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House Committee Proposes to Extend Medicare Telehealth Flexibilities, Eyes PBM Reform to Offset Expenses

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On May 8, 2024, the U.S. House of Representatives Ways & Means Committee passed a bipartisan bill entitled the "Preserving Telehealth, Hospital and Ambulance Access Act" by a vote of 41-0, which will potentially have far-reaching consequences for Medicare beneficiaries, health care providers, and the telehealth and PBM industries. Among other things, the proposed bill extends for two years certain telehealth flexibilities for Medicare enrollees originally adopted during the COVID-19 pandemic and proposes that pharmacy benefit manager (PBM) reform helps offset the telehealth extension expenses.

Key Telehealth Provisions

- *Extending Telehealth Flexibilities*: The bill proposes extending several telehealth flexibilities under Medicare through December 31, 2026 that were initially implemented during the COVID-19 pandemic and set to expire on December 31, 2024. These flexibilities include:- expanding originating sites so that beneficiaries can receive telehealth services from their homes or other locations rather than having to travel to a healthcare facility;- extending telehealth services for federally qualified health centers and rural health clinics.
- - expanding practitioners eligible to furnish telehealth services, including physical therapists, occupational therapists and speech-language pathologists; and
- - removing geographic restrictions so beneficiaries can access telehealth services from any location, not just rural areas;
- *Delaying In-Person Requirements for Mental Health Services*: The bill delays certain in-person requirements for mental health services furnished through telehealth and telecommunications technology until January 1, 2027. This would allow beneficiaries living in rural areas and with limited mobility to access mental health services.
- *Audio-Only Telehealth*: The bill extends the use of audio-only telehealth services.
- *Telehealth for Hospice Recertification*: The bill allows the use of telehealth for recertification of hospice eligibility, with certain restrictions.
- *Guidance for Limited English Proficiency Patients*: The bill requires the Secretary of the U.S. Department of Health and Human Services (HHS) to issue guidance related to best practices for entities providing telehealth services to individuals with limited English proficiency,

including (i) the use of interpreters in telemedicine appointments; (ii) improving access to digital patient portals and instructions on accessing telecommunications systems; (iii) integrating the use of video platforms with multi-person call capabilities for purposes of providing interpretation services during a telemedicine appointment; and (iv) providing patient materials, communications and instructions in multiple languages.

Key Additional Provisions

- *Establishment of Modifier for Telehealth Recertifications of Hospice Care Eligibility*: The bill establishes a modifier for claims related to hospice care recertification conducted through telehealth.
- *Extension of Acute Hospital Care at Home Waiver Flexibilities*: The bill extends the Acute Hospital Care at Home program, allowing hospitals to provide acute care services in patients' homes under certain conditions.
- *Report on Wearable Medical Devices*: The bill requires a study on wearable medical devices used for clinical decision-making.
- *Enhancing Program Integrity Requirements for Durable Medical Equipment (DME)*: The bill introduces measures to enhance program integrity for DME under Medicare.
- *Extension of Increased Inpatient Hospital Payment Adjustment for Certain Low-Volume Hospitals*: The bill extends increased payment adjustments for certain low-volume hospitals.
- *Extension of the Medicare-Dependent Hospital Program*: The bill extends the Medicare-Dependent Hospital program, which provides financial support to eligible hospitals.
- *Extension of Add-On Payments for Ambulance Services*: The bill extends add-on payments for ambulance services.

Budgetary Considerations: Offsets

At the time Congress extended telehealth flexibilities through December 31, 2024, the extension was estimated to cost Medicare more than $2 billion in Medicare spending. The House Ways & Means Committee understood that a move to make these flexibilities permanent would be far more costly. As a way to garner bipartisan support and minimize challenges for the bill, the Committee decided to extend the current state of the telehealth laws under Medicare by two years, until December 31, 2026, to allow Congress to further evaluate and allocate spending for permanent telehealth flexibilities.

To further address the increased Medicare spending as a result of the extension of telehealth flexibilities, the bill proposes to offset some of the spending by (i) adjusting the phase-in of payment changes for clinical laboratory tests under Medicare, (ii) extending the adjustment to the calculation of hospice cap amounts under the Medicare Program, and most importantly, (iii) introducing sweeping new requirements for PBMs, including transparency in agreements, reporting requirements, and prohibition on certain practices.

Implications for Pharmacy Benefit Managers

Over the past few years, PBMs have faced a substantial amount of bipartisan scrutiny and calls for legislative reform from both federal and state governments and regulators. As proposed, the bill sets forth requirements for transparency and reporting, as well as restrictions on certain PBM practices, mostly drawing upon language set forth in the Modernizing and Ensuring PBM Accountability Act (MEPA), a Senate Finance Committee PBM bill that is currently making its way through the legislative

process. Mintz has previously reported on MEPA in its quarterly PBM Policy and Legislative Update.

Contract Requirements

For plan years beginning on or after January 1, 2027, contracts between prescription drug plan (PDP) Sponsors and PBMs will need to meet the following requirements, among others:

1. Set forth PBM fees that are flat, bona fide service fees based on fair market value, that are not directly or indirectly contingent upon (i) drug price; (ii) discounts, rebates, fees or any other remuneration on behalf of any entity or individual; (iii) coverage or formulary placement decisions or the volume or value of business generated between the parties; or (iv) any other methodologies prohibited by the Secretary.
2. Require PBMs to enter into written agreements with its affiliates that require the affiliates to report any remuneration that may have been paid to the PBM affiliate in violation of the bill and require PBM to attest to entering into such written agreement with any relevant affiliate.
3. Define and apply drug pricing-related terms in a transparent and consistent manner to enable the evaluation of a PBM's performance.
4. Require PBMs to annually report drug price and other information to PDP sponsors and the Secretary of HHS, including, without limitation: (i) lists of all drugs covered; (ii) information about dispensing of such drugs; (iii) information about enrollee cost-sharing; (iv) information on other financial relationships between the PBM and the drug manufacturers; (v) information related to net and gross prices and total drug spending; (vi) information about the PBM's affiliates; and (vii) information about any broker, consultant, advisor, or auditor that receives compensations from the PBM or PBM's affiliate for services offered to PDP Sponsor that relate to PBM services. PBMs that are affiliated with a pharmacy must also report the following types of information: (A) information related to dispensing and costs by affiliate pharmacies; (B) information related to acquisition costs; and (C) information related to drugs subject to 340B arrangements.
5. Require PBMs to provide certain audit rights to PDP Sponsors, which would allow PDP Sponsors, on at least an annual basis, to audit the PBM to ensure compliance with the terms and conditions of its contract. Under the audit provision, the PDP Sponsor can request the PBM to provide certain information that may be owned or held by PBM's affiliate.

Enforcement

The bill requires that all agreements between PDP Sponsors and PBMs include certain liability-shifting provisions, which would obligate the PBM or a PBM affiliate, as applicable, to reimburse the PDP Sponsor for any civil monetary penalties imposed on the PDP Sponsor for the PBM's (or its affiliate's) failure to comply with the terms of the law. The agreement between PDP Sponsors and PBMs will also need to include terms whereby the PBM, on behalf of itself and its affiliates, as applicable, agrees to be subject to punitive remedies for breach of contract. The bill will also require the Secretary to maintain a system that enables entities to report, on a confidential basis, violations of the proposed law.

Potential Effects on the PBM Industry

The "Preserving Telehealth, Hospital, and Ambulance Access Act" represents a significant step in expanding telehealth access while also adding pressure on Congress to pass PBM reform. With more than two dozen federal PBM bills currently pending, it will be interesting to see whether tying proposed PBM reform to offset telehealth flexibility expenditures will be the path of least resistance

for moving forward on PBM legislation. As drafted, the bill's provisions related to PBMs could significantly impact the industry and has the potential to increase PBMs' administrative burden and affect profit and revenue. Additionally, the increased scrutiny and potential for civil monetary penalties will require PBMs to ensure not only their own compliance but also on behalf of PBM affiliates.

We will continue to monitor this bill as it progresses in Congress in an effort to help the pharmacy benefit management industry prepare for any changes its passing may bring.

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