REAL-WORLD EVIDENCE ALLIANCE

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–0042–NC
P.O. Box 8013
Baltimore, MD 21244–8013

Re: Docket No. CMS-0042-NC: Request for Information; Health Technology Ecosystem

To the Centers for Medicare & Medicaid Services ("CMS") and Assistant Secretary for Technology Policy ("ASTP") / Office of the National Coordinator for Health Information Technology ("ONC"):

The RWE Alliance appreciates the opportunity to respond to the Request for Information titled "Health Technology Ecosystem" (the "Request for Information" or "RFI").[1] We are a coalition of real-world data ("RWD") and analytics organizations with a common interest in harnessing the power of real-world evidence ("RWE") to inform regulatory decision making to improve the lives of patients. Our members have deep knowledge and experience working with healthcare data across disease areas and patient populations, and we aim to bring these collective insights to bear in support of RWE policies.[2]

The RWE Alliance envisions a future in which data from electronic health records, administrative claims and billing records, product and disease registries, personal devices, wearables, and health applications will be used to generate evidence to support regulatory decision making related to medical product safety and effectiveness. To achieve these goals, the RWE Alliance advocates for policies that will (1) advance FDA's RWE Framework, (2) encourage the use of RWE to better understand treatment effects in underrepresented populations, (3) enhance opportunities for RWE

[1] 90 Fed. Reg. 21034 (May 16, 2025).

[2] For information about our members, please see our website, https://rwealliance.org/who-we-are/.

organizations to consult with FDA, (4) increase communication on the generation and use of RWE, and (5) recognize the unique aspects of and opportunities for RWD/E.[3]

I. General Comments

The RWE Alliance commends CMS and ASTP/ONC for its efforts to advance the state of data interoperability and the health information technology ("IT") infrastructure and to increase the availability of data for all stakeholders. If implemented with research uses in mind, improvements in health data exchange and IT could create new opportunities to generate clinical evidence from real-world sources for a variety of purposes, including for regulatory decision making by FDA. To this end, we encourage CMS and ASTP/ONC to seek feedback from RWD organizations and from evidence "end-users" (such as FDA), with the goal of optimizing the value of data collected and made available through the actions of CMS and ASTP/ONC.

II. Comments on Specific Questions

We address two questions posed by CMS and ASTP/ONC in the *Federal Register* notice below.

In Response to Question TD-7, a: "To what degree has USCDI improved interoperability and exchange and what are its limitations?" "Does it contain the full extent of data elements you need?"

Data collected in healthcare settings using USCDI may be valuable for clinical research, including for studies that incorporate RWD to assess the safety and effectiveness of medical products. We therefore urge ASTP/ONC to continue its efforts to optimize USCDI for research use cases. As these efforts progress, we encourage ASTP/ONC to explore additional data elements that would further support the collection of RWD for research purposes.[4] For example, ASTP/ONC should consider adding data elements from the Observational Medical Outcomes Partnership ("OMOP") Common Data Model ("CDM") that are not in USCDI version 3. OMOP CDM is built for research purposes and facilitates standardized analytics, including support for temporal reasoning (e.g., eras, observation periods); quantitative analysis (e.g., lab values, drug dosages); health economics (e.g., cost data); and population-level studies (e.g., death, provider, location).

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[3] Additional information about what we believe is available on our website, https://rwealliance.org/what-we-believe/.

[4] We also appreciate FDA's outreach to stakeholders on whether USCDI version 3 provides enough information for collecting RWD for research purposes. *See* 90 Fed. Reg. 17067 (Apr. 23, 2025).

In Response to Question TD-7, d: "To what degree has USCDI improved interoperability and exchange and what are its limitations?" "Given improvements in language models, would you prefer a non-proprietary but less structured format that might improve data coverage even if it requires more processing by the receiver?"

We believe this is an important topic and commend ASTP/ONC for considering the potential role of large language models in the analysis of unstructured data. As ASTP/ONC considers the trade-offs between structured and unstructured data in the context of rapidly advancing AI capabilities, we urge consideration of research use cases and consultation with stakeholders in the RWE ecosystem, including FDA.

The RWE Alliance appreciates CMS's and ASTP/ONC's commitment to facilitate health data exchange, including from RWD sources. Thank you for considering these comments, and please let us know if you have any questions. We welcome the opportunity to discuss further.

Best regards,

The RWE Alliance