Tax ID # called "ABC Retail Sales, Inc."

NEW LEGAL ENTITY

- 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.

NEW LEGAL ENTITY

- 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.

NEW LEGAL ENTITY

- 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.

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.

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DME SUPPLIER HAS NO PTAN

DME SUPPLIER HAS NO PTAN

- Certain disclaimers must be made when a supplier sells, without a PTAN, DME to a Medicare beneficiary. 42 U.S.C. §1395m(j)(4)(A) 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.

DME SUPPLIER HAS NO PTAN

- The beneficiary will have no financial responsibility for the expenses, and the supplier will refund any amounts collected from the beneficiary.
- However, the supplier does not have to refund the payment if the beneficiary is informed that Medicare will not pay for DME sold by a supplier that is not enrolled with Medicare prior to making the transaction.

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STATE "BRICK & MORTAR" LAWS

INTRODUCTION

- Most states require a DME supplier to have some type of license. This requirement is imposed on the supplier located within the state as well as the out-of-state supplier shipping into the state.
- A few states (e.g., Tennessee and Colorado) require the DME supplier to have a “brick and mortar” presence in the state before a license will be issued to the supplier. The latest state to impose such a “brick and mortar” requirement is Georgia.

GEORGIA "BRICK & MORTAR" REQUIREMENT

- To the extent that a DME supplier provides items that meet the Georgia statutory definition of "durable medical equipment" and submits claims to the third party payors for such items, it will need to obtain a state DME supplier license **and** maintain an office or place of business in Georgia.

DIFFERENCES AMONG STATES

- It is likely that other states will adopt “brick and mortar” requirements as a precondition to receive a DME license. If the supplier intends to sell products to residents of one of these states, it is important that the supplier carefully read the statutory language. Each state “brick and mortar” statute will have nuances that will likely not be found in other state “brick and mortar” statutes.

DIFFERENCES AMONG STATES

- Examples of such nuances are:
  - Does the statute define how large the facility must be? Must the facility be 1,000 square feet? 500 square feet? 200 square feet? 50 square feet?
  - Can the facility be as simple as subleasing e.g., 200 square feet from a pharmacy or grocery store?
  - Can the facility be a self-storage unit?
  - Is the facility required to be accredited as a DME supplier? Must the facility have a PTAN?
  - Can an out-of-state supplier lease e.g., 200 square feet in the same state but then ship products from out-of-state directly to the residents (i.e., products do not physically come into, or go out of, the facility)?

DIFFERENCES AMONG STATES

- Is the facility required to be open to the public for “X” hours per week?
- Must there be a person in the facility for “X” hours per week? If so, must the person be a W-2 employee of the supplier or can the person be a 1099 independent contractor of the supplier?
- Must the facility have an address that is recognized by the post office?
- Must the facility have a working telephone number?

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INTERNET LEADS

INTERNET LEADS

- Lead generation companies ("LGCs") have been around for years in the non-health care space. However, in the last several years, LGCs have come into the health care market in droves.
- Unfortunately, most LGCs that have been successful in the widget market are clueless regarding the multiple federal and state anti-fraud laws in the health care market, such as the federal anti-kickback statute and certain state anti-kickback statutes.

INTERNET LEADS

- When a DME supplier signs a lead generation agreement ("LGA") with an LGC, an important legal issue involves the federal anti-kickback statute and certain state anti-kickback statutes.
- It is acceptable to purchase a lead; however, it is a violation of anti-kickback statutes to pay for referrals. The line between the two can be blurry.

INTERNET LEADS

- It is acceptable for an LGC to obtain basic information from a lead (name, address, and telephone number) and sell this “raw” lead to a DME supplier.

INTERNET LEADS

- The supplier can, in turn, pay the LGC on a per lead basis. If, however, the LGC obtains "qualifying" information on the lead (e.g., Medicare number, other insurance information, medical condition, physician's name, products currently being used, etc.) and sells the qualified lead to the supplier which, in turn, pays for the lead on a per-lead basis, then it is likely that an enforcement agency will take the position that the supplier is not buying a lead but is paying for a referral, which violates anti-kickback statutes.

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SHAM TELEHEALTH ARRANGEMENTS

ORTHOTICS & TELEHEALTH

- Over the past four years, there has been a noticeable growth in the orthotics market.
- The reasons for this growth are: (i) orthotics are not affected by competitive bidding; (ii) Medicare has historically paid well for orthotics; and (iii) it is relatively easy for a DME supplier to ship orthotics (i.e., braces) all over the country.

ORTHOTICS & TELEHEALTH

- The orthotics phenomenon has been driven by lead generation companies ("LGCs") that can produce large "buckets" of leads.
- LGCs approach "standard" DME suppliers (oxygen concentrators, beds, etc.) and show them how they can make money selling braces throughout the U.S.

ORTHOTICS & TELEHEALTH

- While it is relatively easy for a LGC to convince a prospective customer (usually a Medicare beneficiary) that he needs a brace, it is harder to motivate the prospective customer to drive to his physician's office to obtain an order.
- And so LGCs have hooked up with telehealth companies. Unfortunately, many of these telehealth companies are suspect.
- A standard telehealth company receives its income from patients, patients' employers, and patients' insurance plans.

ORTHOTICS & TELEHEALTH

- A suspect telehealth company receives its money (usually indirectly) from the DME suppliers selling the braces.
- Here is how a suspect telehealth arrangement works: (i) DME supplier pays the LGC; (ii) the LGC pays some of the money to the telehealth company; (iii) the telehealth company pays some of the money to the telehealth physician; and (iv) the telehealth physician writes the order for the brace … with the order going to the DME supplier.
- In reality, the DME supplier is paying the telehealth physician who is writing the order. This implicates the Medicare anti-kickback statute.

PAYMENT SUSPENSIONS

- The industry is witnessing CMS contractors suspending payments to, and conducting prepayment reviews of, DME suppliers that engage in questionable telehealth arrangements.
- For example, a DME supplier recently received a ZPIC letter that says, in part:
  - [The] suspension of your Medicare payments is based on, but not limited to a review of the documentation you submitted to [Name of ZPIC] for a prepayment audit conducted on claims you submitted to Medicare in which supporting documentation was requested from your facility. Our review found that LCD coverage criteria were not met as required examination of joint laxity was not documented or the medical records documented a joint laxity test that could not have occurred **via telehealth visit**. The review resulted in a __% denial (__/__ claims). (Emphasis added.)

CMS WILL PAY ONLY IN LIMITED CIRCUMSTANCES

- According to CMS, Medicare beneficiaries are eligible for telehealth services only if they are presented from an originating site located in:
  - A rural Health Professional Shortage Area (HPSA) located either outside of a Metropolitan Statistical Area (MSA) or in a rural tract; or
  - A county outside of a MSA

CMS WILL PAY ONLY IN LIMITED CIRCUMSTANCES

- CMS defines originating sites as:
  - Offices of physicians or practitioners
  - Hospitals
  - Critical Access Hospitals (CAHs)
  - Rural Health Clinics
  - Federally Qualified Health Centers
  - Hospital-based or CAH-based Renal Dialysis Centers (including satellites)
  - Skilled Nursing Facilities (SNFs)
  - Community Mental Health Centers (CMHCs)

CMS WILL PAY ONLY IN LIMITED CIRCUMSTANCES

- Medicare further states that as a condition of payment, there must be an interactive audio and video telecommunications system that permits real-time communication between the practitioner, at the distant site, and the beneficiary, at the originating site.
- Information from CMS indicates that even if a telehealth encounter complies with state telehealth laws, and even if a claim is not submitted to Medicare for the telehealth visit, Medicare will deny the claim for DME if the physician order arises from a telehealth encounter that does not meet the requirements set out above.

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SWITCHING SUPPLIERS: NEW PHYSICIAN ORDER NOT REQUIRED

SWITCHING SUPPLIERS

- Up until recently, the Medicare Program Integrity Manual ("MPIM"), Chapter 5, § 5.2.7 has required a new physician order "when there is a change in the supplier." This requirement resulted in hardship to Medicare beneficiaries *and* DME suppliers.
- This hardship was exacerbated by competitive bidding. Many beneficiaries, residing in CBAs, have had to switch suppliers.
- It appears that the fall-out from competitive bidding garnered CMS' attention.

SWITCHING SUPPLIERS

- On March 24, 2017, CMS issued Change Request 9886 with an April 24, 2017 effective date. It says, in part:
  - Summary of Changes: "The purpose of this change request (CR) is to instruct contractors to accept timely orders and medical documentation, regardless of whether the supplier received the documentation directly from the beneficiary's eligible practitioner or from another, transferring supplier."
  - Requirement: "Contractors shall, in those instances in which the documentation is not transferred, continue to require a new order/documentation be received by the supplier from the treating physician/practitioner."

SWITCHING SUPPLIERS

- This Change Request is good news for DME suppliers.
- When a Medicare beneficiary switches to a new supplier, for whatever reason, if the new supplier can secure a valid physician's order from the prior supplier, the new supplier does not have to obtain a new physician's order.

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QUESTIONS?

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THANK YOU

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