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PROTECTING INNOVATION IN RARE CANCER

REBALANCE THE IRA

PIRC Meeting

October 13, 2025

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PIRC Purpose

- Speak loudly with one voice
- Provide **a rare cancer perspective**
  - *Educate ourselves (& our communities)*
  - Applaud what we can
  - Prepare for what is coming
  - Fight against what must change
    - NOW AND NEXT YEAR
    - PREPARATION

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Agenda

- IPAY 2028 FINAL GUIDANCE
- IPAY 2028 30-DAY COMMENT OPPORTUNITY
- 2025 EXPERIENCES WITH ACCESS AND SMOOTHING

IPAY 2028 FINAL GUIDANCE: 3 Big Changes from the First Two Rounds of Negotiation

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- CMS begins to select eligible Medicare **Part B** drugs
- First year for drug price **renegotiating** process
- Enhanced protection for Orphan Drugs

IPAY 2028 Final Guidance – Drug Selection Process for Up to 15 Drugs Total, Including Part B Drugs

CMS will identify the 50 highest spend drugs under Part B and the 50 highest spend drugs under Part D.

- For Part B drugs, CMS will use Part B claims and calculate total amount, including beneficiary coinsurance
- NEW IN FINAL: Medicare Advantage (MA) encounter data will also be included. CMS will estimate what FFS would have paid (multiply adjusted units by ASP or payment rate in OPPS/ASC)

CMS will then combine total expenditures under Part B and Part D for the 100 drugs, rank them, from highest to lowest.

- CMS will select the 15 highest ranked drugs based on their combined Part B and Part D expenditures
- Biologics eligible for delay will be removed from the list
- NEW IN FINAL: CMS clarified that when a drug or biologic is selected but ineligible due to biosimilar in pipeline or marketed generic, the drug will still be considered one of the 15 selected (CMS does not move to the next drug on the list)

Orphan Exemption was Expanded for IPAY 2028 and Subsequent Negotiation Cycles

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01

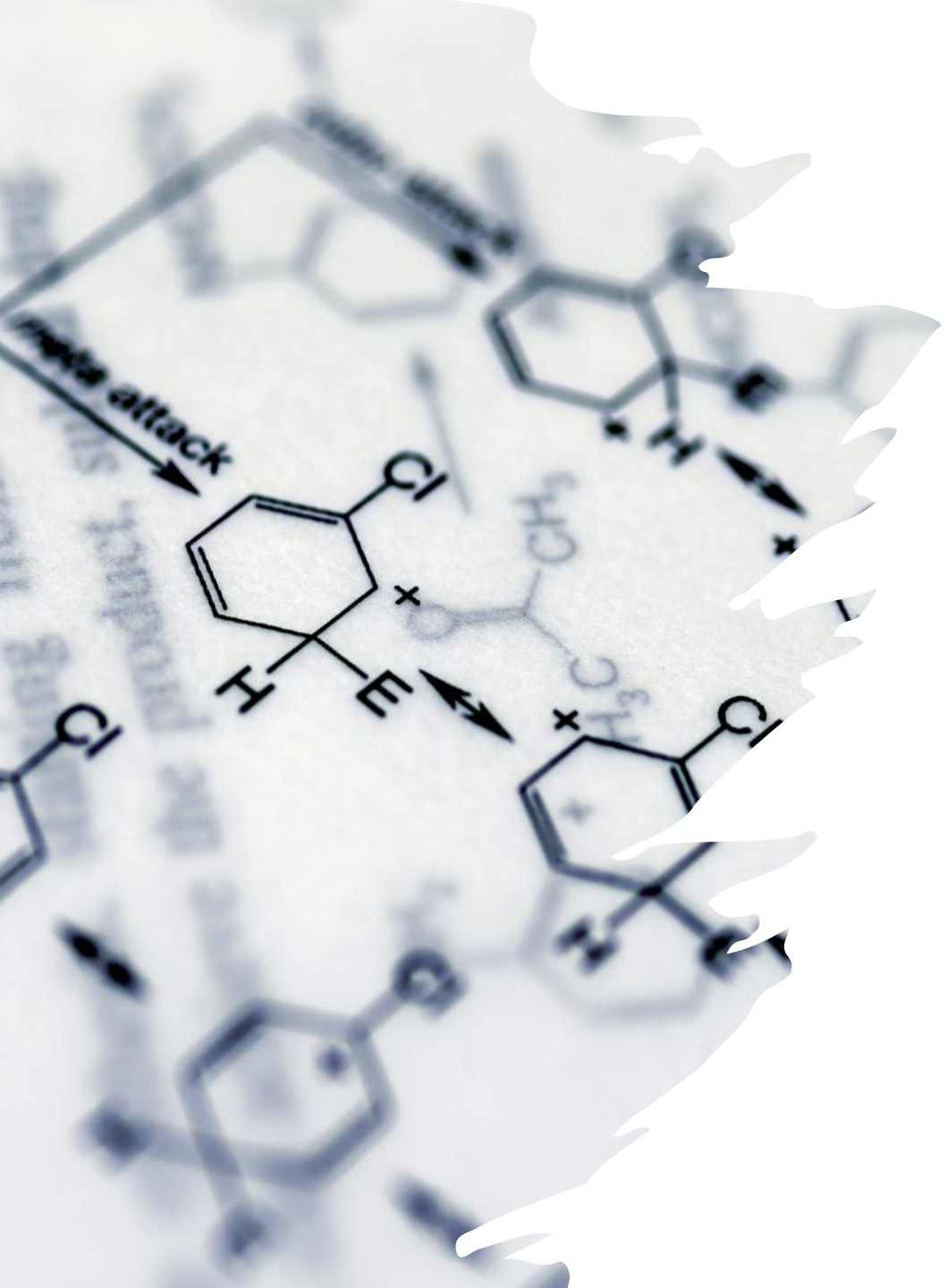
New statutory standard (Working Families Tax Cuts Act)

02

A drug is excluded only if **all** approved uses are for one or more rare diseases.

03

If a drug later gains any **non-orphan** indication it becomes a **former orphan**, and the time clock for selection **starts then**.



Drug Price Renegotiation Process is New for 2028

- **Mandatory/Automatic Selection**: If a previously selected drug transitions to **long-monopoly** status, CMS **must** select it for renegotiation.
- **Discretionary selection**: New indications or material changes to negotiation factors since the last MFP
  - CMS will pick those where the renegotiated MFP is likely to change ≥15% and materially affect Medicare.
- **Data window**: CMS will look at updates through **Nov 30, 2025** for 2028 renegotiation selection decisions

- Selections for renegotiation do NOT count toward “up to 15” drugs for IPAY 2028

Part B Oncology Drugs with Potential for IPAY 2028 Selection

Perjeta® (pertuzumab) — BLA 2012 (meets 11-year rule).

Kadcyla® (ado-trastuzumab emtansine) — BLA 2013 (meets 11-year rule).

Vectibix® (panitumumab) — BLA 2006 (meets 11-year rule).

Erbitux® (cetuximab) — BLA 2004 (meets 11-year rule).

Why not others?

- **Keytruda®/Opdivo®**: earliest non-orphan approvals appear **after** Feb 1, 2015 → **not eligible** for 2028 selection under the updated orphan/"former-orphan" policy.
- **Avastin®/Herceptin®/Rituxan®** (and **Neulasta®/Prolia®/Xgeva®**) face **marketed biosimilars** in 2025, disqualifying them from selection; denosumab biosimilars launched mid-2025.

Part D Oncology Drugs with Potential for IPAY 2028 Selection (Negotiation and Renegotiation)

- **Tagrisso® (osimertinib)** — first approved 2015 (meets 7-year threshold by 2/1/2026) and consistently among higher-spend oral oncology agents in Part D datasets/analyses.
- **Lynparza® (olaparib)** — initial approval 2014 (meets threshold); specialty oncology spend reflected in CMS Part D dataset.
- Several cancer treatments could be renegotiation candidates later if triggers (new indications, material changes from initial MFP, change in “monopoly” status) are met:
  - Xtandi® (enzalutamide)
  - Ibrance® (palbociclib)
  - Pomalyst® (pomalidomide)
  - Imbruvica® (ibrutinib)
  - Calquence® (acalabrutinib)

IPAY 2028 Final Guidance – Setting the "Maximum Fair Price"

The statute and draft guidance calculate a single MFP across all dosage forms and strengths, CMS has been using 30-day supply and seeks comment on 'per-unit' basis instead.

- NEW IN FINAL: CMS did not finalize a shift to unit-based pricing.
- NEW IN FINAL: CMS finalized a mechanism for calculating a single MFP for drugs that are used or administered in a way that makes it difficult to define a "30-day supply" (e.g., one-and-done or infrequent infusions)

CMS proposed additional considerations for MFP ceiling calculations

- For a selected drug covered under Part D but not under Part B, the sum of the plan-specific enrollment weighted amounts for a 30-day supply
  - NEW IN FINAL: CMS will consider WAC in calculating price for Part D drugs
- For a selected drug payable under Part B and not covered under Part D, a weighted average for a 30-day supply using the lesser of WAC or ASP, not adjusted for sequestration.
- For Part B drugs also covered under Part D, an amount equal to the weighted average, per 30-day equivalent supply of each NDC-9, using the amounts calculated above for Part B and Part D drugs. CMS refers to this as the "combined Part B and Part D amount").

IPAY 2028 Draft Guidance – Information on Selected Drug and Therapeutic Alternatives

CMS requests feedback on whether to collect additional forward-looking "market data" (forecasted net revenue and volume) for the negotiation period and/or price applicability period (i.e., "current" year and subsequent 2 years), such as forecasted net revenue and volume. NOT FINALIZED

Alternative Part D therapies would be priced at the lower of either: the Net Part D Plan Payment and Beneficiary Liability, net of discounts, or the MFP negotiated for a prior year. NEW IN FINAL: CMS will also look to WAC for Part D drugs.

When CMS looks to Part B alternative therapies for pricing, it will use lesser of ASP or WAC.

For drugs with multiple therapeutic alternatives, CMS will consider therapeutic alternatives within each indication and weight prices by utilization or other patterns of use. *FINALIZED* -- ***This reduces impact of rare cancer uses in calculating price. CMS seeks comments on alternative methodologies.***

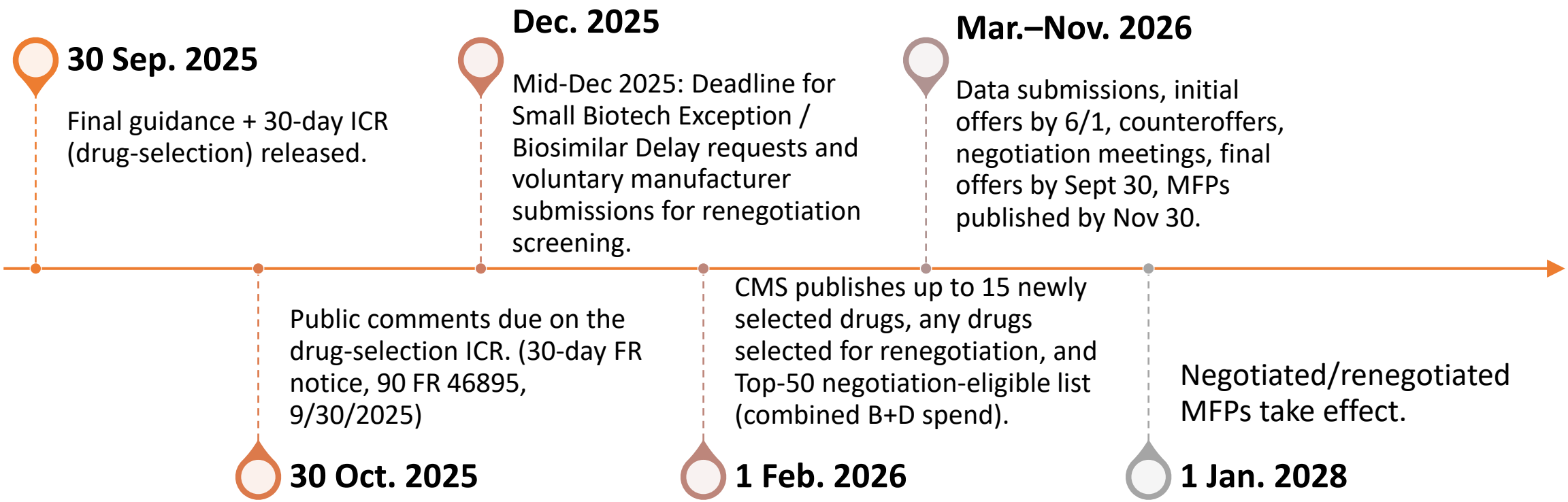
CMS DID NOT finalize proposal to consider Part A or Part B services as potential therapeutic alternatives, reserving this issue for the rulemaking required for cycles beginning with IPAY 2029.

CMS Has Not Decided How to “Effectuate” the MFP for Part B

CMS has solicited comments on how MFP actually gets to physician offices/outpatient centers compared to how it gets to the Part D plan/pharmacy. The final guidance did not provide insight into processes other than the MTF used for Part D drugs.

- How much extra burden will providers face in administering Part B drugs with an MFP?
- What complexities do distributors (and their service agreements) add?
- What impact will an MFP have on clinician reimbursement and willingness to administer drugs in the clinician office or hospital outpatient setting?
- Options proposed to date can either present cashflow problems (retrospective discount) or logistic challenges such as separate inventory tracking.
- This is an issue that can have a tangible impact on access if office-based providers and smaller outpatient departments are unable to adapt to the changes to Part B drug payment.
- Advocates should consider weighing in with CMS outside the comment solicitation vehicles

IPAY 2028 Timeline



“All or Substantially All” . . . ???

CMS is establishing a new centralized intake system for receiving reports related to whether patients and dispensing entities have **access to the MFP of selected drugs --** intended to address complaints and disputes related to MFP availability and the functionality of the Medicare Transaction Facilitator.

There is no corresponding intake system or tracker to track access to ‘all or substantially all’ oncology drugs…

CMS' Final Guidance Provides More Opportunities for Interaction and Price Proposal Exchanges

Manufacturers will have **one optional negotiation meeting** after the first written initial offer and before the statutory written counteroffer is due

If CMS' written response rejects the drug company's counteroffer, CMS will offer the primary manufacturer **one more optional negotiation meeting** to occur by Aug. 14, 2026, and another optional meeting if an agreement is not reached. That meeting must be held by Sept. 11, 2026

Price negotiations with drug companies for selected drugs end before Nov. 1, 2026, for price applicability year 2028

CMS' Information Collection Request (ICR) Has an Open Comment Period Through October 30, 2025

- **Renegotiation – "Optional" Manufacturer Submission**
  - Requires information similar to what is submitted during initial negotiation, but would in theory be submitted annually after the first MFP.
  - Revenue from outside the USA is to be considered in determining recoupment of costs, but expenses toward approvals outside the USA are not considered.
  - Manufacturers of previously negotiated drugs would outline all changes in approvals and off-label uses that are "medically-accepted" for both the manufacturer's drug and any therapeutic alternatives.
  - Any FDA submissions in process must also be disclosed.

We are still waiting for the revised ICR detailing data elements and counter-offer processes. That ICR will have a 30-day comment period.

DISCUSSION

Patient feedback on signing up for and using the “smoothing” mechanism

Any reported changes in Part D impacting patient access or finances?
- Premium increase/decrease?
- Formulary changes?
- New or “enhanced” utilization management barriers?

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Next Steps

NEXT PIRC CALL: November 10, pending any relevant actions