

September 06, 2022

Administrator Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1771-P
PO Box 8013
Baltimore, MD 21224-1850

Re: CMS 1770-P; Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amount

Dear Administrator Brooks-LaSure:

[Civitas Networks for Health \(“Civitas”\)](#), appreciates the opportunity to provide input on the CMS 1770-P; Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amount Proposed Rule (CMS-1770-P) (the “Proposed Rule”). Civitas is a national collaborative of regional and statewide Health Information Exchanges (“HIEs”) and Regional Health 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, 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 provide comment on the sections discussed below.

1. MIPS Quality Performance Category Health Equity Request for Information (“RFI”)

In the Proposed Rule, the Centers for Medicare & Medicaid Services (“CMS”) requests information on how to enhance and increase the number of measures that pertain to health equity within the Merit-Based Incentive Payment System (“MIPS”) and MIPS Value Pathways (“MVPs”). We commend CMS for its continued focus on health equity; as the vehicles for state and regional information exchange and health improvement, Civitas’ members are acutely aware of the inequities presented across the population.

As is well documented in the public health space, both race and ethnicity are strongly associated with prevalence and treatment patterns of numerous medical conditions. Furthermore, race and ethnicity data are important for public health entities who may begin to consider how to best allocate resources in order to support communities who may be at a higher risk for conditions. Regional health data organizations such as HIEs and RHICs can be valuable in this space because they not only serve as a centralized hub for health information sharing, allowing them to impose uniform requirements on data fields for race and ethnicity to the participant organizations who may be connected to them, but they are also able to work with state and public health entities to facilitate a dialogue on how to improve on the collection of these metrics.

In addition, it is challenging to gather accurate and complete race and ethnicity data by using a single data source for information. HIEs and RHICs can remedy this concern by combining and aggregating data from multiple sources to help increase health equity measures. Many of our stakeholders have already begun using HIEs/ RHICs in this manner. For example:

- Vermont utilized their HIE to address race and ethnicity relative to the COVID-19 pandemic. Early in the pandemic, Vermont Information Technology Leaders (“VITL”) worked with the Vermont Department of Health to provide access to its web-based provider portal to the state’s infectious disease epidemiology team. This access allowed the epidemiology team to perform case investigation and reporting, removed the burden of manual data collection from providers, and allowed the epidemiology team to cross-reference medical records to gain more robust race information about COVID-19 cases in Vermont. At the end of March, prior to using the portal, race was unknown in 73 percent of cases. Through their joint work they were able to bring that number down to just 8 percent. Looking forward, the epidemiology team intends to use the portal to perform case investigation on all of its reportable diseases.
- MN Community Measurement (“MNCM”) has been working for over a decade to collect and validate patient-level data on race, ethnicity, language, and country of origin (RELC) to measure and publicly report on health care disparities. MNCM has complete and validated patient-level data on RELC for about 95 percent of the patients included in its statewide quality measure reporting. MNCM’s approach was highlighted in a 2021 RAND Health Care report to the Assistant Secretary for Policy and Evaluation for its “thoughtfully chosen group of measures, incorporation of multiple important social risk factors..., ability to reliably distinguish performance among providers, clear focus on incentivizing achievement for at-risk beneficiaries, and choice to anchor disparities to the overall state average rather than the performance of a predetermined group.”

Civitas strongly encourages the use of HIEs/ RHICs in collecting and evaluating health equity data, as they are uniquely situated to fill gaps relative to race, ethnicity, and other demographic information. Additionally, Civitas would encourage that CMS should apply to MIPS the same “Screen Positive Rate for Social Drivers of Health” measure it has adopted for the HIQR program, to align measures across hospital and provider payment programs and allow CMS to achieve its stated goals in the proposed rule (p.1179). The alignment of these measures will promote data consistency in this space, ensuring that HIEs and RHICs can provide the most robust understanding of the needs of the community through the data they offer.

2. Proposed Changes to the Query of Prescription Drug Monitoring Program Measure

CMS is proposing to make its Electronic Prescribing Objective’s Query of Prescription Drug Monitoring Program (“PDMP”) a mandatory measure in its MIPS eligible clinicians participating in the Promoting Interoperability Performance Category; in addition, CMS is proposing to expand this measure to include not only Schedule II opioids, but also Schedule III and IV drugs. **We support this proposed change to make this measure mandatory and expanding it to include Schedule III and IV Drugs.** Many of our stakeholders manage the PDMPs in their states and/or integrate these data into a larger clinical profile of a patient through their HIEs. Understanding a patient’s medication history is critical to safe, effective, quality care, particularly when Schedule II, III, and IV drugs are prescribed and dispensed.

PDMPs have been enacted in all 50 states, enabling states to better track inappropriate requests for controlled substances, identify patients at-risk for substance use disorder, and to allow healthcare providers to intervene before a negative health outcome may occur. The net results in states that have employed PDMPs is decreased instances of drug abuse and increased individual-level care coordination. These results can be expanded further by requiring PDMPs to integrate with the local or statewide HIE. While some PDMP integration systems are cost prohibitive, there are multiple methods of connectivity available to many HIEs, including FHIR which allow for greater standardization and interoperability to reduce the burden of providers from having to access an external system;

there are integration solutions which are cost-effective. Many of our members, including the HIEs for Nebraska and Maryland, operate a PDMP on an HIE platform, realizing significant improvements that come with this integration. For example, integration has not only led to greater health outcomes for a state's patient population, but it has also led to increased reporting capabilities, expanded use of PDMP to report all dispensed prescription drugs as opposed to only controlled substances, medication reconciliation, lower adverse drug events, reduced readmissions, and increased patient safety. Including Schedule III and IV drugs would only amplify these benefits.

We also encourage CMS to acknowledge that certain MIPS eligible clinicians and PDMPs are subject to more stringent state or federal privacy laws—such as 42 U.S.C. 290dd-2 and 42 C.F.R. Part 2 (the federal Confidentiality of Substance Use Disorder Patient Records) (collectively, “Part 2”)— and may, therefore, be prohibited from redisclosing drugs used in connection with medication assisted treatment programs and other medication-based substance use disorder services. We encourage HHS to consider further changes to the Part 2 regulations that will allow this data to be used and disclosed for treatment, payment, health care operations and public health purposes without a patient's Part 2-compliant consent.

In sum, we support this proposal and encourage CMS to continue the development of this measure in future years beyond a “yes/no” measure to ensure clinicians continue to identify potential opioid use disorders, inform the development of care plans, and develop effective interventions. We also urge CMS to encourage the use of PDMPs in HIEs and other integrated platforms.

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

CMS is proposing to add a new Enabling Exchange Under TEFCA measure to the Medicare Promoting Interoperability performance category, which would provide eligible clinicians with the opportunity to earn credit for the Health Information Exchange Objective in the Promoting Interoperability Program if they are a signatory to a “Framework Agreement” under TEFCA, enable secure, bi-directional exchange of information to occur for all unique patients of eligible clinicians stored or maintained in the electronic health records (“EHR”), and use the functions of certified EHR technology (“CEHRT”). In addition, CMS is requesting comment on other ways it can help advance information exchange under TEFCA.

Although we strongly support a contractual framework, such as TEFCA, that would encourage more data sharing and interoperability among eligible hospitals and CAHs, at this time, we do not believe that TEFCA is mature enough to add such a measure. For example, the regional coordinating entity (“RCE”) has not finalized the application or relevant operating procedure to kick off the vetting and approval process for Qualified Health Information Networks (“QHINs”)- which are critical to establishing the technical framework to support TEFCA- based data exchange. The common agreement itself is only a data sharing framework; it requires a technical network and governing mechanism to operate. The RCE has stated that the vetting and approval process could take up to fifteen (15) months from the time an application is submitted, and the RCE is not expecting to approve all applicants. This is important because many QHINs may be approved on a provisional basis without having a live network on which providers may actively participate. Thus, TEFCA may not fully “go live” until late 2023.

We commend CMS for recognizing there are other methods of bi-directional exchange and proposing to incentivize them equally, since adding incentives specifically and exclusively around TEFCA could encourage eligible clinicians to shift from more mature and interoperable networks, leading to an overall decrease in interoperability. Civitas' stakeholders include many exchange collaboratives that are already functionally exchanging data through agreements which have previously been incentivized by the government, including HIEs and RHICs who are actively supporting community level aggregated data integration into the HIEs to promote a holistic view of a patient's needs and experiences. **We encourage CMS to continue to build upon incentivizing these prior investments while also promoting similar functionality that can be achieved through TEFCA for eligible clinicians not currently participating in similar arrangements once TEFCA is more mature.**

5. Continuing to Advance Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (“FHIR”) in the Quality Payment Program – Request for Information

We commend CMS for moving to utilization of FHIR to access expanded data sets in support of digital quality measures, since this continued shift will enable greater interoperability at lower provider burden. Many of our HIEs have experience collecting and exchanging data based on FHIR application program interfaces (“APIs”). Based on our experience, we recognize that, while the FHIR standard is extremely valuable, it is currently not being used at the level needed to support quality measurement in the way CMS envisions. To realize the benefits of FHIR APIs, the following steps should be pursued:

- Additional investment in data sources to be FHIR-enabled;
- Additional regulatory guidance on FHIR specifications and requirements to support digital quality measurement; and
- Additional enforcement measures on use of FHIR specifications and implementation guides, including enforcement for EHR system conformance.

Regional health data organizations like HIEs and RHICs are extremely valuable tools and mechanisms in obtaining data needed for digital quality measurement and should be incorporated into every aspect of CMS’ vision for digital quality measurement. The federal government invested heavily in HIEs and using them for obtaining information for digital quality measures is one means of ensuring a return on this investment. Because of their existing activities and infrastructure that streamlines and facilitates flows of clinical data, regional health data organizations are ideally positioned to support federal digital quality measurement reporting requirements with minimal additional burden on providers. In addition, HIEs and RHICs may be able to improve the completeness and accuracy of quality measures by leveraging the ability to combine clinical data from multiple providers, where appropriate. For example, results for quality measures like eye exams for patients with diabetes and colorectal cancer screening may be complete and more accurate if regional health data organizations can combine data from multiple provider organizations for relevant patients.

We encourage CMS to consider speaking with our stakeholders about how HIEs and RHICs can be utilized for data flow options and digital measure data collection, further reducing provider burden.

6. Supporting Comment Letters

A number of our HIE and RHIC members, 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 this proposed rule, including from the [XXX]. As you will see, the Civitas 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 comment. 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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Sign-on Organizations:

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Connexus
CyncHealth
MN Community Measurement
Velatura Public Benefit Corporation

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