NHIA TALK INFUSION WEBINAR

Final 2020 Policy Update – Most-Favored Nations, Stark Reform, DMEPOS, and More

December 17, 2020

NHIA
National Home Infusion Association

Today's Presenters

Connie Sullivan
President and CEO

Bill Noyes, Sr. Vice President of Reimbursement Policy

Jeffrey S. Baird, Esq., Chairman of Health Care Group at Brown & Fortunato, PC

Agenda

- Home Infusion Therapy HIT Services 2021
- IVIG Demo Ending
- New ABN for 2021
- DME Proposed Rule
- Most Favored Nations Drug Pricing
- Changes to Stark & Anti-kickback
  - Physician self-referral
  - Rebate rule

IVIG Demonstration Ending 12/31/2020

Since the demonstration ends on December 31, 2020, no payment will be made for demonstration services (supplies and related nursing services to administer IVIG in the home) provided after that date. The traditional Medicare fee-for-service program will continue to pay for IVIG based on coverage requirements, but once the demonstration ends, it will no longer pay for the services and supplies to administer the drug in the home, **unless** the beneficiary is receiving covered Medicare home health services. Beneficiaries currently receiving IVIG in their home must transition to other options for receiving IVIG, as further explained below.

- Receive the IVIG treatment in a doctor's office or other outpatient setting.
- If medically appropriate, transition to a subcutaneous form of immune globulin that can be self-administered.
- In 2021, Medicare also pays for professional services (nursing services) for certain forms of immune globulin, when administered through a pump in your home, under the Home Infusion Therapy benefit. Suppliers must meet certain requirements to bill under this new benefit.

Legislation has been introduced and scored. There is a possibility that it could passed with a Jan. 1, 2021 start date.

New ABN Form Mandatory on January 1, 2021

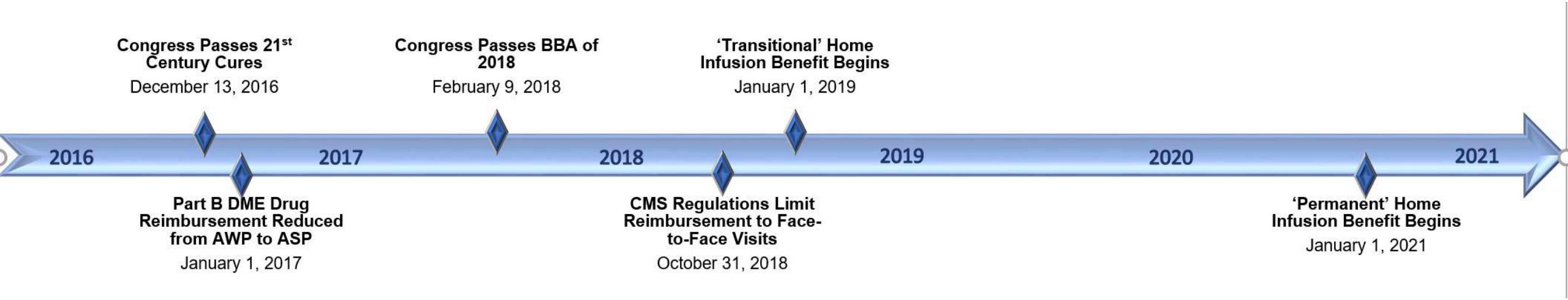
Medicare providers are required to use the newly approved Advance Beneficiary Notice of Non-Coverage Form (ABN) effective January 1, 2021.

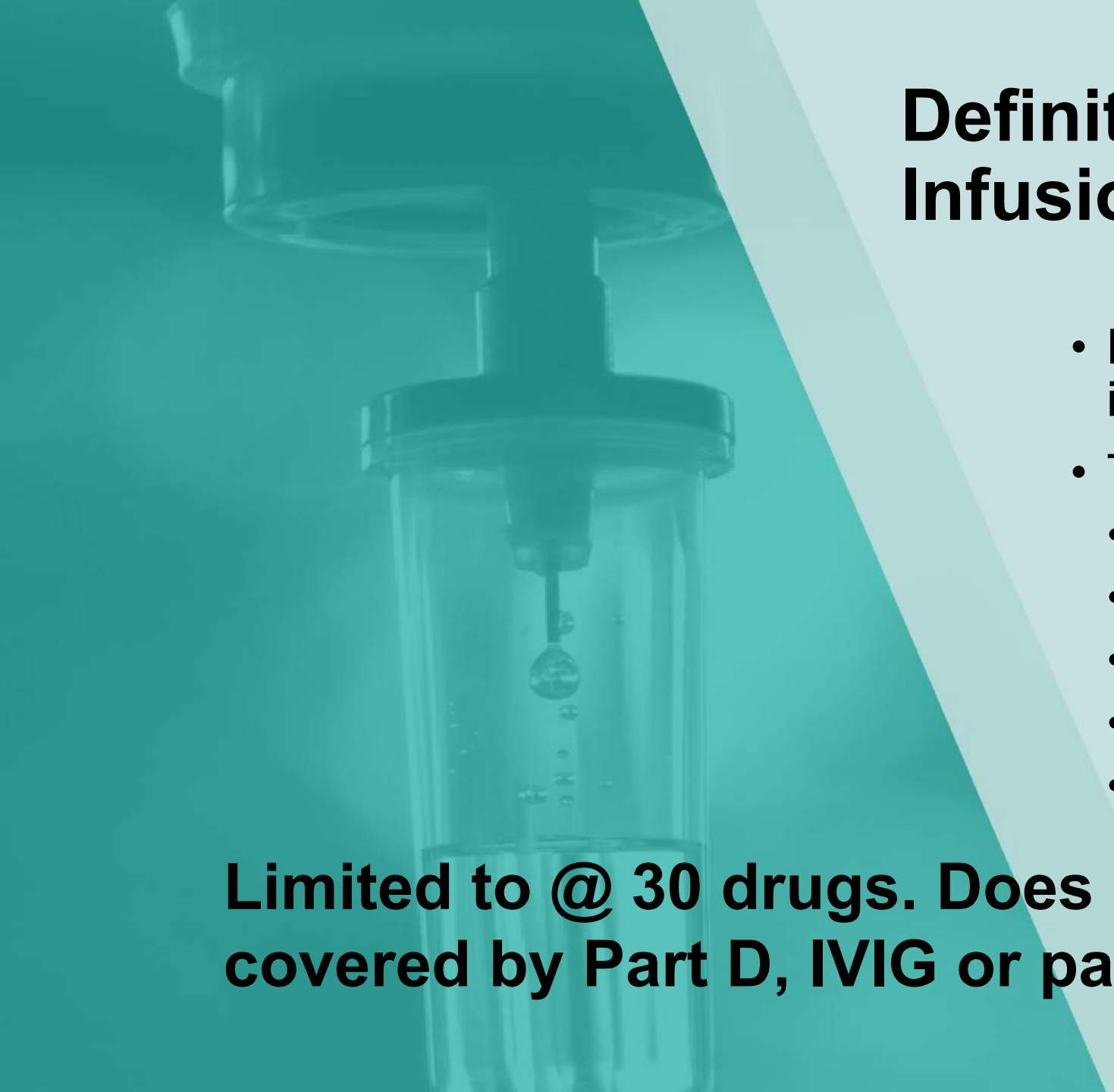
http://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html

Home Infusion Therapy Services 2021

History of Part B HIT Services Benefit

- Congress included provisions in the *21st Century Cures Act* and the *Bipartisan Budget Act of 2018* requiring CMS to create a new home infusion professional services benefit under Medicare.
- Despite the intent of Congress to *increase* access to home-based care, Medicare data shows that utilization of home infusion has actually *decreased* since these laws were passed.





Definition of Home Infusion Drug

- DME-infused drugs administered intravenously or subcutaneously
- Transitional benefit with changes:
  - (-) Hizentra®
  - (-) Morphine PF
  - (-) Ziconotide
  - (-) Floxuridine
  - (+) Xembify® and Cutaquig®

Limited to @ 30 drugs. Does not impact drugs covered by Part D, IVIG or parenteral nutrition.

Qualified HIT Services Supplier

2019–2020

Limited to a pharmacy enrolled as a DME supplier for home infusion

2021

Any of the following provider types:

- Pharmacy
- Physician
- Other state licensed provider of services or supplier

Professional Services

- Services are only billed on days when a skilled professional is in the home.
- The skilled services must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel.
- All services must be within the practitioner's scope of practice.

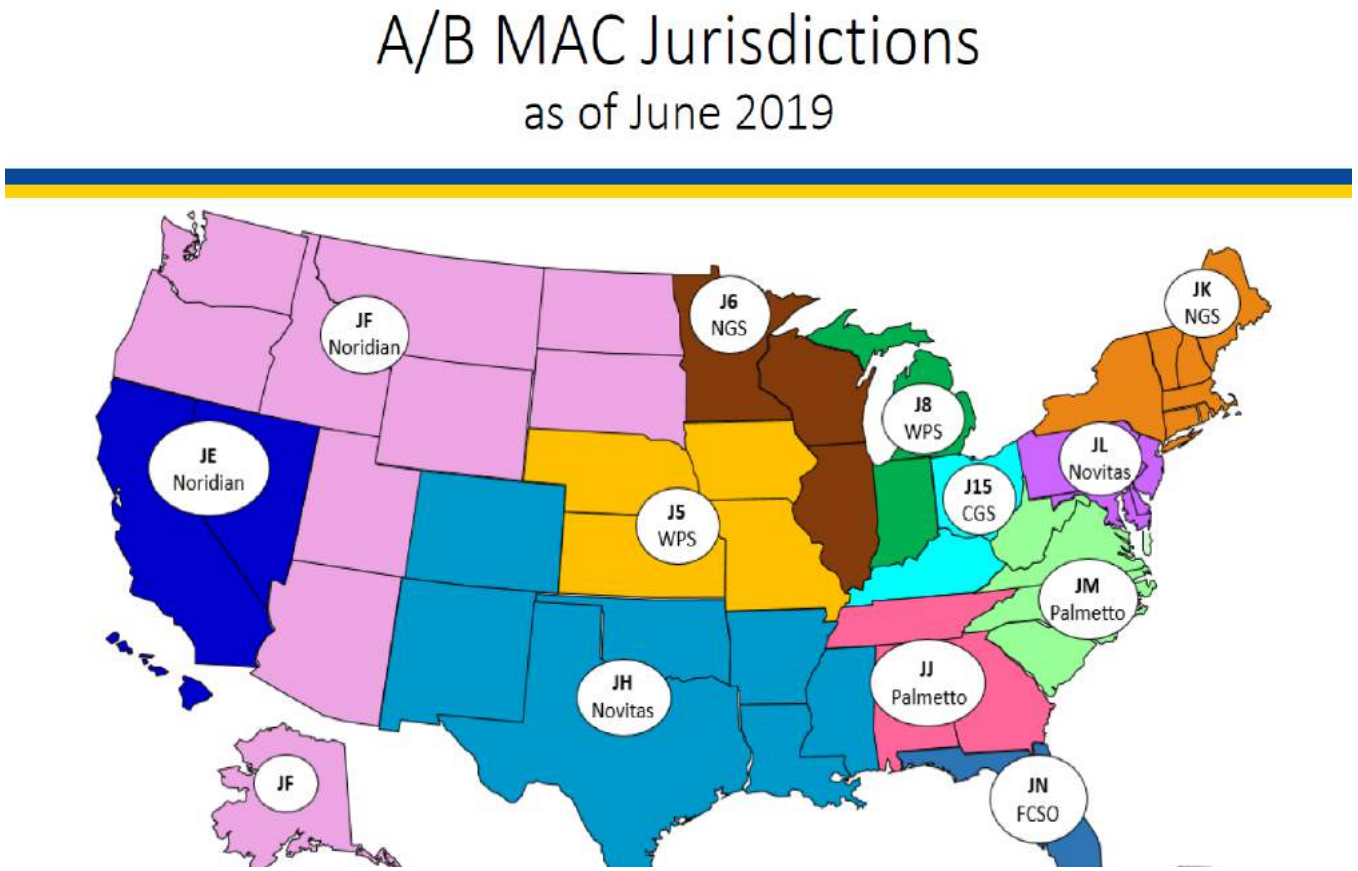
Intersection with Home Health in 2021

- All nursing will be provided under the new Home Infusion Therapy Benefit
- Starting in 2021, a Medicare Certified Home Health Agency may not provide infusion-related nursing under the home health episode of care for Part B drugs.
- Patients do not need to be homebound to receive infusion nursing
- Home Infusion Therapy Suppliers do not need to be Medicare Certified to provide nursing services

Accreditation (Not Traditional Home Infusion Pharmacy Accreditation)

- Must have accreditation by an approved Accreditation Organization (AO) to become a Medicare B HIT services supplier
  - Approved AO's to date include:
    - Accreditation Commission for Health Care (ACHC)
    - Community Health Accreditation Partner (CHAP)
    - National Association of Boards of Pharmacy (NABP)
    - The Compliance Team (TCT)
    - The Joint Commission
    - URAC
- Traditional HIT, specialty pharmacy, or nursing accreditation does NOT qualify
- Suppliers must be accredited prior to enrolling in the program

Enrollment



- CMS will expedite the sub-regulatory process.
  - Instruction to the MACs as to how to implement and “stand up” new benefit
  - Stakeholder education
- Enrollment Policy (MM11954)
  - Enroll “practice location” with A/B MAC
  - Enter Home Infusion Therapy Supplier into the “other” field in section 2A
  - Report all areas you will render services in section 4D application
  - Submit all claims, regardless of the state they are provided to the A/B MAC that your physical location is enrolled
  - Submit CMS-460 form to select Medicare Participating (PAR) or Non-Participating (NON-PAR)

Rates

HCPCS	Note	Short Descriptor	Allowable (estimate)
Category 1			
G0088	*Initial*	Adm IV drug 1st home visit.	$188.85
G0068	*Subsequent*	Adm IV infusion drug in home.	$156.83
Category 2			
G0089	*Initial*	Adm SubQ drug 1st home visit.	$256.83
G0069	*Subsequent*	Adm SQ infusion drug in home.	$213.27
Category 3			
G0090	*Initial*	Adm IV chemo 1st home visit.	$319.80
G0070	*Subsequent*	Adm of IV chemo drug in home.	$256.57

Home Infusion Therapy Services 2021

- Requires enrollment with the A/B MAC as HIT supplier
- Must have HIT Services ACCREDITATION (different from all past Accreditation)
- Continue to bill drug, pump and supplies to DME MAC.
- Only applies to about 30 drugs DME infused drugs that the HIT Services are attached to. HHAs can continue to provide Part A episodic care for infusion related therapies like Parenteral Nutrition, IVIG, and Part D drugs (antibiotics).

https://www.nhia.org/wp-content/uploads/2020/03/Part-B-Tool_v21-1.pdf

DME Proposed Rule

- DMEPOS Fee Schedule
- HCPCS Level II Application Process
- Benefit Category and Payment Determination Process
- Classification and Payment for Continuous Glucose Monitors Under Medicare Part B
- Expanded Classification of EIP as DME
- Exclusion of Complex Rehab from CB

Classification of EIP as DME

Current limitation:

"appropriate for use in the home." = used by a patient or caregiver in the home without the assistance of a healthcare professional

Expanded Classification of EIP as DME

New proposal to interpret this requirement to be met for an external infusion pump if: :

1. The Food and Drug Administration (FDA) labeling requires the home infusion drug to be prepared immediately prior to administration, or administered by a health care professional or both; **and**
2. A qualified home infusion therapy supplier (as defined at §486.505) administers the drug or biological in a safe and effective manner in the patient's home (as defined at §486.505); **and**
3. The FDA-required labeling specifies infusion via an external infusion pump as a possible route of administration, at least once per month, for the drug.

Expanded Classification of EIP as DME

Therefore, we (CMS) propose that in a situation in which a beneficiary or caregiver or both is unable to safely and effectively administer certain drugs or biologicals, the external infusion pump through which such drugs or biologicals are administered could satisfy the definition of **DME if all three of the requirements described previously are met.** The drug or biological could then be covered as a supply under the DME benefit.

Expanded Classification of EIP as DME

CMS proposes that consideration for additional drug coverage would have to go through the DME MAC Reconsideration Process.

DMEPOS is not the way to expand home infusion coverage

An infusion pump is a method – not a route of administration – and the decision about whether to use an infusion pump should be based on the clinical judgment of the physician and infusion team after performing a complete patient and therapy assessment.

NHIA Recommendations on DMEPOS

Confirm	Create	Remove	Limit	Maintain
Confirm the policy does not apply to existing Part B therapies	Create a modern home infusion benefit for drugs in Part D	Remove “prepared prior to administration” as a criteria for coverage	Limit coverage to approved indications	Maintain the requirement for LCD reconsideration

Comment Opportunity

NHIA encourages members to submit their own comments to CMS on this policy.

Link: **CMS-1738-P**

Comment deadline is January 4, 2021, however submit sooner if possible.

Most Favored Nations Drug Pricing Policy

- Goal is to increase price competition for Medicare Part B covered drugs given in hospital outpatient departments and physician offices, and to lower beneficiary cost by removing incentives built into the ASP +6% pricing model for physicians to prescribe the most expensive drug
- To be tested in all states and U.S. territories for 7 performance years beginning January 1, 2021.
- Participation is mandatory
- Bases payments for top 50 most expensive drugs at the lowest price among comparably wealthy nations.
    - Immune globulin exempted despite being among the top drugs in 2019, due to propensity for shortages, complex sourcing, and exploration of potential benefit in treatment of COVID-19

Direct MFN Impacts on Home Infusion

- MFN EXEMPTS: “Medicare Part B drugs that are furnished in the inpatient setting, administered through covered DME, orally administered, or paid under the End-Stage Renal Disease Prospective Payment System (ESRD PPS).
- “we (CMS) also intend that drugs will not be included on the basis of substantial use at home.”
- Thus, in § 513.130(b)(2), we codify the exclusion of claims that were processed and paid by the DME MACs as described in42 CFR 421.404(c)(2), and professional claims with a place of service code that indicates the drug was used in a home, including home-like settings, prior to identifying the top 50 drugs (by HCPCS code).

Indirect Impacts of MFN on ASP

- If manufacturers lower prices for providers subject to MFN, ASP could fall sharply, hurting reimbursement for home infusion pharmacies who often purchase at the high end of the ASP range.
- Home infusion providers do not receive service fees on par with physicians and HOPDs, thus rely more on drug margin to support services
- Access to medications subject to MFN or ASP pricing may be harmed

Comment Opportunity for MFN Policy

Link to rule and comment portal:
https://innovation.cms.gov/innovation-models/most-favored-nation-model#:~:text=The%20model%20will%20operate%20for,)%20ends%20January%2026%2C%02021

Comment deadline:
January 26, 2021

Changes to Stark and the Anti-Kickback Statute

Introduction

- Historically, health care in the U.S. has been based on fee-for-service (“FFS”).
  - Provider paid for what it furnishes to the patient…regardless of whether or not the patient gets better.
  - Very little coordination among providers.
  - Inefficient and expensive.

Introduction

- With 78 million Baby Boomers retiring at the rate of 10,000 per day, the financial strain on the nation's health care delivery system is markedly increasing.
- Third party payors ("TPPs"), including government programs and commercial insurers, are concluding that the FFS approach is no longer viable…and that a new approach is necessary.

Introduction

- The new approach is “value-based care” (“VBC”), also known as “coordination of care” and “patient outcome management.”
- VBC is premised on providers collaborating to furnish health care for a patient and for remuneration, at least in part, to be based on whether the patient’s health improves.
- VBC results in providers referring patients to each other, providing services to each other, and sharing in the remuneration paid for the care of the patient.

Introduction

- The challenge is that VBC has run up against the prohibitions/restrictions of the federal Stark physician self-referral statute (“Stark”) and the federal anti-kickback statute (“AKS”).
- Stark and the AKS came into existence when health care was almost entirely FFS
- While there have been some modifications to the two statutes over the years, such modifications have not addressed how the statutes fit within the VBC framework.

Introduction

- Recognizing the challenge imposed by Stark and the AKS to providers moving into the VBC space, (i) CMS updated Stark and (ii) the OIG updated the AKS.
- In early October 2019, CMS and the OIG simultaneously issued proposed rules modifying Stark and the AKS.
- On November 20, 2020, CMS and the OIG issued Final Rules that are the subject of this PowerPoint.

Stark

- CMS issued three Value-Based Enterprise (“VBE”) exceptions to Stark. They are meant to provide incentives to move toward VBE non-fee-for-service payment models while ensuring that program integrity safeguards are in place.
  - **Full Financial Risk exception –** Applies to value-based arrangements between VBE participants in a VBE that has assumed “full financial risk” for the cost of all patient care covered by the TPP for each patient in the target patient population for a specified time period.
  - **Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician exception –** Protects remuneration paid under a value-based arrangement where the physician is at meaningful downside risk for failure to achieve the value-based purpose of the VBE.
  - **Value-Based Arrangements exception –** Includes compensation arrangements that qualify as value-based arrangements, regardless of the level of risk undertaken by the VBE or any of its VBE participants and will permit both monetary and non-monetary remuneration between the parties.

Stark

- **Clarification of Definition of "Commercial Reasonableness" –** The key question to consider when determining if an arrangement is commercially reasonable is whether the arrangement makes sense as a means to accomplish the parties' goals. Profitability is not a factor.
- **Clarification of Volume or Value Standard and Other Business Generated Standard –** Identifies the universe of arrangements that will be considered to take into account the volume or value of referrals or other business generated. The amount of compensation will be considered to take into account the volume or value of referrals or other business generated only when the formula used to calculate compensation to or from a physician includes the volume or value of referrals or other business generated as a variable.

Stark

- **Clarification of Fair Market Value and General Market Value –** The definition of fair market value means the value in an arm's-length transaction consistent with the general market value of the subject transaction.
- **Clarification of Period of Disallowance –** Deleted the rules on the period of disallowance in their entirety.
- **Clarification of Financial Relationship, Compensation, and Ownership or Investment Interest –** Made changes to the rules relating to financial relationships, including indirect compensation and the special rules on compensation.

Stark

- **Clarification to Indirect Compensation Arrangement Definition –** Simplified the analysis for indirect compensation arrangements to include only those arrangements where the individual unit of compensation is not fair market value, or the individual units of compensation received by the physician is calculated using a formula that varies with the referrals of the physician or varies with the other business generated by the physician in a way that positively correlates to the compensation received by the physician as indirect compensation.
- **Clarification to Patient Choice and Directed Referrals –** Under the special rule for directed referrals, an entity is permitted to direct a physician who is a bona fide employee, independent contractor, or party to a managed care contract, to refer to a specific provider, practitioner, or supplier. Neither the existence of a compensation arrangement nor the amount of compensation may be contingent on the volume or value of referrals to a particular provider, practitioner , or supplier.

Stark

- **Clarification to Documentation and Set in Advance –** Added the ability to document and sign agreements within 90 days of the beginning of the arrangement. Modified the definition of “set in advance” to allow the modification of compensation during the term of an agreement where the modified compensation is not based on the volume or value of referrals.
- **Clarification to the Group Practice Definition –** Finalized a deeming provision related to the distribution of profits from designated health services that are directly attributable to a physician’s participation in a VBE. This distribution will be deemed not to directly take into account the volume or value of the physician’s referrals and will enable physicians in a group practice, who are participating in value-based arrangements, to be rewarded for their participation in such models.

Anti-Kickback Statute

- **New VBE Care Coordination Arrangements safe harbor –** The exchange of in-kind remuneration is permitted pursuant to a value-based arrangement, where the parties establish legitimate outcome measures to advance the coordination and management of care for the target patient population, the arrangement is commercially reasonable, and the recipient contributes at least 15% of either the offeror's cost or the fair market value of the remuneration.
- **New Value-Based Arrangements with Substantial Downside Risk safe harbor –** Protects both in-kind and monetary remuneration between a VBE and a VBE participant if the VBE undertakes the requisite amount of risk.

Anti-Kickback Statute

- **New Value-Based Arrangements with Full Financial Risk safe harbor –** Provides the greatest flexibility because it requires the assumption of the most risk. The remuneration protected under this safe harbor includes both monetary and in-kind remuneration from a VBE to a VBE participant.
- **New Patient Engagement and Support safe harbor –** Provides protection for certain patient engagement tools. Addresses items and services that patients might need to adhere to treatment regiments. Protection is limited to in-kind remuneration provided by VBE participants to patients to assist with the patients' engagement in their care. This safe harbor does not apply to certain VBE participants.

Anti-Kickback Statute

- **Modification of Personal Services and Management Contracts safe harbor –** Includes the protection of certain outcome-based payment arrangements. Payments must be based on the achievement of measure with clinical evidence or credible medical support. Payments for any such arrangement must measurably improve or maintain care or materially reduce costs. This safe harbor does not apply to certain types of providers/suppliers.
  - Removes the requirement that aggregate payment for a management or services arrangement be set out in advance. Going forward, only the methodology needs to be set in advance.
  - Removes the requirement that a part-time arrangement have a schedule of services specifically set out in a written agreement.
- **Modification to Warranty safe harbor –** Allows protection for a bundle of one or more items and related services, provided the items and services are all paid for by the same payor and under the same payment.

Anti-Kickback Statute

- **Modification to Local Transportation safe harbor –** Expands the mileage limits up to 75 miles for residents in rural areas. Eliminates distance requirement for conveying inpatients to their residents upon discharge
- **New ACO Beneficiary Incentive Program safe harbor –** Protects incentive payments made by an ACO to an assigned beneficiary under a beneficiary incentive program if the incentive payment is made in accordance with certain requirements.

Lowering Drug Costs

Introduction

- On November 30, 2020, the OIG issued a Final Rule that makes changes to the AKS pertaining to the cost of prescription drugs covered by Medicare and state Medicaid programs.
- The Final Rule amends the Discount safe harbor by eliminating protection for drug discounts and rebates offered by pharmaceutical manufacturers to PBMs and Medicare Part D prescription drug plan (“Part D”) sponsors.

Introduction

- The Final Rule also creates two new pharmaceutical-related safe harbors:
  - Safe harbor applicable to certain prescription drug point-of-sale discounts offered to Medicare/Medicaid beneficiaries to reduce their direct out-of-pocket prescription drug costs (“Point of Sale” safe harbor).
  - Safe harbor applicable to flat fee arrangements paid by drug companies directly to PBMs for services (“PBM Service Fees” safe harbor).

Introduction

- The Final Rule is in response to the President's July 24, 2020 Executive Order entitled "Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen ("Order").
- According to the Order, the high cost of prescription drugs is in large part related to the Discount safe harbor and the way it provides AKS protections to discount arrangements between drug manufacturers and "middlemen" (PBMs, Part D sponsors and Medicaid Managed Care Organizations)…but not discount arrangements between drug manufacturers and consumers.

Introduction

- The President's May 2018 drug pricing blueprint stated that the current rebate-based system rewards higher list prices, enriches middlemen, and drives up patients' costs.
- According to the OIG, with this Final Rule the OIG is taking action to encourage the drug industry to shift away from the current rebate system and toward a system that offers discounts reflected at the point of sale.

Introduction

- According to the OIG, the current rebate-driven system is characterized by high prices and backdoor arrangements. The OIG asserts that the current system creates three problems for patients:
  - Rebates reward increasing list prices. All parties in today's system, including PBMs and Part D plans, typically negotiate rebates as a percentage of the list price. Then the list prices increase, all parties benefit…except for the taxpayers and the patients paying for the drug.
  - Drug companies pay rebates and other payments to PBMs, but these payments are not reflected in patient out-of-pocket drug costs.
  - The current rebate system discourages the use of safe, effective, lower priced generics and biosimilars. A growing number of Part D plans have moved generic drugs to non-preferred tiers. This occurs because insurers and Part D sponsors can receive higher rebates for brand drugs and biologics. The OIG contends that excluding rival drugs with "rebate walls" distorts competition, discourages generic use and biosimilar adoption, and cause patients to pay more out-of-pocket. According to the OIG, if drug companies offer discounts that must be reflected in the price at the pharmacy counter, then patients will save.

Modification to Discount Safe Harbor

- Effective January 1, 2022, the Final Rule amends the Discount safe harbor to remove safe harbor protection for pharmaceutical manufacturer discounts and rebates offered to Part D sponsors, either directly or indirectly through PBMs under contract with Part D sponsors, unless such discounts are required by law.

New Point-Of-Sale Safe Harbor (Effective January 29, 2021)

- Designed to promote the use of discounts passed directly to consumers and, in turn, lower the out-of-pocket drug expenses experienced by Medicare and Medicaid beneficiaries at the point-of-sale: the pharmacy counter.
- Protects reductions in price on prescription pharmaceutical products offered to Plan D sponsors, MCOs, or through a PBM acting under contract with either if (i) the reduction in price is set in advance; (ii) the reduction in price does not involve a rebate, unless the full value of the price reduction is accomplished through chargebacks or is a rebate required by law; and (iii) the reduction in price is completely reflected in the price the pharmacy charges to the beneficiary at the point of sale.

New Point-Of-Sale Safe Harbor (Effective January 29, 2021)

- Qualifying fixed fee arrangements between pharmaceutical manufacturers and PBMs for the provision of PBM services to one or more health plans are protected from AKS scrutiny. The following requirements must be met:
  - The PBM has a written agreement with the pharmaceutical manufacturer that (i) covers all of the services the PBM provides to the manufacturer and (ii) sets out the compensation associated with the services.
  - The compensation paid to the PBM is (i) fair market value, (ii) fixed (e.g., not a percentage of sales), and (iii) not determined in a manner that takes into account the volume or value of referrals or business generated between the parties.
  - The PBM discloses in writing to each health plan (with which it contracts) at least annually the services rendered to each pharmaceutical manufacturer.

Tell Congress: Support the Preserving Patient Access to Home Infusion Act (H.R. 6218 & S. 3457)

Members of Congress need to hear from you now about why it is important to fix the Part B home infusion therapy services benefit, so that patients can continue to receive these crucial therapies in the comfort of their homes.

NHIA has worked with our congressional champions to introduce legislation that will ensure providers are paid each day of infusion, and to remove the face-to-face requirement for billing.

Support NHIA's efforts to pass this legislation and **send your Representatives and Senators a letter now.**

Access and send a customizable letter now at bit.ly/action-alert-patient-access

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