

CAPITOL STREET

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Healthcare in CR: Medicare & Commercial PBM Reforms

PBM, Pan-Cancer Screening Coverage, Patent Thickets, Hospital Site-Neutral Step Forward & PRV Extension

Relevant Companies



»» Our Take & Next Up

We expect healthcare provisions to pass the House & Senate by the end of the week in time for Dec 20. Link to text [here](#). Given the need for Dem votes, a more generous set of health program extensions and “fixes” (telehealth, FDA PRV, Physician pay) with PBM, MA (not prior authorization, though), and other offsets (sequester) are in the CR (to Mar 14, 2025). We had [said](#) that PBM reforms are looking more likely in the year-end package but will only continue in 2025+. A PBM trio of policies made it (delinking, transparency & banning Medicaid spread) with 100% rebate pass through in commercial as a bit of a surprise. We are also seeing (per our previews) 2 years of telehealth, multi-cancer early detection legislation (starting 2029 ~ GRAIL, EXAS), patent thickets (\$2 B pay for) as well as funding for Medicaid DSH (one-year) and FDA PRV extension.

NEXT UP: Given the 72-hour rule, a full House vote is planned for Friday, December 20, and then the Senate following soon thereafter (they can finish within 24 hours of House vote, i.e. staying in session until Saturday). CR and health extenders are likely to pass by the weekend: Remember that the GOP wants to clear the decks for Reconciliation in 2025. See below for the full list of provisions.

»» Key Points

The healthcare extender policies include the below & we believe votes exist for House & Senate passage late this week. Extension of expiring policies are for either 1- or 2-years and positively impact telehealth, hospitals (Medicaid DSH, add-on payment for low-volume hospitals) and some insurers (HSAs/HDHPs).

- **Hospitals:**
 - Medicaid Disproportionate Share Hospital (DSH) Relief (2 years)
 - Medicare add-on payment for low-volume hospitals and Medicare Dependent Hospitals (1 year)
 - Medicare’s acute hospital care at home flexibilities (5 years)
 - Funding for Medicare bonuses for alternative payment model (APM) participation (3.53% for 1 year)

- **Telehealth & HSAs:**
 - Medicare telehealth flexibility extension (2 years)
 - Allowance for pr-deductible coverage of telehealth services in HSA qualified high-deductible health plans (2 years)
- **Rural ambulance:** Medicare add-on payment for rural ambulance services (2 years)
- **Physician Pay:**
 - Medicare Physician Fee Schedule payment boost (2.5% for 1 year)
 - Medicare GPCI Floor policy for payments to rural physician practices (1 year)
- **Other:**
 - Funding for State Health Insurance Programs (SHIPs) to assist beneficiaries with enrollment choices (2 years)
 - Mandatory funding for Community Health Centers, National Health Service Corps, and Teaching Health Center GME Programs (2 years)
 - Part D coverage of certain oral antiviral drugs (1 year)

Other important programs would be extended, and aid biopharma (5 year of FDA PRV program) substance abuse/opioid as well as pandemic preparedness.

- FDA Pediatric Priority Review Voucher (PRV) Program (5 years)
- Community Health Centers: \$4.5 B for FY 2025 and \$4.6 B for FY 2026 (2 years)
- Funding for the special diabetes program (2 years)
- *Pandemic and All-Hazards Preparedness Act* (2 years)
- *SUPPORT Act* Programs for Opioid Response (5 years)
- Extension of fentanyl analogue scheduling order (1 year)

The offsets are below – PBMs are heavily included, with the following Part D & commercial “pass through” provisions.

- **PBMs (many provisions start 2028) -- 100% commercial rebate pass through is included:**
 - Private Insurance Pharmacy Benefit Manager (PBM) transparency requirements (saves ~\$2.2 B). PBMs will be required to provide group health plans and issuers with detailed data on prescription drug spending at least semi-annually (includes gross and net drug spending, drug rebates, spread pricing arrangements, formulary placement rationale).
 - For ERISA plans, PBMs must fully pass through 100% of drug rebates and discounts, excluding bona fide service fee, for new contracts, extensions, or renewals entered into for plan years beginning 30 months after the date of enactment. The meaning of “covered service provider” under ERISA is also clarified.
 - Medicare Part D transparency requirements & de-linking for PBMs (saves ~\$700 M). Annual requirements set out for PBMs to report on drug prices and other information to Part D plan sponsor clients. PBMs and their affiliates prohibited from deriving remuneration for covered Part D drugs based on the price of a drug. Part D plan sponsors are provided with new audit rights with respect to PBMs.
 - Prohibition of PBM “Spread Pricing” in Medicaid (which we note is a dying contract form in states) (saves \$300 M – 1 B)

- **Hospital Site-Neutral:** Requiring the use of a national provider identifier (NPI) by off-campus hospital outpatient clinics
- **Biopharma:**
 - “Patent Thickets” reforms ([here](#))
 - Orphan drug exclusivity is limited to the approved indication, rather than the potentially broader designation. This resolves the *Catalyst Pharmaceuticals Inc. v. Becerra* issue ([here](#)).
- **Diagnostics (starts 2029):** Phased-in Medicare Coverage of Multi-Cancer Early Detection (MCED) Screening Tests ([here](#))
- **Hospice:** Extension of Medicare hospice aggregate cap policy at past the current expiration date at the end of the budget window
- **Generics:** FDA “Q1/Q2” Policy ~ Q1/Q2 is a term referring to active and inactive ingredient assessments in Abbreviated New Drug Applications (ANDAs). FDA requires certain types of generic products, either by regulation or through product specific bioequivalence guidance to demonstrate Q1/Q2 “sameness,” meaning the generic drug submitted for approval must contain the same active and inactive ingredients (qualitatively the same, or Q1) in the same concentration (quantitatively the same, or Q2) as the reference listed drug (RLD).
- **Home Infusion:** Joe Fiandra Legislation on Adding Certain Drugs to the Medicare Home Infusion Benefit ([here](#))
- **Med Advantage & Part D:**
 - Medicare Advantage provider directories requirements
 - Requiring Medicare Rulemaking on Standard Terms and Conditions in Part D Plans’ Contracts for In-Network Pharmacies
- **Medicare (overall):**
 - Extension of Medicare sequestration at the end of the budget window (additional months at the end of the budget window)
 - Reducing funding in the Medicare Improvement Fund (MIF)

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