



National Home Infusion Association

Providing solutions for the infusion therapy community

January 16, 2018

BY ELECTRONIC DELIVERY

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program. CMS-4182-P.

Dear Administrator Verma:

The National Home Infusion Association (NHIA), representing the nation's providers of infusion therapy in home and alternate-site settings submits these comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule published for comment on November 18, 2017 entitled "*Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program.*"

NHIA commends CMS for their extensive efforts included in this rule and welcomes the opportunity to respond. NHIA has divided our comments by topic.

Part D Tiering Exceptions

As part of the proposed rule CMS proposes to change the exceptions process to make it more congruent with the increasing complexity of tiered formularies. As CMS noted in the preamble nearly all plans now have five or six tiers, including two generic-labeled tiers, which might also include brand name drugs. Because a plan sponsor can currently exempt any dedicated generic tier from its tiering exceptions procedures, almost two-thirds of all tiered plan benefit packages (PBP) could exempt three of their five or six tiers from tiering exceptions without any consideration of medical need or placement of preferred alternative drugs.

NHIA supports CMS' proposed revisions that would establish rules that base eligibility for tiering exceptions on the lowest applicable cost sharing for the tier containing the preferred alternative drug for treatment of the enrollee's health condition in relation to the cost sharing of the requested, higher-cost drug, and not based on tier labels, such as preferred, non-preferred, brand or generic.

A growing number of home infusion patients have rare conditions that only respond to

biologics, which are made using DNA technology. Many biologics can only be given intravenously and disruptions or changes in therapy may prevent the biologic from being effective. Unlike conventional drugs that can be interchanged with generic counterparts, biologics require beneficiaries to maintain the option to access branded drugs. As CMS considers altering the Part D Tiering Exceptions process CMS should recognize that follow-on biologics have unique patient needs and tiering exceptions should be availed to beneficiaries that need branded biologics.

Recent drug shortages of home infusion drugs have also pointed to the need for a Medicare exceptions process for beneficiaries when the generic drug is not available to the home infusion pharmacy. If a pharmacy does not have access to a particular generic drug due to a national shortage, the pharmacy may be forced to dispense the branded drug at the expense of the Medicare program and the beneficiary. In the circumstance where medical necessity is documented or a generic drug is not available, beneficiaries should have access to the lower cost sharing tier.

Any Willing Pharmacy Standard Terms and Conditions

In this section CMS proposes to clarify and revise the definitions of retail and mail-order pharmacies. NHIA encourages CMS to continue to clarify the differences between the increasingly diverse pharmacy sector.

Medicare Part D requires prescription drug plans have an adequate home infusion network. Chapter 5 Section 50.4 of the Medicare Program Integrity Manual states:

"In order to meet the requirements for adequate access to home infusion pharmacies, Part D sponsors must deliver home infusion drugs to enrollees within 24 hours of discharge from an acute setting, unless the next required dose, as prescribed, is required to be administered later than 24 hours after discharge. To ensure Part D sponsors can provide such access, as part of their initial pharmacy access submissions, and through Part D annual reporting requirements (Information Collection Requirements (ICF) OMB 0938-0992), each Part D sponsor must provide a list of all contracted home infusion pharmacies licensed/legally able to serve in all State(s) and/or territories in the service area under each CMS pending contract number."

NHIA has become increasingly concerned that in some cases prescription drug plans are fulfilling this requirement by reporting retail pharmacies that do not meet the standards outlined in Chapter 5 Section 50.4 of the Medicare Program Integrity Manual to fulfill the network adequacy requirement. As CMS continues to clarify the differences amongst pharmacies within the program we encourage you to ensure that Section 50.4 is actively enforced and prescription drug plans are not be allowed to use retail pharmacy locations to fulfill this requirement.

Also, as part of this section CMS solicits comment on the various practices of Part D plan sponsors that limit access to their network and to dispensing specialty drugs, including requiring specific pharmacy accreditations and waiving standard terms and conditions for certain

pharmacies. NHIA supports that CMS proposes to clarify the regulatory requirement for what constitutes “reasonable and relevant” standard contract terms and conditions.

Further NHIA supports efforts to curtail Part D plan sponsors from requiring a Part D plan’s accreditation program. Home infusion has several established accreditation organizations that are independent from the Part D plans which can be relied upon for accreditation requirements. These same organizations are used as part of the Medicare Part B program for home infusion and should be relied upon for this purpose.

NHIA also supports CMS’ proposal to impose deadlines to ensure Part D plan sponsors provide pharmacies with their standard terms and conditions. The proposal addresses an issue that many pharmacies have observed where plan sponsors delay providing standard terms and conditions or require extensive paperwork to demonstrate eligibility to participate in the sponsor’s network. This contradicts the very nature of having any willing pharmacy standard terms and conditions.

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

While NHIA generally supports CMS’ reason for considering giving Part D sponsors more flexibility to implement generic substitutions by permitting sponsors to immediately remove brand name drugs (or to make changes in their preferred or tiered cost-sharing status), when those Part D sponsors replace the brand name drugs with (or add to their formularies) therapeutically equivalent newly approved generics, NHIA has concerns that ample notice must be met. Immediate substitution with limited notice can cause supply chain issues. With little to no notice a home infusion pharmacy may not have access to the generic drug and have no recourse but to dispense the branded drug to the beneficiary.

It must also be noted that this section of the rule appears to move in a different direction than the Part D Tiering Exemptions section of the rule. As discussed earlier home infusion is unique due to the route of administration of the drug and in some cases the branded drug is necessary due to medical necessity. Without adequate pharmacy notice of a move to a generic drug and changes to the tiering structure for home infusion drugs, medical necessity requirements for tiering exemptions may not be met because they were not necessary prior. CMS should consider a process where tiering exemptions and medical necessity can be streamlined along with the expedited substitutions of certain generics.

Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale (Direct and Indirect Remuneration (DIR) Fees)

As part of the rule CMS has solicited comments regarding sponsors being required to include all pharmacy price concessions and a minimum percentage of manufacturers rebates in the drug’s “negotiated price” at the point of sale rather than counting for retrospective pharmacy price concessions and manufacturer rebates as DIR after the completion of the plan year. NHIA supports the approach that would require Part D plan sponsors to recognize retrospective pharmacy concessions as price concessions in the “negotiated price” used to adjudicate Part D

claims at the point of sale rather than as DIR after the termination of the plan year.

DIR Fees have become more prevalent over the past few years and the treatment of these pharmacy price concessions as DIR rather than as reductions in the "negotiated price" of a drug has led to growing concern amongst NHIA's membership. The treatment of pharmacy price concessions as DIR often results in beneficiary cost-sharing that is higher than it should be for certain drugs.

For NHIA members retrospective pharmacy concessions do not allow for home infusion providers to account for the true reimbursement rate for the drug at the prescription level. When a pharmacy is reimbursed at the "negotiated price" absent of retrospective pharmacy concession the reimbursement may be adequate, but months later when a large amount is withheld by a Part D plan sponsor the reimbursement adequacy equation can change dramatically. This could lead to the reimbursement on the claim to be inadequate or even lower than acquisition cost. This is exacerbated when the DIR is calculated on a percentile basis and applied to high cost drugs.

NHIA also notes that many DIR fees are based on quality metrics that are not applicable to home infusion pharmacies. Many Part D plans base their DIR fees on quality performance of pharmacies, the imposition of unrelated quality standards to base their DIR fees on is arbitrary and irrelevant from any real effort to improve the quality of the practice of home infusion.

NHIA appreciates the opportunity to comment on the proposed rule and continuing to work with CMS to ensure Medicare beneficiaries have access to the drugs and services home infusion providers avail to them. Please feel free to have your staff contact Kendall Van Pool, NHIA Vice President of Government Affairs, at (703) 838-2664 or kendallvanpool@nhia.org should you want to discuss our comments further. Thank you for your consideration of NHIA's comments.

Sincerely,



Tyler J. Wilson
President & CEO
National Home Infusion Association