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Scene Health Public Comment on CMS RFI (CMS–0042–NC)

Re: Health Technology Ecosystem | Submitted by emocha Mobile Health, dba Scene Health

CMS spends billions of dollars each year on medications that never fulfill their clinical promise. Net spending, after rebates, on Medicaid prescription drugs rose to $43.8 billion in 2022, an increase largely attributed to high-cost specialty drugs[1]. Medicare Part D spends ~$180 billion on gross drug spending, while Part B costs tens of billions for provider-administered drugs.[2] This is not because these medications are ineffective, but rather because they are not taken – or not taken properly. The issue of medication adherence is not a fringe problem; it is the most fundamental, preventable failure in our healthcare system.

At least 50% of patients with chronic diseases don't take their medication properly,[3] which leads to exorbitant, avoidable costs and waste, in addition to widespread pain and suffering. As Surgeon General Koop stated in the 1980s, "Drugs don't work in people who don't take them." A 2018 study[4] put the annual cost of medication nonadherence in the U.S. at more than $528 billion. Moreover, nonadherence is responsible for over ~125,000 preventable deaths and up to 25% of hospitalizations each year.

Section B. Patients and Caregivers

PC-1 to PC-5: Supporting Medication Adherence Through Digital Tools

Scene Health has modernized Directly Observed Therapy (DOT), the gold standard for securing medication adherence. Scene Health provides video Directly Observed Therapy (video DOT) to support patients with chronic and infectious diseases in taking their medications correctly and consistently. Through asynchronous, smartphone-based video check-ins, Scene enables patients to record themselves taking their medication and receive personalized feedback and encouragement from trained health coaches and clinical staff. This method has been validated in multiple peer-reviewed studies as an effective way to improve adherence, leading to reduced hospitalizations and better clinical outcomes.

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[1] KFF. *Recent Trends in Medicaid Outpatient Prescription Drugs and Spending.* October 11, 2024. Accessed at https://www.kff.org/medicaid/issue-brief/recent-trends-in-medicaid-outpatient-prescription-drugs-and-spending/
[2] CMS.gov. *National Health Expenditure Fact Sheet (2023).* Accessed at https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet
[3] Jimmy B, Jose J. *Patient Medication Adherence: Measures in Daily Practice.* Oman Med J. 2011 May;26(3):155-9. https://pmc.ncbi.nlm.nih.gov/articles/PMC3191684/
[4] Watanabe JH, McInnis T, and Hirsch JD. *Cost of Prescription Drug-Related Morbidity and Mortality.* Annals of Pharmacotherapy 2018 September;52(9):829-837. https://escholarship.org/uc/item/3n76n4z6

While CMS programs like Medicare and Medicaid cover high-cost therapies that depend on perfect execution, they fail to monitor or ensure actual taking of medication, or correct administration. And despite massive spending on medications, CMS still relies on antiquated, refill-based metrics (such as Proportion of Days Covered, or "PDC") to measure adherence. These measures are outdated and misleading – possession is not ingestion – and these administrative illusions do not accurately reflect patient behavior or outcomes. As CMS continues to build on its promise of a digital health ecosystem, it must demand technologies that measure and improve real-world medication adherence: especially for high-cost or high-risk therapies. If adherence is not supported, no app can achieve its clinical promise.

Peer-reviewed publications that support video DOT (specifically, Scene Health's platform / program) include:[5]

- Hallgren KA, Darnton J, Soth S, Blalock KL, Michaels A, Grekin P, Saxon AJ, Woolworth S, Tsui JI. "Acceptability, feasibility, and outcomes of a clinical pilot program for video observation of methadone take-home dosing during the COVID-19 pandemic." *J Subst Abuse Treat*. 2022 Oct 4;143:108896. PMID: 36215911
- Holzman SB, Zenilman A, Shah M. "Advancing Patient-Centered Care in Tuberculosis Management: A Mixed-Methods Appraisal of Video Directly Observed Therapy." *OFID*. 2018, Volume 5, Issue 4. PMID: 29732378.
- Killian, M. O., Clifford, S., Skivington, G., Lustria, M., & Gupta, D. (In Press). "Directly observed therapy to promote medication adherence in adolescent heart transplant recipients." *Pediatric Transplantation*. 2022 Aug;26(5):e14288. PMID: 35436376
- McIntire K, Weis B, Litwin Ye L, Krugman SD. "Feasibility of video observed therapy to support controller inhaler use among children in West Baltimore." *J Asthma*. 2022 Oct;59(10):1961-1972. Epub 2021 Oct 4. PMID: 34550849
- Morris S, Miner M, Rodriguez T, Stancil R, Wiltz-Beckham D, Chorba T. "Notes from the Field: Tuberculosis Control Activities After Hurricane Harvey — Texas, 2017." *MMWR Morb Mortal Wkly* Rep 2017; 66:1362–1363. PMID: 29240726

It is time to finally recognize that MPR and PDC are process proxies, not clinical adherence indicators. To further concretize this reality, CMS should align digital health innovation funding, Medicare Advantage flexibilities, and Medicaid waivers toward outcomes-based adherence programs, and pilot the inclusion of adherence metrics in performance-based models, chronic care management programs, etc.

Patients do not need more portals; they need support, accountability, and human connection. The most effective digital health products do not merely aggregate data – they change behavior. Adherence tools must be simple, mobile, and personalized, particularly for Medicare and Medicaid populations where digital literacy may be low. In the dual and Medicare communities, isolation and loneliness is at an all-time high: necessitating human-to-human connection through video-based tools that offer a uniquely personal touch: combining tech and trust. CMS

[5] For a complete listing of Scene Health's peer-reviewed, clinical studies, visit https://www.scene.health/clinical-validation.

should fund, recommend, and integrate adherence-specific digital tools into its broader infrastructure.

PC-7: Outcomes Measurement
Scene Health routinely collects clinical, utilization, and patient-reported outcomes to assess the impact of adherence programs. These include MPR, PDC, hospital admissions, ER visits, and patient activation measures. CMS should consider requiring or incentivizing similar metrics across digital health solutions to promote evidence-based care. In a real-world evaluation with a Medicaid plan, Scene Health increased PDC by 24 percentage points across asthma and diabetes populations, contributing to improved HEDIS adherence rates and reduced acute care utilization *(unpublished proprietary data; available upon request).*

PC-8 and PC-9: Data Access for Patients and Apps
Patients enrolled in Scene Health programs often face challenges accessing real-time prescription data, discharge summaries, and care plans. We recommend that CMS expand the Blue Button API and other FHIR-based data access tools to include pharmacy fill status and structured adherence indicators to support apps like Scene Health in delivering more customized, personalized support.

Section E: Technology Vendors, Data Providers, and Networks
TD-1 and TD-2: Barriers to Participation
Scene Health faces systemic challenges in accessing timely and complete patient data, especially in Medicaid programs. Fragmented data exchange policies and lack of consistent integration with Medicaid managed care plans hinder the ability to proactively identify patients at risk of nonadherence. CMS can strengthen the ecosystem by creating national standards for API access to prescription data, lab results, and encounter history.

TD-13: Enabling Full EHI Access
CMS should support and incentivize provider and payer APIs that expose full Electronic Health Information (EHI), including medication history, care plans, and patient-provider communications. This would allow digital adherence platforms to more meaningfully support patient self-management and condition control.

Section F. Value-Based Care Organizations
VB-1 to VB-4: Role in Value-Based Models
In value-based care, outcomes matter. Yet no chronic care outcome is achievable if the patient does not take their medication. Scene Health and other digital health tools can support providers in closing this gap by integrating with care plans and providing data to support QI and quality measurement. For any specialty therapy or drug with >$500/month cost, DOT should be the expectation – not the exception. Medication adherence interventions should be incentivized in APMs, VBC models, and chronic care improvement programs. CMS should explore incentivizing adherence confirmation as part of VBC payment models, especially for high-cost drugs and chronic conditions.

To encourage APMs to leverage digital health tools and products, CMS could reimburse for DOT-based adherence support in chronic disease bundles, and / or tie quality bonus payments to verified adherence outcomes (not fill rates). CMS could also offer upfront incentives to adopt adherence programs in high-risk populations.

Scene Health programs are frequently deployed by payers and providers participating in value-based payment arrangements. In one case study with a Medicaid plan, Scene Health-supported members experienced a 40% reduction in asthma-related ER visits and a 2:1 return on investment in less than 6 months *(internal analysis, available upon request)*. We encourage CMS to recognize adherence platforms as critical enablers of ACO and VBC performance.

VB-5 to VB-7: Incentivizing Use of Digital Tools
CMS should provide guidance and incentives to include digital adherence platforms like Scene Health in care management strategies, especially for Medicaid and dually eligible populations. This may include supplemental benefits in Medicare Advantage, integration into Health-Related Social Needs services, and alignment with CMS Quality Strategy priorities.

Conclusion: video Directly Observed Therapy needs broad integration to unlock billions in savings and control chronic conditions

In conclusion, we cannot attempt to fix American healthcare while ignoring the fact that half of medications are not taken as prescribed. Similarly, we will never fully, effectively shift to value-based care without ensuring patients are able to follow through on their care plans. And lastly, we cannot afford to keep paying for drugs that sit unopened in medicine cabinets.

For every high-cost or high-risk medication, confirmed ingestion should be the standard, and video DOT should be the method. There is a clinically-backed, evidence-based way to do this: we must stop measuring the bottle, and start measuring the dose. By integrating real adherence into the digital health ecosystem, CMS can finally unlock the value of medications it already pays for – and give patients the outcomes they deserve.

Many thanks for the opportunity to submit these comments.

Sincerely,

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