PIRC

PROTECTING INNOVATION IN RARE CANCER

REBALANCE THE IRA

PIRC Meeting

March 17, 2025

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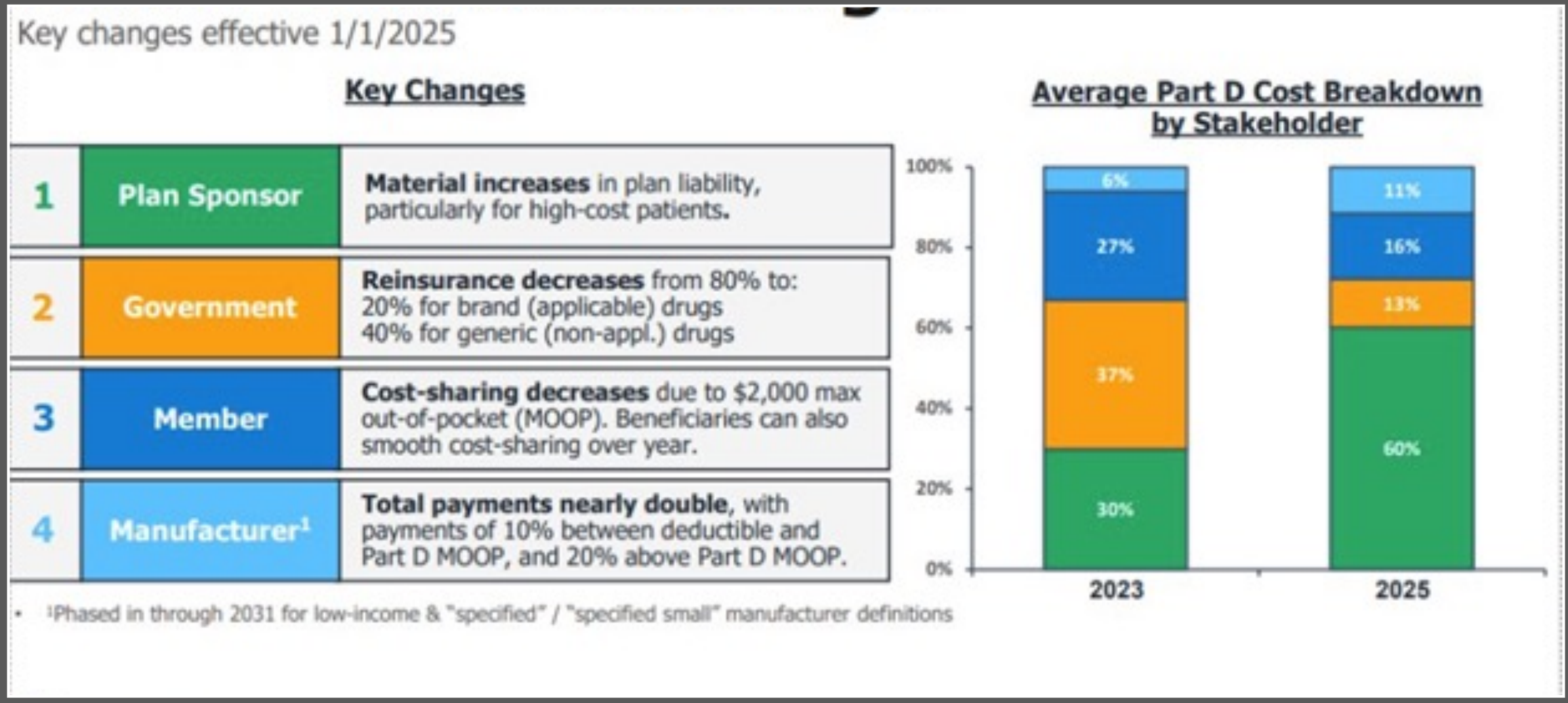
Agenda

- Part D Redesign – 2025 Changes
  - OOP Cap and “Smoothing” Option
  - New Manufacturer Discount Program
  - **NEXT STEPS** – “Form” to collect rare cancer patient experience information w/ Part D in 2025
- Drug Price Negotiation
  - More Cancer Drugs this Year
  - PIRC submission on Calquence (CLL, MCL, GvHD)
  - CMS Engagement Opportunities
  - Efforts to Modify IRA Drug Price Negotiation Provisions
  - **NEXT STEPS** - Proactive engagement on IRA change discussions



IRA Changes Effective for 2025 Shift Costs from Patients & Government to Plans & Manufacturers

The OOP Cap will Relieve Part D Financial Burden; ***However,*** Experts Fear Increased Plan/Manufacturer Costs Might Impact Premiums and Impede Access to Costly Treatments.

- Increased premiums for same plans as prior year
- Fewer plan options (if issuers leave Part D)
- Fewer high-cost treatments on formulary
- Increased prior authorization, step therapy protocols
- More drugs placed on higher tiers
- Formulary restrictions, adverse tiering, and increased utilization management for “small manufacturer” drugs due to “phase in” of full manufacturer discounts through 2032 (manufacturer costs shift to plan).

The New Medicare Prescription Payment Plan Offers Additional Relief from High OOP Costs

- **Opt-in Required:** Individuals must choose to participate in the plan and can opt-in through both traditional Medicare and Medicare Advantage plans with drug coverage.
- **Plans Must Conduct Outreach to Beneficiaries "Likely to Benefit"**
- **No Upfront Payments:** When participants fill a prescription, they will not pay anything at the pharmacy.
- **Monthly Bills:** Part D plans bill participants monthly for their cost-sharing obligation on prescriptions filled to date.
- **Premium Bills:** Premiums are billed separately from payment plan bills. If a plan cannot determine how to apply an enrollee's payment, CMS requires that they apply the funds to premiums.
- **No Interest or Fees:** There are no interest or fees for late payments.
- **Automatic Renewal:** Participation in the plan will automatically renew for the next calendar year unless the participant opts out.

Potential limitations Impacting the Payment Plan for the 2025 Plan Year

Payment Plan election hurdles

- For 2025, beneficiaries will not be able to opt into the payment plan at the pharmacy counter
- When a beneficiary fills a high-cost prescription the pharmacy may provide payment plan information, but the patient may face delays opting in.
- Beneficiaries might delay picking up their medication until their election is processed
- Alternatively, beneficiaries might pay at the pharmacy counter and be unable to use the payment plan effectively.

Variation in beneficiary outreach:

- CMS gave plans flexibility to establish “reasonable guidelines” for identifying beneficiaries likely to benefit from the program
- Expect variability in plan outreach and education that might impact payment plan participation.

Patient confusion due to variable amounts due each month.

- Participants will not pay the same amount each month – the addition of new drug costs and different formulas for 1st month following each prescription fill and subsequent months can be confusing despite CMS’ set of examples.
- If a participant incurs their highest prescription drug costs at the end of the year, the OOP obligation might be unmanageable even with the payment plan. Costs cannot be distributed from one plan year to the next.

NEXT STEPS: Proactive patient outreach and education to identify a "baseline" and document progress or regression in rare cancer patient experience.

Part D Redesign

Impact on premiums and plan choice

Restrictive formularies

Increased utilization management that push prescribers to or away from specific treatments

Medicare Prescription Payment Program

Did patients receive smoothing program information they could understand?

How many options were available to opt in?

How many options were available to pay monthly bills?

What problems have patients experienced with election delays? Confusing bills? Unanticipated high drug costs?

A rare cancer outreach "tool" would enable uniformity to produce a clear and concise set of data on patient experience to help CMS understand what works well and how CMS can "fix" any access concerns.

Like Last Year, PIRC Submitted Information Relevant to a Selected Cancer Drug and More Broadly Applicable to Rare Cancer Treatments

Rare cancer patients and others relying on “specialty” drugs will probably not have OOP reductions due to negotiations.

CMS has acknowledged that negotiated prices could lead to increased rather than decreased premiums.

Our patient communities remain concerned that the MDPNP will reduce the number of new treatments that are brought to market, including initial approvals in rare cancers, follow-on uses in multiple cancers and development of combination therapy regimens

PIRC believes CMS has more discretion in implementing the MDPNP than it exercised in selecting and negotiating drugs for iPAY 2026

CMS should avoid aggregating research costs and revenue as it determines whether a manufacturer has recouped its costs and instead calculate return on investment using indication-specific cost and revenue data.

CMS should consider the failure rate for oncology drug candidates. A recent study noted that approximately 97% of oncology drugs studied for an indication never receive FDA approval for that indication

Cancer treatments are also far less likely to have generic competition than treatments for more common conditions.

The high variability among CLL patients (age, preferences, aggressiveness of disease, comorbidities, and other factors) not only makes clinical studies in CLL particularly difficult but it injects a great deal of uncertainty into any discussion on comparative effectiveness.

Negotiation ss not a new concept for cancer treatments. The statutory price ceilings, however, when applied to small molecules in oncology, create a narrow window of profitability that could reduce the types of research that CLL patients and others with rare cancers rely on to live longer, healthier lives.

CMS has Replaced Last Year's "Listening Sessions" with Events that Enable Interaction among CMS and Speakers

CMS is conducting a set of treatment-specific roundtable sessions. Participation in the roundtable events is open to patients, patient advocacy organizations, and caregivers. Individuals must register to speak at roundtable or town hall before midnight 3/19/25 at Webinar Registration – Zoom

Cancer treatment roundtable events are:

- enzalutamide (Xtandi) - Tuesday, April 29, 2025 at 11:00 AM – 12:30 PM ET
- pomalidomide (Pomalyst) - Thursday, April 24, 2025 at 10:00 – 11:30 AM ET
- palbociclib (Ibrance) - Thursday, April 17, 2025 at 2:00 – 3:30 PM ET
- acalabrutinib (Calquence) - Thursday, April 17, 2025 at 10:00 – 11:30 AM ET

CMS wishes to hear from practicing clinicians and researchers (4 minute statements) at the Town Hall meetings conducted on Wednesday, April 30, 2025:

- Session 1 at 10:00 AM – 12:15 PM ET
- Session 2 at 1:00 PM – 3:00 PM ET
- Registration: Webinar Registration - Zoom

Additional/Upcoming Developments Include Initiatives to Modify the Orphan Drug Exclusion and Change How a Negotiation-Eligible Drug is Defined

Currently, an orphan product cannot qualify for the orphan exclusion if it has designations for multiple rare diseases or conditions, even if the drug has been approved only for indication(s) within a single rare disease or condition.

- Existing initiatives seek to expand the exclusion to permit multiple orphan designations and indications and to "start the clock" on negotiation eligibility at the date the drug loses exclusion eligibility
- This does not incentivize studies of non-orphan treatments in rare cancers

CMS interprets IRA as defining a qualified single source drug (QSSD) by its moiety/active ingredient. A new NDA or BLA – regardless of any divergence from the first approval in formulation, dosing, treatment duration, route of administration is one drug for negotiation eligibility purposes.

- Multiple orphan designations precluded orphan exemption eligibility.
- .Any future NDA in, for example GvHD will be subject to a negotiated price and trigger renegotiation costs and uncertainties.

CMS has flexibility to "select" fewer drugs than the maximum permitted under the IRA (for this year's negotiation, it is up to 15 drugs)

- CMS selected the 15 drugs for IPAY 2027 negotiation days before President Trump took office.
- The new Administration has stated a willingness to consider policies that increase transparency and protect innovation.

NEXT STEPS: IRA Drug Price Negotiation Program

Determine whether you have patients on selected or altnerative therapies, on- or off-label? Identfify community membersur patients use any of the selected drugs?

Identify patient and clinician/researcher speakers if the drug is used within your patient community

PIRC can work with you on your advocacy efforts
Follow-up participation with a written statement to CMS

Listen in on town hall (not on roundtables)

Watch for PIRC sign on opportunity after the round table and after the town hall

CMS has stated an interest in hearing from stakeholders on how to improve negotiation transparency and minimize impact on innovation. Future PIRC meetings will discuss options to present to CMS.

We will also discuss legislative initiatives and options to preserve both access and innovation for rare cancer patients in future meetings.

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Back Up

Experience from Last Year's Listening Sessions

Price/Cost to Medicare vs. Cost to Patient

- Speakers confused the two AND seemed unaware of the 2025 OOP cap.
- 73 yr old Medicare patient on Imbruvica: Imbruvica is not affordable. Believes negotiation pricing will not impede research or innovation since "this" is funded by taxpayers." Asked CMS to continue vigorous negotiations to make ***all cancer treatments*** affordable to all seniors. (Does not understand out of pocket cap or smoothing)
- Patient: Did well on Imbruvica, only minor side effects. Happy there are additional treatments since she had to stop taking it. Pleased Imbruvica included in negotiations b/c she hopes it helps patients concerned w/ drug cost.
- ACSCAN: There is potential for real savings if savings directly reach patients. Patients won't benefit from negotiation unless they pay less out of pocket for their treatment

Other Speakers/Additional Points:

- Enormous unmet need for new cancer treatments. Innovation is hugely important. Work with FDA to monitor impact of IRA on research and development.
- Waldenstrom's patient: Confusing – Said Dana Farber developed Imbruvica, noted concern for effect of negotiations on other BTKs; Cited expense of drugs/need to take for the rest of your life, but said he was now off all treatments but would likely need treatment again at some point.
- Researcher: Also confusing – Spoke of research funded by government, NIH database lists manufacturers as sponsoring 25% of research, but then spoke of costs to manufacturer for a post-approval FDA-mandated study as being 'massive'