

January 4, 2021

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

Re **CMS-9123-P: [Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications; Proposed Rule](#)**

Dear Administrator Verma,

The New York eHealth Collaborative (NYeC) is pleased to provide these comments in response to the Reducing Provider and Patient Burden by Improving Prior Authorization Processes and Promoting Patients' Electronic Access to Health Information Proposed Rule (Proposed 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.

As a leader in New York State (NYS), the SHIN-NY has created a strong statewide foundation for health IT and interoperability. We support CMS' goals to advance interoperability through standards-based APIs, but caution that APIs in and of themselves will not solve all of the challenges to seamless data exchange. Meaningful exchange via APIs requires robust data governance, coordination, and a foundation of reliable data. Health Information Exchanges (HIEs) and Health Information Networks (HINs), like the SHIN-NY, have a proven history of providing these services and should be central to any nationwide interoperability strategy.

Our comments and recommendations regarding the Proposed Rule reflect NYeC's continued commitment to partnering with the Administration to develop policy solutions that will support a cohesive, nationwide strategy that leverages HIEs to enable secure, meaningful, and scalable data sharing across all sectors of care. Highlights of our comments include:

API Proposals

- **Implementation Guides:** NYeC supports CMS' API proposals but cautions that further refinement and testing of the adopted implementation guides will be necessary before they can function as CMS envisions. CMS must first build on and continue to invest in existing efforts to integrate claims and clinical data in-order-to receive the most complete, accurate picture of a patient's health and allow for seamless exchange between all entities involved in a patient's care.
- **HIEs/HINs as Intermediaries:** NYeC strongly advocates for CMS to maintain flexibility for the use of HIEs to facilitate exchange between and among payers and providers. At a minimum, CMS should specifically mention that HIEs/HINs may be used as intermediaries and sources to develop, populate, or facilitate meaningful exchange between APIs.
- **Patient Access API Privacy Attestation:** We applaud CMS' proposal to require a privacy attestation from third-party apps requesting data from payers. We request that CMS coordinate with ONC to clarify that actors subject to ONC's Information Blocking Rule may undergo a similar process before responding to requests from third-party apps, without implicating Information Blocking.

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- **Data Segmentation/Tagging:** We strongly believe that the best approach to coordinated and informed clinical decision support is for the provider to have access to the entire patient record, including sensitive health information, based on the patient's preferences. However, the lack of broad stakeholder consensus and technological solutions on data tagging methods has led to significant silos that need to be addressed as a top priority. It will require significant stakeholder engagement as well as resources to implement.
- **Prior Authorization:** NYeC supports the proposal for payers to implement and maintain the Prior Authorization Support (PAS) API but does not believe it should be a requirement in the MIPS and Promoting Interoperability (PI) Programs until the technology has been tested, refined, and broadly adopted by certified Electronic Health Record (EHR) vendors under ONC's Health IT Certification Program.
- **Fax Machines:** NYeC believes that any solution to reduce use of the fax machine must strike a balance to ensure that its elimination does not create unintended burdens or

eliminate options for exchange among providers without EHRs or broadband access. NYeC recommends that CMS leverage and enhance existing investments and infrastructure in HIEs to reduce further fragmentation and close the digital divide.

- **Behavioral Health (BH):** NYeC encourages CMS to continue to dedicate resources for BH and other “left behind” sectors that focus on financial incentives, regulatory relief, and technical assistance for EHR adoption and HIE participation. EHR adoption must be expanded among BH providers (as well as other left behind sectors) before FHIR-based API exchange can be meaningfully utilized. NYeC urges CMS to implement the authority granted under the SUPPORT for Community and Patient Act, which authorizes the Center for Medicare and Medicaid Innovation (CMMI) to test incentive payments to BH providers to adopt Certified EHR Technology (CEHRT).
- **Social Determinants of Health (SDH) and Community-Based Organizations (CBOs):** The SHIN-NY is increasingly prioritizing CBO participation and exchange of SDH data among our participants. NYeC has recently developed policies aimed at expanding SHIN-NY participation among non-HIPAA entity CBOs with the ultimate goal of exchanging standardized SDH data to help improve value-based care (VBC). NYeC encourages CMS to coordinate with ONC and other federal agencies, as well as industry stakeholders, to foster broader understanding and clarity of the policies around SDH data sharing, as well as promote greater collection, standardization, and integration of SDH data.

NYeC looks forward to continued collaboration with CMS in advancing nationwide interoperability, improving healthcare delivery and the health of our communities, and facilitating patient access to their health information.

Sincerely,

A handwritten signature in black ink that reads "Valerie Grey". The signature is written in a cursive, flowing style.

Valerie Grey
Chief Executive Officer (CEO)
New York eHealth Collaborative

Detailed Comments

Application Programming Interface (API) Proposals

Overall, NYeC supports this Proposed Rule and shares CMS' goals of moving the industry towards more coordinated, interoperable, and patient-centered care through the use of standards-based APIs. We further agree that payers play a critical role in interoperability and in providing access to complete and accurate information. However, we urge CMS to be cautious and thoughtful in the implementation of this rule and to not duplicate or disrupt existing systems and infrastructure that are currently facilitating exchange between and among payers and providers today.

While FHIR APIs have the capability to advance interoperability, they are not turnkey solutions. Rushed implementation of the adopted implementation guides, which are still new and have not been thoroughly piloted at the scale proposed in this rule, could compromise testing and refinement. It will take significant resources, coordination, standards development, and most of all a foundation of meaningful, complete, and accurate data to make this work the way CMS envisions.

Despite acknowledgments in the Patient Access and Interoperability Rule released earlier in 2020 and in the CY 2021 Quality Payment Program, this Proposed Rule makes no mention of Health Information Exchanges (HIEs) or Health Information Networks (HINs), which have demonstrated significant value in facilitating exchange across the care continuum for over a decade.

Many HIEs have robust repositories of clinical and claims data and govern transactions through common sets of policies and standards for data exchange and measurement. HIEs, such as the SHIN-NY, have the added value of long-standing relationships with stakeholders across the care spectrum— including payers, providers, public health agencies, health IT developers, and state and local governments— and are able to leverage these relationships to continuously learn and evolve with the ever-changing healthcare landscape. For instance, NYeC convenes several advisory groups, including a health plan group which advises NYeC on numerous issues and serves as a resource in this area and many others.

Rather than expanding and reinforcing existing infrastructures and processes, the Proposed Rule's requirement for payers to implement and maintain these APIs will necessitate separate, additional integrations that both providers and payers will need to build. As such, we urge CMS to specifically call out and encourage the use of HIEs/HINs as intermediaries as well as sources to develop, populate, or facilitate meaningful exchange between APIs.

Patient Access API

NYeC strongly supports CMS' proposal to require payers to establish, implement, and maintain a process for requesting an attestation from a third-party app developer that indicates the app has

a privacy policy and adheres to certain privacy provisions. We agree with CMS' proposal of ensuring patient options to use and share their data, but request that CMS work with ONC to make the same allowance for actors under information blocking when responding to a request from a third-party app. While we understand that CMS does not have authority over the Information Blocking Rule, we note that the two agencies have previously coordinated regarding the interoperability rules, and we believe that further coordination is appropriate here. If finalized for payers, NYeC encourages CMS to work with ONC to develop clear guidance stating that a request for privacy policy attestation would be an allowable course of action for an actor to take when responding to a request for electronic health information from a third-party app.

It is vital that CMS, ONC, and other federal agencies promote alignment and consistency across and between healthcare entities subject to different regulatory authorities in order to reduce confusion from consumers to providers and health plans. Such alignment makes sense from a patient perspective: if the attestation requirement results in a particular patient telling a health plan not to share their data with a particular app, then presumably that patient would not want their HIE/HIN data shared with that app either. As such, the rules that apply to payers should be consistent with the rules that apply to HIEs/HINs and other actors under Information Blocking.

Payer-to-Payer API and Provider Access API

As discussed above, this Proposed Rule does not acknowledge the role of HIEs in supporting interoperability. NYeC encourages CMS to maintain the flexibility from the previous Interoperability and Patient Access Rule to allow payers to use HIEs to facilitate exchange for both the Payer-to-Payer and Provider Access APIs.

HIEs can serve as a central source for providers and payers to obtain aggregated data across all entities engaged in a patient's care and many already have the capacity to support payers in meeting these requirements today. Further, HIEs provide the added capability of monitoring privacy and security, quality, and completeness of the data exchanged; utilizing the data to perform and report on quality measures that provide insight into health outcomes; and measuring network transactions to understand trends in use.

Over the past decade, Qualified Entities (QEs) in the SHIN-NY have collected and aggregated robust repositories of clinical data from over 100,000 health professionals in New York State (NYS). Further, the SHIN-NY has a long history of payer participation. Recently, the SHIN-NY has made claims integration a priority and is already taking steps to integrate Medicaid claims data with clinical data statewide. Below are some ongoing SHIN-NY initiatives to facilitate exchange between providers and payers:

- Three QEs (Hixny, HEALTHeLINK, HealtheConnections) are first in the nation to obtain a certification from the National Committee for Quality Assurance (NCQA) to provide Healthcare Effectiveness Data and Information Set (HEDIS) supplemental data to health plans. Through this NCQA Data Aggregator Program, the QEs have developed a nationally accredited and certified data set that has undergone a rigorous audit and data validation

process. This certification alleviates the burden on health plans of having to perform their own chart reviews as well as the burden on providers of having to respond to data requests from health plans.

- Four QEs (Healthix, Bronx RHIO, Hixny, and HealtheConnections) participated in the Claims Integration Pilot Program (CLIP) demonstration project with New York State Department of Health (NYSDOH) to investigate the potential benefits of integrating Medicaid claims and clinical information on Medicaid patient outcomes with the eventual goals of creating a more cost-efficient and effective Medicaid program.
- One of our QEs (HEALTHeLINK) has been approved by CMS to use Medicare Fee-for-service (FFS) claims to create quality measures for providers in support of the CPC+ program.

Through these initiatives, the SHIN-NY has shown that we can play a vital role in meaningfully integrating clinical and claims data to facilitate care coordination and quality measurement, thereby supporting better value-based care. NYeC urges CMS to build on and continue to invest in existing efforts to integrate claims and clinical data in order to receive the most complete and accurate picture of a patient's health and allow for seamless exchange between all entities involved in a patient's care.

Requests for Information

Methods for Enabling Patients and Providers to Control Sharing of Health Information

Allowing for patients and providers to have granular control over the sharing of health information has implications that can impact a patient's overall treatment. There is not widespread agreement on standards for identifying specific types of health information. Further, the variety of permutations with respect to privacy policies at both the federal and state levels for different types of information is not easily understood by patients despite that information being necessary for providers to make informed and appropriate care decisions. These pose some very real technical considerations including the ability of EHRs and HIEs to appropriately classify the information that would then increase the granularity for patient preference.

Ideally, the best approach for enabling patients and providers to control sharing of health information would be the acknowledgement that all of a patient's health information, including information currently defined as sensitive, is critical to good patient care and that providers need the ability to have such access based on patient preferences. That said, having the ability to segment the data would provide greater patient control, as well as greater ability to use the data for other purposes, including research.

Electronic Exchange of Behavioral Health Information

NYeC has long advocated for increased engagement of the left behind sectors—e.g., BH, long term and post-acute care (LTPAC), community-based organizations (CBOs), emergency medical services (EMS), and pharmacies—to advance interoperability across the entire continuum. As CMS discusses in the Proposed Rule, these sectors have historically lagged behind hospitals and traditional clinical practices in their adoption of health IT and typically avoid adoption of EHRs due to a lack of requirements, incentives, IT staff, and education or assistance on how to meaningfully use these products.

While NYeC fully supports the goal of advancing electronic data exchange between BH providers, we believe EHR adoption needs to be expanded across this sector (as well as other left behind sectors) before FHIR-based API exchange can be meaningfully utilized. In order to function as envisioned, FHIR APIs must be populated with a foundation of standardized, quality electronic data. Many BH providers still collect and store patient health information using paper records and exchange these records via fax. Furthermore, due to the nature of BH care delivery, much of the data collected by BH providers via notes or assessments is presented in text or document format rather than as discrete data. FHIR APIs still have limited maturity in their ability to support document exchange, free text in notes, and sensitive data tagging. NYeC is not aware of any current, widespread efforts to develop profiles or implementation guides specific to BH exchange. As such, NYeC encourages CMS to continue to support investments in EHR adoption among BH providers to facilitate the collection and capture of BH data in a standardized, electronic format, as well as incentivize connection to HIEs in order to supplement and integrate BH data into a patient’s longitudinal care record.

NYeC encourages CMS to dedicate resources to left-behind sectors that focus on financial incentives, regulatory relief, and technical assistance that would further allow states to invest in EHR adoption and standardized data collection among these sectors. The SHIN-NY has successfully leveraged both federal and state funding over the past decade to support EHR adoption and SHIN-NY participation. For example:

- NYeC served as an ONC-designated Regional Extension Center, helping providers select, implement, and leverage EHRs and health information exchange to transform healthcare. This program evolved into our Healthcare Advisory Professional Services (HAPS), which has supported over 10,000 providers in practices of all sizes in implementing technologies and processes to improve healthcare delivery across NYS.
- In 2017, NYS created a \$10 Million Behavioral Health Information Technology (BHIT) grant to assist HCBS providers to adopt or upgrade their EHR systems. Over a two-year period, NYeC was able to assist 114 organizations across 52 counties in NYS by providing technical assistance to implement their EHR systems before the program ended. Further investments in such efforts would yield greater adoption.

- NYS DOH, with support from CMS through HITECH, established the Data Exchange Incentive Program (DEIP) to increase HIE adoption across the state for Medicaid providers. The program, which is administered by NYeC, helps to offset the cost of connecting to the SHIN-NY for eligible organizations, including: practices with meaningful use providers, BH organizations, EMS agencies, and pharmacies. BH organizations are required to contribute five data classes to the SHIN-NY: demographics, diagnoses, encounters, procedures, and individualized service plans. Since its fruition, the DEIP has helped over 1,200 organizations across NYS participate in the SHIN-NY. This program was funded by HITECH and will end this year.
- NYeC, in collaboration with New York University and the managed care technical assistance center (MCTAC), have convened a focus group with BH providers to develop data driven solutions that combine clinical and claims data sources and utilize HIEs to support such integration.

NYeC encourages CMS to continue to invest in the infrastructure created through these programs and align incentives and requirements between MU-eligible physicians, payers, and the left behind sectors. We have observed more and more BH vendors retiring their certifications rather than updating to the 2015 Edition Health IT Certification Criteria due to the lack of incentives and requirements to do so. CMS should therefore work with ONC to encourage non meaningful use providers to adopt certified EHR technology (CEHRT) by developing certification requirements targeted at health IT developers that support BH and other left behind sectors.

NYeC also urges CMMI to implement the authority granted under the SUPPORT for Community and Patient Act, which authorizes CMMI to offer incentive payments for BH providers that implement EHRs.

Continued support for and alignment between these investments is the only way to create a truly coordinated, interoperable, learning health system that has the capacity to improve patient and population health, lower costs, and empower patients.

Reducing Burden and Improving Electronic Information Exchange of Prior Authorization

NYeC applauds CMS' ambitious efforts in this rule to streamline workflows and decrease burden associated with current prior authorization processes. NYeC encourages novel approaches to solving some of the unintended negative consequences associated with the historical prior authorization process.

While we support the proposal for payers to implement and maintain the Prior Authorization Support (PAS) API, we do not believe the technology is mature or widespread enough yet to include as a requirement in the MIPS and Promoting Interoperability (PI) Programs. Eligible Hospitals and Clinicians in these programs are reliant on the capabilities of their health IT and Electronic Health Record (EHR) vendors, and we have seen that many providers are unable to

meet even the current program requirements due to challenges with their levels of health IT adoption.

Before CMS considers adding the PAS API as a measure for providers, we encourage CMS to collaborate with ONC to include the same requirements for EHR vendors in the ONC Health IT Certification Program. Once the technology has been tested, refined, and broadly adopted by EHRs, CMS should then consider a parallel measure for providers participating in the MIPS and PI Programs.

Reducing the Use of Fax Machines

NYeC supports CMS in its ongoing campaign to “axe the fax” and reduce and ultimately eliminate use of fax technology in the healthcare ecosystem. As CMS discusses at length, continued use of the fax machine in healthcare creates considerable inefficiencies that limit the industry’s ability to reach true interoperability.

However, despite all of the progress state and federal governments have made in advancing adoption of health IT, the fax machine is still deeply entrenched in health care workflows. For example, even large hospital systems in NYS with advanced EHRs and reliable high-speed internet access report using a centralized fax machine to facilitate the coordination and scheduling of referrals and services. Such processes are often made necessary because many left-behind and rural providers (who may be sending or receiving referrals) are still reliant on fax machines due to lack of funding and incentives to adopt health IT.

Further, many providers still use fax to communicate with patients and families, especially those with limited access to broadband and low technical literacy. Even in NYS, which ranks #2 in the country in state broadband access, approximately 419,000 residents have low or no wired internet access.¹

NYeC agrees with CMS that any solution must strike a balance to ensure that the elimination of fax technology does not create unintended burdens or eliminate options for those without internet access or EHRs. Increased and sustained incentives targeted at last mile adoption of health IT or connection to an HIE can help to ease this transition. CMS should also work with states to prioritize access to high-speed internet for patients in remote care settings.

The fax machine is an unfortunate reality of the healthcare ecosystem that is an impediment to true interoperability. As we discuss throughout this letter, along with incentivizing health IT adoption among providers and left-behind sectors, CMS can leverage and enhance existing investments and infrastructure in HIEs to reduce use of the fax, close the digital divide, and ultimately improve care.

¹ Cooper, Tyler. "Internet Access in New York: Stats & Figures." *Broadband Now*. Broadband Now, 06 Feb. 2020. Web. Accessed 24 Mar. 2020. <<https://broadbandnow.com/New-York>>

Accelerating the Adoption of Standards Related to Social Risk Data

Federal and state-based policies, including value-based care (VBC) initiatives, are progressively recognizing the influence of social determinants on health outcomes. The SHIN-NY has increasingly prioritized CBO engagement and the incorporation of Social Determinants of Health (SDH) information into a patient's medical record. Based on NYS DOH's Bureau of Social Determinants of Health CBO Directory, over 250 CBOs participate within the SHIN-NY. QEs provide services to these CBOs, including access to QE clinical viewers, results delivery, and event notifications.

Despite this increasing focus, significant barriers and challenges to the exchange of social risk and social needs data still exist across the healthcare ecosystem. Some of the key challenges include:

- The needs, capacities, and even definitions of CBOs vary greatly within and among states. NYeC is constantly working to shore up data sources for accurately and effectively tracking CBOs across NYS, and are currently collaborating with 2-1-1 New York, Inc. (an affiliate organization of United Way of NYS) on a more expansive CBO directory statewide. Our research on various existing CBO directories, which are often used as community resource referral technology platforms, has found that each rely upon unique standards (i.e. taxonomies) that make connections and referrals across networks difficult.
- Much like BH, funding for CBOs to adopt health IT has been fragmented, resulting in the use of divergent software and systems that solve for either niche or one-off use cases. Much of the funding for health IT adoption for CBOs comes from state or federal grants— many short-term and each with unique goals and requirements— resulting in disjointed, conflicting, and unsustainable processes.
- SDH data is currently captured in unstructured and non-standardized formats with gaps and overlap between existing terminologies and code sets. While we applaud the innovative initiatives to collect SDH data in health care settings, such as CMMI's Comprehensive Primary Care Plus Model and CMS's social risk assessment tool, more work must be done to accurately reflect the wide range of social risk factors as well as standardize their format across medical and social service organizations. The lack of structured, standardized formats of SDH data inhibits the ability to normalize, exchange, and aggregate the data regardless of the data source.

The SHIN-NY and its QEs are uniquely positioned to support CBOs and accelerate the adoption of SDH data. Below are just a few of the many SHIN-NY examples of CBO engagement and promotion of SDH data already underway across NYS:

- The Bronx RHIO is engaged in several initiatives to address SDH and CBOs, including obtaining SDH data elements such as homeless/housing status, employment status, and correctional health registration data. Bronx RHIO is also participating in the Bronx FUSE Initiative, which will identify homeless high utilizers in health plans and set them up with

housing opportunities with coordination by the Corporation for Supportive Housing (CSH).

- Healthix, located in the New York City area, is working on several CBO & SDH involved initiatives, including a pilot project to standardize and incorporate SDH screenings from Federally Qualified Health Center (FQHCs).
- Hixny, in the Capital Region of NY, is working in partnership with the Alliance for Better Healthcare PPS on a Consumer Directed Exchange project aimed to assist increase access to care for vulnerable populations.
- The Rochester RHIO is adding other data sources into their HIE to support clinical quality care, including data from corrections and law enforcement, housing, and public health.
- HealtheConnections, in the Central NY region, has created the myData Platform, which is in the beginning stages of adding an SDH report that incorporates ICD-10 Z-codes. It is anticipated that the PCMH Registry and the Preventive Care Registry will incorporate the SDH table into the User Interface to assist with care management opportunities at the practice level.

These initiatives are just the beginning. As evidence of our commitment to CBO engagement and SDH data exchange, the SHIN-NY Policy Committee recently recommended policy updates to facilitate further CBO participation in the SHIN-NY. These policy modifications include allowing non-HIPAA entities access to the SHIN-NY (with privacy and security safeguards) and revising the definition of Care Management to better reflect CBO use cases.

Further, NYS and the SHIN-NY understand the imperative for SDH data in supporting VBC. NYS requires that all value-based purchasing Level 2 (Shared Savings) and 3 (Capitation) arrangements must implement, at a minimum, one SDH intervention and must also contract with at least one Tier 1 CBO. NYeC convenes a CBO Advisory Group which advises NYeC on numerous issues and serves a resource in this area and many others.

Finally, NYeC is an active member of the Gravity Project, which is a multi-stakeholder initiative to develop use cases and identify common data elements and associated value sets for SDH. Earlier this year, the Project developed a consensus-based set of recommendations for capturing and grouping SDH data elements, which they submitted to ONC for consideration in the USCDI v2. NYeC submitted comments² to ONC in favor of the Project's submission and recommends that CMS work with ONC to adopt such data elements in the USCDI v2, as well as in relevant certification criteria.

NYeC encourages CMS to coordinate with ONC and other federal agencies, as well as industry stakeholders to foster broader understanding and clarity of the policies around sharing of SDH

² <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>

data and promote greater collection, standardization, and integration of SDH data into provider workflows.