Depression and Bipolar Support Alliance

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DBSA Policy Statement on the IRA & Mental Health Treatment Access

Depression and Bipolar Support Alliance (DBSA) believes that individuals living with mood disorders deserve affordable, effective, and individualized mental health treatments—and that those with lived experience must be meaningfully involved in decisions shaping access to care.

While the Inflation Reduction Act (IRA), which was enacted into law in 2022, aims to lower drug costs, early evidence suggests some of its provisions may create harmful barriers—particularly for people living with mood disorders.

- **Out-of-pocket costs are rising, not falling.** According to Pioneer Institute data, seven of the nine drugs selected for negotiation under the IRA saw average patient out-of-pocket (OOP) costs rise by 32%, from $74.51 to $98.42[1]
- **Formulary access is shrinking.** One analysis found a nearly 4% decrease in Medicare Part D formulary placement for these negotiated drugs.[2] Other reports indicate insurers have tightened coverage using prior authorization, step therapy, and higher copays—policies that disproportionately burden patients with chronic and complex conditions.[3]
- **These trends especially harm people with mood disorders,** many of whom live on fixed incomes, including older adults. When medications become more expensive or harder to obtain, many often skip doses or stop treatment altogether, putting their mental health at serious risk. Medication nonadherence in this population is associated with symptom recurrence, hospitalization, and increased suicide risk.[4,5]
- **Cost-related non-adherence leads to worse health outcomes.** Individuals with chronic conditions, including mental health, who reduce or stop treatment due to financial barriers are more likely to experience hospitalizations and deteriorating health.[6] The impact is even more severe for low-income individuals, where high cost-sharing can prevent consistent care.[7]

The "Pill Penalty" Could Threaten Innovation in Oral Medications

Under the IRA, oral "small molecule" drugs become exposed to price negotiation just nine years after FDA approval, while biologics (injectables) are protected for thirteen years.[8] This discrepancy, often called the "pill penalty," threatens investment in oral drug development and reformulations of existing medications. Patents incentivize drug development by giving companies temporary exclusive rights to sell new medications, allowing them to recoup research costs and fund future innovation. Additionally, these policies could lead to discontinuation of production of existing medicines.

- **Early-stage investment in small molecule drug development has declined by 68% since the passage of the IRA**, with the steepest reductions affecting therapies intended for the Medicare-aged population.[9] This shift reflects growing investor concerns about the IRA's nine-year price control window for small molecule therapies, compared to thirteen years for biologics.

- Analysts from the Information Technology and Innovation Foundation (ITIF) confirm that biotech investors are shifting toward biologics, leaving psychiatric innovation behind.[10]

Why small molecule drugs matter:

- They cross the **blood-brain barrier**, making them more effective at precise, targeted treatment of mental health conditions. The "pill penalty" threatens their development, forcing reliance on drugs that more broadly affect the central nervous system, which cost more to develop to get the same effect and have the potential for more side effects.
- They are often more **logistically feasible** than injectable therapies, offering **flexibility and convenience** and can be taken **at home**, which supports autonomy and access for those in rural or underserved areas.

Lived Experience Must Be Central to Negotiation Processes

Robust engagement of people with lived experience—especially in mental health—is not just ethical, it's essential for equitable and effective health policy. When peers and caregivers are involved in system design, outcomes improve and unintended harms are better mitigated.[11,12,13]

Best-practice guidance emphasizes the need for **domain-specific**, trauma-informed, and power-aware engagement strategies in mental health settings. These approaches prioritize peer expertise, ensure equitable compensation, and prevent tokenistic involvement.[12,13,14]

Recommendations

To protect access, promote innovation, and ensure equitable implementation of the Inflation Reduction Act, DBSA urges CMS and federal policymakers to:

- **Convene dedicated, compensated roundtables** focused on psychiatric conditions and therapies, including meaningful roles for mental health peer specialists, caregivers, and lived experience experts.
- **Integrate lived experience** into CMS's clinical value assessments and decision-making processes—alongside traditional clinical and economic metrics.
- **Treat lived experience as professional expertise**, essential to equitable, effective policy implementation.
- **Pass the bipartisan EPIC Act (H.R. 1492 / S. 832)** to align incentives for small molecule drugs with biologics, supporting future innovation in oral mental health treatments.
- **Safeguard access to essential psychiatric medications**, not just the lowest-cost options.
- **Mitigate rising out-of-pocket costs** by ensuring that Medicare beneficiaries directly benefit from IRA savings.
- **Preserve at-home treatment options**, especially in rural and underserved communities where barriers to care are greatest.

- **Designate federal funding for research and development** of new treatments to offset the deterrence of private investment in innovation that has resulted as an unintended consequence of forced price negotiations.

Conclusion

The Inflation Reduction Act promised affordability. But, for people living with mood disorders, access and choice are equally essential—and both are currently at risk. Psychiatric medications are being excluded or deprioritized in coverage decisions. Peer-led and mental health–specific voices are not yet formally prioritized in CMS's engagement plans. Without urgent action, innovation in oral mental health treatments could stall, and those most affected may be left behind.

DBSA calls on CMS and policymakers to course correct. Fix what's not working. Protect innovation. And most importantly—**ensure that people with lived experience have a seat at the table** in shaping the future of mental health treatment access.

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1. Pioneer Institute. (2025). *IRA Medicare Drug Access Tracker*. https://pioneerinstitute.org/featured/pioneer-institute-launches-tracker-showing-drug-price-controls-are-raising-out-of-pocket-costs-for-medicare-patients/
2. DLA Piper. (2025). *Keeping watch on the Inflation Reduction Act: Medicare poses Part D formulary access challenges*. https://www.dlapiper.com/en/insights/publications/2025/04/keeping-watch-on-ira-medicare-for-people-with-serious-health-conditions
3. Aimed Alliance. (2025). *Prior authorization and formulary exclusion trends under the IRA*. https://www.aimedalliance.org/
4. Zewdu, W. S., Dagnew, S. B., Tarekegn, G. Y., Yazie, T. S., Ayicheh, M. A., Dagnew, F. N., & Moges, T. A. (2025). Non-adherence level of pharmacotherapy and its predictors among mental disorders in a resource-limited life trajectories: a systematic review and meta-analysis. BMC psychiatry, 25(1), 512. https://doi.org/10.1186/s12888-025-06838-9
5. Lintunen, J., Lähteenvuo, M., Tanskanen, A., Tiihonen, J., & Taipale, H. (2023). Non-adherence to mood stabilizers and antipsychotics among persons with bipolar disorder: A nationwide cohort study. *Journal of Affective Disorders, 333*, 403–408. https://doi.org/10.1016/j.jad.2023.04.097
6. Fusco, N., Sils, B., Graff, J. S., Kistler, K., & Ruiz, K. (2023). Cost-sharing and adherence, clinical outcomes, health care utilization, and costs: A systematic literature review. *Journal of managed care & specialty pharmacy*, *29*(1), 4–16. https://doi.org/10.18553/jmcp.2022.21270
7. World Health Organization. (2003). Adherence to long-term therapies : evidence for action. World Health Organization. https://iris.who.int/handle/10665/42682
8. Brownstein Hyatt Farber Schreck. (2024). *The EPIC Act and small molecule access under the Inflation Reduction Act*. https://www.bhfs.com/insight/reflections-on-the-inflation-reduction-act-s-pill-penalty/
9. Schulthess, D. G., O'Loughlin, G., Askeland, M., Clausen, D., Reaves, N., & Chee, M. (2025). *The Inflation Reduction Act's impact upon early-stage venture capital investments*. Therapeutic Innovation & Regulatory Science, 59(4), 769–780. https://doi.org/10.1007/s43441-025-00773-3
10. Ezell, S., Kann, L., & Barbosu, S. (2025, February 25).
The Inflation Reduction Act is negotiating the United States out of drug innovation.
Information Technology and Innovation Foundation (ITIF).
https://itif.org/publications/2025/02/25/the-inflation-reduction-act-is-negotiating-the-united-states-out-of-drug-innovation/
11. Cancer Support Community. (2024). *Principles for patient-centered engagement*.
https://www.cancersupportcommunity.org/article/principles-patient-centered-engagement
12. ASPE (Office of the Assistant Secretary for Planning and Evaluation). (2023). *Engaging people with lived experience in federal research and policy*. U.S. Department of Health and Human Services. https://aspe.hhs.gov/lived-experience

13. Center for Health Care Strategies. (2021). *Meaningfully engaging people with lived experience in behavioral health system transformation: A guide for states*. https://www.chcs.org/resource/meaningfully-engaging-people-with-lived-experience-in-behavioral-health-reform-a-guide-for-states/
14. Institute for Healthcare Improvement & 100 Million Healthier Lives. (2020). *Engaging people with lived experience of inequity: A framework for practice*. https://www.ihi.org/sites/default/files/100MLives_EngagingPeopleWithLivedExperienceInequity_AssessmentToolResourceGuide.pdf

Uncited references

BIO (Biotechnology Innovation Organization). (2025). *BIO Applauds Introduction of Bipartisan Bill to Eliminate the Pill Penalty*. https://www.bio.org/press-release/bio-applauds-introduction-bipartisan-bill-eliminate-pill-penalty?utm_source=chatgpt.com
Centers for Medicare & Medicaid Services. (2024). *Medicare Drug Price Negotiation Program: Patient-focused listening sessions*. https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation
Kaiser Family Foundation. (2024). *FAQs about the Inflation Reduction Act's Medicare Drug Price Negotiation Program*. https://www.kff.org/medicare/issue-brief/faqs-about-the-inflation-reduction-acts-medicare-drug-price-negotiation-program/