

March 13, 2023

Civitas Networks for Health
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Portland, ME 04101

Centers for Medicare & Medicaid Services
Office of Burden Reduction and Health Informatics
Alexandra Mugge, Chief Health Informatics Officer
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-0057-P Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children’s Health Insurance Program (“CHIP”) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (“MIPS”) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program. Submitted at [Regulations.gov](https://www.regulations.gov).

Dear Ms. Mugge:

[Civitas Networks for Health \(“Civitas”\)](https://www.civitasnetworks.org/) appreciates the opportunity to provide input on the Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children’s Health Insurance Program (“CHIP”) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (“MIPS”) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program (CMS-0057-P) (the “Proposed Rule”). Civitas is a national collaborative of regional and statewide Health Information Exchanges (“HIEs”) and Regional Healthcare Improvement Collaboratives (“RHICs”). We are significant stakeholders in the health data interoperability landscape, helping providers, other key stakeholders and facilities achieve many of the policy goals presented in this Proposed Rule. Representing more than 95% of the United States, Civitas is comprised of member organizations working to use health information exchange, health data, and multi-stakeholder, cross-sector approaches to improve health. We educate, promote, and advocate to the private sector and policymakers on matters of interoperability, quality, coordination, health equity, access, and cost-effectiveness of healthcare. While there are many areas of this rule on which Civitas’ work and stakeholders’ expertise is applicable, we would specifically like to comment on the sections discussed below.

1. Provider Access Application Program Interface (“API”)

The Centers for Medicare and Medicaid Services (“CMS”) is proposing to “require that impacted payers implement and maintain a Health Level Seven® Fast Healthcare Interoperability Resources® (“FHIR®”) API that makes patient data available to providers who have a contractual relationship with the payer and a treatment relationship with the patient” by 2026. (87 Fed. Reg. 76254). As part of this requirement,

CMS is also proposing that payers allow patients to “opt-out” of their data being exchanged through this API and use a method for attributing patients to providers appropriately. As CMS notes, “impacted payers may already have multiple arrangements in place with providers to support data exchange, [including] health information exchanges (HIEs). In many cases, these HIEs include patient attribution capabilities for which payers may already have a process...” (87 Fed. Reg. 76259). Our HIE members have extensive experience in attribution, including robust Master Patient Indexes, and opt-out and many have connections with and between payers and providers. HIEs are ideal partners to work with payers to provide the Provider Access API because they have extensive experience and expertise with patient matching and attribution and with opt out models. Moreover, our existing data sharing relationships with our healthcare provider participants mean that we can be leveraged to further reduce burden because the HIE could serve as a one stop shop for providers to obtain information from both Impacted Payers and Hospital data suppliers, and furthering the Interoperability Rule’s intent of reducing provider burden by reducing the number of end points that they must go to in order to obtain information for treatment and care coordination. **Accordingly, we encourage payers to work with the HIEs in their states on the rule’s implementation. In addition, we encourage CMS to work with HIEs both now and in the future to pilot these capabilities and create implementation guides and plans.**

Next, we strongly encourage CMS to clarify in that 42 CFR 431.306(d) and 42 CFR 457.1110(b) do not prohibit Medicaid and CHIP programs from sharing beneficiary information with HIEs for the purposes of the Provider Access API. Without clarification, some Medicaid and CHIP agencies may interpret the rule as effectively prohibiting Medicaid and CHIP agencies from participating in HIE for treatment, payment and health care operations covered by their HIPAA Notice of Privacy Practices.

In addition, while we agree with an opt-out approach, **in our experience, patients find it confusing and disheartening when they must go to multiple places to opt-out of data sharing. Therefore, we encourage CMS to work with other stakeholders to integrate centralized consent solutions, allowing patients to go to one platform to opt-out/in of various health data sharing.** Many of our members are implementing such solutions in their states and could work with CMS to pilot an integrated, state-based solution.

2. Payer-to-Payer API

Similar to the Provider Access API proposal, CMS is proposing to require affected payers “to implement and maintain a payer-to-payer data exchange using a FHIR API.” (87 Fed. Reg. 76268). In contrast to the Provider to Payer API, patients must *opt-in* for this type of data exchange. CMS is proposing to require that, beginning 2026, all impacted payers “develop and maintain process to identify a patient’s previous and/or concurrent payer(s)” and allow them to opt-into data sharing prior to the start of coverage. (87 Fed. Reg. 76271). As noted above, our members are experienced in both opt-in and opt-out models and have created technology to ease the burden of these processes. Indeed, HIEs are in an ideal spot to support the persistent access needs of concurrent payers, contingent on CMS adopting an opt-out Model in lieu of the proposed opt-in model, because we would be able to reduce burden on Impacted Payers. **We encourage impacted payers to work with the HIEs in their states to implement these requirements.**

In addition, based on our members’ experience, we note that opt-in models typically result in significantly reduced participation, in contrast to opt-out models. With this proposal, it is likely that few patients will opt-in; we understand, however, CMS’ legal and policy constraints, and we encourage CMS to work with the community on outreach and education campaigns to encourage opting-in.

CMS is also proposing to require that “information received by an impacted payer through [the Payer-to-Payer API] must be incorporated into the patient’s record with the new payer” so that a patient’s cumulative record would follow them between payers. (87 Fed. Reg. 76275). We agree with the intent of this proposal, but, based on our experience, are concerned about its implementation. **This proposal will likely require extensive data translation and de-duplication; our members have expertise in these areas, and we encourage payers to work with HIEs in their state to implement this requirement.**

Similar to our comment related to Provider access above, we strongly encourage CMS to clarify in that 42 CFR 431.306(d) and 42 CFR 457.1110(b) do not prohibit Medicaid and CHIP programs from sharing beneficiary information with HIEs for the purposes of the Payer-to-Payer API. Without clarification, some Medicaid and CHIP agencies may interpret the rule as effectively prohibiting Medicaid and CHIP agencies from participating in HIE for treatment, payment and health care operations covered by their HIPAA Notice of Privacy Practices.

3. FHIR Prior Authorization Requirements, Documentation, and Decision (“PARDD”) API

Beginning in 2026, CMS is proposing to require impacted payers to implement and maintain a FHIR PARDD API to facilitate transparency for prior authorization requests. Payers would be required to include functionality that would allow a patient and provider to track the prior authorization requirements and stages. (87 Fed. Reg. 76291). As noted above, many HIEs are already connecting payers and providers and could be utilized further for tracking prior authorization. We are additionally strongly supportive of policies that, over time, minimize the use of prior authorization or other utilization requirements that tend to slow down care for vulnerable patients.

In our experience, however, the health technology requirements for prior authorization pale in comparison to the governance and documentation requirements, much of which must still be developed. We appreciate the timeline for implementation of these requirements, therefore, and encourage CMS to provide best practices for creating these documents.

4. Electronic Prior Authorization for the Merit-Based Incentive Payment System (“MIPS”) Promoting Interoperability Performance Category and the Medicare Promoting Interoperability Program

CMS is proposing to add a new measure to MIPS and the Medicare Promoting Interoperability Program that would be included in the HIE objective of the programs. Specifically, eligible clinicians and hospitals could earn points in the programs for reporting that they use a PARDD API for requesting prior authorization. **We agree with CMS that using these APIs should be incentivized in the provider community and note that HIEs could provide a means, as described above, for continuing to connect providers and payers, including for purposes of prior authorization.**

5. Request for Information: Accelerating the Adoption of Standard Related to Social Risk Factor Data

Increasingly, our members’ work includes the vital exchange of social needs data from community-based organizations and community care hubs. These data treat the underlying causes and consequences of diseases, including housing and food insecurity, which are often best addressed outside the traditional healthcare system. Data exchange with and including organizations that have traditionally been outside the scope of CMS’s authority treats the whole patient and breaks down the underlying systems of disparity and inequity.

With generous support from the Robert Wood Johnson Foundation (RWJF), Civitas launched a project in November of 2022 to support dissemination and implementation of Gravity Project® standards. We

partner closely with Gravity Project leadership, HL7® and Civitas members to engage with national, regional, and local partners and community members to learn from and support existing Gravity learning community activities. The project focuses on those organizations that have existing or evolving partnerships with community-based organizations, public health, human services and patients. Civitas engages with experts to provide webinars, technical assistance, implementation guidelines and best practices, tools and resources, and opportunities for ongoing interaction and support. The project aims to leverage existing community level infrastructure, identify opportunities for new infrastructure, systems, and support that enable communities to successfully adopt and advance SDOH data collection and use—ultimately resulting in equitable care for all. We would like to direct CMS’ attention to the [letter that the Gravity Project submitted on January 4, 2020](#), in response to CMS’ previous Request for Information on Accelerating Adoption of Standards Related to Social Risk Data, File No. CMS-9123-P.

In their letter, the Gravity Project highlighted challenges regarding standardization, including terminology and terminology standards gaps, the dearth of gold-standard screening tools, a lack of consensus for how to define, screen, and diagnose, and in diagnostic criteria. They also highlighted issues regarding privacy and consent, especially as data moves between HIPAA and non-HIPAA-covered entities, and issues regarding participation and data sharing with patients and beneficiaries of services. They noted that most social risk data is currently collected and exchanged within non-standard exchange mechanisms and systems, and only some is contained or exchanged within EHRs and HIEs. Finally, they strongly recommend that health care payers establish reimbursement for providers and community-based organizations to assess and document social risk and provide appropriate integrations and align with national interoperability standards and implementation guides like those resulting from the Gravity Project consensus-based community’s work.

Furthermore, in addition to HIEs, CMS should include working with RHICs to advance the interoperable goals of sharing social risk factor data. While they have not received as much attention in federal regulations, RHICs are referenced and supported through statewide initiatives to improve healthcare and would be critical assets to CMS in understanding the barriers and successes in bringing these data sources together.

6. Request for Information: Advancing Interoperability and Improving Prior Authorization Processes for Maternal Health

We commend CMS for its continued focus on maternal health and decreasing Maternal Mortality. Many RHICs have been at the front lines of the efforts to combat maternal mortality, focusing on health equity, health literacy, pre-conception care and postpartum efforts to ensure that patients’ voices are heard in their health-related experiences. **Civitas commends and supports CMS’ efforts in the maternal health space as we recognize that the clinical quality metrics proposed will give focus to improving outcomes and create understanding on gaps in care.**

7. Request for Information: Advancing the Trusted Exchange Framework and Common Agreement (“TEFCA”)

CMS requested comment on how TEFCA could facilitate the Proposed Rule, whether it should incentivize payers under TEFCA, and other concerns about TEFCA. Our members are actively engaged in the implementation of TEFCA, including announcing intentions to apply to be a Qualified Health Information Network (“QHIN”) or connecting to a QHIN. Although we strongly support a contractual interoperability framework, building on the success of public-private entities such as regional and statewide HIEs and national approaches like Carequality, that would encourage more data sharing and interoperability, at this time, we caution CMS in incentivizing participation before TEFCA has been implemented. **We**

encourage CMS to wait until go-live and until QHINs have been able to implement various standard operating procedures before it incentivizes participation, which may drive payers and providers away from other, more tested and effective, exchange types.

CMS also asks for comment on whether it should encourage exchange under TEFCA to ensure “more patients are informed about the privacy and security implications of using health apps to access their information” since TEFCA requires privacy and security requirements above and beyond existing federal laws. (87 Fed. Reg. 76249). As noted by CMS, the Common Agreement raises the bar for privacy through TEFCA for Individual Access Services, above and beyond the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) Privacy and Security regulations. We are concerned that, because the Department of Health and Human Services (“HHS”) and the Federal Trade Commission (“FTC”) do not have similar rules, entities may be less likely to participate in TEFCA, and patients’ privacy expectations will be different and confusing based on the way their data is accessed, a highly technical concept that is beyond the average knowledge of patients. In fact, most patients would likely assume that privacy and security standards are the same, regardless of the back-end aspects of data exchange. **Therefore, we encourage CMS to work with other government entities to harmonize privacy requirements so that patients expect the same level of privacy regardless of the way they access their data.**

Thank you for the opportunity to comment. Several of our members, who are listed below, wish to add their individual support for the items raised in this comment letter. Please do not hesitate to reach out to Civitas if we can be a resource as we work together to make a more interoperable health care system.

Sincerely,



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CIVITAS MEMBERS WHO JOIN THIS COMMENT LETTER

Chesapeake Regional Information System for our Patients (CRISP)

Connexus (formerly known as Integrated Care Collaboration)

Contexture

CRISP DC

Greater Houston HealthConnect

Healthy Alliance

Indiana Health Information Exchange

Michigan Health Information Network (MiHIN)

New York eHealth Collaborative

SYNCRONYS

Velatura HIE Corporation

Virginia Health Information

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