PUTT Concerns with the FTC's Proposed Express Scripts Settlement

Settlement Document:
https://www.ftc.gov/system/files/ftc_gov/pdf/d09437caremarkproporder-esiresps.pdf

Major Concerns with Definitions Section (pages 2-5)

Retail Community Pharmacy Definition is Too Restrictive

- The settlement defines retail community pharmacy as businesses with three or fewer retail stores. This definition would exclude many community pharmacies including regional chains, grocery store pharmacies, and independent pharmacies with 4+ locations.
- Express Scripts has inconsistent definitions across their own documents - one document defines independent pharmacies as 10 or fewer stores.

PUTT recommends using the U.S. Code definition from law.cornell.edu, which defines retail community pharmacy as independent, chain, or supermarket pharmacies (excluding mail order and long-term care). The current definition would exclude pharmacies serving military populations, which tend to be located near larger cities with chain pharmacies.

Missing and Problematic Definitions

- Connecticut General Corporation is referenced in the document but never defined in the findings section, despite being the parent company that Cigna operates as a DBA of.
- List price/WAC are incorrectly equated - these are not always equal.
- Net unit cost definition creates gray areas around rebates that could enable continued manipulation.
- Non-dispensing services are mentioned but Express Scripts typically doesn't pay for these services like vaccinations.
- "Standard offering" is poorly defined and could easily be designed to be unattractive so no plan sponsor selects it.
- First-dollar coverage and preferred drug list are not defined.

Section I: Non-Discrimination of Low WAC Versions - Major Loophole | page 6

The first section only applies when a single drug manufacturer markets both a high WAC and low WAC version of the same product. This is relatively rare and excludes most generic competition.

Key problems identified:

- The language should apply to any AB-rated generic equivalent regardless of manufacturer, not just authorized generics from the brand manufacturer.
- Biosimilars should be explicitly included.
- The "insufficient supply" caveat in the second paragraph creates an exploitable loophole - manufacturers can simply claim they cannot supply enough, allowing Express Scripts to continue preferring high WAC versions.

- The therapeutics committee only meets twice per year (July and January), which delays formulary updates and allows Express Scripts to continue problematic practices for up to 6 months after a generic becomes available. This should be changed to require review at the next meeting scheduled.

Section II: Patient Out-of-Pocket Costs - Dispensing Fee Issue | page 6

- The language states that member out-of-pocket costs cannot exceed net unit cost, but this appears to exclude the dispensing fee. This could mean patients have responsibility for the dispensing fee, which should come from Express Scripts, not patients.
- There is no protection against Express Scripts raising patient premiums as a result of these requirements.
- Dispensing fees should be tied to a public benchmark such as state Medicaid Fee-For-Service.
- **PUTT suggests** Express Scripts should be required to seek approval for premium increases, similar to how utilities must justify rate increases.

Major Concern:

Without a clear definition of how dispensing fees should be determined, Express Scripts' practice of paying pharmacies little to no dispensing fees will continue.

Section III: Trump Rx Integration - Major Red Flags | pages 6-7

This section appears to integrate TrumpRx into Express Scripts' platform in a way that is deeply concerning. The section only applies to the limited "standard offering" to pharmacies with three or fewer locations.

Key concerns:

- If plan sponsors opt out, this entire section becomes meaningless.
- Express Scripts may be forcing claims through Trump Rx/Good Rx on the back end without pharmacy consent.
- The integration raises questions about what Express Scripts knows about Trump Rx's business model that isn't public.
- Data sharing implications are unclear and concerning.
- Express Scripts could impose additional fees on pharmacies to participate.

Section IV: Insulin Products - Opt-Out Loophole | page 7

- The patient assurance program ($35 insulin cap) can be opted out of by plan sponsors in writing. This opt-out will likely be buried in lengthy contract documents.
- The patient assurance program is an Express Scripts program that is not well-defined and can be changed at any time without notification.

Recommendation: Simply state that insulin products should have a $35 copay maximum, in line with existing law, without the opt-out provision or reference to Express Scripts' own program.

Section V: Point-of-Sale Rebates - Who Pays? | page 7

The language about "actual cost to pre-fund any rebate" is dangerously ambiguous. It's unclear whether Express Scripts would charge this fee to pharmacies, plan sponsors, or patients.

PUTT strongly recommends clarifying that retail pharmacies should not be involved in funding or administering rebates in any way.

Additional problems:

- The document never specifies what percentage of rebates members receive - only "the benefit" of rebates.
- Express Scripts has a documented history of violating state laws prohibiting spread pricing, as shown in West Virginia and Tennessee audits. There is no reason to trust they will comply with this provision.
- Spread pricing can be accomplished through undefined fees even when not technically called "spread pricing."

Section VI: De-linking Compensation - Missing "Rebates" | page 7

- Section 6 discusses compensation from drug manufacturers but notably never uses the word "rebate." Previous sections say "compensation including rebates" but this section omits rebates entirely.
- "Compensation" is not defined anywhere in the document.

PUTT questions whether this section actually reduces rebates or is simply window dressing, as it's unclear what compensation would be based on if not list price.

Implementation Timeline Concerns

- The "as soon as commercially feasible" language is problematic. Based on industry experience, implementation can happen within 30 days or even 72 hours.
- The settlement should specify 90 days from signature for implementation, not wait until 2028 (which would allow a new administration to potentially overturn it).

Section VII: Transparency for Plan Sponsors | page 8

Current Requirements:

- Standard offering must include additional automated reporting for plan sponsors by January 1, 2028
- Annual report disclosing drug product costs and pharmacy claim-level reporting
- Disclosure of compensation paid to consultants or brokers

Concerns and Recommendations:

- Format should be easily readable (e.g., Excel) rather than large machine-readable files like JSON
- Claim-level reporting must not be in aggregate and should break down payment differences by pharmacy type (mail order, vertically integrated, independent retail)
- Annual reporting is insufficient - plan sponsors need data with enough time to take action before open enrollment
- Reports should be available within timeframes that allow plan sponsors to change providers if needed

Recommendation: quarterly or biannual reporting, with data available by July 1 to allow for October open enrollment decisions

Section VIII: Standard Offering to Retail Community Pharmacies | page 8

Definition Issues:

- "Retail community pharmacy" is currently defined as 3 or fewer stores, not affiliated with the respondent
- This definition is problematic and inconsistent, likely an Express Scripts definition
- Should be changed to align with CMS definition and include "not vertically integrated or owned by PBMs"
- Current definition excludes grocers, Walgreens, and pharmacy owners with more than 3 locations

Compensation Structure:

- Settlement requires compensation based on actual acquisition cost plus dispensing fee
- Pharmacies must provide quarterly data to validate acquisition costs
- Pharmacy acquisition costs should be disclosed only when underpayments occur, and can be accomplished utilizing the current MAC appeal process already in place
- **Major concern**: Under the settlement's definition of community pharmacy, pharmacies with 3 or fewer locations will shoulder a disproportionate share of the administrative burden of filing quarterly reports.

Recommendation: using NADAC (National Average Drug Acquisition Cost) as benchmark instead. NADAC is public, updated monthly, and can be easily programmed into systems

Non-Dispensing Services:

- Settlement mentions additional payments for non-dispensing services but doesn't define them
- Should include: immunizations, MTMs, medication synchronization, blister packaging, counseling
- The PBM needs to define these services with specific reimbursement rates
- Should not be performance-based

Network Participation:

- Settlement states PBM will not exclude pharmacies willing to agree to terms
- This language sounds like "any willing provider" which has mixed results
- Current language could allow PBM to exclude pharmacies from TRICARE and other plans

Recommendation: Should apply to ANY plan offering, not just "standard offering"

Section IX: Marketing and Promotion | pages 8-9

Key Concerns:

- PBMs cannot require or coerce plan sponsors to adopt plans that differ from standard offering
- However, PBMs have created workarounds by offering cheaper plans without transparency requirements
- Should include prohibition on financial incentives to choose non-standard plans
- "Material" (printed or electronic) should also include verbal communications
- Concerns about narrow networks and preferred networks - all pharmacies providing services should be allowed to participate

Section X: Rebate GPO Functions and Transparency | page 9

Current Requirements:

- Rebate GPO functions must be moved onshore
- GPO must comply with safe harbor reporting and disclosure operations

Recommendations:

- Should repeal safe harbor protections entirely
- Question why PBMs should be allowed to have GPOs at all
- PBMs should not be able to create new offshore entities or rename GPO structures

- GPO should have fiduciary duty to plan sponsor

Recommendation: Reporting requirements from Section 7 should also apply to GPOs

West Virginia Audit Example:

- Caremark audit showed how PBM profits from rebates while underpaying pharmacies
- For diabetes drug (likely Jardiance): 78% manufacturer discount, PBM kept 8% ($45 per prescription)
- Pharmacies lost $200 per fill while PBM profited $45 per prescription
- PBM excluded cheaper alternatives (Brenzavvy at $60/month vs Jardiance at over $100/month even with rebates)

Section XI: Meeting Competition (Major Loophole) | pages 9-10

The Problem:

- Nothing prevents PBMs from offering plans that differ from standard offering if requested in writing
- If terms differ from standard offering, plan sponsor just signs acknowledgment form (Exhibit A)
- This essentially allows PBMs to continue current practices with a waiver
- Mirrors the "plan design" excuse used in hearings: "the plan sponsor chose this"

Exhibit A Issues:

- Letter emphasizes benefits of standard offering but allows plan sponsors to opt out
- Heavy messaging implies patients will pay more if plan sponsor doesn't choose standard offering
- Becomes just another "terms and conditions" document buried in contract signing

Recommendations:

- Acknowledgment should include statement that plan sponsor was not financially incentivized, coerced, or enticed to choose non-standard plan
- Require side-by-side cost comparison showing: cost to plan sponsor, cost to patient, administrative fees, and other expenses for both standard and alternative plans
- Comparison should be public information or at least available to anyone considering Express Scripts
- PBM should have to report to FTC when offering non-standard plans

- Ultimately, pharmacies and patients must be protected regardless of which plan sponsor chooses

Section XII: Monitor Provisions (Significant Concerns) | pages 10-12

Monitor Selection Process:

- Express Scripts nominates three candidates
- FTC Bureau of Competition and Bureau of Consumer Protection have 30 days to complete conflict checks
- If candidates are rejected, Express Scripts gets 15 days to propose new candidates
- Process repeats until monitor appointed
- After 3 months, if no agreement, roles reverse but no end date specified
- **Major problem**: PBM should not be choosing their own monitor - FTC should decide

Monitor Composition:

- Minimum of one appointee should represent community retail pharmacies
- Monitor should not be associated with any vertically integrated companies or original respondents

Monitor Powers and Limitations:

- Monitor can receive complaints from non-parties but has no requirement to investigate or act on them
- Must notify FTC only 5 days before entering into arrangement creating conflict of interest
- The intent of the Monitor's role is to maintain compliance and foster better working practices. There should be no allowance for conflicts of interest of any kind
- Monitor should wait at least one year after leaving position before working for any related entity
- Need serious qualifications defined for monitor role

Reporting Structure Issues:

- Monitor reports to respondent's chief legal officer
- This should be reversed - creates responsibility without authority
- Monitor reports to FTC only annually - should be quarterly
- Monitor serves for 3 years after implementation, but FTC chair can terminate anytime

- Need minimum period before monitor can be removed
- If monitor raises concern to chief legal officer and isn't satisfied, the monitor notifies the board of directors (of Express Scripts) – the FTC should be notified as well

Access and Cooperation:

- Respondent must cooperate with monitor and provide full access to personnel, information, and facilities
- Respondent pays monitor fees and expenses
- Cannot terminate monitor except with FTC consent or for serious misconduct
- Settlement doesn't adequately reflect the serious allegations and decades of harm

Section XIII: Compliance Reports | page 12

Current Requirements:

- Interim compliance reports due 30 days after order, then every 90 days until implementation
- Annual compliance reports on anniversary date
- Additional reports as FTC requests
- Reports must contain sufficient information for FTC to determine compliance independently

Recommendations:

- Need explicit requirement to provide ALL information, as seen in Florida and Tennessee audits where information was withheld
- Establish timeframe: respondent must provide requested information within 30 days
- Compliance reports should be publicly viewable, especially by retail community pharmacies
- Reports are funded by taxpayer dollars and should be public
- Must retain documents for 5 years

Section XIV: Change in Respondent | page 13

Current Requirements:

- Must notify FTC 30 days prior to dissolution, acquisition, merger, consolidation, or other changes
- Notification only required for changes "that might affect compliance obligations"

Recommendations:

- Delete qualifier "that might affect compliance obligations" - any change must be disclosed
- Respondent must stay in compliance even if absorbed by another entity
- Settlement only applies to specific entity, preventing transfer to avoid compliance

Section XV-XVII: Access, Cooperation, and Termination | pages 13-14

- FTC agents can access facilities, inspect records, and interview personnel with 5 days notice
- Respondent must cooperate with commission in legal proceedings
- Order remains in effect for 10 years following implementation date

Additional Notes from PUTT's Review

Fundamental Issues with "Standard Offering" Approach

- The entire settlement is structured around a "standard offering" that only applies to retail community pharmacies (defined as 3 or fewer locations) and only if plan sponsors opt in. This design severely limits the settlement's impact:
- Express Scripts can make the standard offering financially unattractive so plan sponsors don't select it.
- Plan sponsors can opt out of key provisions simply by signing paperwork.
- The protections should apply to ALL offerings and ALL pharmacies, not just a narrow "standard offering."

Monitoring and Enforcement Concerns

- Throughout the document, there are questions about transparency, enforcement, and verification.
- There is no mechanism for anyone other than Express Scripts to report or verify compliance.
- Given Express Scripts' documented history of violating state laws and settlement agreements, the monitoring provisions (as discussed in Section 11) are critical.
- The PBMs will claim that disclosing information about plan design (i.e. what exactly is the standard offering and how it differs from non-standard offerings) puts them at a competitive disadvantage and this information is proprietary and not to be shared.