PIRC

PROTECTING INNOVATION IN RARE CANCER

REBALANCE THE IRA

PIRC Meeting

March 4, 2024

Guest Speaker: M. Kay Scanlan, JD

mkayscanlan@consilstrat.com

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PIRC Purpose

- Speak loudly with one voice
- Speak from 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

We have the “benefit” of the President’s focus on cancer… let’s use that credibly and responsibly…

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Agenda

- UPDATE on “First 10” Drugs
  - Listening Sessions – mtg requested
  - Initial offers made
  - Rejected today
  - **Website: https://rarecancerira.org/**

- CMS’ New “Smoothing” Draft “Part Two” Guidance and Final “Part One” Guidance
  - **Info@rarecancerira.org**
  - **mkayscanlan@consilstrat.com**

CMS Releases Final Part 1 and Draft Part 2 "Smoothing" Guidance. Part 2 Comments Due ***March 16***

Part 1 and Part 2 Guidance are intertwined.

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

Among the finalized 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).

Discussion: Remaining/Unresolved Issues for CMS Comments

1. POS option to opt-in/out should come sooner rather than later. **(We will continue to ask for this, but pharmacy systems may need time to accommodate this. We will push for enabling patients to present their election confirmation number and plan member ID to the pharmacy when picking up prescription.)**
2. Allow auto-renewal after first opt-in (w/ notice to patients to opt out)
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? **CMS cannot, by statute, do this, but we will ask that these patients receive "targeted" information that they are likely to benefit in subsequent years.**
5. Can every plan be required to use uniform processes, forms, etc. Easily accessed on website? Standardized.
6. "Likely to benefit" – ways to identify patients in helpful way vs. leave it to the plans (esp. given plans required to provide extra communication). **We will recommend that the threshold for a single-fill be based on all prescriptions filled (or submitted for filling) in a day rather than a single prescription.**
7. Ensure that plan communications regarding what the program is and how to opt-in have a conspicuous notation on the envelop and first page of the communication so that patients don't assume documents are "routine" and fail to see this important information.
8. Should CMS create public service ads similar to what was done when the Affordable Care Act was implemented and individuals needed to know how to enroll and what deadlines they should be aware of?

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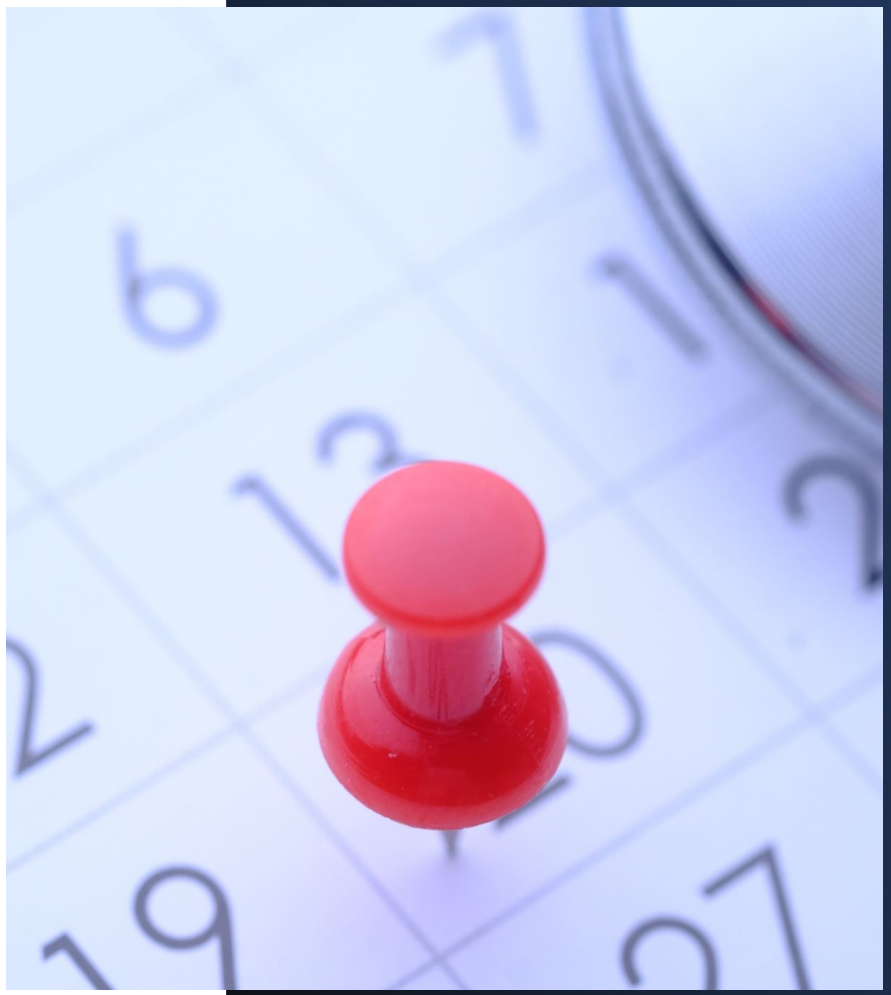
A. Part D or MA Plan Role

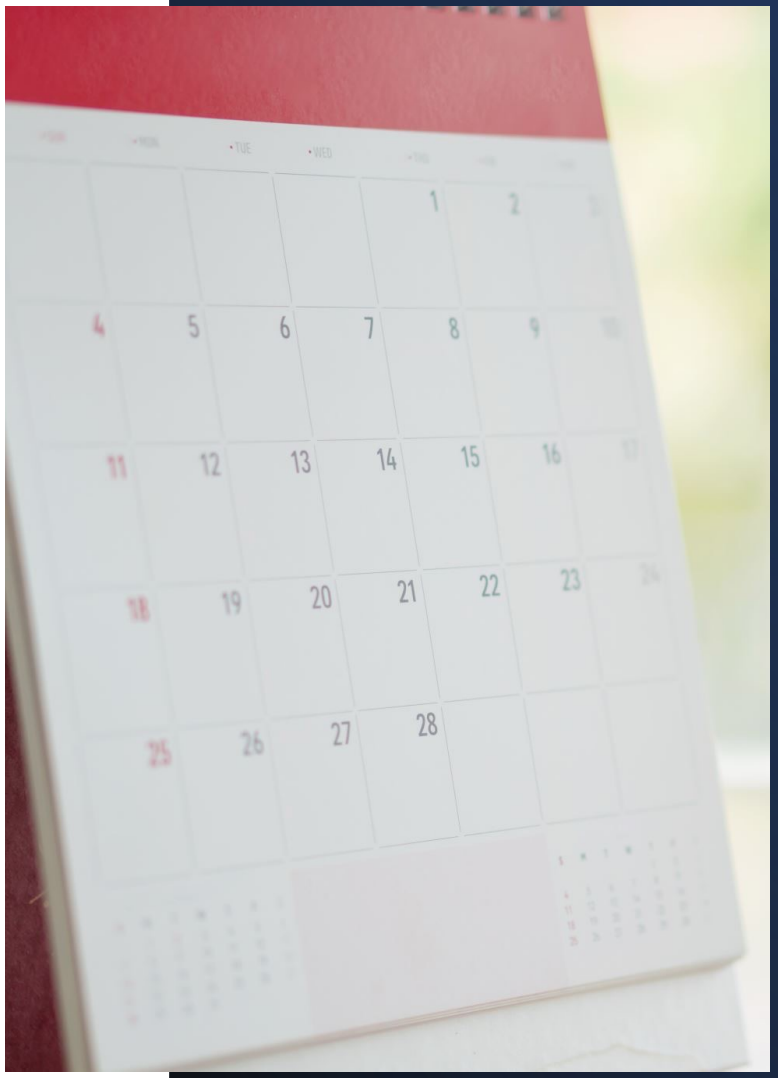
- Plan must have paper, 800#, online, other ways to enroll in program. **CMS' finalized guidance requires that Plans provide a confirmation number to enrollees when their election is completed by telephone or online, as PIRC requested in comments.**
- Plans must include program participation details in plan enrollment forms/processes. **As PIRC requested, CMS also proposes (Part Two) to require plans to include the information with their other routine communications (e.g., EOBs, plan documents, etc.)**
- Plan must acknowledge receipt of opt-in request completed before plan year starts w/in 10 days. (**Final)**
  - 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.
- 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 refund any incurred OOP costs if Plan misses deadline and 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). **Final. CMS also proposed in Part 2 guidance to urge Plans to implement real-time enrollment by phone or online.**
- Plans must communicate about Program to all eligible patients, with additional outreach to patients/pharmacies re: 'likely to benefit' patients. **Details in Part 2 draft guidance.**

B. Monthly payments - FINAL

- 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.*
- 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 after patient has opted 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

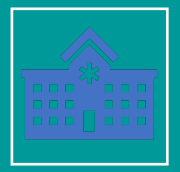


- Plans should allow flexibility on which day of every month patients want to be billed and should offer a variety of payment methods. **CMS received push-back on this and is considering limited flexibility such as due dates on either the 1st or 15th of the month (Part 2)**
- Monthly Statements must 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. **Final**
- Patients can pay extra each month, but plans can't bill more than the monthly calculated amount.
- No late fees or interest payments allowed. **Some commenters suggested that this is unfair to plans and urged CMS to enable fees for returned payments and other costs that are outside the control of plans (Part 2).**

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. **New clarification – patients are ineligible to participate if they remain in a Part D plan with the same Part D sponsor that they have failed to pay prior year's monthly bill. This continues until overdue amounts are paid or individual switches to a different plan with a different sponsor.**
- 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.***

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 – **Finalized despite pushback.**

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 (if they have not met their out of pocket cap).

CMS' target outreach approach will require plans to look at prior years' drug costs for their enrollees and provide targeted "likely to benefit" information to these individuals before start of plan year. Throughout the year, *single-fills with out-of-pocket costs exceeding $600 would trigger plan requirement to have pharmacy provide program information to the patient.*

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