January 4, 2021

The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
330 C Street, S.W.
Washington, DC 20201

Submitted electronically via Regulations.gov for CMS-9123-P


Dear Administrator Verma,

On behalf of the Strategic Health Information Exchange Collaborative (SHIEC), which represents 800 health information exchanges and health information networks (collectively, “HIEs”) across the nation, we appreciate every opportunity to provide feedback on proposed changes to requirements around the sharing of payer data. SHIEC understands the primary goals of CMS-9123-P are to improve patient care and reduce provider burden by requiring certain CMS-regulated payers (“impacted payers”) to more efficiently approve necessary procedures for members and to share administrative, clinical and formulary data with a members’ current and future health care providers and payers through the creation of five different application programming interfaces (APIs), including a Provider Access API and Payer-to-Payer API. SHIEC supports these goals and believes HIEs can be a key partner in achieving them.

HIEs are already engaged in the important interoperability work that aligns with the provisions of the proposed rule, as well as assisting payers and providers with other federal and state requirements, including admission, discharge, and transfer (ADT) event notifications and state prescription monitoring programs. SHIEC’s member HIEs serve 95% of the United States population and also power the nationwide interoperability framework for ADT alerts—called Patient Centered Data Home (PCDH)—which alerts a patient’s home care team of an ADT event no matter where in the United States the care occurred.

By serving as a hub of health information for their communities, HIEs apply data standards across communities by leveraging connections with providers, payers, and others to distribute necessary information across HIE participants (e.g., to providers, payers, and public health authorities). For this reason, and because the core functions of HIEs include standardizing patient matching, consent management, transmitting data, and other technical data alignment,
CMS should consider HIEs central to community data exchange. We believe that CMS’s interoperability and data exchange policy should leverage HIEs to enable secure, meaningful, and scalable data sharing across all communities. We have collected feedback from our membership on the proposed rule here, and welcome an opportunity to discuss these comments in more detail with CMS:

1. **Existing HIE infrastructure should be leveraged to satisfy the interoperability goals underlying the proposed Provider Access API and Payer-to-Payer API requirements**

   The proposed rule relies on impacted payers creating, maintaining and using point-to-point connections to satisfy new Provider Access API and Payer-to-Payer API requirements that mimic existing trusted data exchange frameworks supported by state and regional HIEs. Specifically:

   - The Provider Access API would require impacted payers to build and maintain an API for payer-to-provider data sharing, including requests for individual patient data and group (or bulk) requests. The accessible patient data would include claims and encounter data (but excluding cost information), clinical data as represented in the U.S. Core Data for Interoperability, version 1 (USCDI v.1), formulary data in some instances, as well as active and pending prior authorization data (collectively, “covered data”). The Provider Access API would permit health care providers to use an impacted payer’s API to access this covered data—without patient involvement and regardless of the provider’s in- or out-of-network participation—for patients to whom they currently provide care or are planning to provide care. CMS is proposing to permit (but not require) impacted payers to use an opt in process for the Provider Access API and also seeks comment on whether to require use of an opt out process.

   - The Payer-to-Payer API would require impacted payers to rebuild and significantly expand the initially required Payer-to-Payer Exchange to support payer-to-payer data sharing of the same covered data in Provider Access API. In addition to patient directed and approved payer-to-payer exchange, the Payer-to-Payer API would require impacted payers to share the covered data, without direct patient involvement, with a new payer or when a patient identifies concurrent coverage with another payer, at the end of the annual open enrollment period or, if they do not have such a period, at the end of the first calendar quarter of each year. CMS further proposes to require impacted payers to engage in data sharing quarterly with a plan that provides concurrent coverage. CMS proposes to require an opt in data sharing model for both the annual and quarterly data sharing.

   *This type of query-based provider and payer data exchange—built on opt-in or opt-out patient participation models—is precisely the type of data exchange that existing HIE connections are*
intended to support. The missing component has been full health plan participation in sharing the covered data among HIE participants. Thus, CMS can leverage existing HIE infrastructure by requiring that impacted payers share the covered data through a community, state or regional HIE connection.

However, CMS’s vision of data sharing—as currently proposed—excludes the existing HIE infrastructure that states and the federal government have developed over the past decade with significant state, federal and industry investment. Developed initially through the Health Information Technology for Economic and Clinical Health Act (HITECH) Act requirements on community data exchange, HIEs serve as critical data hubs in their communities, offering a single connection point for participating entities and saving the time and cost of establishing point-to-point connections among a fluid mix of entities. The data hub infrastructure facilitates an efficient mix of data exchange methods for participating entities, including query-based data exchange, ADT alerts (e.g., push notifications), access to longitudinal patient records, or any other use a community permits through its HIE’s data governance structure.

CMS emphasized the importance of HIEs in connection with the CMS Interoperability and Patient Access final rule and CY 2021 Medicare Physician Fee Schedule and Quality Payment Program final rule. However, CMS-9123-P does not mention HIEs, despite over a decade of demonstrated value in facilitating data exchange across the care continuum.

SHIEC member HIEs have robust repositories of clinical and claims data, are built around multi-stakeholder governance models (e.g., payers, providers, public health, state, and local government), and are tailored to meet the needs of the regions, states, and communities that they support. Moreover, SHIEC member HIEs have developed deep expertise on the complex technical and legal frameworks that must be in place to support data exchange between health care providers and payers for treatment, payment and health care operation purposes (like care coordination and case management) in compliance with federal and state privacy laws. If burden reduction is the goal of this proposed rule, then HIEs should be a core part of the proposed solution, either through specific guidance indicating that payers can leverage HIEs to meet Provider Access API and Payer-to-Payer API requirements or a specific exemption to the Provider Access API or Payer-to-Payer API requirements if an impacted payer can demonstrate full participation in its community HIE.

Indeed, the cost to impacted payers to build new data sharing infrastructures from the ground up is significant. CMS estimates that it will cost the industry up to $110 million for Provider Access API\(^1\) and $41.8 million for Payer-to-Payer API.\(^2\) This is on top of the already $1.03 billion

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2. 85 Fed Reg 82586, 82654.
in estimated costs (over 10 years) to meet existing Patient Access API requirements in the CMS Interoperability and Patient Access final rule. Recognizing the significant amount of financial and human resources involved in this endeavor, CMS is offering to give 1-year exceptions and exemptions to certain impacted payers. CMS specifically requested comment on these exceptions and exemptions. SHIEC respectfully requests that CMS consider creating an exemption from the Provider Access API and Payer-to-Payer API requirements if an impacted payer can demonstrate that it is making accessible the same types of covered data through a community HIE.

CMS does not have to wait until finalization of ONC’s Trusted Exchange Framework and Common Agreement (TEFCA) to provide for such an exemption. At its core, TEFCA is a voluntary attempt to standardize what has already been accomplished by state and regional HIEs that engage in nationwide date exchange, such as the SHIEC PCDH initiative and the Data Use and Reciprocal Support Agreement (DURSA). Moreover, given that the proposed applicability dates for the Provider Access API and Payer-to-Payer API are January 1, 2023, TEFCA or a similar agreement should be finalized and implemented by that date. Thus, incorporating such an exemption would align with other HHS initiatives to achieve true interoperability while respecting patient choice and the protections afforded to them by existing state and federal health information privacy laws.

SHIEC appreciates CMS’ consideration and inclusion of HIEs in a national interoperability solution. SHIEC recognizes that HIE coverage and access varies by state and region, but throughout most of the country, HIEs exist that can support impacted payers in meeting the proposed Provider Access API and Payer-to-Payer API requirements.

*We ask that CMS provide guidance that, where such infrastructure exists, payers and plans may use HIEs to perform these functions without requiring impacted payers to build new data sharing infrastructures from scratch. We urge CMS to specifically mention that HIEs may be used as intermediaries and sources to develop, populate, or facilitate meaningful exchange that meet CMS’s goals.*

2. Smaller payers, plans, and providers need financial support and technical assistance to accomplish the health data exchange goals described in the proposed rule.

The proposed rule will require substantial resources to support effective payer-to-payer and payer-to-provider interoperability and data exchange. Through the HITECH Act and Meaningful Use incentive payments, providers had access to capital investments to build out the necessary technological infrastructure, such as interfaces with trusted organizations, and HIEs have

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leveraged resources to provide technical assistance to communities to ensure a unified approach. As CMS seeks to require payers to share data with one another and with providers, it should also consider the costs to establish effective networks and provide opportunities for stakeholders to access resources to achieve regulatory goals.

Given all we have learned about the challenges, workflow interruptions, and expense of developing and integrating new data exchange systems, SHIEC hopes CMS will provide the financial and regulatory support necessary to implement the proposed changes, perhaps through a statewide or regional center of excellence system. Without this support, the changes meant to reduce burdens within the health system may instead create new encumbrances for payers.

In line with this request, we would like to provide a response to the Request for Information on the Electronic Exchange of Behavioral Health Information.

As noted, several factors have led to an EHR adoption rate that is significantly lower among behavioral health providers compared to other types of health care providers, likely due to the exclusion of these providers from the HITECH Act incentives for EHR adoption. However, we do not believe that “skipping” the important step of moving away from paper-based data collection and information exchange is possible. We encourage HHS and CMS to invest in the digitization of important left-behind sectors, such as behavioral health, long-term and post-acute care (LTPAC), and community-based organizations (CBOs).

These organizations need financial support to license and onboard EHR systems, as well as ongoing technical assistance for workflow upgrades, training, and workforce development. In order to ensure that EHR adoption leads to interoperability and health data exchange between behavioral health providers and the rest of the health care system, CMS and the ONC should ensure that EHRs support the most recent efforts in standardizing behavioral health and social determinants data collection, and support and incentivize connections to HIEs to encourage behavioral health and other social determinants data are integrated into longitudinal patient records, where allowable by state and federal law.

3. More time is needed to provide feedback

This proposed rule grapples with important issues related to patient care and data exchange; given the truncated window in which to respond, SHIEC hopes CMS will consider extending the comment period and meeting with stakeholders directly. We would be very happy to bring SHIEC member HIEs and their payer partners to a meeting to discuss the work they are already doing to enable data exchange in their communities. We thus respectfully request CMS extend the comment period to match the 60-day comment periods afforded by HHS in response to other significant rule making, such as the first CMS Interoperability and Patient Access
proposed rule and the ONC Cures Acts proposed rule. Because the proposed rule was published in the Federal Register on December 18, 2020, such an extension of the comment period would result in a February 16, 2021 deadline.

4. Supporting comment letters

A number of our HIE members, which are listed below, wish to add their individual support for the items raised in this comment letter. We would also like to draw your attention to the comment letters from other HIE members which have been separately submitted in response to CMS-9123-P, including from the New York eHealth Collaborative and Manifest MedEx (California). As you will see, the SHIEC HIE community is deeply engaged in health information exchange and interoperability across the country, and we stand ready to collaborate to achieve the goals of this proposed rule.

Thank you for the opportunity to provide feedback and for your continued commitment to improving interoperability and health information exchange. If you have questions please do not hesitate to reach out to SHIEC’s interim CEO, Lisa Bari at lisa.bari@strategichie.com.

Sincerely,

Lisa Bari
CEO (Interim)
Strategic Health Information Exchange Collaborative (SHIEC)

SHIEC HIE MEMBERS WHO JOIN THIS COMMENT LETTER
CORHIO, Colorado’s regional HIE
Health Current, Arizona’s statewide HIE
Midwest Health Connection, Missouri’s regional HIE
Nebraska Health Information Initiative, Nebraska’s statewide HIE