September 6, 2022

Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: 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 Amounts [CMS-1770-P)

Dear Administrator Brooks-LaSure:

The College of Healthcare Information Management Executives (CHIME) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2023 Medicare Physician Fee Schedule and Quality Payment Program (QPP) proposed rule, as published in the *Federal Register* on July 29, 2022 (Vol. 87, No. 145).

Background

CHIME is an executive organization dedicated to serving chief information officers (CIOs), chief medical information officers (CMIOs), chief nursing information officers (CNIOs) and other senior healthcare IT leaders. With over 5,000 members, CHIME provides a highly interactive, trusted environment enabling senior professional and industry leaders to collaborate; exchange best practices; address professional development needs; and advocate for the effective use of information management to improve the health and healthcare in the communities they serve.

Key Recommendations

In our comments, CHIME provides responses to specific policies in the proposed rule. Additionally, we offer feedback and recommendations to constructively improve the final rule. Our comments reflect the views of our association, as well as input received from our provider members from across the country. CHIME believes the following areas are especially important for CMS to consider when finalizing the provisions in this important proposed rule, and our detailed recommendations are included below.

- New Coding and Payment for General Behavioral Health Integration (BHI) billed by Clinical Psychologists (CPs) and Clinical Social Workers (CSWs)
- Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)
- Changes to the Promoting Interoperability (PI) Performance Category
- Payment for Medicare Telehealth Services Under Section 1834(m) of the Act
- Requests for Information (RFIs)

Detailed Recommendations

- **New Coding and Payment for General Behavioral Health Integration (BHI) billed by Clinical Psychologists (CPs) and Clinical Social Workers (CSWs)**

CHIME applauds CMS for their 2022 Behavioral Health Strategy[1] and the related policies included in this proposed rule intended to modernize coverage for behavioral health services and improve access and quality. The goal to improve access to and quality of mental health care services is something many of our members are dedicated to. CHIME agrees with CMS that, due to the current needs among Medicare patients for improved access to behavioral health services combined with the existing workforce shortages, that access to needed treatment for behavioral health is impeded. Therefore, we support CMS's proposals to reduce existing barriers and make greater use of the services of licensed professional counselors (LPCs) and Licensed Marriage and Family Therapists (LMFTs). We appreciate the proposals to allow LPCs, LFMTs, and other types of practitioners to bill Medicare under general supervision. We also agree that the proposed changes will facilitate utilization and extend the reach of behavioral health services.

CHIME is broadly supportive of the proposal to allow psychiatric diagnostic evaluations to serve as the initiating visit for behavioral health – and allowing additional clinicians to provide integrated behavioral health services as part of a patient's primary care team. Critically, CHIME believes these proposals will assist in providing relief from "clinician burnout" for providers of behavioral and mental health services and provide a temporary stopgap in the workforce shortage of these providers and clinicians. We would encourage CMS to continue to explore ways to address not only clinician burnout, but the ongoing and pressing clinician workforce shortages as well.

- **Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)**

CHIME is supportive of CMS's goal to improve access to and quality of mental health care services – including the objective to "increase detection, effective management and/or recovery of mental health conditions through coordination and integrations between primary and specialty care providers."[1] Further, CHIME appreciates that CMS acknowledges that circumstances related to the COVID-19 Public Health Emergency (PHE) have likely contributed to the increase in demand for behavioral health services, while exacerbating existing barriers in patients' access to this important and needed care. CHIME continues to work to address treatment of Opioid Use Disorder (OUD) through our Opioid Task Force founded in 2018 to address the opioid epidemic through the use of technology-based solutions. Unfortunately, COVID-19 has created a "crisis on top of a crisis" – with the opioid epidemic worsening since start of the pandemic.

We therefore support CMS's proposals to modify the regulations and policies governing Medicare coverage and payment for OUD treatment services furnished by Opioid Treatment Programs (OTPs). Additionally, CHIME appreciates and supports the proposals allowing OTPs to bill Medicare for services furnished via mobile units – and agrees with CMS that they are an opportunity to expand access to medications for treatment of OUD for Medicare patients by extending the reach of OTPs, particularly in rural and/or underserved areas.

According to data from the Centers for Disease Control and Prevention (CDC), over the past decade (1999-2020) more than half a million people in our country have died as a result of an opioid overdose.[2] Healthcare providers and industry stakeholders are and will continue to be in need for more resources to fight the opioid epidemic. Therefore, CHIME fully supports any efforts to provide essential, timely access to OUD treatments – especially to communities that need it the most – which includes the policies in this proposed rule.

- **Promoting Interoperability (PI) Performance Category**

  - ***Health Information Exchange (HIE) Objective: Addition of Alternative Measure for Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA)***

[1] CMS Behavioral Health Strategy | CMS. (2022, May 5). CMS Behavioral Health Strategy. Retrieved August 31, 2022, from https://www.cms.gov/cms-behavioral-health-strategy

[2] Understanding the Opioid Overdose Epidemic | CDC's Response to the Opioid Overdose Epidemic | CDC. (2022, June). CDC - Understanding the Opioid Overdose Epidemic. Retrieved August 31, 2022, from https://www.cdc.gov/opioids/basics/epidemic.html

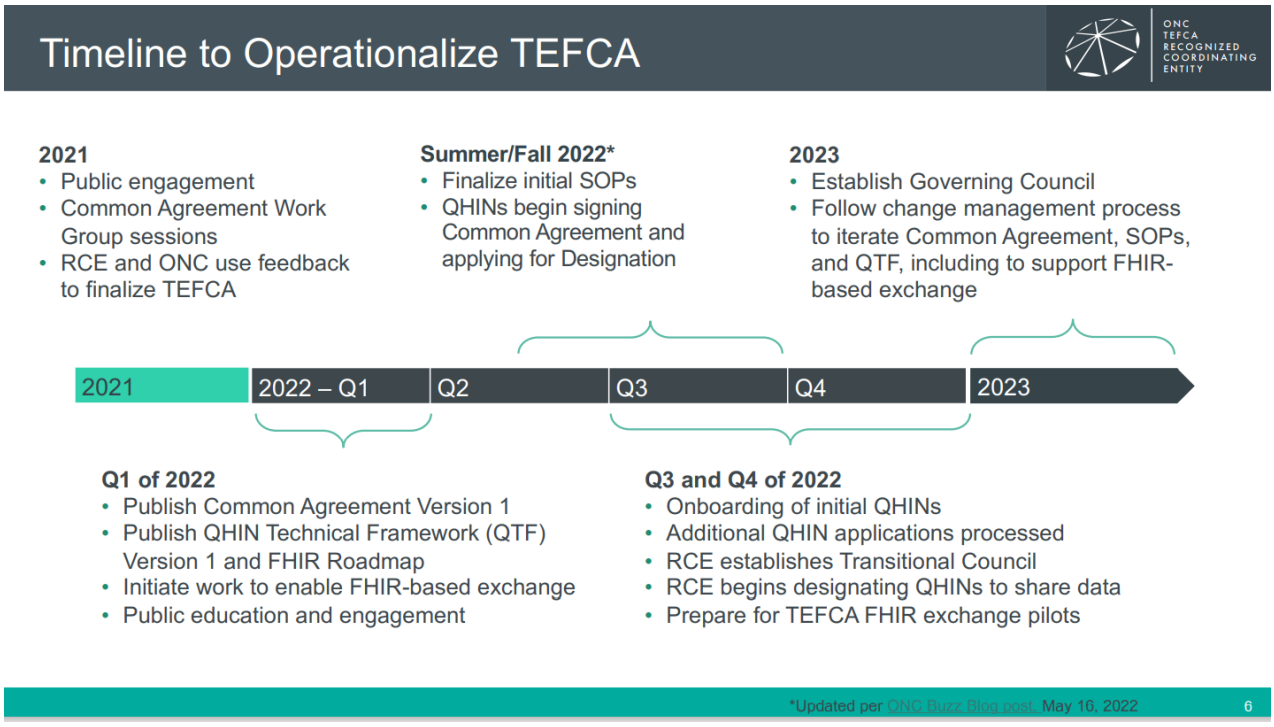
CMS is proposing to add a new, optional measure to the HIE Objective "Enabling Exchange Under TEFCA", which would be worth 30 points – beginning performance period CY 2023. Merit-based Incentive Payment System (MIPS) eligible clinicians would attest to the following:

- Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the *Federal Register* and on ONC's website) in good standing (i.e. not suspended) and enabling secure, bidirectional exchange of information to occur, in production, for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period, in accordance with applicable law and policy; and
- Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework.

CMS is proposing a MIPS eligible clinician would report the "Enabling Exchange Under TEFCA" measure by attestation, and the measure would require a "yes/no" response. A "yes" response would enable a MIPS eligible clinician to earn the proposed 30 points allotted to the HIE Objective.

CMS believes the new measure for Enabling Exchange Under TEFCA that is proposed would incentivize MIPS eligible clinicians to exchange information by connecting directly or indirectly to a Qualified Health Information Network (QHIN) and support health information exchange at a national level. CMS believes that fulfillment of this measure is an extremely high value action. CHIME agrees with the overall TEFCA goal of establishing a universal floor of interoperability across the country – and appreciates that it aligns with CMS's commitment to promoting and prioritizing interoperability and exchange of healthcare data. We also agree with CMS that incentivizing healthcare providers to enable exchange under TEFCA is a critical component to advancing healthcare data exchange nationwide.

While we strongly support the move to TEFCA, we believe this measure is premature. According to the below "Timeline to Operationalize TEFCA" from the Office of the National Coordinator for Health Information Technology's (ONC) Recognized Coordinating Entity (RCE) Monthly Informational Call held on August 16, 2022[3] – TEFCA still has a long way to go before it is fully operational. Therefore, much work must be done before this measure is fully executable, including QHINs joining TEFCA and state HIEs joining QHINs. **As such, we urge CMS to maintain this measure as optional in future years and during the growth of the TEFCA-HIE network.**



[3] Yeager, M., Coleman, J., Ciso, R., & Swenson, A. (2022, August). RCE Monthly Informational Call. In *Sequoia Project*. Retrieved August 31, 2022, from https://rce.sequoiaproject.org/wp-content/uploads/2022/08/RCE-Monthly-Info-Call-8.16.22-FINAL.pdf

Additionally, before implementing this measure, CHIME respectfully requests clarification from CMS on the requirements for providers and clinicians participating in multiple state HIEs (e.g., providers and practices near state borders). For example, if one state's HIE is a TEFCA signatory and the other state's HIE is not, would the MIPS eligible clinician qualify for a "yes" attestation under this new proposed measure?

- ***Public Health Reporting and Information Blocking***

CMS states that not submitting electronic health information (EHI) to public health authorities (PHAs) could be considered information blocking. Specifically citing a "Frequently Asked Questions" (FAQ) section of the ONC website, CMS notes that "practices would be evaluated to determine whether the unique facts and circumstances constitute information blocking, consistent with additional ONC frequently asked questions."[4] Furthermore, CMS references another ONC FAQ that highlights important points about public health reporting and information blocking."[5]

The FAQ referenced states specifically that: "If an actor is required to comply with another law that relates to the access, exchange, or use of [electronic health information] EHI (as defined in 45 CFR 171.102), failure to comply with that law may implicate the information blocking regulations." This FAQ provides two examples of laws where non-compliance by an actor may implicate the information blocking regulations." One of the examples provided says that if a state law "requires actors to submit EHI to PHAs, an actor's failure to submit EHI to PHAs could be considered an interference under the information blocking regulations."

Although this section was solely informational and no proposals were made, CHIME strongly urges CMS to wait to enact any information blocking disincentives until the HHS Office of the Inspector General (OIG) publishes the final rule on Information Blocking investigation and enforcement. As CMS works to encourage the exchange and utilization of public health data, CHIME urges the slow implementation of policies via the rulemaking process. This will in turn help ensure all providers can participate, and that the time and implementation burdens are not significantly increased on providers.

In addition, we wish to underscore that statute and regulation state that, a healthcare provider can only be considered to be engaging in information blocking if "such provider knows that such practice is unreasonable and is likely to interfere with the access, exchange, or use of EHI."[6] We understand and agree with the desire to encourage public health reporting, however, we note that many providers and clinicians are still not familiar with the minutiae of information blocking policies and how they must comply. As a result, we continue to encounter basic questions about the policies across our membership. CHIME conducted a recent **survey** to gauge provider's readiness for the next information blocking compliance deadline (October 6, 2022). In surveying our members, we found that 14% are not aware of the upcoming deadline to comply with information blocking requirements. Furthermore, when asked what their main concerns around compliance were, 17% of members chose "education" as one of their top three concerns, with education being defined as "overall uncertainty and confusion related to new mandates and the need for more education related to compliance."

To improve the collective provider and clinician understanding of the information blocking regulations, we strongly urge CMS, ONC, and the HHS OIG to engage in more education targeted to the provider community. Providers need best practices and implementation guides offered and published that they can reference as they strive to comply with the regulations. Without real-world guidance, providers will continue to struggle with implementing internal policies in order to avoid allegations of information blocking.

Finally, as HHS considers how best to implement disincentives for providers found to be information blocking, we request that appropriate provider-based disincentives include an initial warning and corrective action letter prior to moving towards a penalty phase. This structure of warning and corrective action is utilized across multiple other programs throughout HHS.

- ***Query of the Prescription Drug Monitoring Program (PDMP)***

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[4] *How would any claim or report of information blocking be evaluated?* | *HealthIT.gov*. (2022, February). www.healthit.gov. Retrieved August 31, 2022, from https://www.healthit.gov/faq/how-would-any-claim-or-report-information-blocking-be-evaluated

[5] *Would not complying with another law implicate the information blocking regulations?* | *HealthIT.gov*. (2022, February). Retrieved August 31, 2022, from www.healthit.gov. https://www.healthit.gov/faq/would-not-complying-another-law-implicate-information-blocking-regulations

[6] 42 USC § 300jj-52(a)(1)(B)(ii)

CMS is proposing to require MIPS eligible clinicians to report the Query of Prescription Drug Monitoring Program (PDMP) measure (which requires a "yes/no" response) for the PI performance category beginning with the CY 2023 performance period. CMS is also proposing to expand the Query of PDMP measure to include not only Schedule II opioids, but also Schedule III, and IV drugs. In other words, for at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician must use data from CEHRT to conduct a query of a PDMP for prescription drug history.

To align with the proposed policy for the Query of PDMP measure with regard to Schedule II opioids, CMS is proposing the query of the PDMP for prescription drug history must occur prior to the electronic transmission of an electronic prescription for a Schedule II opioid or Schedule III or Schedule IV drug. CMS notes that this measure would include all permissible prescriptions and dispensing of Schedule II, III, or IV drugs no matter how small the amount prescribed during an encounter in order for MIPS eligible clinicians to identify multiple healthcare provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, and controlled substances prescribed in high quantities.

Further, CMS is proposing that multiple prescriptions for Schedule II opioids or Schedule III and IV drugs prescribed on the same date by the same MIPS eligible clinician would not require multiple queries of the PDMP and only one query would have to be performed for this measure. MIPS eligible clinicians would have flexibility to query the PDMP using data from CEHRT in any manner allowed under State law. If CMS finalizes these proposals, CMS believes that an exclusion for this measure would be needed for MIPS eligible clinicians.

If finalized, CMS is proposing two exclusions beginning with the performance period in CY 2023: 1) any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; and 2) any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.

Due to lack of sufficient data regarding the number of clinicians who voluntarily submitted data for optional measures in the PI performance category, CMS has consistently been unable to estimate the associated burden for the reporting of such measures. Therefore, CMS is not proposing to adjust their currently approved time required for clinicians to submit data for the PI performance category because they are unable to account for any change in burden due to the proposed change to require the currently optional Query of PDMP measure. CMS is also proposing that if a MIPS eligible clinician claims an exclusion for the Query of PDMP measure, they would redistribute the points associated with the Query of PDMP measure to the e-Prescribing measure under the Electronic Prescribing Objective.

In proposing to make the Query of PDMP measure required, CMS would retain the 10 points associated with it, which are allocated as bonus points for the performance period in CY 2022. To accommodate this change if this proposal is finalized, CMS is proposing to reduce the points associated with the HIE Objective measures from the current 40 points to 30 points beginning with the CY 2023 performance period.

CHIME supports these proposals – as well as the proposed exclusions. As stated previously, CHIME has continued to encourage and support policies that will address the opioid epidemic – including the e-prescribing of controlled substances mandate.

- **Payment for Medicare Telehealth Services Under Section 1834(m) of the Act**

CHIME understands that CMS requires additional authority (i.e., Congress granting rulemaking authority to federal agencies) and continues to endorse and support legislation that would expand access to virtual care during and after PHE. Access to telehealth and virtual care has been transformational – patients now expect and often prefer telehealth as a key component of our health care system and providers have been able to reach many patients that previously had access barriers through virtual care. CHIME acknowledges that the majority of telehealth access has been possible only under the flexibilities and waivers granted under the current PHE. Furthermore, a recent study found that the emergency authorities used by CMS to expand telehealth utilization during the COVID-19 PHE – in particular, providing flexibilities to provide patients with medications for OUD were associated with improved retention in care and reduced odds of medically treated overdose.[7]

Additionally, the Consolidated Appropriations Act, 2022[8] amended section 1834(m) of the Act to extend a number of flexibilities that are in place during the PHE for COVID-19 for 151 days after the end of the PHE. To align the

[7] Jones CM, Shoff C, Hodges K, et al. Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID-19 Pandemic. *JAMA Psychiatry.* Published online August 31, 2022. doi:10.1001/jamapsychiatry.2022.2284

[8] (CAA, 2022) (Pub. L. 117-103, March 15, 2022)

availability of these services with those flexibilities extended under the Act, CMS is proposing to continue to allow certain telehealth services that would otherwise not be available via telehealth after the expiration of the PHE to remain on the Medicare Telehealth Services List for 151 days after the expiration of the PHE. While CHIME appreciates the temporary extensions CMS is proposing, we would like to reiterate that the short-term nature continues to heighten the significant uncertainty into our healthcare system. Providers must weigh the costs of investing in the technological and clinical infrastructure required to maintain telehealth programs at scale against the uncertainty of when these telehealth policies may end. Further, patients who utilize telehealth as part of their care plan face the possibility of a forced return to in-person care. This is particularly concerning for patients utilizing telehealth to reach experts at longer distances and those receiving ongoing remote care for chronic conditions. **CHIME continues to respectfully request that CMS create a more flexible reimbursement policy around the use of telehealth – such that Medicare pays providers for using it and supports patient care when and where they need it.**

CMS is not proposing changes to the length of time the services that were temporarily included on a Category 3 basis will remain on the Medicare Telehealth Services List; these services will continue to be included through the end of CY 2023. CMS notes that in the event the PHE extends "well into CY 2023" – they "may consider revising this policy." Regardless of the "official" end of the COVID-19 PHE, CHIME urges CMS to consider revising this policy in the final rule to continue to include the services on the Medicare Telehealth Services List on a Category 3 basis – including some of which had not previously been added but will be added on a subregulatory basis[9] – until at least the end of CY 2024.

CMS reminds interested parties that the criterion for adding services to the Medicare Telehealth Services List under Category 1 is that the requested services are similar to professional consultations, office visits, and/or office psychiatry services that are currently on the List, and under Category 2 that there is evidence of clinical benefit if provided as telehealth. Additionally, CMS notes that they continue to believe there is sufficient evidence of potential clinical benefit to warrant allowing additional time for interested parties to gather data to support their possible inclusion on the Medicare Telehealth Services List on a Category 1 or 2 basis – which CHIME supports and appreciates. We strongly encourage CMS provide additional education, guidance, and information relevant to how stakeholders can meaningfully engage in and successfully request to add services to the Medicare Telehealth Services List permanent addition (i.e., supporting documentation required, the review process, details on the criterion and processes established by CMS, etc.).

CMS allows stakeholders to submit requests for adding services to the list of Medicare telehealth services on an ongoing basis. Requests must be submitted and received no later than February 10 of each calendar year to be considered for the following year's proposed rule (i.e. requests must be received by February 10, 2023, to be considered during the 2024 rulemaking cycle that establishes physician fee schedule rates for January 1, 2024). **CHIME respectfully requests that for the 2024 rulemaking cycle, the submission date of February 10 be delayed by at least of three months.** CMS uses the annual PFS rulemaking process as the vehicle to make changes to the Medicare Telehealth Services List and assesses codes to determine their appropriateness for inclusion on the List. Providing stakeholders with a temporary extension and a May 10, 2023 deadline will give CMS ample time for their review period before the PFS proposed rule for CY 2024 is released (typically in mid to-late July).

Furthermore, CMS has assessed whether or not certain telehealth services can, outside of the circumstances of the PHE, be furnished using the full scope of service elements via two-way, audio-video communication technology, without jeopardizing patient safety or quality of care. CMS states that they now believe that there are additional services that would be appropriate for addition to the Medicare Telehealth Services List on a Category 3 basis that they did not identify in the CY 2021 rulemaking. CMS is proposing to add these additional services to the Medicare Telehealth Services List on a Category 3 basis. **CHIME appreciates CMS's consideration and addition of these services; subsequently, we would respectfully request that the requests received in CY 2023 for adding services to the List that may not meet CMS's criterion due to a lack of documentation, confusion around the deadline and what is required, be considered for temporary addition on a Category 3 basis.** This would provide CMS with additional time to work with the requestors to obtain all information needed – while allowing patient access to essential telehealth services.

[9] Title 42 Chapter IV Subchapter B Part 410 Subpart B § 410.78

- **Requests for Information**
  1) Advancing the TEFCA
  2) Continuing to Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs; Approaches to Achieve FHIR eCQM Reporting; and Data Standardization Activities to Leverage & Advance Standards for Digital Data

- ***Advancing the TEFCA***

CHIME appreciates that CMS is requesting feedback from the public and stakeholders on ways they can advance the Trusted Exchange Framework and Common Agreement (TEFCA). CHIME has been an ardent supporter of TEFCA since its inception. CMS is requesting feedback on the best ways to approach incentivizing or encouraging information exchange under TEFCA through CMS programs. CHIME believes that the best way for CMS to assist providers adopt and participate in TEFCA is to provide a financial incentive for those beginning participation in TEFCA. However, CHIME does not recommend requiring TEFCA participation at this time (please refer to our above comments regarding the proposed addition of an alternate measure to the HIE Objective for enabling exchange under the TEFCA). Given the current timeline to operationalize TEFCA, initial participation is likely to create challenges for providers in managing components of value-based care. These challenges would create disruption and decreased productivity for clinicians – and with the current nationwide physician and nursing workforce shortages – could exacerbate an already arduous situation.

Further, it would create a significant financial burden for providers and increase the need for additional support staff, of which there is currently a substantial need and lack of qualified individuals to fill these roles. The Health Resources & Services Administration's (HRSA) Allied Health Workforce Projections, which are obtained by studying the national-level supply and demand projections for allied health professionals, demonstrates how dire this situation is and will continue to worsen. By 2030, HRSA projects the following demand for allied health workers – including Community Health Workers (CHWs) and Emergency Medical Technicians (EMTs):[10]
Further exacerbating nurse doc work

- 11% increase in demand for CHWs (to 67,560)
- 17% increase in demand for EMTs and paramedics (to 305,770)
- 19% increase in demand for clinical laboratory technologists (to 198,440)
- 22% increase in demand for occupational therapists (to 127,260)
- 26% increase in demand for physical therapists (to 298,820)
- 19% increase in demand for pharmacists (to 359,770)
- 21% increase in demand for registered dieticians (to 95,540)
- 30% increase in demand for respiratory therapists (to 144,100)

CHIME would be interested in further discussions with CMS specifically relating to the creation of a TEFCA billing code to potentially assist in alleviating some of the issues providers and clinicians are facing. CMS should offer providers and clinicians with information related to the potential benefits of participation through widespread, easy-to-understand, multi-modality education. This would allow providers time to analyze workflows, costs, and benefits of participation. Currently, there remains much confusion about TEFCA in the provider community. Offering clarity regarding TEFCA will drive participation – but only when coupled with a delay in any future mandates or penalties.

- ***Continuing to Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs; Approaches to Achieve FHIR eCQM Reporting; and Data Standardization Activities to Leverage & Advance Standards for Digital Data***

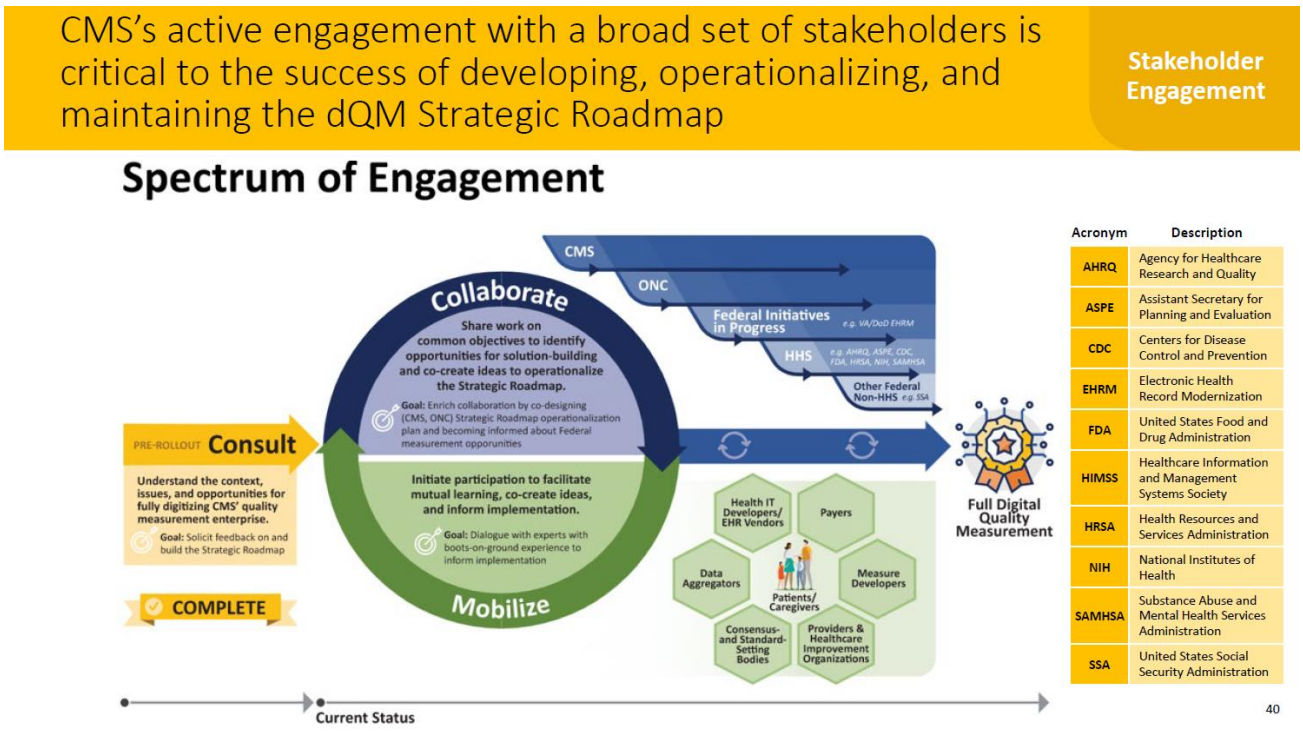
CMS has previously stated their aim to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs. As part of this modernization of CMS's quality measurement enterprise, CMS is gathering additional public input on the transition to digital quality measurement. CHIME appreciates that CMS is requesting feedback from the public and stakeholders. We agree with CMS that by aligning technology requirements for payers, healthcare providers, and health IT developers, HHS can advance an interoperable health IT infrastructure that ensures providers and patients have access to health data when and where it is

[10] Allied Health Workforce Projections | Bureau of Health Workforce. (2019). HRSA - Allied Health Workforce Projections. Retrieved August 31, 2022, from https://bhw.hrsa.gov/data-research/projecting-health-workforce-supply-demand/allied-health

needed. **We applaud the movement to develop more comprehensive measures of care quality – however, CHIME is extremely concerned that the current state of uncertified technology will make digital quality measurement more difficult to achieve and poses potential electronic health information (EHI) privacy and security risks that have yet to be addressed. Furthermore, the current timeline outlined in the Digital Quality Measurement Strategic Roadmap[11] is extremely ambitious – and could be inadvertently detrimental to the success of advancing quality measurement across the healthcare continuum.**

CHIME broadly supports the refined definition of Digital Quality Measures (dQMs) such that a dQM is a "quality measure, organized as self-contained measure specification and code package, that uses one or more sources of health information that is captured and can be transmitted electronically via interoperable systems." However, CMS notes specifically that the definition of dQM was revised based on comments received that the term "software" is confusing. This is concerning to CHIME; if the healthcare industry broadly doesn't understand the term "software", beginning to adopt FHIR Application Programming Interface (API) and shifting to eCQM reporting using FHIR standards will not simply require a "plan to transition incrementally." It will involve substantial time and education for providers and clinicians in order to achieve a quality measurement system fully based on digital measures – an effort CHIME broadly supports.

Additionally, CMS's Digital Quality Measurement Strategic Roadmap, as currently written, includes "stakeholder engagement", but does not specify or focus on educating providers and clinicians. While CHIME agrees that active engagement with a broad set of stakeholders is critical to the success of developing, operationalizing, and maintaining the dQM Strategic Roadmap – we believe the crucial element of "education" should be expanded. We appreciate CMS's desire to educate and work with CHIME's members specifically on the dQM Strategic Roadmap, but we would appreciate a larger focus on educating providers broadly. As shown in this graphic from the "Executive Summary Slide Deck"[12] – the dQM Strategic Roadmap does not mention education anywhere in the "Spectrum of Engagement". Given that these and other seismic changes related to interoperability and digital health are underway, combined with the fact that providers and healthcare delivery organizations have a limited bandwidth, we would encourage a more reasonable timeline to ensure that the shift to digital quality measurement is done in a thoughtful, meaningful way.



Slide 25 of the "Executive Summary Slide Deck" denotes that the "provider implements FHIR API that transforms data into a standardized data view"; and Slide 27 states that "the aim of the Measure Calculation Tool technical architecture is to minimize provider burden." These statements are seemingly at odds; one small part is extremely

[11] *Digital Quality Measures | eCQI Resource Center*. (n.d.). Retrieved August 31, 2022, from https://ecqi.healthit.gov/dqm

[12] CMS Digital Quality Measurement Strategic Roadmap: Executive Summary. (2022, March). CMS Digital Quality Measurement Strategic Roadmap. Retrieved August 31, 2022, from https://ecqi.healthit.gov/sites/default/files/dQMStrategicRoadmapExecSummarySlides_032022.pdf

complex for providers to understand yet alone implement, and the other indicates that it will help reduce provider burden. Therefore, CHIME encourages CMS to further incorporate provider and clinician education into the dQM Strategic Roadmap. If there is confusion amongst stakeholders regarding the term "software", it indicates that there is a significant gap in knowledge that needs to be addressed across the healthcare industry. Given the difficulties we have outlined regarding non-EHR vendors and FHIR implementation, CHIME would appreciate and respectfully request that CMS re-convene stakeholders to make refinements to the Roadmap to digital quality measurement containing not only education – but concrete steps, timelines, and timeline progress reevaluation points. This will allow the timelines flexibility to match progress, as well as to permit the required time needed for safe upgrades. Furthermore, this is the same change management process that hospitals and providers use to the maintain their ability to remain operational and, more importantly, to protect their patients.

CHIME members are executives and senior healthcare IT leaders – and we are offering to continue to serve as a resource to CMS as they potentially refine the Roadmap and continue towards their goal of a fully digital measurement system. CMS states that these goals include reduced burden of reporting; provision of multi-dimensional data in a timely fashion, rapid feedback, and transparent reporting of quality measures; digital measures leveraged for advanced analytics to define, measure, and predict key quality issues; and quality measures that support development of a learning health system, which uses key data that are also used for care, quality improvement, public health, research, etc. Our members are extremely knowledgeable and have decades of experience executing CMS's goals of a fully digital measurement system in their own healthcare systems and delivery organizations.

We agree that the best path forward for digital quality measurement is through FHIR. Specifically, CHIME encourages the use of FHIR Release 4 (R4), as required by the ONC Cures Update API certification criteria. The path to getting third parties on FHIR R4 could be lengthy and financially burdensome for all involved. Furthermore, many vendors run their services on out-of-date software. Additionally, uncertified technology is not required to communicate in a standard way with electronic health records (EHRs) or other systems. Therefore, extracting, quantifying, and packaging this data would range from difficult to nearly impossible, depending on the data source.

To address these issues, we recommend that CMS only include data from sources able to export the data required by any measure using FHIR. Setting this standard across the board should encourage the digital health industry to begin the transition to machine-readable, standardized data. CHIME continues to support the use and adoption of FHIR APIs across the health system. However, prior to further requiring or implementing FHIR-based APIs for reporting, the federal government must wait for the FHIR-based API requirements to take effect and be implemented on the provider level. FHIR can be a small piece of reporting and burden reduction solutions – but it cannot be treated as a cure-all for every problem until it is implemented and proven at the provider and clinician action level.

CHIME believes that only data outlined in the United States Core Data for Interoperability (USCDI) should be included in dQMs. Through the standards version advancement process (SVAP), this data set will grow over time as certified technology is able to standardize the data elements, allowing for an intentional transition to accurate digital quality measurement. Moreover, using only the data in the USCDI and encouraging the appropriate regulatory bodies to begin requiring digital health tools to have the ability to export USCDI data will create and further harmonization across regulations. This will lower the threshold and burden of delivering dQMs for providers, clinicians, and technology developers. As the USCDI is currently required by ONC and has a defined SVAP, CHIME believes this is an appropriate data set for inclusion in future dQMs.

Additionally, third party health applications are not required to abide by the Health Insurance Portability and Accountability Act (HIPAA). Although the Federal Trade Commission (FTC) clarified last year that the HIPAA breach notification rule applies to these applications, there is no robust privacy or security requirement for these applications. Breaches from third-party vendors nearly tripled last year and third-party applications and data aggregators have been shown to be vulnerable to hackers.[13] CHIME strongly encourages CMS to work with the Food and Drug Administration (FDA) and FTC to ensure that all medical device manufacturers and third-party health vendors and developers are required to meet the legal privacy and security standards for handling EHI.

[13] Torrence, R. (2021, October 20). *Fierce Healthcare - Security flaws in health apps, APIs potentially put millions of patient records at risk, report finds*. Fierce Healthcare. Retrieved August 31, 2022, from https://www.fiercehealthcare.com/tech/report-shows-patient-data-vulnerable-to-hacks-third-party-aggregators

Finally, non-EHR data sources present a problem with the ability of clinicians to monitor their performance during the year. Without the availability of performance feedback during the reporting year, it will be extremely burdensome if not impossible for providers to effectively identify deficiencies and execute any improvements.

Conclusion

CHIME appreciates the proposals included to modernize coverage for behavioral health services, increase the clinical workforce and reduce clinician burnout while improving access and quality for Medicare patients. We also applaud CMS for the proposals related to Medicare coverage for OUD treatment services furnished by OTPs, as well Modifications Related to Medicare Coverage for OUD Treatment Services Furnished by OTPs. CHIME thanks CMS for the proposals regarding mobile units as an opportunity to expand access to medications for treatment of OUD for Medicare patients by extending the reach of OTPs, particularly in rural and underserved areas.

We respectfully request that CMS take our comments on the Promoting Interoperability (PI) performance category proposals into consideration. CHIME and our members remain committed to seeing a successful implementation of promoting Interoperability with strong and meaningful data exchanges. Additionally, we express our gratitude for CMS's efforts during the COVID-19 PHE to utilize flexibilities and waivers available to them to provide patients with access to telehealth and virtual care, which has been transformational to the health care system. CHIME urges CMS to continue to use the authorities they currently have to maintain patient access to telehealth services. Finally, we appreciate the opportunity to provide responses to address the specific questions included in the various RFIs.

In closing, we would like to thank you for providing the opportunity to comment and CHIME appreciates the chance to help inform the important work being done by CMS. We look forward to continuing to be a trusted stakeholder and resource to CMS and continuing to deepen the long-standing relationship we have shared. Working together through the rulemaking process, such as with the PFS, is just one way we can accomplish our shared goals and make meaningful changes in healthcare. Should you have any questions or if we can be of assistance, please contact Chelsea Arnone, Director, Federal Affairs at carnone@chimecentral.org.

Sincerely,

Russell P. Branzell, CHCIO, LCHIME
President and CEO CHIME