



January 16, 2018

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Room 445-G
Washington, DC 20201

Submitted electronically via www.regulations.gov

RE: CMS-4182-P, 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

Dear Administrator Verma:

Smith & Nephew, Inc. (SNI) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS) above-referenced proposed rule and request for information, in particular on policies and regulations related to the Part D prescription drug program.

SNI is a global medical technology business dedicated to helping healthcare professionals improve people's lives. With leadership positions in Orthopedic Reconstruction, Advanced Wound Management, Sports Medicine and Trauma & Extremities, SNI has around 16,000 employees and a presence in more than 100 countries.

Executive Summary

We support CMS efforts to improve the Part D program's quality, accessibility, and affordability. Soliciting public input on improving patient access to prescription drugs by lowering out-of-pocket costs at the point of sale is timely given the large increases in direct or indirect remuneration (DIR), mostly through manufacturer rebates.

Our specific recommendation is as follows:

- Develop a proposed rule to require Part D sponsors to be transparent and to apply price concessions through DIR at the point of sale, as the benefits of lowering out-of-pocket expenses far outweigh modest decreases in future monthly premiums.
- Ensure that all appropriate direct or indirect remuneration fees are being used to benefit the patient by lowering their out of pocket costs.

SMITH & NEPHEW, INC. COMMENTS AND RECOMMENDATIONS

Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

As a medical technology business with two wound biologic agents available to Medicare beneficiaries through the Part D program, we see firsthand how direct or indirect remuneration (DIR) costs have increased about twice as fast as total Part D drug costs.

We appreciate CMS's request for information (RFI) on considerations related to requiring sponsors to improve DIR transparency to include a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug in the drug's negotiated price at the point of sale. We strongly support this requirement, as it would increase prescription drug access by reducing the out-of-pocket expenses incurred by beneficiaries.

With respect to the two biologic agents manufactured by our company, we note steep declines in fill rates when the out-of-pocket costs reach \$70-\$80. This can be burdensome and discourage patients from filling their prescription.

While we appreciate DIR is intended to lower a beneficiary's future monthly premiums, the out of pocket expenditure for a given prescription, depending on its placement on a Plan's formulary, may greatly exceed the monthly premium. This effectively bars access to the prescription when the patient needs it most. Reducing the expense would ease the cost sharing and improve access.

Coverage Gap Implications

Reduced out of pocket costs would also slow the patient's advance into the coverage gap. The advancement into the coverage gap is based on the beneficiary's and drug plan's total drug cost. This means an overall reduction in the negotiated price would slow the beneficiary's advance in the coverage gap, where beneficiaries must pay a percentage of the cost for brands and generics (unless the plan has an enhanced benefit). Applying this reduction at the point of sale would reduce beneficiary costs in the gap.

SNI Recommendation:

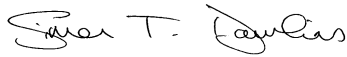
- Develop a proposed rule that promotes transparency and specifies how to best apply rebates and price concessions at the point of sale, in order to reduce cost sharing and improve Medicare patient access to medications prescribed by their health care practitioner.

CONCLUSION

Smith & Nephew, Inc. fully supports CMS triple aim policy objectives, and taking steps to reduce patient access barriers to their medications advances this goal, leading to improvement in health outcomes for Medicare beneficiaries.

We look forward to reviewing the proposed rule on this important policy topic and working with CMS staff on the issues we have raised. If you have any questions concerning our recommendations, please contact me at 727-692-2658.

Sincerely,



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