September 9, 2021

Administrator Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Service
500 Security Boulevard
Baltimore, MD 21244

Submitted Virtually Through Regulations.gov

Dear Administrator Brooks-LaSure:

The College of Healthcare Information Management Executives (CHIME) welcomes the opportunity to submit comments in response to the Centers for Medicare and Medicaid Services (CMS) "Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements" proposed rule published in the *Federal Register* on July 23, 2021.

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 more than 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.

We appreciate the regular work the administration continues to do while simultaneously fighting the COVID-19 pandemic. Providers and the American healthcare system have faced a relentless number of threats this year from both COVID-19 and the constant threat of ransomware attack. With this in mind, CHIME members are grateful to see efforts from CMS in the CY22 Physician Fee Schedule (PFS) proposed rule to remove reporting duplicity, while also aiming to streamline pieces of the Promoting Interoperability (PI) program. It is also important to highlight that while many of the proposals were made in a spirit of burden reduction and automation, the proposals themselves may be too forward-looking, putting providers in the difficult situation of needing to respond to complex scoring areas without the ability to fully understand what they will be scored on, or how best to respond to the criteria. Similarly, while CHIME members support the expansion of public health requirements in our nation's health system, they are also concerned that doing too much, too fast, puts them in a position where they are unable to meet expectations due to circumstances outside of their control.

CMS is often asked to accomplish the difficult task of moving healthcare forward, while not overburdening any single sector. CHIME is sympathetic to that challenge and notes through much of its response that the provider community has a deep interest in partnering with CMS to develop and implement common sense changes that benefit both CMS and providers. As the COVID-19 pandemic has shown, the nation's healthcare system is ripe for rapid progress and problem solving, and we as a representative of the provider community look forward to providing direction and suggestions for how CMS and other federal agencies can use rapid iteration to create a more sustainable system for everyone involved.

CHIME's broad comments on the CY22 PFS include:

1. **CMS should work with providers to determine the correct timing and manner to implement shifts in the MIPS Value Pathways (MVP) program to ensure providers have adequate time to review the new proposed measures, as well as for CMS to determine how best to utilize quality measure databases to ensure additional cost and reporting is not incurred.**
2. **CHIME is supportive of continued efforts by CMS to broaden and expand access to telehealth services, including tele-mental health services.**
3. **CHIME supports the efforts of CMS to reduce the reporting burden on the provider by eliminating duplicative requirements, and CHIME encourages CMS to examine other programs to determine other duplicative reporting requirements.**
4. **CHIME is supportive of efforts to determine health equity gaps and close them, however, CMS must ensure that providers who are unable to comply with any new reporting requirements are not inappropriately penalized despite actively working to combat equity gaps in care.**
5. **Application programming interfaces (APIs) and the Fast Healthcare Interoperability Resource (FHIR) are two technological innovations CHIME wholeheartedly supports, but also cautions CMS and the broader HHS community against embracing them as the only interoperability or data exchange solution before the technology has reached proven maturity.**

Specific comments to the proposed rule are as follows:

Expansion of Telehealth

CHIME supports the federal government's efforts to expand and make permanent the tele-mental health provisions first made available as part of the COVID-19 public health emergency (PHE) policy relaxations and included as part of the SUPPORT Act previously passed by Congress. CHIME recommends CMS expand these provisions to include all Medicare Telehealth Services permanently. It is important to increase access to these potential life-saving services, especially given the reported "shadow pandemic" in which many Americans face both substance use disorder (SUD) and mental health crises because of the pandemic. In addition to the expansion of services, CHIME also supports CMS' expansion of the definition of the distant site to include the patient's home. CMS should include expanding this permanent provision to all distant sites not just the patient's home. Many facing SDOH challenges may be unable to receive services at home and instead may need to access them from a car, homeless encampment/shelter or from work. Expanding the originating sites greatly increases the ability for those who need these services the most to access them. Additionally, CMS should propose an expanded definition of what constitutes a home domicile given some of the SDOH considerations as stated above to ensure no patient is left behind.

In addition, CHIME strongly urges CMS to consider providing a robust list of exceptions to requirements stating that all recipients of tele-mental health services have an in-person visit within six months of receiving the tele-mental health service. Many of the patients who need access to these services the most are unwilling or unable to attend an in-person visit within this timeframe. When discussing this proposal, one CHIME member stated, "If I have to have a patient come in every six months and they are in a behavioral health or SUD program, I most likely won't see them." Additionally, not every patient is able to attend an in-person visit given socioeconomic or family constraints. An advantage of receiving tele-mental health services is the patient can access them outside of the standard business hours of a physician service. Requiring an in-person requirement requires a patient to juggle work and other obligations that may prove difficult to reconcile with an in-person physician visit.

A solution to this issue would, as stated above, be for CMS to provide a set of robust exceptions a physician could utilize when allowing a patient to opt-out of the in-person requirement. These exceptions would need to be documented by the physician with justification of why a patient is not able to satisfy this

requirement and how the physician intends to continue providing tele-mental health care in absence of the regular six-month in-person check-in.

In addition to supporting efforts by CMS to expand access to these services, CHIME also applauds CMS for expanding the definition of what constitutes a telecommunications system to include audio-only technology. As a further improvement, CHIME urges CMS to remove requirements for providers to possess the ability to do two-way audio/video services in addition to audio-only services. Many rural providers or those without access to proper broadband are only able to offer audio-only services instead of both audio-only and audio/video services. It is crucial these facilities are not penalized and locked out from being able to offer audio-only telehealth services because of services they are not able or eligible to have in their facilities.

In addition to supporting the broader expansion of tele-mental health services. CHIME strongly supports CMS' expansion of tele-mental health services to those receiving care at RHC/FQHC providers. Similarly, to above, we recommend CMS expand this access to all Medicare Telehealth Services and provide a robust set of exceptions for patients unable or unwilling to fulfill the once every six months in-person visit requirement. We were also encouraged to see CMS expand the reimbursements for these services to include RHCs/FQHCs offering real-time two-way audio services and recommend CMS do the same to all Medicare Telehealth Services.

Finally, CHIME supports efforts by CMS to expand available telehealth services to include the G2252 HCPCS codes for virtual visits.

Electronic Prescribing of Controlled Substances (EPCS)

CHIME strongly supports the delay of EPCS compliance from January 1, 2022 to January 1, 2023. This delay is welcomed by providers as it allows them to continue focusing on the numerous health IT provisions they already are working to comply with while also fighting the COVID-19 pandemic on the front lines. CHIME remains a fervent supporter of the EPCS requirements but asks CMS to continue to monitor provider readiness through the coming year and, if needed, to delay the compliance date further from 2023 to 2024 if providers are still struggling with both compliance and other key activities such as fighting the pandemic.

Pertinent as it relates to the long-term care (LTC) proposed delay in compliance from January 1, 2022 to January 1, 2025, we ask CMS to maintain a robust discussion with NCPDP and the LTC community around standards that enable easier medicine reconciliation, as well as EPCS reporting, are developed, implemented and balloted. Only after these standards have been reviewed and approved can developers implement them into their products. While it is unclear at this time if 2025 is too soon for these standards to be implemented, we ask CMS to closely monitor and communicate with both NCPDP and the LTC community as it relates to readiness and adjust compliance accordingly. This is in addition to expanding the requirements on EPCS for Part D in LTC to include Part A, as that expansion would capture the full care continuum within the LTC community.

CMS included a series of exceptions in its EPCS proposals as part of this proposed rule. CHIME thanks CMS for including such exceptions but has significant concerns with the exceptions themselves, beginning with the base requirement that 70% of all prescriptions be completed electronically per year. It is unclear how CMS will monitor this requirement and audit providers to ensure compliance. Similarly, given many providers will need to wait until later in the year to determine if they are in compliance, some may struggle to determine if they are in need of utilizing an exception. Additionally, these proposed exceptions do not provide for the fact that currently, federal and state EPCS requirements remain unaligned, requiring many providers to adhere to two different sets of requirements. These unreconciled requirements complicate the regulatory environment, and if a provider is not able to take an exception because of these mismatched requirements, then CMS must work with states to ensure they are aligned.

One specific comment regarding the exceptions themselves deals with the exception for when the prescriber and prescribing pharmacy are the same entity. The exception does not provide for the common scenario in which a private prescriber, separate from the entity, works in the same facility as the pharmacy. This is common as a private practitioner may work in a facility that has an on-site pharmacy, but for billing purposes is not billed under the same entity. The exceptions need to provide further clarity on what legal entity means and how to proceed forward when they prescriber and entity may work within the same database but are not legally bound to each other.

Finally, as it relates to penalties, CHIME recommends CMS refrain from implementing penalties related to EPCS at this time. The lack of alignment related to requirements and accurate understanding of the ability for CMS to measure and report on EPCS utilization creates an unclear and murky situation that complicates a provider's ability to understand and comply with the requirements.

MIPS Value Pathways

CHIME previously provided substantial comments related to the MIPS MVP program in the past and were pleased to see the common sense, phased-in approach for how to shift from traditional MIPS to the MVP program included in this proposed rule. With that in-mind, it is important for CMS to continue to monitor readiness and a provider's ability to comply with these requirements throughout the CY2024 to CY2027 voluntary timeline. Providers may be working to the best of their ability, but as described below, their ability to comply may not always be within their control.

Specifically, CHIME members stated they have significant concerns related to the way the MVPs and quality measures included as part of the MVP program will be developed, implemented and required. Members are concerned they will be required to pay for individual specialty quality measure registries to obtain the handful of measures needed to meet MVP requirements. This would be a significant cost burden on providers who have multiple specialties in their practice. These measures are also incredibly difficult to measure and for specialty groups to achieve 90th percentile or 100% success. It should be up to the provider group to determine and choose the correct measures, as opposed to having to follow the proposed CMS quality measure selection rubric. With that in-mind, CHIME also recommends CMS remove the high and medium weighted pieces of measurement selection as it continues to provide unneeded complexity to the process.

Additionally, it is crucial that the EHR vendor community is required to implement these newly required quality measures and that they are available to providers. Without that mandate it will become nearly cost-prohibitive for all the individual quality measures to be purchased and implemented.

Finally, if CMS proceeds with the proposed MVP structure, it is crucial for the agency to provide better data on what constitutes a high- or low-cost provider. Currently, if a provider is not a member of the shared savings program, it is difficult for that provider to achieve the data needed to make this determination.

Optional Query of Prescription Drug Monitoring Programs (PDMP) in CY2022

CHIME encourages CMS to keep the query of PDMP as an optional category moving beyond just this proposed iteration of the PFS. There are multiple issues that must be addressed within healthcare prior to shifting the query of PDMP from an optional category to a permanent one.

Those challenges include:

- The readiness of FHIR for PDMP and the ability to report on the query requirements are not at a level of maturity that would allow for this requirement. The security restrictions placed on querying a PDMP does not allow for FHIR to access or report to PDMPs. With this in-mind, FHIR will also not lessen the burden of PDMP query activity, as the main constraint preventing providers from participating in PDMP query is with states having active PDMPs ready to receive FHIR based queries and the ability for providers to implement the query activity in their workflows.

- Similarly, State PDMPs, if they are in-place, often are not able to meet the FHIR API baseline as needed for this level of exchange to continue. CMS should continue to monitor readiness across State PDMPs and adjust requirements on providers accordingly.
- Larger health systems are currently able to meet this requirement, but smaller providers will struggle to meet this requirement.
- Additional funding will be required to help raise the technology floor for some providers in order to help them meet this requirement if it would be made permanent.

Proposed Changes to the Availability of Patient Data

CHIME strongly recommends CMS reconsider the proposal to require MIPS eligible providers to make patient data dating back to 2016 available indefinitely and instead require eligible hospitals and CAHs to ensure information remains available for one year. As it exists today, the technology is not available to allow for this data exchange and access to remain in place in perpetuity and providers are largely unable to transfer this data from EHR-to-EHR if they were to choose to change EHR vendors after this requirement comes into effect. Additionally, other regulations at both the federal and state level already dictate records retention requirements for providers, making this requirement a direct conflict with other current existing requirements. Similarly, keeping information available indefinitely presents an inherent risk to patient data compromise, as any unauthorized access to the available information would be of far greater consequence if a larger section of a patient's record is available as opposed to just a year's worth of information.

If CMS were to decline eliminating the proposed requirement, CHIME urges CMS to delay implementation to CY2023 to give the technology additional time to mature and allow for CMS to develop a concrete and expansive set of exceptions for when providers would not need to make the data available indefinitely and ensure all requirements align with other federal programs.

Modifications to the Public Health and Clinical Data Reporting Objective

CHIME continues to support the federal government's efforts to advance the availability and exchange of available public health data. It was made clear as a result of the COVID-19 pandemic that the health system as a whole must work together to better increase its ability to capture, share and utilize this important data. This is especially true during emergent events such as pandemics and other widespread crises. As a result, CHIME strongly urges CMS to refrain from implementing these permanent public health reporting measures until further technological advancement can be achieved.

As CMS works to encourage the exchange and utilization of public health data, CHIME proposes several recommendations to ensure all providers can participate and that the burden on those providers is not increased on the provider. Those recommendations include:

- CHIME recommends CMS implement an on-ramp to mandatory public health reporting like other past CMS programs, allowing for a provider organization to meet one of the two requirements and then increasing the requirements over a two-year period.
- Prior to requiring immunization registry reporting, CMS should ensure there are exclusions available if there is not a state immunization registry available for providers.
    - Additionally, CMS should survey the state immunization registries to determine if there is readiness at the state level to conduct this level of exchange.
- Prior to requiring CMS needs to determine if states are willing to also move towards more robust electronic data exchange. Many state agencies continue to mandate manual reporting; if they continue to do so, and CMS mandates online reporting it will increase the burden on providers as they will need to report in two different formats.
- Finally, prior to requiring the adoption of electronic case reporting (eCR), CMS needs to engage with ONC, the CDC and the vendor community to gauge the ability for eCR to be implemented and utilized by the proposed deadline of CY2022. Currently, CHIME harbors significant concerns that

the ability for eCR to implementation varies significantly across the provider community and vendors currently have a significant variance in readiness.

SAFER Guides

CHIME supports the inclusion of the SAFER guides as part of the PI program. Still, CHIME urges CMS to determine the burden level placed on providers to complete the SAFER guides every year. If CMS does determine that completion of the full SAFER guides is too burdensome, CMS should require a hospital to complete all nine SAFER guides over a three-year period, with three guides of the provider organization's choosing completed each year. Every three years, all nine SAFER guides would be completed, and providers would then remain in compliance. If CMS is unable to determine burden placed on the provider by this requirement, then it should undertake a pilot program before mandating this requirement for everyone.

CHIME also recommends CMS work with ONC to update the SAFER guides prior to implementation, as the guides will be over five years old by the time they are mandated.

Actions to Limit or Restrict Compatibility or Interoperability of CEHRT Removal of Attestation Statements

CHIME supports the work CMS is doing to eliminate duplicative reporting burden and encourages CMS and HHS to engage in further activity to remove administration reporting burden through duplicity.

Health Equity Requests for Information (RFI)

CHIME supports the federal government's efforts to identify and capture data related to health equity and the gaps that currently exist in care. Within the CY22 PFS, CMS proposed multiple health equity RFIs asking for information on a variety of topics. CHIME has opted to respond to those RFIs collectively, instead of individually, as we believe our broader comments on health equity pertain to multiple RFIs.

Comments include:

- CHIME encourages CMS to work with the Office of Management and Budget (OMB), the Office of the National Coordinator for Health Information Technology (ONC) and other relevant federal government agencies to refine and update the federal requirements for social determinants of health (SDOH) and sexual orientation and gender identity (SOGI) data collection. As it currently stands, the OMB-dictated requirements are too limited and are often out of date compared to state level requirements. This limits the federal government in understanding how accurate its collected SDOH and SOGI data is and creates an environment where each state will set its own standards, requiring providers and technology developers to track and implement multiple different sets of data collection requirements. To remove this unnecessary burden, relevant SDOH and SOGI data experts and the public should be consulted to draft updated and accurate SDOH and SOGI data categories for implementation at the federal level.
- CMS should work to determine the best method of standardizing and ensuring accuracy for the collection of data related to health equity. One area CHIME recommends CMS explore is utilizing and expanding the ONC United States Core Dataset for Interoperability (USCDI) to better target and determine how and what data should be collected during the care process.
- CHIME recommends CMS continue to harmonize the data collection process and data standardization process across federal agencies and technologies prior to creating a hospital equity score. There are multiple standards and exchange requirements that must be designed and implemented prior to the federal government even being able to determine what needs to be measured. Similarly, CMS needs to better understand and determine how to account for the impacts of geography and economics on the providers who would be subject to this equity score to ensure no providers are penalized for issues outside of their control.

FHIR API RFIs

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 piece of all reporting and burden reduction solutions, however it cannot be treated as a cure-all for every problem until it is implemented and proven at the provider action level.

Patient Access Outcomes Measures RFIs

CHIME encourages CMS to refrain from measuring and tracking third-party app utilization and connection at the provider level. Doing so would prove burdensome for providers, as once the FHIR APIs are implemented in 2023, patients will be able to access their record with no action required on the provider side. Tracking the potentially infinite number of apps connecting to an API would be challenging given that the open API format does not necessitate a tracking requirement. Similarly, there is no clear way for a provider to measure a patient's access to their EHI or assess the utilization of that data in order to determine benefit of access. Furthermore, history has shown that process measures such as these are not a proxy for better care.

Clinical Notes RFIs

CHIME encourages CMS to refrain from implementing any requirements related to OpenNotes or measuring how patients access or utilize their information. Currently, these activities are next-to-impossible for providers to measure, and in many cases, the standards related to notes are still in development or yet to be implemented. CMS should work further with ONC on their work with the United States Core Data for Interoperability (USCDI) to ensure all note types have standards and those that are required to be implemented are made clear by ONC prior to requirements being put in place through the PFS.

We appreciate the opportunity to comment and welcome the chance to help inform the important work being done by CMS. We look forward to continuing to be a trusted stakeholder throughout your tenure as CMS Administrator and continuing to deepen the long-standing relationship CHIME and CMS have shared. Together, we can work to envision and achieve the 21st century health system of the future we have long dreamed of implementing. Working together through the rulemaking process, such as with the PFS, is just one way we can accomplish that goal together. Should you have any questions about our letter, please contact Andrew Tomlinson, Director of Federal Affairs, at atomlinson@chimecentral.org.

Sincerely,

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

John Kravitz
Chair, CHIME Board of Trustees
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