Billing MCOs and Cash-Pay Patients: Opportunities and Challenges

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Amarillo · Dallas

FACE
CHALLENGES
CONFIDENTLY

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Medicare Advantage: Background

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MEDICARE ADVANTAGE 2023 ENVIRONMENT

- >30.8 Million enrolled in Med Advantage
- >51% of Medicare beneficiaries enrolled in Med Advantage
- More than doubled since 2007, CBO estimates 61% by 2032
- $454 billion of total federal Medicare spending (54%)
- 3,998 plans available nationwide in 2023 (6% increase over 2022)
- 59% HMO, 40% PPO, 1% PFFS
- 99.7% of Medicare beneficiaries have access to Med Advantage
- The average Medicare beneficiary has the choice of 43 plans by 9 firms in 2023
- 7 out of 10 MAP enrollees with Prescription Drug Coverage have no additional premium

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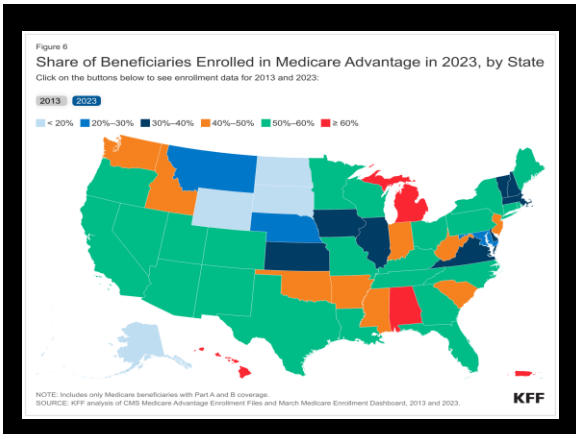

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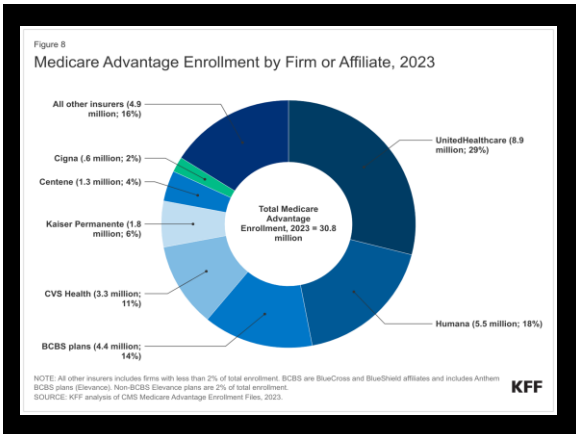

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MEDICARE ADVANTAGE BONUS PAYMENTS

- Established by the Affordable Care Act
- *"A key feature of the quality bonus program is the star rating systems. Star ratings are used to determine two parts of a Medicare Advantage plan's payment: (1) whether the plan is eligible for a bonus, and (2) the portion of the difference between the benchmark and the plan's bid that is paid to the plan. The benchmark is the maximum amount the federal government will pay for a Medicare Advantage enrollee and is a percentage of estimated spending in traditional Medicare in the same county, ranging from 95 percent in high-cost counties to 115 percent is low-cost counties. The bid is the plan's estimated cost for providing services covered under Medicare Parts A and B."*
- Plans may but are not required to use bonus payments to cover the cost of supplemental benefits.
- $12.8 Billion bonus in 2023 is 28% higher than 2022 ($2.8 billion)
- Average Bonus Per Enrollee in 2023 is $417
- Increase of 126% since 2015

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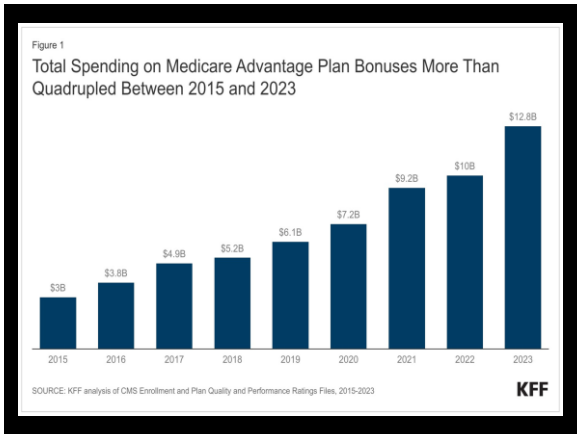

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MAP BONUS/ENROLLMENT SUMMARY

Health Plan	% of Enrollment	2023 Bonus Payment	% of Bonus Payments
United HealthCare	29%	$3.9 Billion	30%
Humana	18%	$2.3 Billion	18%
BCBS Plans	14%	$1.7 Billion	13%
CVS Health	11%	$1.3 Billion	10%
Kaiser Permanente	6%	$966.8 Million	8%
Centene	4%	$321.6 Million	2.5%
Cigna	2%	$247.3 Million	1.9%

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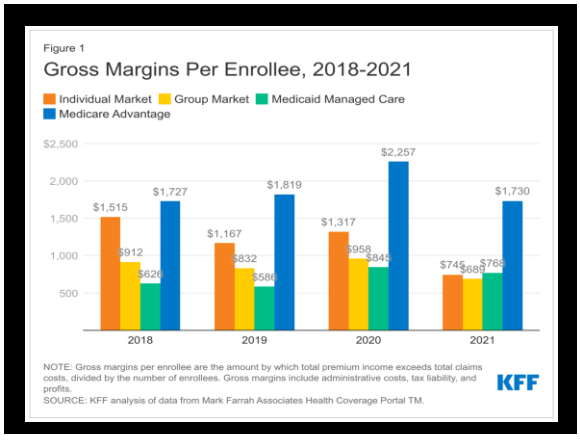

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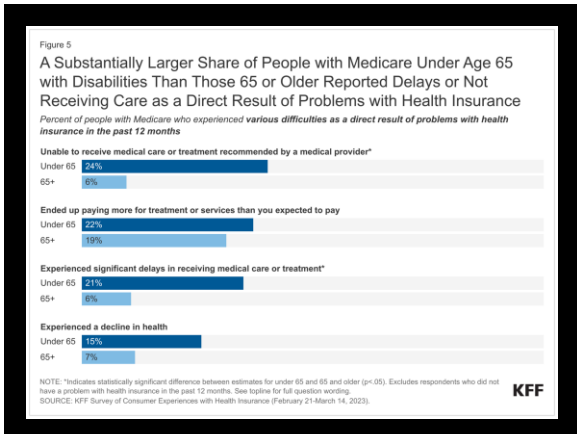

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CONSIDERATIONS FOR PROVIDERS:

- What percentage of your business is Medicare Advantage?
- How has it grown over the last 5 years?
- What education can you give your customers on how to choose the best MAP for them?
- What processes can you implement to improve interactions with MAPs?

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Medicare Advantage: 2024 Final Rule Breakdown

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CMS: 2024 MEDICARE ADVANTAGE AND PART D FINAL RULE (CMS-4201-F)

- *Prior Authorization*
- *Prior authorization policies may only be used to confirm the presence of diagnoses or other medical criteria and/or ensure that an item or service is medically necessary.*
- *Codifying sub regulatory guidance that indicates prior authorized equipment cannot be later denied for medical necessity.*
- *Requires that approval of a prior authorization request for a course of treatment must be valid for as long as medically reasonable and necessary.*
- *Minimum 90-day transition period when an enrollee switches to a new plan, new plan may not require prior authorization for an active course of treatment.*

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AAHOMECARE ASKED MED ADV PLANS:

- **Regarding Prior Authorization**: The rule stipulates that a prior authorization request for a course of treatment must be valid for as long as medically reasonable and necessary. Please clarify how this will impact lifetime prior authorizations for treatment, such as oxygen therapy? When a prior approval is in place, what will be the expectation for medical necessity documentation?
- **Regarding the 90-Day Transition Period**: How will your plan implement the requirement for a 90-day transition period without prior authorization for active treatment?

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CONSIDERATIONS FOR PROVIDERS:

- What are the claims review protocols for your MAP contracts? Do they look to determine medical necessity before claims payment even when no auth is required? Are the published coverage criteria and medical documentation rules clear for the products you provide?
- What tools and resources can you implement in your business to speed up prior auth review and take advantage of the 90-day transition requirement?

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SAMPLE COVER SHEET

- Call out as new enrollee
- Reference 90-day transition rule
- Reference previously authorized

XYZ Company 111 Maple Ave. Anytown, ST 00000 111-1111 www.xyzcompany.com	**To:** ABC Payer **Fax number:** 555-5555
	From: XYZ Company **Fax number:** 111-1111
	Date: 1/1/0001
	Regarding: 90-day transition authorization for Jane Doe
	Phone number for follow-up: 111-1111

New enrollee for ABC Medicare Advantage Plan.

This is a new auth request to put an existing auth that is within the 90-day transition period in ABC payer's auth format. Please process this quickly per the 90-day transition Medicare final rule.

Jane Doe is waiting for delivery of their DME which was already prior authorized and reviewed for medical need by 123 Medicare Advantage plan (previous Medicare payer for this member).

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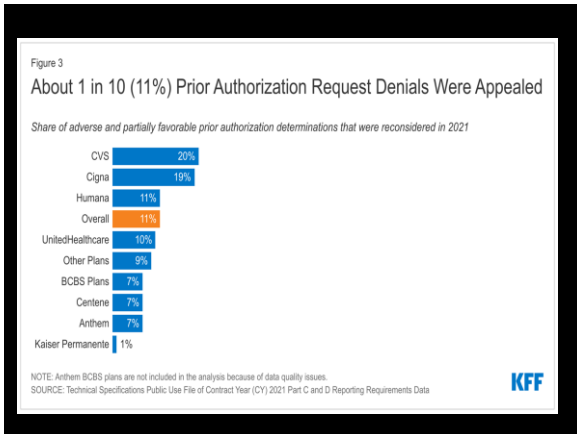

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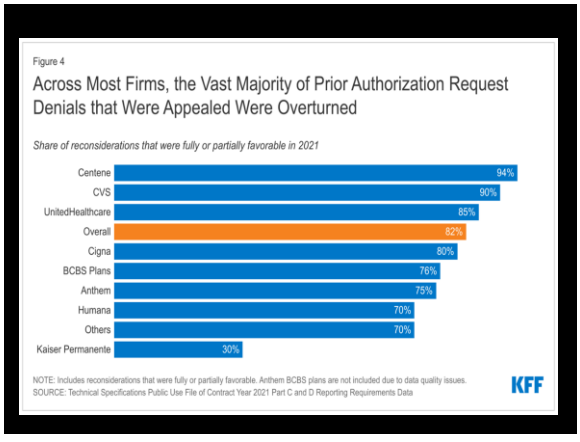

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CMS: 2024 MEDICARE ADVANTAGE AND PART D FINAL RULE (CMS-4201-F)

- ***Strengthening Quality: Star Ratings Program***
  - *CMS finalizes a health equity index (HEI) reward, beginning with the 2027 Star Ratings, to further encourage MA and Part D plans to improve care for enrollees with certain social risk factors.*
  - *CMS also reduces the weight of patient experience/complaints and access measures to further align with other CMS quality programs and the current CMS quality strategy.*

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AAHOMECARE ASKED MED ADV PLANS:

- Hospital Avoidance and Star Ratings: How can we collaborate and assist in efforts to keep beneficiaries out of the hospital and improve Star Ratings?

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CMS: 2024 MEDICARE ADVANTAGE AND PART D FINAL RULE (CMS-4201-F)

- ***Advancing Health Equity***
  - *CMS clarifies current rules, expanding the example list of populations that MA organizations must provide services to in a culturally competent manner.*
  - *Requirements for MA organizations to develop and maintain procedures to offer digital health education to enrollees to improve access to covered telehealth benefits.*
  - *Requires MA organizations to include providers' cultural and linguistic capabilities in provider directories.*
  - *MA organizations' quality improvement programs must include efforts to reduce disparities.*

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AAHOMECARE ASKED MED ADV PLANS:

- How will these Medicare policy changes be communicated to your network DMEPOS suppliers? When a Medicare coverage policy is not in place and you create a new policy specific to your plan, how are those policies communicated to DMEPOS suppliers?

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CONSIDERATIONS FOR PROVIDERS:

- How can we as an industry work on advancing health equity and use that in partnership with the payers?
- Is this an opportunity for providers to partner with MAPs on things like shared community events/outreach?

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CMS: 2024 MEDICARE ADVANTAGE AND PART D FINAL RULE (CMS-4201-F)

- ***Utilization Management***
- *MA plans must comply with national coverage determinations (NCD), local coverage determinations (LCD), and general coverage and benefit conditions included in Traditional Medicare regulations.*
- *When coverage criteria are not fully established, MA organizations may create internal coverage criteria based on current evidence in widely used treatment guidelines or clinical literature made publicly available to CMS, enrollees, and providers.*
- *MA plans establish a Utilization Management Committee to review policies annually and ensure consistency with Traditional Medicare policies.*

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AAHOMECARE ASKED MED ADV PLANS:

- Regarding Your Utilization Management Committee: What's your plan for establishing this committee, and what will its composition and responsibilities be?
- Regarding UM Annual Reviews: How will the committee conduct annual reviews of utilization patterns?
- Regarding HME Industry Involvement: Can a representative from the DMEPOS industry, like AAH, participate in or meet with the Utilization Management Committee?

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CONSIDERATIONS FOR PROVIDERS:

- Make sure NCDs and LCDs are regularly reviewed to ensure consistency.
- If no active NCD or LCD be sure you are aware of the payer's coverage criteria.

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CMS: 2024 MEDICARE ADVANTAGE AND PART D FINAL RULE (CMS-4201-F)

- ***Marketing Requirements***
- *CMS is prohibiting ads that do not mention a specific plan name as well as ads that use works and imagery that may confuse beneficiaries or Medicare logos in a way that is misleading, confusing, or misrepresents the plan.*
- *CMS also reinstates important protections that prevent predatory behavior and finalized changes that strengthen the role of plans in monitoring agent and broker activity.*
- *Protecting Medicare beneficiaries by ensuring they receive accurate information about Medicare coverage and are aware of how to access accurate information from other available sources.*

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CONSIDERATIONS FOR PROVIDERS:

- What types of marketing issues are you seeing with the Medicare Advantage Plans?
- What questions or suggestions do you have on this regulation?

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CMS: 2025 MEDICARE ADVANTAGE AND PART D FINAL RULE (CMS-4205-P)

- ***Summary***
- *A goal is to keep patients out of the hospital, thereby improving Star Ratings.*
- *A goal is to focus on cultural and linguistic issues (e.g., community events/outreach).*
- *MA plans will establish a Utilization Management Committee to ensure consistency with traditional Medicare policies.*
- *A goal is to protect beneficiaries from predatory marketing practices.*

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Litigation and Legislative/Administrative Action

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CIGNA SETTLEMENT

- The Department of Justice ("DOJ") issued a press release in September 2023 announcing the civil settlement of a fraud lawsuit against CIGNA.
  - CIGNA paid $37 million to settle the lawsuit.
  - The lawsuit began as a whistleblower (qui tam) lawsuit. Allegedly, CIGNA submitted false/invalid patient diagnosis codes to artificially inflate payments to CIGNA.
  - In addition to paying the restitution, CIGNA was required to enter into a five-year Corporate Integrity Agreement with the OIG.

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CLASS ACTION LAWSUIT AGAINST UNITED HEALTHCARE ("UHC")

- A class action lawsuit was recently brought against UHC. The allegation is that UHC required its employees to utilize an algorithm designed to deny rehabilitative care to seriously ill patients.
- UHC allegedly knew that the algorithm had a high error rate.

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BIDEN ADMINISTRATION ACTION

- On 12/7/23, the Biden Administration announced steps to increase transparency in the Medicare Advantage ("MA") space. One of the Administration's steps was to issue an RFI to solicit public feedback.
- According to the Administration, the government is expected to pay $7 trillion to MA plans over the next decade.
- The Biden Administration is focusing on (i) access to care, (ii) prior authorizations, (iii) provider directories, (iv) supplemental benefits, (v) marketing, (vi) care quality and outcomes, and (vii) value-based care.

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SENATE COMMITTEE REPORT

- A Report was issued by the Majority Staff of the U.S. Senate Committee on Finance. According to the Report:
  - The number of complaints about MA marketing more than doubled from 2020 to 2021.
  - MA marketing is too aggressive and results in false and misleading information being provided to seniors.
  - Seniors are besieged with in-person encounters, television ads, telemarketers, and robo-calls.

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Resources and Evaluation

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EVALUATING MAP PLANS IN YOUR SERVICE AREA

- Explore your Medicare coverage options www.medicare.gov/plan-compare
  - Enter Zip Code
  - Recommend zip code with highest population for high volume cities
  - Select Medicare Advantage Plan (Part C) and Click Find Plans
  - "Help with your costs" Select "I don't get help from any of these programs"
  - "Do you want to see your drug costs when you compare plans?" Select No and Next
  - Plans will be sorted from Lowest drug + Premium Cost

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EVALUATING MAP PLANS IN YOUR SERVICE AREA

1. HealthPartners Journey Pace (PPO)
HealthPartners | Plan ID: H4882-009-1
This plan got Medicare's highest rating (5 stars)

- **MONTHLY PREMIUM**
  $0.00
  Includes: Health & drug coverage
  Doesn't include: $164.90 Standard Part B premium
- **TOTAL DRUG & PREMIUM COST (for the rest of 2023)**
  $0.00
  Only includes premiums for the months left in this year when you don't enter any drugs
- **OTHER COSTS**
  $0
  $300.00
  $8,950 In and Out-of-network
  $5,200 In-network
  Plan Details
  Add to compare

PLAN BENEFITS
- Vision is available
- Dental is available
- Hearing is available
- Transportation is not available
- Fitness benefits is available
- Worldwide emergency is available
- Telehealth is available
- Over-the-counter drugs is available
- In-home support is not available
- Home safety devices & modifications is not available
- Emergency response device is not available

COPAYS/COINSURANCE
Primary doctor: $0 copay
Specialist: $40 copay per visit

DRUGS
Add your prescription drugs
Enter drugs you take regularly (if any) to see your estimated drug + premium cost

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CMS MONTHLY REPORT: MA ENROLLMENT BY STATE/COUNTY/CONTRACT

https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-advantagepart-d-contract-and-enrollment-data/monthly-ma-enrollment-state/county/contract

- Monthly Link to MAP enrollment by State/County/Contract
  - Filter by State
  - Lists by:
    - Counties
    - Organization Name
    - Organization Type
    - Plan Type

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DO YOU HAVE A PROCESS TO:

- ❑ Verify customer benefits after re-enrollment
- ❑ Confirm prior authorizations are moved to new MAP during 90-day transition period
- ❑ Evaluate for new MAPs in your coverage area
- ❑ Make sure you are contracted with all MAPs in your coverage area
- ❑ Appeal denied prior authorizations
- ❑ Review LCDs, NCDs, other Medicare coverage docs & MAP coverage criteria
- ❑ Educate your customers about MAP benefits, coverage, & the appeals process
- ❑ Leverage importance of Star ratings to demonstrate how your business benefits MAPs

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KEY TAKEAWAYS

- Patient complaints – **1-800-MEDICARE**
- Stakeholder complaints – Regional Office Contacts and https://dpap.lmi.org
- AAHomecare continues to provide global industry feedback and proposed solutions directly to CMS Part C leadership
- AAHomecare Payer Relations team meeting with top 6 health plans
- Educate payers/request their implementation plans
  - Utilize AAHomecare Summary of 2024 MA Final Rule
  - Utilize template letter with questions in your outreach to MA plans
- Check out our new website and resources available: www.AAHomecare.org

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Cash-Only Retail

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INTRODUCTION

- While most DME suppliers will never get away from billing traditional Medicare and MAPs (collectively referred to as "third-party payors" or "TPPs"), it is wise for suppliers to diversify their payment sources.
- In particular, DME suppliers should look at selling products (Medicare-covered and non-Medicare covered) for cash.
- Two obvious benefits from cash sales are (i) the supplier receives immediate money and (ii) the supplier does not have to worry about post-payment recoupments.

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INTRODUCTION

- This brings us to today's…and tomorrow's…DME customers.
- Today's customers are the 78 million Baby Boomers who are retiring at the rate of 10,000 per day. Boomers (i) will live longer than earlier generations and (ii) want to remain independent as they age.
- Many Boomers have disposable income that will allow them to purchase "Cadillac" products for cash…as opposed to being relegated to receiving "Cavalier" products paid for by Medicare.
- And tomorrow's customers are the almost equal number of millennials.

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INTRODUCTION

- This "passing of the torch" from earlier generations to Boomers…and then to millennials…afford suppliers the opportunity to products for cash.
- The law allows retail cash sales but as is often the case, the "devil is in the details."
- The following slides focus on the "details."

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Cash Prices That Can Be Charged

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NO PTAN

- If a DME supplier does not have a PTAN, then there are no restrictions on the prices the supplier sets for Medicare covered and non-covered items.

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HAS A PTAN

- No restrictions on the prices that the supplier sets for items not covered by Medicare.
- If the supplier is non-participating and provides a covered item on a nonassigned basis, then the supplier can, without limitation, charge more than the Medicare allowable.

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HAS A PTAN-PROVISION OF DISCOUNTS TO CASH CUSTOMERS

- Assume that the supplier is non-participating, provides a covered item on a non-assigned basis, and desires to charge less than the Medicare allowable.
- There is a federal statute that says that a DME supplier is prohibited from charging Medicare substantially in excess of the company's usual charges, unless there is good cause.
- The current regulations do not give any guidance on what constitutes "substantially in excess," "usual charges," or "good cause."

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HAS A PTAN-PROVISION OF DISCOUNTS TO CASH CUSTOMERS

- The clearest guidance comes from a 2003 proposed rule that was not subsequently implemented. This proposed rule contemplates the "usual charge" to be either the average or median of the supplier's charges to payors other than Medicare (and some others).
- Under the proposed rule, a DME supplier's usual charge should not be less than 83% of the Medicare fee schedule amount (i.e., up to a 17% discount from the Medicare fee schedule).

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HAS A PTAN-PROVISION OF DISCOUNTS TO CASH CUSTOMERS

- There would be an exception for good cause, which would allow a supplier's usual charges to be less than 83% of the Medicare fee schedule, if the supplier can prove unusual circumstances requiring additional time, effort or expense, or increased costs of serving Medicare beneficiaries.
- The proposed rule would include charges of affiliate companies into the calculation of a supplier's usual charges.
- An affiliated company is any entity that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with the DME supplier.
- The proposed rule explicitly excludes fees set by Medicare, State health care programs, and other Federal health care programs (except TRICARE). By implication, charges not specifically excluded will be included.

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Key Issues for Cash-Only Supplier

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MASTER CHARGE LIST

- The cash-only DME supplier should maintain a list of the usual and customary price it charges for each of the products it sells to its customers.
- Even though the supplier will not hold any third-party contracts, the supplier should charge the same price to each customer for the same product to avoid any issues with reimbursement of Out of Network Provider ("OONP") claims a patient may submit to his/her insurance carrier.
- The supplier may offer a reasonable discount for products paid for in cash. This is appropriate because the administrative burden the supplier may take on if it elects to submit OONP claims on behalf of its patients (verifying the validity and medical necessity of prescriptions, filling out paperwork, etc.) is reduced if the patient pays for the product in cash.

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AVOIDANCE OF DISCRIMINATION

- The best avenue to avoid discrimination risk is for the supplier not to submit OONP claims on behalf of insured patients.
- No matter the payor, the supplier should collect the full usual and customary price of the product directly from the patient at the time of checkout. Then, if the patient wishes, he/she may choose to submit an OONP claim to his/her insurance carrier.
- This approach is best, not only to mitigate the risk of a discrimination issue, but also to ensure that the supplier is paid the full price it charges for a product without the administrative challenge of working with insurance carriers.

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SUBMISSION BY SUPPLIER OF OONP CLAIMS

- In the event that the supplier elects to submit OONP claims on behalf of its insured patients, discrimination issues and reimbursement (such as whether the supplier is expected to collect the full charge from the patient or whether the supplier should collect only a copayment from the patient) will be payor-specific.
- By utilizing a Master Charge List, and ensuring that insurance carriers are not charged above the usual and customary price that the supplier charges for the products, will help mitigate the risk of a discrimination or reimbursement issue.

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NOTICE TO MEDICARE BENEFICIARY

- If the cash-pay supplier sells a product to a beneficiary, the supplier must let the beneficiary know that (i) the supplier is not a Medicare supplier, (ii) the supplier will not submit a claim to Medicare on behalf of the beneficiary, and (iii) the beneficiary will receive no reimbursement from Medicare.
- This type of notification is easy to do on a website when a beneficiary is buying a product from the supplier online.
- This type of notification is more challenging with walk-in customers.

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NOTICE TO WALK-IN MEDICARE BENEFICIARY

- Ideally, when a beneficiary walks into the supplier's facility to purchase a product, the supplier will have the beneficiary sign an ABN.
- If that is unrealistic, the supplier can ask the beneficiary to sign some type of document acknowledging the same.
- And if that is unrealistic, the supplier should provide something in writing to the beneficiary stating the points above.
- Additionally, the supplier should have signs conspicuously hanging that point out the supplier is not a Medicare supplier.

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Charging Cash Customers Less Than What is Billed to State Medicaid

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CHARGING CASH CUSTOMERS LESS THAN WHAT IS BILLED TO STATE MEDICAID

- Billing and collecting from state Medicaid programs is more expensive and time consuming for a DME supplier than collecting from a cash-paying customer. It is logical for suppliers to desire to charge a cash-paying customer less than what the supplier bills Medicaid. The question thus arises: Is it permissible for the supplier to do so?
- Most state Medicaid programs require the supplier to bill the Medicaid program its usual price.

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Separate Legal Entity for Retail Business

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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. 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."

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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.
- 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.

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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.

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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.

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NEW LEGAL ENTITY

- 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.

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NEW LEGAL ENTITY

- 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:

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NEW LEGAL ENTITY

- 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.

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REASONS FOR A SEPARATE LEGAL ENTITY

- There are three 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.

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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.
- **Bringing in Investors** – If the retail business is successful and needs to bring in additional investment capital in order to expand, then it can do so if the retail business is in a separate legal entity.

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Co-Location With Another Provider

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CMS GUIDANCE

- 42 CFR § 424.57(c)(29) states that a DME supplier "is prohibited from sharing a practice location with any other Medicare supplier or provider."
- NSC published an FAQ that expands on this supplier standard.

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CMS GUIDANCE

- FAQ – Question: If a DME supplier decides to co-exist with a sleep lab that is jointly owned by physicians and a related hospital system entity and there are separate and distinct entrances into the facilities, is this permissible under the supplier standard rule?

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CMS GUIDANCE

- FAQ – Answer: In order to comply with DMEPOS supplier standard 424.57(c)(29), the locations must be separate suites with separate suite numbers recognized by the U.S. Post Office. They should not share personnel, equipment, or inventory.

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CMS GUIDANCE

- FAQ – Question: With regard to co-location of DMEPOS suppliers, we would like to confirm that a DMEPOS supplier in the same building as another DMEPOS supplier is not considered to be "sharing a practice location" with another supplier if it has a separate suite, a separate address, a separate entrance from the outside, a separate telephone number, and both suppliers are using separate equipment.

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CMS GUIDANCE

- FAQ – Answer: We confirm this. However, we expect each DMEPOS supplier to separately meet all supplier standards.

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Sharing Space With a Non-Provider

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SHARING SPACE WITH A NON-PROVIDER

- A DME supplier may desire to lease some of its retail showroom space to a "lifestyle" company, that is not a health care provider, in which the lifestyle company offers products and services that will help the aging Baby Boomer enjoy the active lifestyle that he or she is accustomed to having.
- Assume that ABC Medical Equipment, Inc. desires to lease a portion of its showroom to XYZ Senior Lifestyle, Inc. XYZ is not a Part B supplier; it sells items for cash. It will be important for ABC to retain at least 200 square feet and continue its Medicare Part B business operations in accordance with the Supplier Standards.

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SHARING SPACE WITH A NON-PROVIDER

- When the NSC inspector comes on-site to inspect ABC, it will be important that ABC's and XYZ's spaces be configured so as to avoid any confusion on the inspector's part. For example, the two stores can be separated by seven foot high grid walls, and each store can have its own cash register, telephone line, and sales representatives.
- On the front of the building, the logo and hours of operation for each store will be displayed. The logo of each store will be displayed in the area of the showroom that is occupied by the applicable store.

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Qualification as a "Foreign" Corporation

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QUALIFICATION AS A "FOREIGN" CORPORATION

- If the DME supplier decides to sell products for cash to residents of other states, then then supplier may need to qualify as an out-of-state or "foreign" corporation in those states.
- The requirement to register or "qualify" as a foreign corporation generally hinges on whether an entity is "doing business" in a state according to that state's foreign corporation statute. Most states do not statutorily define what constitutes "doing business" in the state; instead, the statute sets forth a non-exhaustive list of activities that do not constitute "doing business" in the state and "interstate commerce" is frequently listed as one of the exceptions.
- In most states, solely (1) obtaining a DME license, and (2) shipping products into the state will not result in the supplier being required to qualify as a foreign corporation in the state.

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QUALIFICATION AS A "FOREIGN" CORPORATION

- Note that qualification as a foreign corporation will subject the DME supplier to potential state business income taxation in some states.
- If a DME supplier does decide to qualify as a "foreign corporation" in another state, the qualification process typically involves filing fees and an application for foreign corporation qualification with the secretary of state's office, maintaining a registered office and/or registered agent in the state and filing an annual report. Most states will not allow an entity to qualify and conduct business in the state under a name that is not distinguishable from a name already on file in that state.

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QUALIFICATION AS A "FOREIGN" CORPORATION

- The requirements for withdrawing registration as a foreign corporation are generally more onerous than the initial application to qualify as a foreign corporation. Certain states require detailed financial information and most require clearance from other state agencies in order to withdraw. All states require the withdrawing entity to certify, under penalty of perjury, that it is no longer conducting business in the state, and surrender its authority to conduct business in the state.
- Doing business in another state may result in the DME supplier owing certain types of taxes to that state. Because the state tax laws frequently use criteria that differ from the state foreign corporation statute, these taxes may be owed even if the business isn't otherwise required to register as a foreign corporation.

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State “Brick and Mortar” Laws

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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, Georgia, Colorado) require the DME supplier to have a “brick and mortar” presence in the state before a license will be issued to the supplier.

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DIFFERENCES AMONG STATES

- It is likely that other state will adopt “brick and mortar” requirements as 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.

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DIFFERENCES AMONG STATES

- Examples of such nuances are:
  1. Does the statute define how large the facility must be? Must the facility be 1000 square feet? 500 square feet? 200 square feet? 50 square feet?
  2. Can the facility be as simple as subleasing e.g., 200 square feet from a pharmacy or grocery store?

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DIFFERENCES AMONG STATES

3. Can the facility be a self-storage unit?
4. Is the facility required to be accredited as a DME supplier? Must the facility have a PTAN?
5. 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)?

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DIFFERENCES AMONG STATES

6. Is the facility required to be open to the public for "X" hours per week?
7. Must there be a person in the facility for "X" hours per week? If so, must the person be a W2 employee of the supplier or can the person be recognized by the post office?
8. Must the facility have an address that is recognized by the post office?
9. Must the facility have a telephone with a working telephone number?

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Competing with Amazon: Fulfillment Arrangement with Distributor

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PURCHASING FROM AMAZON

- The customer receives the product delivered to his door. Shipping is not "free." The shipping cost is built into the cost of the product.
- The cost of the product is likely lower than what the customer can buy the same product for from a local supplier. However, the cost is often not that much lower.
- And that is pretty much it. The sum total of the benefits of buying off of Amazon is the (i) delivery to the door and (ii) the lower cost.

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PURCHASING FROM AMAZON

- If the product needs to be assembled, then it is up to the customer to assemble it. If the customer needs to be educated on how to use the product, then such education will be in the form of (i) the customer reading instructions from the seller and/or (ii) talking to a person over the phone.
- If the customer purchases the product off of Amazon and the product does not work properly, or does not work at all, or needs to be repaired, then the customer will need to resolve the problem long distance with the seller.

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COMPETING WITH AMAZON: FULFILLMENT ARRANGEMENT

- The local DME supplier can enter into a fulfillment arrangement with a distributor of products. It will be important for the distributor to have a large selection of products.
- The distributor's products will be described on the supplier's website. While the customer can review the Amazon website and observe a wide selection of products, the same customer can review the local supplier's website and also observe a wide selection of products.

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COMPETING WITH AMAZON: FULFILLMENT ARRANGEMENT

- When the customer orders a product from the supplier, then the supplier will direct the distributor to ship the product to the customer. The customer will receive the product within 24 to 48 hours.
- The label on the product and/or on the shipping package will reflect the supplier's name.
- By working with a distributor in a fulfillment arrangement, the supplier does not have to incur the cost of carrying large quantities of inventory.

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COMPETING WITH AMAZON: FULFILLMENT ARRANGEMENT

- Now this is where competing with Amazon becomes interesting.
  - The local supplier can advertise that on the same day that the customer receives the product, a supplier employee will go to the customer's house and (i) set the product up and (ii) educate the customer on how to use the product. Amazon cannot offer this.
  - The local supplier can advertise that if the product subsequently needs to be repaired, then the supplier will pick the product up from the customer and allow the customer to use a loaner. After the supplier repairs the product, the supplier will return the product to the customer and pick up the loaner. Amazon cannot offer this.

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COMPETING WITH AMAZON: FULFILLMENT ARRANGEMENT

- The local supplier can advertise that if the product needs to be replaced, then the supplier can provide a loaner until the distributor ships the new product to the customer Amazon cannot offer this.
- If the distributor has a large number and variety of products, then the cost of the product will likely not be much more than what the customer can purchase the product for off of Amazon.
- When the customer purchases a product off of Amazon, then the customer pays cash. If the product is reimbursable by Medicare, then it is likely that the customer (himself or herself) will need to file a claim with Medicare for reimbursement.

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COMPETING WITH AMAZON: FULFILLMENT ARRANGEMENT

- It is unlikely that the seller (of the product through Amazon) will submit a claim to Medicare on behalf of the customer. There are several reasons for this: (i) the seller may not have obtained a physician's order; (ii) the seller may not have obtained other Medicare-required documentation; (iii) the seller may not be licensed in the state where the customer resides; and/or (iv) the seller may not even have a PTAN.
- On the other hand, the local supplier will treat the customer (who receives the product from the distributor) the same way that the supplier treats a customer who walks into the supplier's facility. The supplier will collect the physician's order, will collect other Medicare required documentation, will take an Assignment of Benefits ("AOB") from the customer, will bill and collect from Medicare, and will only expect the customer to pay the required copayment. If the local supplier is non-participating, then it can ask the customer to pay cash to the supplier. In turn, the supplier can submit a claim (on behalf of the customer) to Medicare for reimbursement directly to the customer.

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FULFILLMENT AGREEMENT: KEY PROVISIONS

- When a supplier executes a Fulfillment Agreement with a distributor, the agreement should include the following key provisions:
  - Title to the products, shipped by the distributor to the customers, will be in the supplier's name.
  - Labeling on the product and/or the package will reflect the supplier's name and address.
  - The supplier will be obligated to pay the distributor for the product…regardless of whether or not the supplier is paid for the product.

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FULFILLMENT AGREEMENT: KEY PROVISIONS

- The product will be delivered to the customer within a set period of time (e.g., within 24 hours or 48 hours).
- The distributor will obtain written proof of delivery that, in the supplier's opinion, will suffice to meet third party payor requirements.
- The agreement will include a HIPAA-compliant BAA.

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PROMOTING THE FULFILLMENT MODEL

- In promoting the fulfillment model to customers, the supplier must be careful not to violate the federal beneficiary inducement statute. This statute prohibits a supplier from offering anything of value to a federal healthcare program ("FHP") patient that the supplier knows, or should know, will induce the patient to purchase an FHP-covered product from the supplier.
  - There is, however, the "nominal value" exception to the inducement statute. This exception states that the supplier can offer a non-monetary gift to an FHP patient if the gift has a retail value of $15 or less. And the supplier can offer multiple gifts to an FHP patient so long as all of the gifts, combined, do not have a retail value in excess of $75 during a 12 month period.

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PROMOTING THE FULFILLMENT MODEL

- If the supplier will take assignment from Medicare or other third party payor, then the supplier must make a reasonable effort to collect the copayment. The supplier can waive the copayment only if the patient establishes a financial inability to pay. The supplier cannot advertise the existence of a copayment waiver policy based on an inability to pay.
- Assume that the supplier is non-participating and that the supplier requires the customer to pay cash for the product. If the customer is a Medicare beneficiary, then the supplier will be required to submit a claim (for reimbursement) to Medicare on the customer's behalf.

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PROMOTING THE FULFILLMENT MODEL

- In promoting the fulfillment model to physicians, the supplier needs to be careful not to violate the federal anti-kickback statute ("AKS") and the federal Stark physician self-referral statute ("Stark").
  - The AKS prohibits a supplier from offering anything of value to a physician in exchange for (i) referring an FHP patient, (ii) arranging for the referral of an FHP patient, or (iii) recommending the purchase of a product or service that is covered by an FHP. The AKS has a number of "safe harbors." A safe harbor is a hypothetical fact scenario such that if an arrangement falls within it, then as a matter of law the AKS is not violated. If an arrangement does not fall within a safe harbor, then it does not mean that the AKS is violated; rather, it means that the arrangement needs to be carefully analyzed in light of the language of the AKS, published OIG guidance, and court decisions.

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PROMOTING THE FULFILLMENT MODEL

- Stark states that if a supplier and a physician have an ownership or compensation relationship, then the physician cannot refer Medicare/Medicaid patients to the supplier. While the AKS does not have safe harbors, it does have a number of exceptions. One exception is the non-monetary compensation exception, which allows a supplier to spend up to a certain amount each year on non-monetary gifts for physicians. In 2024, the amount is $507. This exception does not apply to the physician's staff.
- A safe way to promote the fulfillment/home delivery model to referring physicians is for the supplier to sponsor an educational lunch for the physician and his/her staff. The risk is low that a governmental agency will assert that such a lunch violates the AKS. And the physician's portion of the lunch should be around $15…well below the $507 limit for 2024.

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HIPAA Restrictions on Marketing

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HIPAA RESTRICTIONS ON MARKETING

- The Health Insurance Portability and Accountability Act ("HIPAA") requires "covered entities" to obtain a valid authorization from individuals before using or disclosing protected health information ("PHI") to market a product or service to them.
- HIPAA broadly defines "use" of PHI to include the sharing, employment, application, utilization, examination, or analysis of such information. 42 CFR § 160.103. The HIPAA definition of marketing states what is not marketing:

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HIPAA RESTRICTIONS ON MARKETING

- Marketing does not include a communication made: . . . [f]or the following treatment and health care operations purposes, except where the covered entity receives financial remuneration in exchange for making the communication[,] …
- to describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication.

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Cooperative Marketing Program

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COOPERATIVE MARKETING PROGRAM

- A DME supplier and another provider (e.g., pharmacy) may enter into a cooperative marketing program. The costs and expenses of the program should be proportionately shared by the DME supplier and other provider.

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Promotional Items to Customers and Potential Customers

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PROMOTIONAL ITEMS TO CUSTOMERS AND POTENTIAL CUSTOMERS

- The DME supplier can offer a non-cash/non-cash equivalent item of nominal value (i.e., retail value of not more than $15) to customers/prospective customers covered by a government health care program.
- Over a 12-month period, the DME supplier may not give items to any one customer that have a combined retail value greater than $75.
- If the customer is not covered by a government health care program, then the DME supplier must nevertheless determine if there are any applicable state statutes that address gifts to customers/prospective customers.

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Health Fairs, Luncheons, Kiosks and Open Houses

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HEALTH FAIRS, LUNCHEONS, KIOSKS AND OPEN HOUSES

- The DME supplier can participate in local health fairs. Similarly, the supplier can put on a short program during lunch at a senior citizens' center, at which time the supplier can distribute promotional literature.
- The DME supplier can place a kiosk in a mall that promotes the supplier's products and services. On a periodic basis, the DME supplier can hold an open house.

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