

BY ELECTRONIC DELIVERY

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

Re: Medicare Program; Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses.

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 Service's (CMS) proposed rule published for comment on November 30, 2018 entitled "*Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses*".

NHIA commends CMS's efforts to increase transparency, competitiveness and lower beneficiary out of pocket drug costs. NHIA has divided our comments by topic.

Providing Plan Flexibility To Manage Protected Classes (§ 423.120(b)(2)(vi))

Implement broader use of prior authorization (PA) and step therapy (ST) for protected class drugs, including to determine use for protected class indications.

NHIA supports CMS's proposal to increase the use of prior authorization for protected class drugs and long as the authorization approval process can be completed swiftly so as to not negatively affect patient access to medically necessary medication. In the same light, NHIA supports the increased use of step therapy for protected classes of drugs for newly prescribed beneficiaries and recommends using the existing step therapy protocols for non-protected class drugs. NHIA recommends that Part D plans be required to post a listing of all drugs requiring step therapy and the step therapy requirements on their website.

Exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market.

NHIA does not support exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market. If CMS moves forward with this exclusion it should strongly consider allowing beneficiaries already using the drugs continued access.

Exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period.

NHIA does not support CMS allowing Part D plans to exclude from the formulary any protected class drug whose price increases, relative to the price in a baseline month and year, beyond the rate of inflation. As stated in the above exclusion proposed rule, If CMS moves forward with this exclusion it should strongly consider allowing beneficiaries already using the drugs continued access.

E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards (§ 423.160)

While NHIA agrees with the potential efficiencies that may result from increased use of e-prescribing and electronic medical record we believe systems should be sufficiently tested prior to making them mandatory in all instances. If CMS moves forward with this rules with a 2020 effective date, NHIA request an exception for patient specific infusion drug orders that often require reconstitution or compounding of multiple ingredients.

Medicare Advantage and Step Therapy for Part B Drugs (§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, and 422.619)

NHIA supports the use of Part B Drug Step Therapy for newly prescribed beneficiaries and strongly agrees with the need to improve adjudication, determination and appeal timeframes, not only for Part C and Part B, but all areas of Medicare. NHIA recommends that MA plans be required to post a listing of all drugs requiring step therapy and the step therapy requirements on their website. In addition to managing drug cost/ utilization MA plans should be encouraged to management cost by utilizing site of care optimization programs that allow for use of the home site of care and infusion suites operated by pharmacies as alternatives to hospital and physician run infusion centers.

Pharmacy Price Concessions to Drug Prices at the Point of Sale (§ 423.100)

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 Direct and Indirect Remuneration (DIR) Fees 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 Bill Noyes, NHIA Senior Vice President of Reimbursement Policy, at (703) 838-2661 or bill.noyes@nhia.org should you want to discuss our comments further. Thank you for your consideration of NHIA’s comments.

Sincerely,

Connie Sullivan
President & CEO
National Home Infusion Association