



November 13, 2023

Benjamin Stidham, Contract Specialist
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 212441

RE: Request for Information: Medicare Transaction Facilitator (MTF) for the Medicare Drug Price Negotiation Program

Dear Mr. Stidham:

The National Health Council (NHC) appreciates the opportunity to provide feedback on the Request for Information (RFI) regarding Medicare Transaction Facilitator (MTF) services as part of the Medicare Drug Price Negotiation Program.

Created by and for patient organizations over 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, equitable, and sustainable health care. Made up of more than 155 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses and organizations representing biopharmaceuticals, devices, diagnostics, generics, and payers.

The NHC's primary concerns revolve around the need to ensure beneficiaries' data is protected and that their access to critical medications is maintained. Given the importance of these issues, we wish to provide further clarification and recommendations specifically related to the following question that are most relevant to the NHC's perspective and expertise.

3. What MTF functions should be prioritized in a phased development and implementation process for immediate impact and burden reduction?

The NHC supports prioritizing specific MTF functions that can yield immediate benefits and alleviate the burdens faced by beneficiaries, manufacturers, and dispensing entities. Timely reimbursement is of critical importance to ensure uninterrupted access to critical drugs for beneficiaries. When pharmacies are compelled to hold onto funds for extended periods as part of the retrospective payment process, it can strain their financial resources, potentially leading to difficulties in maintaining sufficient medication

supplies, thereby disrupting patient access.¹ This delay or uncertainty in reimbursement may result in increased costs, potentially impacting patients through higher co-pays or out-of-pocket expenses, potentially limiting their ability to afford necessary medications.^{2,3} Furthermore, pharmacies grappling with financial strain due to retroactive payments may face the risk of reducing services or even closing, particularly in underserved areas, ultimately leading to disruptions in patient access to vital pharmacy services and medications.^{4,5,6}

Efficient transaction and customer support services are essential for the seamless exchange of data between pharmaceutical supply chain entities when dispensing selected drugs. Additionally, the collection of prescription claims-level data from Part D plan sponsors and other entities is imperative for comprehensive data collection and crucial in monitoring and ensuring compliance with negotiated prices. These prioritized functions are pivotal for improving the MTF process and safeguarding patient access to essential medications.

6. What additional security needs should CMS consider to ensure adequate protection of data exchanges?

The NHC underscores the utmost importance of implementing robust data security measures to safeguard patient data throughout the MTF process. To this end, we recommend that CMS clarify that the MTF is designated as a covered entity under the Health Insurance Portability and Accountability Act (HIPAA), ensuring full compliance with patient data privacy and security laws. The NHC recommends the implementation of advanced encryption to secure all data exchanges and prevent unauthorized access to sensitive patient information.^{7,8} Additionally, strict access controls should be

¹ Mello, M. (2020). Barriers to ensuring access to affordable prescription drugs. *Annual Review of Pharmacology and Toxicology*, 6(60), 275-289.

² Kyle, M., Blendon, R., Benson, J., Abrams, M., and Schnieder, E. (2019). Financial hardships of Medicare beneficiaries with serious illness. *Health Affairs*, 38(11), <https://doi.org/10.1377/hlthaff.2019.00362>

³ Durham, D., Landon, B., Casalino, L., and Richman, B. (2021). Pharmacy benefit managers: transparency, accountability, and impact on patient care. *Journal of Managed Care & Specialty Pharmacy*, 27(7), 903-907.

⁴ IQVIA. (2019). Drug Distribution Data 2019.

⁵ Salako, A., Ullrich, F., and Mueller, K. (2018). Update: independently owned pharmacy closures in rural America, 2003-2018. *Rural Policy Brief*, 2018(2), 1-6.

⁶ Qato, D., Alexandr, G., Chakraborty, A., Guadamuz, J., and Jackson, J. (2019). Association between pharmacy closures and adherence to cardiovascular medications among older US adults. *JAMA Network Open*, 2(4), doi: 10.1001/jamanetworkopen.2019.2606

⁷ Basil, N., Ambe, S., Ekhatior, C., and Fonkem, E. (2022). Health records database and inherent security concerns: a review of the literature. *Cureus*, 14(10), doi: 10.7759/cureus.30168

⁸ Van Daalen, O. (2023). The right to encryption: privacy as preventing unlawful access. *Computer Law & Security Review*, 49(105804), <https://doi.org/10.1016/j.clsr.2023.105804>

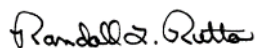
implemented to restrict data access exclusively to authorized personnel, fortifying data confidentiality.⁹ It is also crucial to maintain comprehensive data audit trails to monitor data access and modifications, enhancing accountability and data integrity.¹⁰ Furthermore, conducting regular security audits and assessments is essential to systematically identify vulnerabilities and proactively address them. We firmly believe that these security measures will not only protect patient data but also foster trust in the MTF process among all stakeholders involved.

Conclusion

The NHC thanks CMS for the opportunity to provide input through this RFI and look forward to continued collaboration with CMS and other stakeholders to address these concerns and ensure the best possible outcomes for patients.

Please do not hesitate to contact Eric Gascho, Senior Vice President of Policy and Government Affairs, if you or your staff would like to discuss this feedback in greater detail. He is reachable via e-mail at egascho@nhcouncil.org.

Sincerely,



Randall L. Rutta
Chief Executive Officer

⁹ Kruse, C., Smith, B., Vanderlinden, H., and Nealand, A. (2017). Security techniques for the electronic health records. *Journal of Medical Systems*, 41(8), doi: 10.1007/s10916-017-0778-4

¹⁰ Harman, L., Flite, C., and Bond, K. (2012). Electronic health records: privacy, confidentiality, and security. *Virtual Mentor*, 14(9), 712-719.