Johnson & Johnson
HEALTH CARE SYSTEMS INC.

Providing Services for Janssen, the Pharmaceutical Companies of Johnson & Johnson March 2019 cp-83594v1

Advocacy for Access – Rebate-Safe Harbor Proposed Rule

Advocating for Patient Access

We have added an new section in our transparency report – *Advocating For A Better Way.*

One of our key areas of focus is ensuring that patients and providers have optimal access and choice to the therapies that they need.

As many of you know, we have worked closely with our patient and provider advocacy partners to inform about the importance of laws and rules that affect patient access and provider choice.

Janssen has made a commitment to take a more proactive and visible approach to leading efforts to increase awareness and education regarding these “utilization management” practices that restrict patient access and provider choice.

Our Position: Our First Responsibility is to our Customers and Patients

- We believe treatment decisions belong in the hands of patients and their healthcare providers.
- We are concerned about clinically stable patients being switched to other therapies for non-medical reasons.
- We do not proactively seek arrangements with payers that require patients who are clinically stable on a medicine to switch to a different medicine.
- However, when we are asked to bid on contracts that require patients to utilize just one preferred medicine, we do so in order to ensure patients have continued access to our medicines.

Proposed Rebate Safe Harbor Rule: Potential Restrictions on Patient Access & Provider Choice

- HHS has issued a Proposed Rule that would
  1) Exclude rebates from the definition of a "discount" in the discount safe harbor.
  2) Proposes two new safe harbors:
     1) for rebates passed through to patients at the point-of-sale; and
     2) for PBM service fees based on a flat FMV amount and not based on list prices.
  3) **By excluding rebates from safe harbor protection for Medicare Part D plans and Medicaid managed care organizations, the proposed rule goal is to allow manufacturers to lower list prices**

- Janssen supports efforts to increase access through improved transparency and affordability.

- Once rebates are eliminated, PBMs and Payers may choose to manage costs by restricting patient access and provider choice by limiting the number of drugs per category.
  - This action may further restrict access/choice by limiting the number of drugs per category without any recourse from pharmaceutical companies.

- We support Congress/HHS to establish clear guidelines that limit the ability of PBMs/plans to further restrict patient access and provider choice.

Commenting on the Proposed Rule

Submit comments electronically using file code file code HHSIG-2019-0001-0001 at www.regulations.gov or mail written/printed comments to:

- Aaron Zajic, Office of Inspector General, Department of Health and Human Services,
  Attention: OIG-0936-P, Room 5527, Cohen Building
  330 Independence Avenue SW, Washington, DC 20201.

- *Please allow sufficient time for mailed comments to be received before the close of the comment period.*

Public comments are due by no later than 11:59 p.m. EDT on April 8, 2019.