PIRC

PROTECTING INNOVATION IN RARE CANCER

REBALANCE THE IRA

PIRC Meeting

September 11, 2023

Carly Boos, Executive Director, CLL Society

Brian Koffman, EVP/CMO, CLL Society

Guest Speaker: M. Kay Scanlan, JD

PIRC

PROTECTING INNOVATION IN RARE CANCER

REBALANCE THE IRA

Agenda

- RECAP on “First 10” Drugs
  - Previous Discussions’ Content on our website
  - **Website: https://rarecancerira.org/**
  - Two Sets of Comments
- CMS’ New “Smoothing” Draft Guidance
  - **Info@rarecancerira.org**
  - **mkayscanlan@consilstrat.com**

Sept 1 = "**First 10"** drugs for direct government price negotiation

Imbruvica – only one cancer drug chosen for the first year of the program

Sept 1- Oct 2 – Registration opens for Speaking Slots at Listening Sessions

- 20 Speakers to be chosen randomly (patients, caregivers, doctors, associations)
- Three minutes to speak
- All Listening Sessions will be streamed live/be open to the public – first one Oct 30; (HHS Live Streaming | HHS.gov)
- Nothing said here will be considered 'comments' to the docket CMS will review for negotiations

Oct 2 – Comments due to CMS (broad or specific)

Nov 6 – Imbruvica Listening Session (12:00-1:30pm ET)

- CMS will listen, not engage
- Comments can be broad or specific
- Timing allows you to condense key points from your submitted comments
- Otherwise, share your stories/concerns
- Share difference between cancer and other disease areas – e.g., combination regimens, etc.

Draft Plan for Written Submissions

1. Broad PIRC Comment
2. Specific CLLS Comment

Specifically Working Together

- ✓ Share CMS' Qs with treating physicians, medical advisory board
- ✓ Translate feedback into As that reflect CMS' understanding of terms (Kay Scanlan webinar)
- ✓ CLL Society to share draft comments as early as feasible (Kay Scanlan engaged by CLL Society)
- ✓ Model responses to our draft if helpful/relevant?

Broadly Working Together:

Will Affect Cancer Drugs on CMS' "Next 10" list…

- ✓ Sign-On Opportunity for PIRC members/rare cancer groups
- ✓ Kay Scanlan engaged to draft comments submitted under PIRC's name
- ✓ Focus to include (welcome suggestions):
  - (Non)Relevance of QALYs in rare cancers
  - Usefulness of Comparative and Cost Effectiveness in Rare Cancers
  - Redefining Unmet Medical Need in Rare Cancers
  - Rethinking 'therapeutic alternatives' in rare cancers

>> DUE OCT 2

PIRC

PROTECTING INNOVATION IN RARE CANCER

REBALANCE THE IRA

Agenda

- "First 10" Drugs
  - Previous Discussions' Content on our website
  - **Website: https://rarecancerira.org/**
- CMS' New "Smoothing" Draft Guidance
  - **Info@rarecancerira.org**
  - **mkayscanlan@consilstrat.com**

CMS Releases "Smoothing" Proposal for Comment – Comments Due ***Sept 20***

"Part 1" Smoothing Guidance

- ✓ After **Part D and MA beneficiaries** "enroll"
- ✓ *Opt-in* to "participate" in
  - ✓ "Medicare Prescription Payment Plan"
  - ✓ "Maximum Monthly Cap on Cost-Sharing Payments program"

Among the proposed logistics:

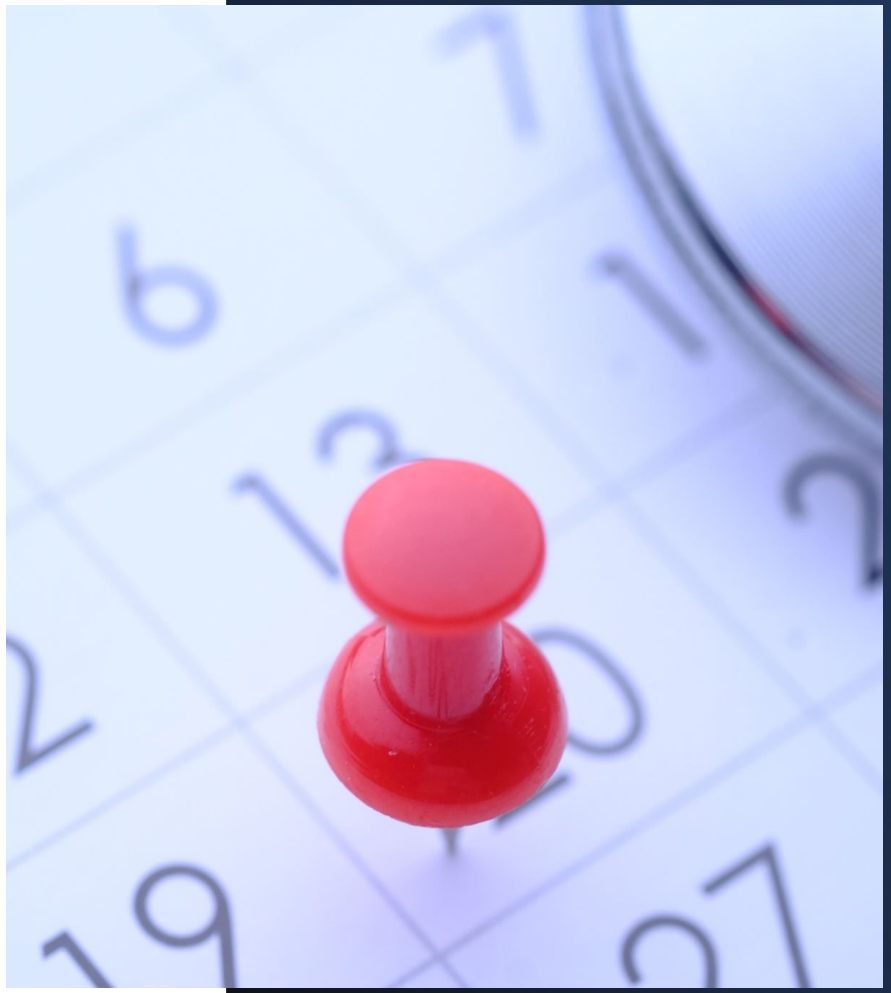
1. Opt-in at the start or anytime during their 'plan year.'
2. Monthly payments (up to a maximum allowable cap) are spread across the Plan Year.
   - ✓ Beneficiaries will want to consider if opting in makes sense mid/late-year.
3. Patient no longer pay at the pharmacy/"point of sale"/POS.
   - ✓ Part D plan pays pharmacy and bills patient based on calculation of monthly smoothing (Pharmacy not expected to carry any costs).

A. Part D or MA Plan Role

- Plan must have paper, 800#, online, other ways to enroll in program. Plan must limit data elements to opt-in: name, Medicare ID# and agreeing to program terms and conditions.
- Plans must include program participation details in plan enrollment forms/processes.
- Plan must acknowledge receipt of opt-in request w/in 10 days.
  - If request incomplete, Plan can't deny/must request add'l info and 21 days to respond, then deny but document reasons/provide appeal w/in 10 days of denial;
  - Upon approval, provide patient with program overview, rights/responsibilities, protections, procedures for involuntary termination, reinstatement, examples of max monthly calculations, LIS info, etc.
- Plan must integrate info on opting in another year in reenrollment paperwork, and process requests in 10 days.
- Mid-year opt-in requests -- process in 24 hours for "urgent needs" to avoid delays (CMS asks if an interim approval could come even faster). Plans must also allow retroactive participation and pay any incurred OOP costs if Plan misses deadline and if patient requests retroactivity w/in 72 hours of urgent claim. (Plan must notify patient immediately if plan deems request non-urgent or if patient didn't file in 72 hours).
- Plans must communicate about Program to all eligible patients, with additional outreach to patients/pharmacies re: 'likely to benefit' patients.

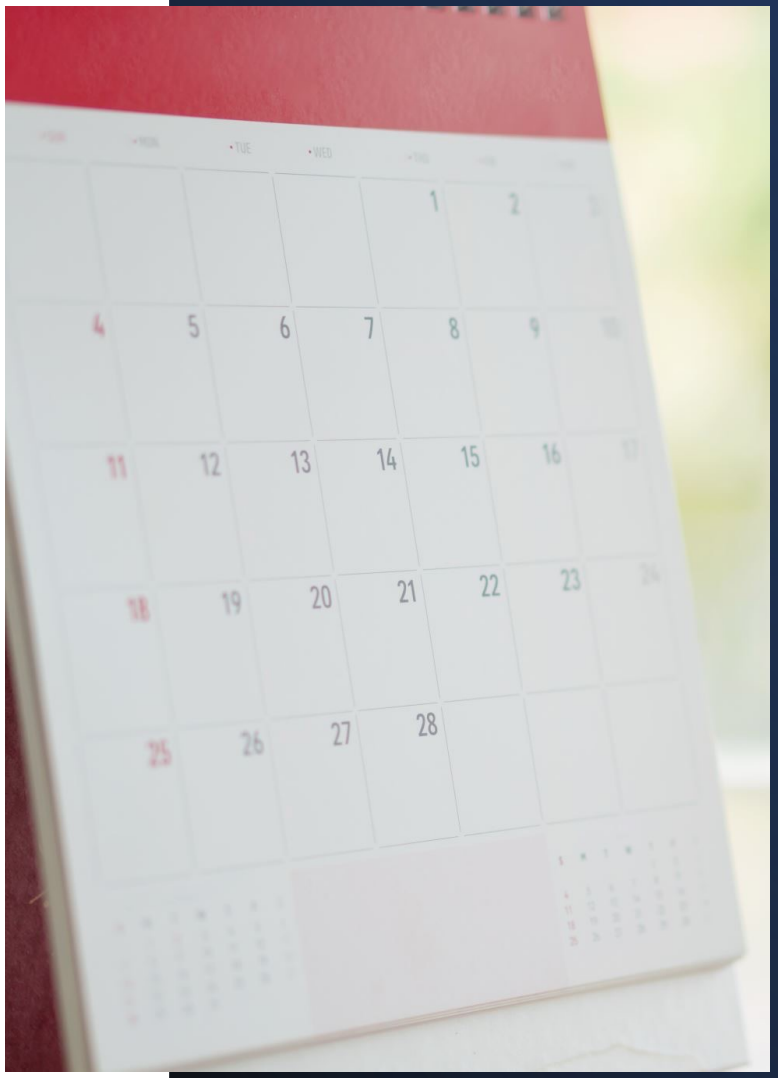
B. Monthly payments

- Program applies to spreading out OOP costs for deductibles too.
- Costs incurred before opting into the program are not spread across the calendar year (they were paid at pharmacy counter).
- Only covered drugs are included in the program.
- Program doesn’t impact what counts toward Troop and what doesn’t. (true OOP); costs incurred for drugs to be used over multiple months will spread across the months starting the month the cost was incurred, regardless of how long the drug is used. (So if OOP costs for a drug are $2K for one month and after one month, the patient is no longer taking the drug, the monthly obligation is still paid.)
- Monthly maximums are determined by plan based on a formula proposed by CMS - annual OOP threshold minus any Part D costs incurred before opting in, divided by months remaining in the plan year.
- Plan can’t bill patient for anticipated costs, only those incurred at the time of opting in.
- As additional OOP costs are incurred, the plan recalculates the monthly max, and can add in past due amounts to calculate monthly max.



C. Participants receive a monthly bill

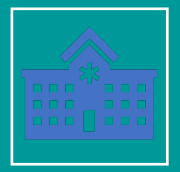
- Plans should allow flexibility on which day of every month patients want to be billed and should offer a variety of payment methods.
- Monthly Statements must include list of prescribed items to help the patient understand the payment, options for opting out, etc.
- Premiums are billed separately, but if/when it is unclear what a payment is for, the plans should allocate it to premiums, so patients aren't at risk of losing their Part D plan.
- Patients can pay extra each month, but plans can't bill more than the monthly calculated amount.
- No late fees or interest payments allowed.



D. What if participant does not pay monthly bill?

- Plan can terminate patient for failure to pay monthly billed amount ***after a grace period,*** beginning w/ notice w/in 15 days of missed payment date (notice to incl. termination date, how to make payment (which will continue to be owed after termination), opp. to enroll in LIS, and info that patients can't opt-in in future years if balance isn't paid, and provide dispute process)
- **Grace Period:** at least two months, Plan must reinstate terminated patient if patient demonstrates good cause for failure to pay during grace period and pays all amounts overdue. Patient to show 'no control' or couldn't 'reasonably foresee';
- Plan must send 2nd Notice w/in 3 days of grace period ending, stating patient must pay pharmacy directly going forward, that patient is still enrolled in the Part D plan, information on paying outstanding balance, and dispute resolution process. If notice is returned undeliverable, plan must research change of address, etc.
- Plan can keep patient from opting-in in subsequent year until patient pays overdue balance.
- A Part D sponsor with different Part D plans can have different preclusion policies but must apply them uniformly within each plan.
- ***Plan can't disenroll patient from the Plan because patient didn't pay amount due in the program.***
- Plans must have dispute/appeals process in place and must use this same process for any program dispute; plan must provide meaningful process for timely hearing, resolution per their underlying plan processes

E. Additional details



If patient switches plans mid-year, original plan continues to bill monthly or also offer a pay off amount; patient can enroll in program with the new plan as well. First plan can't stop patient from participating with a new plan, even if the first plan terminated patient for nonpayment

Plan must have a process for patient to opt out of the program, even as they continue to bill the patient for costs incurred (incl. option to repay in full after opting out) and patient returns to paying pharmacy directly at POS.

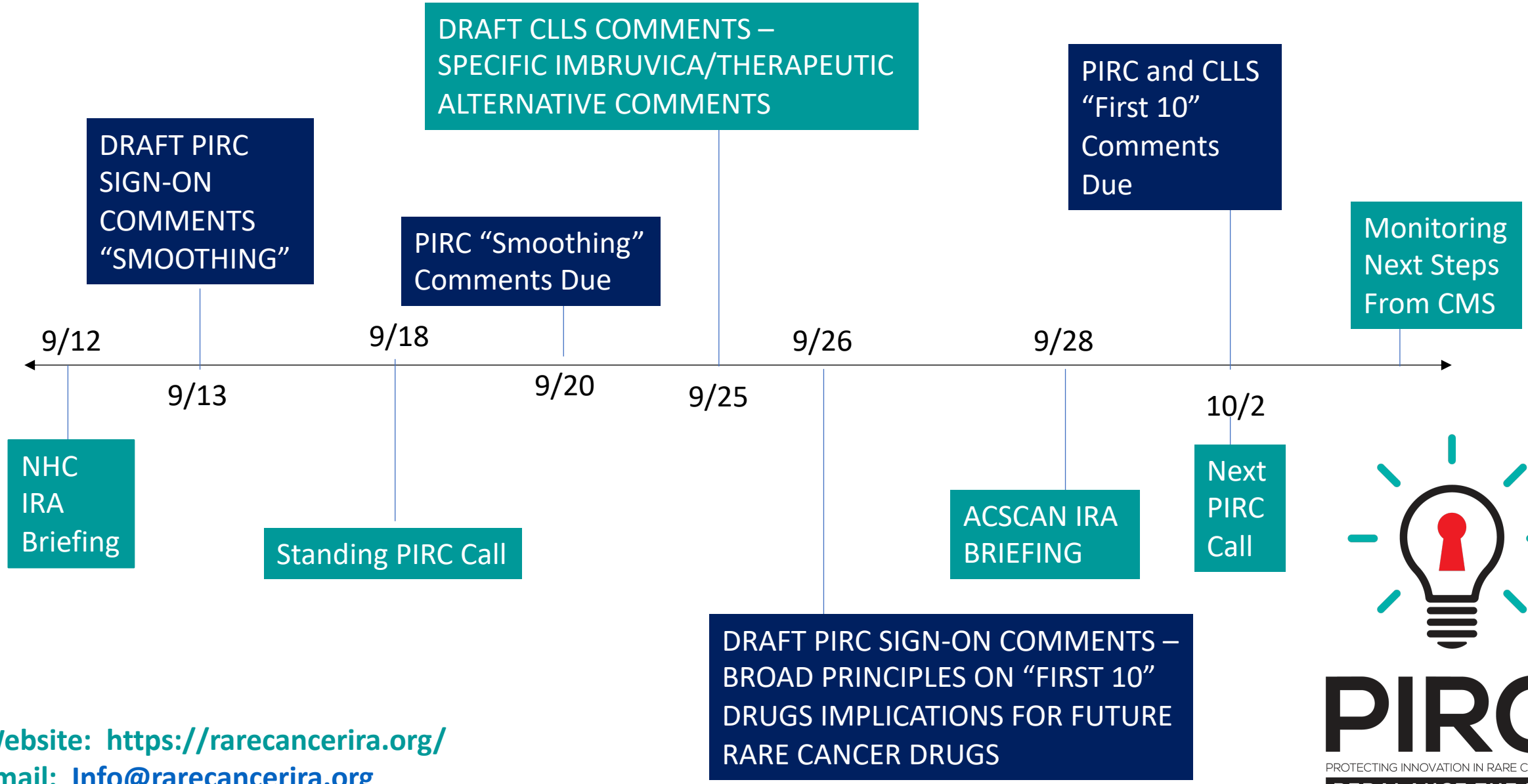
Plans must have a process to develop, compile, evaluate and report to CMS (and to patients and public) statistics related to cost of operations, patterns of utilization of its services, availability, accessibility of its services, info demonstrating a fiscally sound operation, pharmacy performance measures, etc.

Discussion: Initial Concerns/Recommendations for CMS Comments

1. POS option to opt-in/out should come sooner rather than later.
2. Allow auto-renewal after first opt-in (w/ notice to patients to opt out ….like traditional Medicare)
3. CMS mentions counting unidentified payments towards premiums;
4. Is there a way to handle high costs hitting mid-year and not benefitting as much – e.g., any circumstances warranting rolling one year's obligations into next year?
5. Grace period of a quarter (3 mos.); Reinforce that even missing grace period doesn't mean that if obligation is satisfied, you can't re-enroll.
6. Relatedly, can appeals be made easier?
7. Can every plan be required to use uniform processes, forms, etc. Easily accessed on website? Standardized.
8. Annual Plan reports – unusual drop out rates or other red flags should require immediate remedial action, must allow previous patients to appeal, etc."
9. Prohibit any contractual relationships between Plans and pharmacies – could force delays, require physician documentation re urgent claim opt-in, etc.
10. "Likely to benefit" – ways to identify patients in helpful way vs. leave it to the plans (esp. given plans required to provide extra communication). Previous year's spend threshold? Or certain diagnoses? Etc.
11. Helpful or harmful for pharmacy to remind participants that payments are still due? (Patient will start paying at the POS again, and yet may have outstanding bills from the program)
12. Should the full OOP that is unpaid (but subject to program) count toward patient's max OOP? Or only the portion already paid count toward max? Since patient theoretically must pay it sometime, plans should probably apply entire amount toward the max.

PIRC
REBALANCE THE IRA

NEXT STEPS…



Website: https://rarecancerira.org/
Email: Info@rarecancerira.org
mkayscanlan@consilstrat.com

PIRC
PROTECTING INNOVATION IN RARE CANCER
REBALANCE THE IRA