June 16, 2025

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

RE: Request for Information; Health Technology Ecosystem

Dear Administrator Oz:

Civitas Networks for Health ("Civitas") appreciates the opportunity to submit public comments on the Request for Information, Health Technology Ecosystem (CMS-0042-NC), published in the *Federal Register* on May 16. Civitas is a national nonprofit collaborative comprised of more than 175 member organizations—health information exchanges (HIEs), regional health improvement collaboratives (RHICs), quality improvement organizations (QIOs), All-Payer Claims Databases (APCDs), and service providers to meet their needs—working to use data frameworks, information infrastructure, and multi-stakeholder approaches to improve health for individuals and communities. We educate, promote, and guide the private sector and policymakers on matters of interoperability, quality, coordination, and cost-effectiveness within the health system.

CMS and ASTP/ONC are seeking feedback on "the state of data interoperability and broader health technology infrastructure" to inform their efforts to accelerate the development of a more efficient and patient-centered system. This system would utilize existing policy frameworks and resources; break down barriers; and use what works now to deliver progress by emphasizing flexibility and responsiveness. In order to be successful, such a system must bring patients, providers, payers, technology vendors, networks, and value-based care organizations into alignment around an accessible baseline of technical and operational standards that is sufficient to enable innovation without being overly prescriptive and burdensome. Civitas was in attendance at HHS headquarters on June 3rd to hear directly from CMS and ASTP/ONC senior leadership about the imperative of moving from a "sick care" system to a true healthcare system that better incorporates prevention, the private sector, and non-federal partnerships as solutions to uncontrolled spending and excessive top-down controls.

Fortunately for CMS and ASTP/ONC, this system is already in place—or at least coming into place in a real way, without the need for massive amounts of new federal investment or layers of Beltway bureaucracy. The organizations that Civitas represents are collectively building and refining an architecture of health data from the ground up, on the state, regional, and community levels. At its core is public and nonprofit infrastructure operated for public benefit but leveraging technologies from private vendors, connections to proprietary EHRs, and partnerships with committed experts in the integration and analysis of clinical and non-clinical data sets. The simplest way to describe the structure created by our members' activities is to say that HIEs and APCDs (63 statewide and regional HIEs across 48 states and D.C., with another 25 APCDs in as many states) are the wiring and processing; the RHICs (16 in a dozen states, just counting among Civitas members) are the local auditors and neutral convenors, and the 14 QIOs nationwide

recognized by CMS as current or previous contractors under the Medicare QIO program (and working extensively with many state Medicaid programs) are the technical support for quality care delivery improvements. The earliest foundations for this structure were laid 20 years ago, and the largest federal contributions necessary to get it off the ground (namely, the incentive funding through the HITECH Act) were phased out nearly four years ago. At this point, key elements—the majority of HIEs and APCDs—have been officially recognized via state legislative or executive action, and much of the rest are also deeply engaged with public health agencies across their service areas through formal data use agreements, service contracts, advisory seats, and other mechanisms.

The Civitas members and other organizations whose activities continue to expand this structure and help drive the health technology ecosystem forward are deeply involved with CMS and ASTP programs, from state Medicaid agencies and section 1115 waivers to hospital Promoting Interoperability, MIPS, USCDI measure development, CEHRT deployment, information blocking, TEFCA, and Medicare quality improvement. Elsewhere at HHS (CDC and FDA), many of our members have shared data directly on a regular or provisional basis, and the opportunities for deeper real-time collaboration are substantial. What the agencies can do now is orient federal policy with the goal of facilitating productive convergence between the federal government and the non-federal ecosystem on the terms that suit it best—a "decentralized but connected" approach. The following potential changes recommended by Civitas members are especially noteworthy:

Technical Standard Baselines and Enforcement
RFI questions PR-2, PR-3, PR-5, PR-7, TD-4, TD-10, and TD-14

- Civitas members have emphasized the necessity of ASTP/ONC enforcing requirements for pre-FHIR baseline standards that should apply to much of the general EHR/EMR landscape, including (at minimum) LOINC codes for eCRs and eLRs, sending and receiving HL7, and sending and receiving C-CDAs. These and other standards are enshrined in the latest 45 CFR 170.315 certification requirements for HIT modules, yet the functional inability of many EHR systems to process them at the requisite level is an ongoing handicap for statewide health data exchange and public health applications because HIEs must frequently resort to formatting conversions themselves.

  The CEHRT regulations include a review and decertification process ("Direct Review") under 45 CFR 170.580 for non-compliance in addition to "in-the-field" surveillance of certified EHRs by ONC-Authorized Certification Bodies under 45 CFR 170.556 and 170.523. However, only a handful of EHRs have ever been decertified by the agency, and at present only a few more are in discussions with the agency and its three ONC-ACB contractors for non-conformity. ASTP/ONC should consider reforms to make the process of engaging potentially non-compliant eCRs and enforcing baseline standards faster and more responsive. To do so without adding additional layers of federal funding and personnel, Civitas suggests that ASTP/ONC explore rulemaking that would allow state authorities to become ONC-ACBs and exercise their authorities.

- Support for ASTP/ONC simplifying existing CEHRT requirements in tandem with enforcement by eliminating criteria that do not support interoperability or otherwise create duplication. At

the same time, the agency should refrain from adding additional requirements that are already far in advance of the de jure and (especially) de facto technical level that EHRs and providers maintain. This includes any attempt to mandate the forthcoming USCDI version 6 in the near future, given how 45 CFR 170 and 171 are only requiring USCDI version 3 in January of next year. Overall simplification works in tandem with enforcement to focus ASTP/ONC attention on those standards and specifications which are most critical to pushing the ecosystem forward right now—notably FHIR. Virtually all Civitas HIEs and APCDs are FHIR-capable and have been for some time, which enables seamless multi-directional exchange of data with clinical and non-clinical providers that is ultimately accessible to patients through APIs using FHIR as the baseline (like CMS' Blue Button 2.0). In many states, the designated HIE is leading adoption as the statewide "FHIR translator" with a central and official role converting old formats to the new standard. CMS and ASTP/ONC should take this dynamic into consideration when designing future interoperability incentives.

- ASTP/ONC should modify the annual real-world testing requirements for CEHRT under Parts 170 and 171 so that developers' testing plans must incorporate more robust trials of interoperability between older and newer versions of their EHR products. Apart from the frequently encountered absence of pre-FHIR standards functionality described above, Civitas HIEs' most persistent complaints on the ground involve the bottlenecks created when network participants using the same platforms nonetheless have difficultly transmitting information because software created years apart no longer functions as one system. This happens at least as often within health systems—doctors at different hospitals or clinics in the same health system unable to access the same data from different locations—as between them. Inter-version testing by the ONC-ACBs is already part of CEHRT's SVAP process, but currently not enough emphasis is placed on transmission between nonconsecutive versions of EHRs. To the extent that this stems from the three contract ONC-ACBs having limited bandwidth, it is another argument for opening the designation to state authorities.
- For the time being, Civitas does not support the wholesale replacement of EHR certification with API certification based on specific use cases. While FHIR is becoming more common, it is far from universal across all platforms—especially those platforms used (or not used) by smaller and more rural providers that Civitas members serve. Rather, some Civitas HIEs would encourage ASTP/ONC to explore a "tiered" approach in which components of EHR certification, like USCDI, may be selected or declined at the developer's request based on the specific use cases and functionality in question.

  Allowing vendors the leeway to tailor their products to their preferred markets with high priority certifications (including the standardized API criterion for patient and population services) absent the need for extensive "throwaway" software development and updates would speed the deployment of the most in-demand digital tools and boost interoperability as a result. Some Civitas members have reported an unwelcome accumulation of administrative and financial data within USCDI that has resulted from a lack of flexibility, crowding out the intended clinical workflows. Mitigating that burden would address the complaint, and the ultimate effect would be similar to streamlining the overall CEHRT requirements.

TEFCA
RFI questions PC-10, PC-11, and TD-6

- Most Civitas HIEs have been operating for a decade or more, and have been participants in national networks like Carequality and eHealth Exchange for years. Civitas as an organization led the development of the Patient-Centered Data Home (PCDH) national framework for statewide HIEs utilizing an expansion of ADT capability to notify each other in real time when patients are receiving out-of-state care to ensure record consistency. All of which is to say that our members' experience in the space predates TEFCA—and while TEFCA has grown significantly since "going live" 18 months ago, its use-case functionality remains far below what many Civitas HIEs can offer in their own service areas.

  Nonetheless, statewide HIEs in Alabama, Alaska, Maryland, Virginia, and the District of Colombia have either joined TEFCA in full or entered into partnerships with QHINs built around the public health use case. A common complaint among these members is that eCR functionality via TEFCA is often below that of their own networks, in part because TEFCA's "facilitated FHIR" exchange excludes FHIR Queries (eCRs can only be transmitted by FHIR Push). As ASTP/ONC reviews and refines the previous Administration's TEFCA approach, maximizing FHIR's applicability within even the limited public health functions currently designated should be a priority.

- CMS and ASTP/ONC have expressed a strong desire to move from a centralized, "top heavy" model of trusted data exchange to a more devolved and collaborative model that is responsive to the needs of existing infrastructure. In keeping with that approach, ASTP/ONC should review the previous Administration's relatively closed TEFCA governance structures (the Governing Council and Participant/Subparticipant caucus) and give HIEs, APCDs, and RHICs more prominent roles. A more representative governing structure can better ensure that the priorities of the non-federal ecosystem are reflected in the federal framework such that it operates as an accessory and force multiplier to that ecosystem, rather than a competitor.

- In considering the question of TEFCA versus a prospective "nationwide provider directory of FHIR endpoints" in terms of practical data exchange functionality, Civitas members have underscored the unrealized value of state and regional networks as potential "last mile" endpoints on behalf of their participants. The ongoing adoption of FHIR has yet to reach many small providers in rural or otherwise underserved areas, while FHIR functionality among state and local PHAs varies considerably. Other health stakeholders that participate in HIEs as members of wider clinical and non-clinical referral networks (including community-based organizations, public social service agencies, LTCs and behavioral health facilities) are even less likely to be FHIR-capable for lack or resources and staff education. HIEs would therefore be needed to serve as "FHIR endpoints" on behalf these participants in any national provider directory—not unlike how the same HIEs serve or are considering serving as "TEFCA onboarding" platforms for many of the same service providers. As FHIR endpoints, they would facilitate data transfer at the FHIR baseline and manage the conversion of data exchanged between entities to data that is more patient-accessible via FHIR APIs.

Non-Medical Drivers of Health
RFI questions PC-1, PC-5, Pc-8, and TD-7

- Civitas understands the argument that policymaking in recent years has reflected an excessive focus on non-clinical factors contributing to individual and population health—factors which have complex historical, socioeconomic, and cultural etiologies rooted outside the health system and beyond its ability to address. While we certainly agree that these "social determinants of health (SDOH)," health-related social needs (HRSNs)," or "non-medical drivers of health" (as they are called in some states) cannot be fixed exclusively or even primarily by healthcare providers, our members have nonetheless seen firsthand how certain disciplined and data-informed activities can help patients tackle complications outside the exam room. In doing so, the health system not only improves outcomes for the patients in question, but reduces the burdens on overworked healthcare professionals and paraprofessionals and lowers utilization rates to drive down costs. Discrete and proven interventions that mitigate non-medical drivers as part of patient-centered care regimes are thus an important form of preventative care, in accordance with HHS' mandate to Make America Healthy Again.

  The most effective non-clinical interventions, according to HHS' own demonstrations (like the landmark CMS Accountable Health Communities Model that ran from 2017-2022) are also the simplest and most widely applicable for all Americans: access to food, housing, medical transportation, utilities, employment, and community safety. Such interventions need not actually be provided by the health system directly. Rather, the role of healthcare providers is to enable these interventions via digital referral networks involving social service agencies, community-based organizations, and the private sector. The foundation of all such referral networks is a set of standardized, interoperable data elements that can record and quantify measures of wellbeing across the ecosystem of providers, public and commercial payers, PHAs, and community-based organizations. As such, Civitas recommends that ASTP/ONC continue to recognize the eleven SDOH Domains laid out in USCDI version 3, which per the HTI-1 final rulemaking will be a CEHRT requirement starting in January 2026. The domains, developed in large part by the Gravity Project (of which Civitas, ASTP/ONC, and CMS are members) are as follows: food insecurity, housing instability and homelessness, inadequate housing, transportation insecurity, financial strain, social isolation, stress, interpersonal violence, education, employment, and veteran status.

  Civitas and its partners continue to develop and refine these domains with input from four ongoing pilot projects sponsored by Gravity in Arizona, New York, Colorado, and Oklahoma involving Civitas HIEs and RHICs. The results to date have catalyzed a focus on four "protective factor" domains related to food access, neighborhood/community safety, financial security, and health literacy that correlate particularly well with lower patient health risks, greater resiliency, and better outcomes—as well as with positive indicators down the longer list of USCDI v3 domains. To the extent that AST/ONC is looking to streamline the SDOH domains in the forthcoming USCDI version 6, Civitas recommends prioritizing these protective factors as the highest-impact and highest-value subset of the non-medical driver portfolio.

- CMS has indicated that it intends to scale back its use of SDOH metrics in the Medicare program, most notably in the current FY26 Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System NPRM. The Proposed Rule

would eliminate a total of ten relevant measures: two from the Hospital Inpatient Quality Reporting Program (IQR), four from the Inpatient Rehabilitation Facility Quality Reporting Program (IRF-QRP), and another four from the Long-Term Care Hospital Quality Reporting Program (LTCH-QRP). None of these measures are more than two years old, and only the IQR measures—Screening for Social Drivers of Health (SDOH-1) and Screen Positive Rate for Social Drivers of Health (SDOH-2)—have actually been implemented (albeit very recently, with mandatory reporting for hospitals beginning in January 2024). It is therefore reasonable, in Civitas view, to question CMS' contention that the costs of administering these measures outweigh their long-term benefits when no real-world cost-benefit analysis or accounting of their cumulative impact has had sufficient time to be performed.

To the extent the claimed administrative burden is a function of "screening patients via manual processes, manually storing data, training hospital staff, and alternating workflows," the solution is to accelerate digitization and lean into the wider infrastructure that Civitas members represent. At the same time, CMS can and should consider streamlining the SDOH and non-medical driver reporting elements in a way that maximizes practical impact while reducing the number of reporting requirements in any form, per our aforementioned emphasis on the "protective factors" for USCDI v6. An equivalent step within Medicare could include consolidating the five HRSNs attached to the SDOH-1 and SDOH-2 IQR measures (currently food insecurity, housing instability, transportation needs, utility difficulties and interpersonal safety) into just food and housing measures. Likewise, the four LTCH reporting measures on the chopping block associated with living situation, food, and utilities (the LTCH "standardized patient assessment data elements" that would be required starting in October 2026) could be launched in a pared-down format limited to the two food-related measures.

- HIEs are well-positioned to provide secure, neutral, and collaborative, and (in many cases) officially state-designated networks that are responsive from the ground-up, not the top down. Their work is enhanced by that of our APCD and RHIC members, who combine data with expertise and deep local partnerships to identify and implement solutions that lead to better outcomes and lower costs. Most notable in the Medicare context are the Quality Improvement Organizations (QIOs), the nonprofits designated by CMS' own long-running QIO program as in-house suppliers of specialized technical assistance to providers in their assigned regions. The QIOs' activities are designed to target gaps in clinical best practice that have an outsize impact on beneficiary outcomes and program costs, while also assisting providers—especially small, rural, and otherwise underserved providers—with navigating the requirements for Medicare's quality reporting and incentive payment rules. Their track record over decades of multi-year program cycles speaks for itself (CMS recently made awards under the 13th scope of work for the QIN-QIO program).

Information Blocking
RFI questions PR-12, PR-13, and TD-18

- Civitas supports the series of regulations since 2020 implementing Section 4004 of the 21st Century Cures Act, and we appreciate the consistent efforts of ASTP/ONC and CMS to make the law a reality on the ground for the patients and providers who depend on access to complete and timely health data. Nonetheless, state and regional HIEs still encounter information blocking on a regular basis. The problem takes different forms, and the responsibility for ongoing violations is not equally distributed across the landscape. In our

members' experience, the worst offenders remain disproportionally clustered within the commercial laboratory and pharmacy sectors—areas where the HHS-OIG CMPs and CMS-imposed disincentives are conspicuously absent, because the enforcement authorities under the current disincentive regulations (45 CFR 171.1001) do not cover enough of them.

As written, healthcare providers that are determined by HHS-OIG to have committed information blocking will be excluded by CMS from participation in the Medicare Promoting Interoperability Program, the MIPS pathway within the Quality Payment Program, or the Shared Savings Program. The issue is that very few (if any) freestanding pharmacies and labs are direct participants in any of these programs, despite the definition of "health care provider" in 45 CFR 171.102 including labs and pharmacies. This gap in enforcement capability has serious consequences: prescription and diagnostic lab data is absolutely essential to patient medical records and the wider matrix of epidemiology, population health, and value-based care that Civitas members and PHAs are working to advance. ASTP/ONC has likewise noted the importance of improving pharmacy interoperability (such as in its responses to HITAC reports), and other divisions of HHS (e.g. CDC) have made higher rates of state-to-federal ELR transmission a key component of data modernization.

To bring labs and pharmacies under the disincentive umbrella, Civitas continues to recommend that CMS leverage the full scope of existing Medicare authorities by using its power to enforce Part C and Part D contract terms (SSA sections 1860(D)-12(b)(3)(D), 1871, and 1102) via its "preclusion list" system for revoking participation in Medicare Advantage. Over 64,0000 pharmacies nationally participate in Medicare Advantage drug plans, while every major commercial lab network and thousands of independent labs are likewise MA participants—making this a potent tool against information blocking violations as a breach of terms for lack of compliance with CMS regulations.

- Civitas members' experiences in the field have highlighted the need for clarification regarding the information blocking fees exception (45 CFR 171.302). The exception stipulates that any charges for access to electronic health information must be based on "objective and reasonable criteria that are uniformly applied," as well as "reasonably" related to the costs that an actor incurs for providing the EHI and allocated among all similarly situated persons or entities in the same way. At the same time, fees cannot be based on the status of the requestor as a "competitor or potential competitor…or use of the EHI in a way that facilitates competition"; cannot be based on the value of any specific request, non-standard usage of the health IT product, "intangible assets," unrelated opportunity costs, or IP-related royalties.

  These conditions sound good in theory, yet determining how they might apply in a given circumstance is a legally and operationally fraught endeavor. Civitas HIEs serve as a direct line to many of the smallest and most financially limited providers in their service areas, including FQHCs, RHCs, and behavioral health clinics which lack the EHR platforms equipping larger health systems. Attempts by such facilities to acquire EHRs are often met by quotes in the high five-figures with additional five-figure subscription and maintenance charges, far beyond their ability to sustain. Such charges hamper digital modernization at large and HIE networks in particular, because Civitas members generally benefit from connectivity with EHR systems that enhance their participants and partners' data faculties.

  Excessive onboarding fees are thus a clear example of information blocking in practice. However, in the language of the regulation it remains unclear the extent to which they could

be justified by the vendor as "reasonably related to costs" of connectivity or shown to be "reasonably allocated among all similarly situated persons or entities to whom the technology or service is supplied" (because price transparency and cross-provider comparisons are not readily available in most cases). "Finding out" by filing complaints through the OIG process takes time, and more importantly creates a degree of public and potential legal exposure that many smaller providers are simply not equipped to face. The solution is for ASTP/ONC to be proactive and offer greater clarity in an official capacity via formal guidance materials, if not actual revisions to the rulemaking text that would add useful detail to the fees exception in this regard. As HHS has done in other contexts (like quality reporting), a formula to quantify the meaning of "reasonable" vs "unreasonable" charges with some objective and easily-understood parameters—for example, cost per projected transactions per facility based on patient numbers or utilization rates—would address the core of the issue without the need to radically alter the current approach.

Patient Identification and Digital Identity
RFI questions PR-9, PR-10, TD-3, TD-7, and TD-9

- Like much of the rest of the health data ecosystem, Civitas members continue to be hampered by Congress' inability to authorize the development of a "national patient identifier" (thanks to the section 510 appropriations rider) or pass legislation that would address many of the same serious problems created by patient misidentification without using a national identifier (such as the bipartisan MATCH IT Act). In light of these obstacles and the continuing damage to care quality and efficiency caused by mismatched records—estimates put the nationwide cost at $6.7 billion annually, averaging $2.5 million per hospital—Civitas strongly encourages ASTP/ONC and CMS to explore the use of rulemaking authority under CEHRT and the Promoting Interoperability Program to enact some of the necessary measures. As envisioned by the MATCH IT Act, the key components needed are a consensus definition of "patient match rate" that government and industry can use to standardize process improvement alongside an industry standard data set which covers the elements most important for enabling stakeholders to ultimately reach the optimal 99.9% patient match rate.

On behalf of Civitas and our members, thank you again for your consideration of our comments. The Civitas community is deeply engaged in multiple corners of the health data policy and regulation space, and we stand ready to collaborate to achieve our shared goal of creating a higher-value health system.

Please do not hesitate to reach out if you have any questions or comments for us.

Sincerely,

Jolie Ritzo
CEO, Civitas Networks for Health