

October 5, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building 200 Independence Avenue, S.W.,
Room 445-G
Washington, DC 20201

Re: Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

Dear Ms. Verma,

The New York eHealth Collaborative (NYeC) is pleased to provide these comments in response to the proposed Year 2021 rule.

NYeC is a 501(c)(3) and New York's State Designated Entity (SDE) charged with the governance, coordination, and administration of the Statewide Health Information Network for New York (SHIN-NY). In this capacity, NYeC works in a public/private partnership with the New York State Department of Health (NYS DOH) on the development of policies and procedures that govern health information exchange through the SHIN-NY. The SHIN-NY is a "network of networks" consisting of six Qualified Entities (QEs) also known as Regional Health Information Organizations (RHIOs) and a statewide connector that facilitates secure sharing of clinical data from participating providers' electronic health records (EHRs). The SHIN-NY is a public utility that connects all hospitals in the state, is used by over 100,000 healthcare professionals, and serves millions of people who live in or receive care in New York. NYeC also served as a Regional Extension Center and leads a variety of programs designed to help providers select, implement, and leverage EHRs and health information exchange to transform healthcare.

During the COVID-19 Public Health Emergency, Health Information Exchanges and Networks (HIEs/HINs) such as the SHIN-NY have demonstrated their large role in advancing public health outcomes and will continue to improve both the quality and value of healthcare in the future. We applaud CMS for their continued commitment to improving quality, promoting interoperability, and demonstrating HIE value in order to improve health outcomes.

NYeC appreciates the opportunity to provide comments and input on the proposed rule. Highlights of our comment letter include:

Telehealth

- Support changing the definition of direct supervision to allow the supervising physician to be remote and use real-time, interactive audio-video technology, but recommend making the change permanent
- Promote use of HIEs to provide interoperability between telehealth data and data collected from in-person visits

Quality Payment Program (QPP), MIPS Value Pathways (MVP)

- Support the inclusion of the 5th MIPS Value Pathways (MVP) Guiding Principle stating that MVPs should support the transition to digital quality measures
- Continue to prioritize interoperability and health information exchange as a foundational requirement in the new MVP Program
- CMS could strengthen quality measurement by further promoting HIE usage and learning from New York's experience

MIPS Promoting Interoperability Performance Category

- Support extending the PDMP measure under the electronic prescribing objective as optional
- Strongly support the alternative HIE measure under the health information exchange objective, with some clarifications
- Recommend that CMS continue to include this as a required measure in the MVP program and request that CMS adopt a complementary measure in the Inpatient Promoting Interoperability Rules
 - Suggest phasing in language on every patient encounter and beginning with transitions or referrals for new patients only
 - Suggest that CMS allow state Medicaid agencies, if they desire, to select a state designated HIE to meet this requirement
 - Clarify that applicable law applies to each attestation statement
 - Modify "every record stored within the EHR" to the minimum data required for exchange as defined in the USCDI
 - Critical need for investment, support, and incentives for non-Meaningful Use (MU), left-behind sectors including LTPAC to truly transform healthcare and improve quality of care for Medicare beneficiaries
 - Suggest that CMS provide a lag period between when Health IT Developers adopt the 2015 Cures Update and when providers must be onboarded to the Cures Update criteria

NYeC looks forward to continued collaboration with CMS.

Sincerely,



Valerie Grey
Chief Executive Officer

Telehealth and Other Services Involving Communications Technology (section II.D.)

Direct supervision via Telehealth

NYeC supports and appreciates CMS's efforts to promote the use of telecommunication technologies in delivering patient care. The COVID-19 crisis has highlighted both the need and the potential for technology to play an enhanced role in the delivery of healthcare virtually.

CMS proposed a temporary change to the definition of Direct Supervision to allow the supervising physician to be remote and use real-time, interactive audio-video technology. NYeC supports the proposed change in definition and advocates for CMS to make this change permanent. NYeC recently conducted a survey of Medicaid Eligible Professionals connected to the SHIN-NY to gauge use and value of telehealth services. Results show that telehealth is an effective tool for these providers and the majority of physicians plan to continue to use telehealth in their practices after the public health emergency ends. As CMS notes, the definition of Direct Supervision in §§ 410.26 and 410.32(b)(3)(ii) currently does not require the physician to be present in the room when the service or procedure is performed. Therefore, making this change permanent is a relatively modest action that will enhance patient access to care and increase flexibility for health care providers without significantly changing the way care is delivered today.

In response to CMS' request for comment on additional guardrails or limitations to ensure patient safety, NYeC believes that telehealth platforms and data collected from telehealth visits should be subject to the same privacy and security rules as required under HIPAA. CMS could also leverage ONC's recently updated Security Risk Assessment (SRA) Tool to help healthcare providers conduct a security risk assessment that includes an assessment of telehealth platforms.¹

Further, as we encourage the use of more robust telehealth technologies in every-day patient care, it is critical to promote interoperability between telehealth data and data collected from in-person visits. Currently, providers report needing to manually enter telehealth data into the electronic health record (EHR). HIEs are in the unique position to allow for such interoperability to occur as well as ensure providers can access patient data in support of a telehealth encounter without placing additional burden on the clinician or the patient to facilitate the exchange.

Updates to CY 2021 Quality Payment Program (section IV)

MIPS Value Pathways (MVP)

We appreciate CMS's efforts to ease the transition to the MVP Program by delaying implementation until at least the 2022 performance year. As part of CMS's broad goal to address clinician burnout, we encourage the agency to provide flexibility to providers during the early adoption and evolution of these new specialty measure sets.

The proposed updates to the MVP guiding principles are reflective of CMS' goals and the proposed development criteria. As called out in the development criteria, we urge CMS to continue to prioritize interoperability and health information exchange as a foundational requirement in the new MVP Program.

¹ <https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool>

We applaud CMS for creating a collaborative process for updating guiding principles and development criteria for MVPs. We encourage the agency to continue to make sure the process is open, transparent, and inclusive of diverse stakeholders from across the industry.

Finally, we support the inclusion of the 5th MVP Guiding Principle stating that MVPs should support the transition to digital quality measures. As discussed below, HIEs are a trusted source of information from multiple locations and are in the best position to meet these goals of reducing provider burden.

Quality Reporting and Third-Party Intermediaries

We support CMS' proposal that third-party intermediaries be allowed to support the reporting of MVPs. HIEs have the unique capacity to aggregate data from across multiple sources and have the capacity to provide more consistent, accurate, and complete reporting. We applaud CMS' goals to prevent inaccurate or misrepresentative reporting and feel that that CMS could accelerate these goals by explicitly incentivizing reporting via HIEs. Some examples of how HIEs currently support quality measures include:

- Two Qualified Entities in the SHIN-NY (HEALTHeLINK and HealtheConnections) are approved 2020 Qualified Registries, authorized by CMS to submit Quality Measures, Promoting Interoperability Measures, and/or Improvement Activities on behalf of MIPS eligible clinicians, groups, and/or virtual groups for purposes of MIPS for the 2020 performance year.
- One Qualified Entity (Bronx RHIO) has been performing Healthcare Effectiveness Data and Information Set (HEDIS) measure-related calculations and reporting for two Performing Provider Systems (PPS) for five years. This HIE has also developed over 40 clinical quality measures for two PPSs and an ACO to calculate measure performance at both the provider and payer level.
- All Qualified Entities provided data for PPS quality measures in supporting the medical record review process.
- Four Qualified Entities (Hixny, HEALTHeLINK, HealtheConnections, Healthix) have generated reporting user interfaces that providers have used for both gaps in care as well as quality measurement reports.

Further, the SHIN-NY has developed quality measurement capabilities with pilots as part of our State Innovation Model with Centers for Medicare & Medicaid Innovation. These pilots led to collaboration with the National Committee for Quality Assurance (NCQA) on a Data Aggregator Program, which enables HIEs to provide HEDIS Supplemental Data for health plans, including Medicare Advantage and NYS Medicaid Managed Care Plans.

Three QEs (Hixny, HEALTHeLINK, HealtheConnections) will be the first HIEs in the nation to obtain a certification that demonstrates that the HIE passed certain robust data validation processes. This alleviates the burden on health plans of having to perform their own audit of data received from an HIE and on providers from having to respond to data requests from health plans. We believe that an opportunity exists for CMS to leverage these NCQA processes and apply them towards data validation and audit requirements of third-party intermediaries.

Finally, HEALTHeLINK has been approved by CMS as a “data aggregator” for Comprehensive Primary Care Plus (CPC+) and will be using Medicare Fee-for-service (FFS) claims to create quality measures for providers in support of the CPC+ program. This is a great start, but we encourage CMS to make all the FFS Medicare claims available to HIEs. This would further the ability of HIEs to support quality objectives and would have multiple benefits that are central to CMS’s goals, including reducing long-term provider burden, ensuring data integrity, and promoting interoperability.

MIPS Promoting Interoperability Performance Category

Electronic Prescribing Objective

Query of Prescription Drug Monitoring Program (PDMP) Measure

We support CMS’s proposal to extend the measure as optional in CY 2021 to allow time for further progress around efforts to integrate PDMPs into EHRs. New York has a robust and operational PDMP (I-STOP) that is presently queried by providers at a rate of over 18 million queries annually. However, these queries are not typically performed via CEHRT but rather through a process that exists outside of the clinician’s EHR via a state-secured portal. While the ultimate goal is to support widespread EHR integration with the PDMP, this level of integration is not yet in place. Considering the current state of EHR to PDMP integration, it is expected that comprehensive statewide implementation of PDMP query via CEHRT will take significant time to implement across all providers and EHRs in the state.

Health Information Exchange Objective

Engagement in Bi-Directional Exchange Through Health Information Exchange (HIE)

NYeC strongly supports CMS’ proposal of an alternative measure for bi-directional exchange through an HIE under the Health Information Exchange objective. Given that greater use of HIEs for bi-directional exchange will immediately contribute to enhanced care coordination across settings, NYeC believes this measure should not be optional for 2021. Additionally, we recommend that CMS continue to include this as a required measure in the MVP program and request that CMS adopt a complementary measure in the Inpatient Medicare and Medicaid Promoting Interoperability programs.

- 1. Do these statements reflect appropriate expectations about information exchange capabilities for eligible clinicians that engage with HIEs capable of facilitating widespread exchange with other health care providers?*

This new optional measure would require that bi-directional exchange occurs for all patients and for all patient records without exclusion, exception, or allowances made for partial credit. This is broader than the current measure, which includes only new patients and known transitions or referrals that occur during the performance period. While clinicians are participating in HIEs at unprecedented levels, they are not yet participating in bi-directional exchange for “every patient encounter, transition or referral, and record stored or maintained in the EHR.” We suggest phasing in language on every patient encounter and beginning with transitions or referrals for new patients only. This is more reflective of where providers currently are with HIE integration and will encourage more robust future participation.

In developing this new requirement, CMS should clarify that none of the language in the attestation statements conflict with applicable state law and guidance. For example, New York State is an “opt-in”

state and requires a patient's written affirmative consent for providers to access their data via the SHIN-NY. Further, SHIN-NY participants abide by statewide policy guidance that sets certain criteria for participation and data access. We are also aware of several HIEs that have differing state laws and guidance. We suggest CMS modify the attestation language to account for such variation.

Finally, we appreciate CMS' reference to CEHRT in the third attestation statement and suggest that CMS clarify that the minimum set of data needed to meet this measure's requirement for bi-directional exchange align with the CEHRT criteria for the Common Clinical Data Set (CCDS) soon to be US Core Data for Interoperability (USCDI). The USCDI serves as the baseline set of data required for interoperability and is what EHRs are commonly exchanging with HIEs today.

2. How should CMS effectively identify those HIEs that can support the widespread exchange with other health care providers?

CMS could allow each state Medicaid agency, if they desire, to select a state-based mechanism that would meet this requirement (i.e. participation in a state designated HIN/HIE). CMS would then deem participation in that mechanism as one way for providers in the state to demonstrate compliance with the new requirement.

CMS could also adopt metrics to define widespread exchange or broad network (as stated in the attestation statements). Such metrics could be based on participation or usage, but should encompass a wide network of providers, including those not traditionally eligible for Meaningful Use. For example, CMS could define a broad network as one in which HIEs exchange data among a diverse array of stakeholders outside of traditional practices (i.e. LTPAC, behavioral health, pharmacies, CBOs, etc.). Additionally, because of this wide span and variation, particularly in resources, CMS could define a broad network as one that comprises a significant preponderance of the Medicare beneficiary's care based on the ability of the care team to receive a patient record through an HIE.

3. How are eligible clinicians currently using CEHRT to exchange information with HIEs, and do the proposed attestation statements allow for different ways health care providers are connecting with HIEs utilizing certified health IT capabilities?

HIEs are currently interacting with health care providers using certified health IT in a variety of ways. NYeC appreciates that CMS allows for substantial flexibility in how health care providers use certified health IT to exchange data using HIE. The flexibility provided in the proposed rule by CMS allows for maximum interoperability growth and is likely to result in more clinicians using HIEs in their communities.

We strongly encourage CMS to consider policy levers and financial incentives to support providers in adopting certified EHRs and participating in the electronic exchange of health information, particularly the "left behind" sectors (i.e. long-term and post-acute care, behavioral health, and pharmacies) that were not eligible for meaningful use. Many post-acute (PAC) and home and community-based service providers (HCBS) avoid adoption of EHRs due to lack of resources, staff, and education or assistance on how to meaningfully use these products. Success in value-based care and health information exchange will require bringing a broader array of healthcare providers and non-traditional entities into the electronic data infrastructure fold. New York is focused on the role of social determinants of health and we see many opportunities for alignment and collaboration with HIEs to improve health outcomes in the future.

In section III.M. of this proposed rule, CMS proposed that after a period of 24 months, all eligible clinicians and hospital will have to update their certified technology to the 2015 Edition Cures Update. As the proposed rule points out, this is meant to align with ONC's Cures Rule Update, which also gives Health IT Developers 24 months to update their technology (although it should be noted that ONC provided a 3-month enforcement discretion on this requirement²).

We strongly suggest that CMS provide a sufficient lag period between when Health IT Developers adopt the new certification criteria and when providers must begin use. In our network there are still a handful of providers who are unable to participate in the Promoting Interoperability programs because they are still operating on 2014 CEHRT. We anticipate that many developers will require the full 27 months to upgrade their technology and therefore will only begin rolling it out to providers after the end of that period. Developers will then be busy with upgrades and it may take several more months to update all user systems. We believe that providing an additional, delayed phase-in period for providers to update to the new certification criteria will ensure widespread participation and continuous growth across provider networks.

² https://www.healthit.gov/cures/sites/default/files/cures/2020-04/Enforcement_Discretion.pdf