September 13, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1751–P
Submitted electronically to: http://www.regulations.gov

Re: 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 (CMS–1751–P)

Dear Administrator Brooks-LaSure:

On behalf of the Premier healthcare alliance serving approximately 4,400 hospitals and health systems, hundreds of thousands of clinicians and 225,000 other provider organizations, we appreciate the opportunity to submit comments on the Centers for Medicare & Medicaid Services CY 2022 Physician Fee Schedule (PFS). Premier maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Our comments primarily reflect the concerns of our hospitals and health systems, their employed physicians and independent physicians aligned with them. Premier runs the largest population health collaborative in the country, the Population Health Management Collaborative, has worked with well over 200 accountable care organizations (ACOs) and is currently comprised of more than 70 ACOs.

MEDICARE SHARED SAVINGS PROGRAM (MSSP)

Amended ACO Quality Reporting and Quality Standard

During last year's rulemaking, CMS finalized several fundamental changes to the MSSP quality performance standard, including sunsetting the Web Interface in CY2022 and requiring ACOs to report electronic clinical quality measures (eCQMs) or MIPS CQMs. At the time, Premier, along with several other stakeholders, raised several concerns with this policy and recommended that CMS provide a smoother transition to the new requirements.

In response to stakeholder concerns, CMS is proposing several changes to transition ACO quality reporting away from the Web Interface. Under the proposal, ACOs would have the option of reporting either the 10 Web Interface quality measures or the three eCQMs /MIPS CQMs in PY2022 and PY2023. To further the transition, CMS proposes that ACOs that choose to report Web Interface measures in PY2023 would also be required to report at least one of the three eCQMs /MIPS CQMs. CMS also seeks comment on further extending the CMS Web Interface.

We appreciate that CMS has taken our recommendations into consideration and is now proposing a more gradual transition to these requirements. While we had long advocated for allowing ACOs to report measures through reporting mechanisms other than the Web Interface and reducing the number of

required measures, we are concerned that the policy places significant burden on providers, during a time when they were still actively responding to the COVID-19 pandemic. **As a result, we ask CMS to use caution in advancing this new reporting approach.** We are concerned that two years will not be sufficient time for ACOs to adapt to these changes. **We recommend that CMS continue to collect more data and stakeholder feedback prior to sunsetting the CMS Web Interface and requiring reporting of eCQMs / MIPS CQMs.**

We offer the following recommendations for improving the ACO quality reporting standard:

- **Recognize the reporting burden associated with eCQMs**
- **Recognize ACO reporting as fundamentally different from reporting by clinicians and groups**
- **Retain the current quality performance standard**
- **Reduce the data completeness threshold and explore sampling approaches**
- **Seek additional input on MSSP quality measure set**
- **Retain pay-for-reporting option for new entities or when measures are newly introduced or modified**

We have provided additional information on each of these recommendations below.

Recognize the burden association with eCQMs and MIPS CQMs

If implemented as currently proposed, the MSSP quality reporting standard would be the only pay-for-performance program that requires reporting of an eCQM measure set. For the past several years CMS has gradually increased the number of eCQMs across all quality reporting programs. In recognition of the challenges associated with reporting eCQMs, CMS has provided notable flexibility in these programs. For clinicians reporting in MIPS, the flexibility is provided by allowing clinicians to select their reporting mechanism and measures. For hospitals, while measure sets are defined, eCQM reporting is limited to the pay-for-reporting programs; eCQMs have not been required in hospital pay-for-performance programs due to the inability to guarantee accuracy of scores for payment purposes. **It is unreasonable to place a more stringent reporting approach on ACOs, that must combine data across settings, while setting-specific quality programs are provided with additional flexibility.** We understand that the policy, as proposed, would give ACOs the option of reporting MIPS CQMS; however, ACOs face the same data aggregation and accuracy challenges with combining data across participant TINs when reporting either eCQMs or MIPS CQMS.

We believe ACOs quality reporting can be the leaders in advancing digital quality measurement, as ACOs are inherently incented to collect data across the continuum for their beneficiaries. ACOs represent an opportunity to understand how we can use existing and novel data sources to accurately assess care across the continuum. However, we must also recognize the challenges inherent in data sharing and aggregation:

- **ACOs vary widely in their electronic data extraction and aggregation capabilities.** Some ACOs have a single electronic health record (EHR) that covers the entire organization, but more commonly ACOs have multiple different EHR instances across the organization – in some cases, numbering well over 100 different EHR instances. For ACOs with multiple EHRs, producing eCQMs from those disparate systems requires time, money, effort in changing workflows and acquiring new technology services.

- **Certified EHR technology (CEHRT) standards have not advanced enough to support quality measurement derived from multiple sources.** The interoperability standards aim to ease data sharing across providers; however, these standards are still under development and evolving. As a result, aspects of the ACO quality policies are not feasible in current systems. For example, CEHRT only allows for reporting eCQMs from a single EHR. As a result, combining data from multiple EHRs to produce a single result is not a capability that most ACOs will have. Similarly, CMS requires that ACOs submit deduplicated patient data. However, at this time there is no technical way to deduplicate data when submitting aggregate QRDA III files, since these files do not have patient-level data.

Recognize ACOs are fundamentally different than clinician and groups

The new reporting requirements essentially align the MSSP quality standard with MIPS. This is a fundamentally flawed approach. ACOs reflect coordination of care across the continuum, as compared to MIPS, which reflect point-in-time encounters by individual clinicians and groups. ACOs are a network of aligned providers rather than a specific provider type. While we generally support alignment across CMS programs, the current policies set MIPS as the gold standard, with APMs as the entity that must align with MIPS. This is antithetical to the goal of moving clinicians from volume to value. Rather, **we should create the ideal measurement approach for APMs and align setting- and provider- specific measurement so that providers are encouraged to move to APMs.**

Another significant change to the reporting requirements is that CMS will now require ACOs to report on all patients who meet the measure specifications, rather than just Medicare beneficiaries aligned to the ACO. We understand CMS' intent is to assess the quality of care across all patients and all payers, similar to the approach CMS uses in other quality reporting programs. All-payer measurement is ideal for setting and provider-specific measurement as you are holding providers accountable for their entire patient population. ACOs are held accountable for cost for a defined patient population by partnering with providers to innovate care. ACOs do not directly provide care. Moreover, the ACO entity does not have the ability or flexibilities to design care interventions for other patients. Requiring ACOs to report on the all-payer population of its participant providers is comparable to requiring a health plan to report on other payer populations.

CMS also states its belief that these requirements will further promote health equity by holding all ACO clinicians to a single set of standards for all patients they treat. This argument is flawed for several reasons. First, other payers have quality measure requirements that are not aligned with the CMS quality requirements. Accordingly, clinicians in ACOs will not have single set of standards. Second, CMS is currently exploring ways to better address health equity in its quality measurement programs, such as through collecting additional sociodemographic data and further stratification of its data. This approach directly addresses health equity. Finally, the quality measures do not account for other patient clinical characteristics that vary between populations. For example, Diabetes Poor Control (HbA1c <9%) is a measure frequently used in CMS programs and across payers. Achieving A1c less than 9 may be more reasonable for younger patients with access to resources, as compared to older patients where goals may shift from achievement to reducing A1c (e.g. going from 12 to 10) or Medicaid patients who have reduced access to resources. Accordingly, the patient mix of the participant clinician population may have a strong impact on performance.

At a minimum, CMS should limit the ACO reporting population to all Medicare beneficiaries. This would set a single performance standard for all Medicare patients served by the ACO's participant clinicians. This approach would also align with approaches used in other payer APMs. Often other payer

APM arrangements were an evolution of pay-for-performance approaches. Accordingly, the APM entity is held accountable for the entire payer population, not just the population included in the APM arrangement.

Retain the 30th percentile quality performance standard

CMS proposes to revise the ACO quality performance standard to delay adoption of the higher standard until PY2024. Under the proposal, the quality performance standard would remain at the 30th percentile across all MIPS Quality performance category scores through PY2023. In PY2024, the quality standard would increase to the 40th percentile. To further incent ACOs to adopt the new reporting requirements earlier, CMS proposes that ACOs that report the three eCQMs/ MIPS CQMs in PY2022 and PY2023 would be deemed to have met the quality standard if at least one of the three measures met the 30th percentile quality threshold. CMS also seeks comment on maintaining the threshold at the 30th percentile for an additional year in 2024.

Premier supports CMS' proposal to provide ACOs additional time to transition to these new requirements. However, as noted above, a number of technical issues remain unresolved. **CMS should delay increasing other requirements – such as requiring reporting on one eCQM or raising the quality threshold.**

Reduce the data completeness threshold and exploring sampling approaches

As we discuss above, ACOs should not be held accountable for performance of patient populations served by other payers. While we believe ACOs should be held accountable for only their aligned population, at a minimum, CMS should limit the population to Medicare population. Regardless of the approach (i.e. all-payer, Medicare only, aligned beneficiaries only), the policy will require ACOs to report on a significantly larger population. For example, currently an ACO with approximately 76,000 aligned beneficiaries would be required to report a sample of about 600 aligned beneficiaries per measure under the Web Interface reporting structure. Shifting to the new eCQM reporting requirements, the same ACO would be required to report on anywhere from 43,000 to 269,000 patients across all payers, depending on the eCQM.

To reduce the reporting burden, CMS should employ the following approaches:

- **Lower the data completeness threshold.** Starting with a lower threshold would allow ACOs additional time to adapt their various data systems to extract data from affiliated clinicians. This approach also aligns with how CMS implemented reporting for clinician and group reporting, which began with a data completeness of 40 percent and increased gradually to 70 percent.
- **Test sampling approaches.** ACOs are large entities with a minimum of 5,000 beneficiaries resulting in millions of patient encounters. The inclusion of all data points is not needed in order to have a clear picture of quality. CMS has precedence for using a sampling approach in other programs—the Medicare Advantage Star Ratings and CAHPS.
- **Test options to limit the population by patient type.** While we recommend CMS limit ACO reporting to aligned beneficiaries or the Medicare patient population, we recognize that at this time many ACOs do not have the technical capabilities to report on a subset of their population through eCQMs or MIPs CQMs. The QRDA I files do not include information on payer type so ACOs are unable to segment the populations. We encourage CMS to work with stakeholders to develop alternatives for compiling data and identifying patient subsets.

As noted above, numerous technical issues remain for ACOs to report eCQMs or MIPS CQMs. We recommend that CMS recruit ACOs to pilot test various approaches.

***Set quality performance benchmarks specific to MSSP*.**

Under the new quality performance standard, ACOs must achieve at least the 30th percentile across all MIPS Quality performance category scores in order to be eligible for shared savings. CMS proposes to increase the threshold to the 40th percentile in PY2024. We believe ACOs will be unfairly disadvantaged when compared against the MIPS quality performance scores. Since MIPS participants can select which measures they report, participants are incentivized to choose measures on which they have historically and are currently performing well. As a result, the MIPS overall quality score tends to skew high, even if individual measures do not. Based on our analysis of past performance by non-Web Interface reporters, ACOs will need to achieve the 6th decile or higher on each individual measure in order to achieve the 30th percentile of overall quality score.

In the rule, CMS notes that PY2019 MIPS Quality performance category score at the 30th percentile was equivalent to 87.9 and at the 40th percentile was equivalent to 95.7. Using the 40th percentile, approximately 20 percent of ACOs would fall below the 40th percentile in PY2023 and therefore not be eligible to share in savings. CMS should provide additional information on how it calculated this analysis. Additionally, since MIPS scores have continued to increase in recent years, we would anticipate that the thresholds could be even higher in PY2023 and beyond.

We also recommend that CMS continue to publish in advance the quality measure benchmarks. Currently, CMS publishes the quality measure benchmarks that ACOs must achieve in advance of the upcoming performance year. This information is valuable in informing ACOs' quality improvement activities and helps identify the performance standard they are aiming for.

Finally, CMS proposes to set its MIPS quality measure benchmark for 2022 based on the actual 2022 performance period, rather than using its standard approach of setting the benchmark based on data from two years prior to the performance period, or 2020. CMS also seeks comment on an alternative approach to set the 2022 benchmark based on 2019 performance. We appreciate CMS taking action to avoid use of 2020 data, which was significantly impacted by the ongoing COVID-19 PHE. However, **we recommend that CMS finalize its alternative methodology to use 2019 data.** At this time, it is unknown what impact the PHE will have on 2022 performance. Additionally, as noted above, we continue to encourage CMS to set quality measure benchmarks in advance so that providers can utilize information inform their quality improvement activities.

***Seek additional input on MSSP quality measure set*.**

While we appreciate the significant reduction in number of measures required for reporting, **we urge CMS to take additional time to seek stakeholder input on the types of measures that should be included in the MSSP measure set.** It is critical to ensure that the MSSP measure set reflects the program and includes measures that assess how care is provided across the continuum. **CMS should use the Measure Applications Partnership (MAP) to provide input on the ideal measure set for MSSP,** as the statutory intent of the MAP is to evaluate quality measures to ensure the measures appropriately fit a program.

CMS also seeks input on allowing ACO participant TINs to report on either the MIPS eCQMs/CQMs or MVPs applicable to their specialist. While specialists play a critical role in managing certain high-cost chronic conditions, ACO-aligned beneficiaries only make up a small portion of the population that specialists see. As a result, specialist-focused measures will not be a true metric of care furnished by the ACO. Additionally, focusing on specialist measures has the potential to further incentivize ACOs to remove specialists from the TIN since the ACO may have a minimal role or tools to improve performance on these measures.

CMS should instead focus on developing measures that reflect the holistic care that ACOs furnish across the continuum and the ability of ACOs to manage populations across multiple providers, including specialists. For example, focusing on outcomes for high-cost conditions, such as cardiovascular conditions or diabetes, will reflect care provided by specialists.

***Retain pay-for-reporting option for new entities or when measures are newly introduced or modified*.**

Providing a year of pay-for-reporting in these instances grants ACOs valuable time to evaluate current workflows, data capture, and other operational strategies necessary to monitor and report a measure. This flexibility is particularly important for new ACOs and those with practicing providers on multiple EHR systems, where changes to measure specifications will require significant system updates. **As a result, we recommend that CMS retain a pay-for-reporting option for new entities, new measures, and measures that undergo significant changes.**

Use of Regional FFS Expenditures in Establishing, Adjusting, Updating, and Resetting the ACOs' Historical Benchmark

Under the current MSSP benchmarking methodology, CMS uses historical expenditures from an ACO's assigned beneficiaries, as well as factors based on national and regional FFS expenditures. The purpose of incorporating regional expenditures into the benchmark calculation is to mitigate the "race to the bottom" approach that results when a benchmark is based solely on an ACO's historical experience. However, an ACO's assigned population is included in the regional reference population. For ACOs with a large penetration in the region, this may have the unintended consequence of continuing to set the benchmark solely based on an ACO's historical performance, thus perpetuating the race to the bottom. CMS seeks input on a methodology that balances removal of ACO-assigned beneficiaries without adding too much complexity and potential for calculation error.

Premier supports modifying the benchmarking methodology to ensure ACOs are not penalized for efficiencies they have gained through participation in MSSP. As noted above, current benchmarking approaches, which are based on a participant's historical experience, set-up a scenario whereby ACOs are competing against themselves and must continue to achieve year-over-year savings. This methodology is not sustainable and will make it more challenging for ACOs to continue participating in the MSSP.

While we support removing an ACO's population from the regional reference population, we ask that CMS explore and provide stakeholders information on the potential impact to ACOs with large portions of specialist participants. Under MSSP, beneficiaries are assigned to an ACO based on the plurality of primary care services. Advanced practice providers operating in specialists' officers are classified as primary care providers for purposes of attribution. Beneficiaries who are attributed through these providers may have higher costs as a result of a high-cost episodes of care for which they are seeing the specialist, such as cancer or a cardiac event. We are concerned that ACOs with a large proportion of specialists may have a patient population that is very different (i.e. historically more costly) than the remaining region.

CMS should also consider other sustainable approaches to benchmarking. For example, to address concerns over the impact of ACO-assigned beneficiaries on the regional trend factor, CMS should modify the region it uses for setting the trend factor so that no more than 50 percent of the region's assignable beneficiaries are assigned to that ACO. By increasing the regional population, CMS will help to mitigate the impact of past performance on the calculation of the regional trend and adjustment factors, while ensuring that CMS still maintains a large enough population to accurately calculate the factors.

CMS should also explore ways to further stratify benchmarking based on patient risk factors. The current benchmarking and risk adjustment methodologies favor patients who are attributed based on primary care services. As a result, benchmarks are often artificially lower for certain high-cost patient populations, which can disincentivize inclusion of specialists in ACOs. For example, in recent years we have seen a rapid increase in Part B drug costs for oncology patients. These increased costs are not sufficiently accounted for in existing benchmarking or risk adjustment methodologies, resulting in losses for ACOs who may serve a large oncology population. To better account for these high-cost patients, CMS should further stratify its current benchmarking approach to set separate benchmarks for patients with certain high-cost chronic conditions or treatments.

Request for Comment on the Shared Savings Program's Risk Adjustment Methodology

CMS also seeks input on ways to improve its risk adjustment methodology, particularly to better account for medically-complex, high-cost patients. Additionally, CMS seeks comment on different approaches for capping ACO risk score growth.

CMS utilizes varying risk adjustment methodologies across its programs and models. With different approaches, providers have different incentives which lead to inconsistent practices. For example, MSSP ACOs have the opportunity to improve their benchmark by up to 3 percent over the course of their agreement period with more accurate coding documentation. In Medicare Advantage, there is no limit to risk score increases or decreases. Clinicians are the primary source of coding documentation and are incented to maximize coding as part of their negotiations with payers, but must negotiate their risk-based arrangements with payers to maximize a share of risk adjustment. There is a need to standardize the risk adjustment methodology across all Medicare programs and models. At a minimum, CMS should align the methodology used in MSSP Enhanced with Medicare Advantage.

Premier also strongly urges CMS to increase the risk score cap to 5 percent and to apply a symmetrical cap on decrease in risk score. Increasing the cap to 5 percent will better account for changes in risk score over the agreement period. The current methodology of normalizing risk adjustment in a region can penalize ACOs who have been coding accurately and who maintain the same level of risk over their agreement period. Under this scenario, an ACO could see a decrease in their risk score if others in their region increase their coding intensity. This issue is further exacerbated for ACOs who include a large number of specialists, since they have less opportunities to increase their risk score. CMS has previously indicated that it is hesitant to introduce a cap on decreases in risk score because it is concerned it could create a gaming opportunity for ACOs. CMS has other tools for monitoring for potential gaming, such as continuing to monitor voluntary alignment.

Across all Medicare programs and models, CMS should work to recalibrate the risk adjustment methodology by:

- ***Updating HCC Model to use ICD-10 codes.*** The current methodology is based on ICD-9 codes, which have been largely phased out under the Medicare payment systems in favor of the ICD-10 code set. ICD-10 codes allow for multiple clinical concepts, offering more specificity than ICD-9. In the past, CMS has expressed concerns that coding has not stabilized. However, the health industry has been using ICD-10 codes for more than six years and the risk adjustment model needs to be updated to reflect the new code set. CMS should work with stakeholders to explore ways to incentivize more accurate ICD-10 coding.
- ***Refining HCC Diagnoses*.** Data integrity and the refinement of the HCC models is dependent on the data quality and the reporting of the most specific, accurate diagnosis information. To further

incentivize accurate coding, CMS should remove certain. unspecified codes that should have specificity. For example, diabetes with unspecified complications, unspecified heart failure, and unspecified peripheral vascular diseases are diagnoses that lack specificity but are still assigned as an HCC category, even though complications can vary significantly

- ***Incorporating Social Determinants of Health.*** Social determinants of health (SDOH) are widely recognized as important predictors in clinical care. Incorporating SDOH disease interactions would provide a mechanism to encourage the collection of SDOH without incentivizing coding intensity for financial improvement. We believe SHOH should be used as a disease interaction methodology to appropriately capture the impact of SDOH on patient severity reporting. Just as the AMA has recognized the important of SDOH in the medical decision-making component used in the assignment of evaluation and management code level methodology, a SDOH component should be factored into the HCC severity calculations.

Revisions to the Definition of Primary Care Services used in MSSP Beneficiary Assignment

CMS proposes to update its definition of primary care services used for beneficiary assignment to ACOs, beginning in CY2022. These changes would align with additional codes that CMS is proposing for the PFS. Additionally, CMS proposes that certain telephone E/M services will continue to be available for assignment so long as they continue to be deemed payable under Medicare FFS telehealth policies. Finally, CMS proposes a process to directly replace CPT or G-codes on the list of primary care services used for beneficiary assignment when codes undergo routine updates. This process will shorten the gap between when codes are updated and finalized for use in assignment.

Premier supports CMS' proposals to update the list of primary care services available for beneficiary assignment. These changes will help ensure alignment with the PFS and that beneficiaries are appropriately aligned with the ACO.

Beneficiary Information Notice for ACOs with Prospective Assignment

CMS proposes to update its requirements for beneficiary notification to better align with the MSSP's assignment methodologies. Currently, ACOs must notify all FFS beneficiaries who are eligible for assignment, including beneficiaries who may not be ultimately assigned to the ACO. Under this proposal, ACOs under prospective assignment would only need to notify those beneficiaries who are assigned to them at the start of the performance year. ACOs that selected preliminary prospective assignment would continue to be required to notify all Medicare FFS beneficiaries who may ultimately be assigned to the ACO. CMS also seeks comment on whether it should modify the frequency with which beneficiary information notifications are provided, such as reducing the frequency to once per agreement period.

Premier supports modifying the beneficiary notification requirements for ACOs that are prospectively aligned. The proposal will help reduce administrative burden on the ACOs and will reduce beneficiary confusion by only requiring prospectively aligned ACOs to notify beneficiaries that will be aligned to the ACO. **Premier also supports reducing the frequency of required notification to beneficiaries to once per agreement period.** Requiring ACOs to notify beneficiaries annually when there have been no programmatic changes can cause unnecessary confusion and burden on patients. Additionally, removing this annual requirement will significantly reduce burden on ACOs.

Repayment Mechanism Amount Calculation

CMS proposes changes to its methodology for calculating repayment mechanism amounts, which will both reduce the required amount and modify the threshold for determining if ACOs must increase their

repayment mechanism during the agreement period. As part of this, CMS proposes to allow ACOs in existing agreement periods to modify their repayment mechanism if the new methodology will result in a lower amount.

Currently, CMS sets the repayment mechanism amount as the lesser of either 1 percent of total per capita Parts A and B fee-for-service (FFS) expenditures for the ACO's assigned beneficiaries or 2 percent of total Parts and B FFS revenue of its ACO participants. For both calculations CMS uses data from the most recent calendar year for which data is available. Under its proposal, CMS would reduce these percentages by half and set the percentage based on the lesser of 0.5 percent of total per capita expenditures or 1 percent of total revenue. CMS also seeks comment on an alternative methodology by which it would set the repayment mechanism amount based on a percentage of actual historical median per capita shared losses multiplied by the number of beneficiaries assigned to the ACO. Under this alternative framework, CMS would set different percentages for high- and low-revenue ACOs.

Premier generally supports CMS proposed changes to the repayment mechanism amount as it will better align amounts with potential repayment liability risk. We are supportive of setting the amount based on some percentage of historical median per capita losses weighted by the number of assigned beneficiaries. This methodology is more transparent and would allow ACOs to better predict their repayment mechanism amount prior to moving to two-sided risk. **However, we are not supportive of setting different percentages based on whether an ACO is high- or low-revenue**. The high-low revenue distinction in MSSP is arbitrary and creates an uneven playing field for ACO participants. Additionally, the policy has had the unintended consequence of discouraging partnerships between certain types of providers, such as hospitals and specialists. CMS must stop using this distinction in MSSP policies as it only penalizes ACOs who work to include a variety of provider types in the participant list.

Reducing MSSP Application Burden

CMS also proposes a number of changes to the application process which will reduce the amount of information that ACOs must submit. Specifically, CMS will no longer require ACOs to disclose prior participation in the program unless requested by CMS. Additionally, CMS will no longer require ACOs to submit sample ACO participant agreements nor executed ACO participant agreements at the time of initial application or participation renewal.

Premier supports the proposed changes to the application requirements. As CMS notes, these changes will reduce administrative and programmatic burden on ACOs, while continuing to ensure the integrity of the MSSP.

MSSP Innovation

MSSP ACOs have been instrumental in transforming our healthcare system through improved quality and reduced costs. In 2020 alone, MSSP ACOs saved the Medicare program approximately $1.9 billion and achieved shared savings of nearly $2.3 billion. More than 12.1 million Medicare fee-for-service beneficiaries benefit from care furnished by providers affiliated with an ACO.[1]

To further build on these successes, ACOs need additional flexibilities and tools to advance value-based care. Innovating care requires flexibility beyond what is currently allowable in fee for service, yet current

[1] CMS Press Release, "Affordable Care Act's Shared Savings Program Continues to Improve Quality of Care While Saving Medicare Money During the COVID-19 Pandemic," August 25, 2021, https://www.cms.gov/newsroom/press-releases/affordable-care-acts-shared-savings-program-continues-improve-quality-care-while-saving-medicare

programs and models have provided minimal flexibility. As part of Innovation Center models, such as Direct Contracting, CMS has introduced new payment and attribution methodologies, along with enhanced waivers and flexibilities. ACOs participating in MSSP should not have to leave this permanent program to take on more advanced risk or to utilize new flexibilities.

Premier urges CMS to utilize MSSP as an innovation platform to provide ACOs with additional tools to drive care innovation, including:

- **Establishing an opportunity for participants to elect 100% risk.** Under this track, participants would be eligible for 100% shared savings/losses. Similar to Next Generation ACO (NGACO) or the Direct Contracting full-risk track, CMS could apply a discount to guarantee Medicare savings.

- **Providing a glide path to capitation.** Premier has long advocated for a model which allows an ACO to establish primary care capitation and bundled payments within the ACO. CMS should provide MSSP participants a similar option which would allow them to reduce a certain percentage of FFS payments in exchange for receiving a prospective population-based payment. CMS has employed similar methodologies in Direct Contracting and NGACO, such as through the All-Inclusive Population-Based Payment (AIPBP).

- **Testing new options for alignment.** To achieve the Health Care Payment Learning and Action Network's (LAN) goal of 100 percent of payments through risk-bearing arrangements, we must think beyond primary care attribution approaches. Voluntary alignment is beneficial but is still limited to beneficiaries with an ongoing relationship with a primary care provider. CMS should consider testing new approaches to aligning beneficiaries, such as through other types of non-primary care providers (e.g., specialists) or based on the ACO's affiliation with Medicaid Managed Care Organizations (MCOs). CMS should also explore geography-based alignment. CMS sought to include a similar alignment methodology in the Direct Contracting Geographic Model. However, this model was problematic as it created overlap challenges with providers currently participating in APMs.

- **Establishing additional benchmark options based on patient population and clinical need,** especially for complex patient populations. To drive innovation in care, providers need adequate budgets to meet the care needs of various populations. CMS has recognized the need to modify benchmarking approaches to meet the needs of certain populations through other models, such as the Primary Care First Seriously Ill Population and the Direct Contracting High Needs track. We urge CMS to consider additional benchmarking approaches for certain high-needs or high-cost Medicare populations. This approach will be critical as CMS seeks to align additional beneficiaries with APMs. Unassignable beneficiaries typically have not received primary care services and are frequent emergency department users. As a result, current benchmarking and risk adjustment approaches, which are based on historical claims, are unlikely to capture the costs of these patients.

- **Offering enhanced waivers or benefits.** CMS should expand the types of waivers and enhancements available under MSSP to match those that are offered under the NGACO and Direct Contracting. For example, CMS should improve the MSSP Beneficiary Incentive Program to match flexibilities granted under the NGACO model. CMS should also look to adopt flexibilities granted under the COVID-19 PHE, such as hospital at home model and additional telehealth flexibilities

TELEHEALTH AND OTHER SERVICES INVOLVING COMMUNICATION TECHNOLOGIES

Telehealth has been an essential tool for providers in addressing the healthcare needs of patients during the COVID-19 public health emergency (PHE). **We appreciate the flexibilities that CMS has provided and urge CMS to continue to expand Medicare coverage and payment of all types of virtual services involving communications technologies including telehealth, online visits, and audio visits.** We also urge CMS to expand telehealth flexibilities granted under the public health emergency to APMs.

Revised Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis

As part of last year's rulemaking, CMS had finalized a new category of telehealth services (Category 3), which would allow services to be added on a temporary basis while it continued to develop and assess the clinical evidence base to support permanent adoption. Under this policy, Category 3 services would remain on the telehealth list through the later of the end of CY 2021 or end of the PHE.

CMS is proposing to revise this policy to allow coverage of Category 3 telehealth services through the end of CY 2023. **The Premier health alliance supports CMS' proposal to extend the timeline of coverage of Category 3 telehealth services.** This will allow additional time for data collection and analysis to demonstrate clinical benefit, as well as provide time for stakeholders to submit requests to CMS for moving a Category 3 service permanently to the telehealth list.

Broader Telehealth Reforms

Premier continues to believe that telehealth services offer the ability to enhance medical management between patients and providers, enable remote monitoring, and greatly improve communication and education between primary and specialty care providers. **We continue to recommend that CMS expand telehealth flexibilities in APMs**. Specifically, the following waivers should be implemented without burdensome documentation requirements across all downside risk arrangements:

- **Originating Site Restrictions**: Several current CMS APMs include waivers for these requirements allowing patients to be outside of these geographic areas when receiving telehealth services and to use the patient's home as an originating site. These waivers greatly expand the utility of telehealth for both patients and providers but have been challenging to implement due to burdensome documentation requirements. CMS should develop uniform language for this waiver that can be incorporated into the design of future models. Additionally, CMS should look to minimize the administrative burden of implementing a telehealth waiver.

- **Asynchronous Service Delivery:** Telehealth services are generally limited to synchronous (real-time) interactions between patients and providers. Some CMS APMs (for example the Next Generation ACO model) have included waivers to allow asynchronous telehealth where images and other relevant information are transmitted to a distant site provider for review and response at a later time. This flexibility is limited to dermatology and ophthalmology and must be done using secure electronic communications systems that include visualization of the patient. CMS should extend this flexibility to additional APM participants. Furthermore, we recommend that CMS expand the ability to provide asynchronous telehealth to other provider types and service areas where real-time communication is not essential for treatment decisions and where such a flexibility could be reasonable expected to improve patient access to services.

- **Cross-State Licensure**: As part of the COVID-19 PHE response, CMS implemented a temporary waiver allowing providers to deliver telehealth services across state lines as long as they met a standard set of licensure requirements. This waiver, intended to improve access during the PHE, also creates an opportunity to improve patient access to services overall and provides a pathway for improved continuity of care for patients that have moved or are traveling across state lines. CMS should work in support of state efforts to develop standards for telehealth licensure and participation in interstate medical licensure compacts that would allow for care delivery across state lines and incorporate this flexibility into the design of future APM models.

We also encourage CMS to work with Congress to adopt broader telehealth reforms.

PHE Flexibilities for Direct Supervision Requirements

Certain Medicare regulations impose more restrictive supervision requirements than existing state scope of practice laws which hinder healthcare professionals from practicing to the full extent of their licenses. During the COVID-19 PHE CMS has enacted several key flexibilities around supervision and scope of practice which have been essential in ensuring access to healthcare for the Medicare population and has greatly improved the efficient of care delivered during the PHE. One of these key flexibilities has been the ability of healthcare professionals to meet supervision requirements through the use of audio/visual real-time communications technology.

Premier urges CMS to permanently adopt its policy to allow practitioners to meet direct supervision requirements through a virtual presence. As part of the rule, CMS seeks comment on whether this policy should be applied to a subset of services. If CMS is concerned that adequate oversight will not be provided, CMS should extend the policies allowed during the COVID-19 PHE for a sufficient number of years to collect robust data on patient outcomes and satisfaction and access to care for Medicare beneficiaries, especially in rural areas and in communities with shortages of healthcare personnel

Concurrent Billing for Care Management Services

CMS proposes to allow RHCs and FQHCs to concurrently bill for transitional care management (TCM) services and other care management services when these services are furnished to a beneficiary during the same service period and all other requirements for billing are met, beginning in CY2022. CMS had previously extended this policy under the PFS, beginning in 2020; however, it had not extended this to RHCs and FQHCs, which continue to be restricted from billing care management services with TCM. **Premier supports CMS proposal to allow for concurrent billing of TCM and other care management services.** As CMS notes, these services complement one another and will help improve access to these critical services.

RHC and FQHC Telecommunication Technology

Under the COVID-19 PHE, RHCs and FQHCs can serve as distant sites for purposes of furnishing telehealth services. However, once the PHE expires, RHCs and FQHCs will no longer be eligible to bill for telehealth services. CMS is proposing to modify the RHC and FQHC benefit categories to allow for certain mental health services to be furnished via telehealth. This proposal aligns with adoption of provisions under the CAA, which allows for a Medicare beneficiary's home to serve as an originating site for telehealth services billed under the PFS when furnished for the purposes of diagnosing, evaluating, or treating mental health disorders. CMS seeks comment on whether it should adopt requirements around in-person services, similar to what is required under the PFS for initial visits and CMS' proposal for subsequent visits.

We applaud CMS for taking steps to improve access to mental health services in rural areas. While prevalence of mental illness in rural areas is comparable to those living in urban areas, rural residents often face significant barriers to accessing mental health services, which result in significant disparities in care. Barriers include limited access to specialized mental health service in their community and underutilization of available services.[2] HRSA has identified that more than 26 million individuals live in rural areas that have been designated as mental health professional shortage areas (HPSAs).[3]
As a result, patients in rural areas often must travel long distances to receive specialized care such as mental health services. Being able to access these services through local RHCs and FQHCs via telehealth will help to increase the frequency in which rural residents can access to mental health services. **We recommend that CMS maintain flexibility and not specify requirements around in-person visits.**

APPROPRIATE USE CRITERIA FOR ADVANCED DIAGNOSTIC IMAGING

The Protecting Access to Medicare Act (PAMA) directed the Secretary to establish the Appropriate Use Criteria (AUC) program which requires ordering professionals to consult AUC through a qualified clinical decision support mechanism (CDSM) for certain imaging services. CMS has addressed components of this program in prior rulemaking. In this rule, CMS makes several proposals for continuing implementation.

Timing of Payment Penalties

The payment penalty phase of the AUC is scheduled to begin January 1, 2022. CMS believes the earliest that the claims processing system can begin screening claims using the AUC program claims processing edits for the payment penalty phase is October 2022. CMS does not think it would be possible for it to finalize implementation and claims processing plans in this final rule as implementing these types of claims processing edits generally require a long lead time. To align the effective date for the claims processing edits, CMS proposed the payment penalty phase to begin the later of January 1, 2023, or the January 1 that follows the declared end of the PHE.

We appreciate that CMS has considered the impact of the public health emergency on providers as well as the remaining claims processing items that are a barrier to implementation**. Premier supports delaying the payment penalty phase until January 1, 2023; however, we ask that CMS continue to work toward full implementation as soon as possible.** We ask that CMS establish an ongoing dialogue with providers and CDSM vendors to rapidly resolve any remaining implementation issues. Feedback provided in this rule about the number of claims meeting the requirements should be made public more frequently during this testing and operations phase.

We also encourage CMS to provide incentives to clinicians who are meeting the AUC requirements. These incentives should begin during the testing and operations period. CMS currently gives half credit in the improvement activities category of MIPS; however, more credit should be given across MIPS categories in recognition of the significant investment and improvements associated with using CDSM to consult AUC. As consulting AUC addresses both cost and quality, CMS could give credit in these categories as well.

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[2] Morales DA, Barksdale CL, Beckel-Mitchener AC. A call to action to address rural mental health disparities. J Clin Transl Sci. 2020;4(5):463-467. Published 2020 May 4. doi:10.1017/cts.2020.42
[3] HRSA, Designated Health Professional Shortage Areas Statistics, Third Quarter of Fiscal Year 2021 Designated HPSDA Quarterly Summary, 30 June 2021, https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport

Modified Orders

The Medicare Benefit Policy Manual (BPM) states that when an interpreting physician determines that a different or additional imaging service that is not included on the order should be performed, the interpreting physician or testing facility generally may not perform the test until a new order from the treating physician has been received. The manual includes circumstances under which the interpreting physician or testing facility may furnish the additional imaging services. CMS believes under these circumstances, the interpreting physician/practitioner is exercising their professional judgement to provide the ordering professional with additional diagnostic test results for managing the patient's care and it would not be appropriate to consider the interpreting professional as acting as the ordering professional.

CMS proposes that when the furnishing professional for an advanced diagnostic imaging service performs one or more additional services under the circumstances described above, neither the ordering professional nor the furnishing professional are required to consult the AUC for the additional services(s). In these situations, the AUC consultation information from the original order should be reported on the claim line for the additional service(s). When these conditions are not met, it is expected that a new order will be submitted to the furnishing entity by the original ordering (treating) provider. CMS expects situations where AUC consultations do not occur for new or modified orders to be infrequent.

This proposal conflicts with guidance CMS issued in 2018, in which CMS stated "In instances when the furnishing professional must update or modify the order for an advanced diagnostic imaging service, the AUC consultation information provided by the ordering professional with the original order should be reflected on the Medicare claim to demonstrate that the requisite AUC consultation occurred." Accordingly, EHRs to implement functionality that automatically applies AUC information from an original order to the order to which it is modified without any verification that the requirements for order modification specified above were met.

We believe there will be instances in which a new AUC consultation will be required yet providers will not have systems in place to correctly identify modified orders that require AUC consultation. **In recognition of the earlier guidance provided by CMS, we ask that CMS allow providers to apply the MH modifier to any situation in which a furnishing professional determines a new or modified order should be performed without first requesting that the new or modified order be submitted by the original ordering professional.** This would maintain the consistency of ensuring that AUC consultation is required for orders placed by ordering professionals without extending the requirements to furnishing professionals. At the same time, it should be readily implementable by EHRs and billing systems given the work already done to operationalize previous guidance. Ultimately this approach we believe will minimize impact to furnishing professional workflows and timely delivery of care.

Claims Processing

CMS discusses the operational and administrative issues related to implementation of the payment penalty phase. CMS states that full implementation of the AUC program requires edits in the claims processing system to deny Medicare claims that fail to report the required AUC consultation information. CMS notes it needs workable solutions that allow the AUC program to accurately pay and deny claims using available claim's information, while working within the limitations of the Medicare claims processing system. **We appreciate that CMS recognizes the implementation challenges associated with the AUC program.** As we note above, we encourage CMS to engage in an ongoing dialogue with providers and vendors rather than solely relying on the notice and comment rulemaking process.

Inpatients Converted to Outpatients

CMS discusses the situations where a beneficiary's hospital inpatient status changes to outpatient and the criteria that must be met. When these criteria are met, condition code 44 (inpatient admission changed to outpatient) is appended to the institution claim. CMS proposes to allow institutional claims meeting these requirements to use condition code 44 to bypass AUC claims processing edits. **We support this proposal; however, we are concerned that not all patients who are moved from inpatient to outpatient during an encounter will meet the criteria for applying condition code 44.** As a result, health systems are performing AUC on all inpatient imaging orders to avoid missing AUC consultation when the patient is inpatient, but the imaging is not performed until the patient is outpatient.

As a result, this policy will mandate AUC consultations for all imaging ordered in the inpatient setting. We recommend that CMS create an exemption for any inpatient order for advance imaging services that is furnished within a short period (e.g. 5 days) after the inpatient discharge. We suggest that CMS develop a new modifier (e.g. MI) to address inpatient imaging orders that are performed in the outpatient setting shortly after discharge.

Deny or Return Claims that Fail AUC

CMS is considering whether claims that do not pass the AUC processing edits, and therefore will not be paid, should be initially returned to the healthcare provider so they can be corrected and resubmitted, or should they be denied so they can be appealed. CMS seeks comments on whether claims should be initially paid or denied and whether the payment penalty phase should begin first with returning claims and then transition to denying claims. CMS notes that a transition may be helpful as professionals and facilities submit claims under the AUC program.

Medicare as a Secondary Payer

CMS discusses stakeholders concerns that in some EHRs, the secondary payer information is typically not available. CMS notes that when Medicare is the secondary payer no Medicare payment would be made after the primary payer makes payment. Medicare is reported as the secondary payer for the approximately 1.5 percent of advanced diagnostic imaging service subject to the AUC program. **We support CMS' proposal to allow claims that identify Medicare as the secondary payer to bypass the AUC program claims processing edits.**

Date of Service and Date of Order

CMS will specify a start date for when the AUC program claims process edits become effective. Because CMS cannot identify the order date for an advance diagnostic imaging service based on claims information, CMS proposes that the AUC program claims processing edits for the payment penalty phase will be applicable for services furnished on or after the effective date of the claims edit. **We support this proposal and appreciate that CMS has addressed the gap in current regulations for orders placed in 2022 but furnished in 2023.**

HCPCS Modifiers

CMS created modifiers for use during the educational and operations testing phase. CMS intends to discontinue the use of Modifier QQ (ordering professional consulted a qualified CDSM for the service and the related information was provided to the furnishing professional) and MH (AUC consultation information was not provided to the furnishing professional and furnishing facility) at the end of the education and operations testing period. **We support this change as proposed.**

QUALITY PAYMENT PROGRAM

MIPS Value Pathways

CMS proposes several policies to operationalize the MIPS Value Pathways (MVPs). Under the proposals, clinicians would have the option to voluntary report one of seven MVPs beginning with performance year 2023. CMS had previously established that MVPs would begin in 2021 and subsequently delayed reporting until 2022 due to the public health emergency. CMS discusses a potential timeline with MVPs as the sole reporting option beginning with performance year 2028. **Premier appreciates the delay in the transition to the MVPs. We continue to believe that MVPs should not be required until there are MVPs applicable to 90 percent of clinicians.**

We appreciate that CMS acknowledges having internal data submission limitations that could slow the pace of actual burden reduction by MVPs until the agency can move its quality programs to fully digital platforms. CMS should also recognize that clinicians having varying capacities to adapt to these new requirements. **Premier recommends that CMS provide robust stakeholder feedback during the MVP voluntary reporting periods.** Additionally, the pathway to MVPs and digital measurement should be an iterative process that takes into account stakeholder feedback as there are updates to the CEHRT standard, measure specifications, and other requirements.

CMS also notes that optimal relationship between MVPs and APMs remains unclear. **We urge CMS to design MVPs so that providers are prepared and better incented to adopt APMs.** Requiring MVPs to include a population health measure and incorporating health equity measures over time is a step towards encouraging movement into APMs. However, every aspect of MVPs should be designed to encourage the movement to APMs, including measure scoring and weights, multispecialty group/subgroup reporting composition, and reporting exceptions. Currently MIPS provides little to no incentive for moving to value-based arrangements because the bar for avoiding a negative payment adjustment in MIPS remains low and many clinicians are exempt from MIPS. Moreover, as we discuss above, CMS has incorrectly aligned measurement for clinicians in APMs, such as the MSSP with measurement in MIPS. When designing the MVPs and determining scoring approaches, **CMS should consider the incentives inherent in APMs (i.e. coordinating care to improve outcomes and reduce costs) to ensure the MVPs are designed to encourage adoption of APMs.**

Advancing to Digital Quality Measurement

CMS articulates its goal of moving to fully digital measurement by 2025. As part of this goal CMS aims to streamline the approach to data collection, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, improvement, and learning. Premier appreciates CMS' commitment to advancing digital measurement. We have long been committed to advancing providers' capability to analyze data from multiple sources and to manage the health of their populations. We offer the following comments on advancing digital quality based on experience with supporting providers in advanced data analytics and quality reporting:

- ***Definitions***. CMS defines digital quality measurement as software that processes digital data to produce measures scores. While we support this definition, we caution CMS from creating separate standards or requirements for digital quality measurement software. Many systems such as EHRs, health information exchanges (HIEs), and registries currently meet this definition and are regulated by CMS and ONC. Any requirements of these tools should be incorporated into existing

regulation in order to reduce inconsistencies in requirements and timelines and alleviate any additional provider reporting burden.

- ***Data Access***. CMS notes that data sources for digital quality measurement may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information HIEs, or registries, and other sources. We appreciate that CMS is broadly considering numerous types and sources of data; however, we note that providers currently have limited real-time access to robust claims and EHR data. Federal efforts are needed to accelerate adoption and consistent implementation of data and interoperability standards, enhance certification of EHRs, require seamless and unfettered provider data access at the point of care and within the workflow, and make claims-data more readily available to providers. As access to existing digital data sources is limited, we ask that CMS speed access to those sources and consider provider access to novel digital data sources (e.g. wearable device) prior to implementing measures that require use of novel data.

- ***Timing.*** We appreciate the commitment to rapidly move to digital quality measurement by 2025. We ask that in setting timelines for the transition CMS consider how digital quality measures timelines align with other implementation timelines, such as ONC's promoting interoperability and CEHRT.

- ***Data Standards.*** CMS notes that its potential action steps are to leverage and advance standards for digital quality and to redesign measures to be self-contained tools. Specifically, CMS discusses using FHIR for electronic clinical quality measures (eCQMs) and designing software solutions for digital quality measures to be compatible with any data sources that implement standard interoperability requirements. A holistic approach is needed for data standards whereby standards are developed and adopted for use across care settings. There are at present a limited number of common data elements across inpatient, outpatient, and post acute care; however, these elements could serve as a starting point for cross-continuum patient assessment. While FHIR will likely make development and maintenance of measures easier over time, measure developers are just beginning to test measures using FHIR. We will need sufficient testing and consideration by multi-stakeholder groups such as HITAC and NQF prior to wide-spread adoption. A critical component to using FHIR for eCQMs is the adoption of bulk FHIR transactions to simplify and speed transmission. In the absences of bulk FHIR transactions, providers will be unable to support FHIR implementation. CMS needs to work with ONC to advance the adoption and consistent implementation of data and interoperability standards so that provider data collection and reporting requirements are enabled by health information technology

  Meanwhile, we ask that CMS and ONC continue to address some of the underlying data issues. For example, the annual iteration of QRDA-I file standards creates a burden on EHRs to frequently adopt and roll-out the new standards to their customers and this results in many health systems/practices not being able to produce a current-year file through much of the reporting year. The costs of these annual updates are often factored into the pricing of these reporting modules, which can be cost-prohibitive to smaller health systems/practices. Where possible, Premier encourages CMS to promote backward compatibility in both reporting modules and measure development/updates

- ***Data Aggregation.*** CMS discusses actions to better support data aggregation. In addition to EHR oversight, claims data access and promotion of standards. Premier urges HHS to continue efforts

to address the need for a national strategy and approaches to improve patient identification and matching to support patient care and facilitate more accurate data aggregation. In the absence of this it is difficult to track patients across a single encounter, rending it impossible to assess outcomes using numerous types of data.

- ***Measure Alignment.*** CMS notes its continued focus on aligning measurement across reporting programs. Alignment would focus on measure concepts, specifications and individual data elements used to calculate measures. We appreciate the continued focus on measure alignment across CMS programs and the private sector. In aligning measures, we urge CMS continue to continue to address the need for more timely access to robust data.

Closing the Health Equity Gap in CMS Hospital Quality Programs

Reducing disparities in care and achieving health equity across communities requires a holistic approach to care, shifting the incentives in our health system from sickness-based to wellness-based**. When providers are responsible for total cost of care for their patients and have flexibility to address social determinants of health, providers will be proactive in addressing inequity and disparities.** Addressing the underlying social and economic inequities as well as systemic barriers and biases that drive disparities in care requires (1) data collection and monitoring of key outcomes and health equity measures and (2) shifting the payment system to account for a more comprehensive set of services that address disparities. We appreciate CMS' commitment to closing health equity gaps in the CMS quality programs and look forward to partnering with CMS in this area.

Stratification of Measure Results by Race and Ethnicity

CMS seeks comment on approaches to stratify measures by race and ethnicity. Stratifying measures by race, ethnicity, gender and disability will give providers needed insight into potential disparities. Premier has partnered with HHS' Office of Women's Health to leverage Premier's data and proven performance improvement methodology to scale advancements in care for mothers and infants across the nation. This effort includes stratifying measures by race and ethnicity with the aim of reducing health disparities and scaling standardized, evidence-based practices. We believe stratification of outcomes is one of several useful tools to improve health disparities.

CMS seeks comment on using algorithms to indirectly estimate the race and ethnicity of Medicare beneficiaries to overcome the current challenges with demographic information collection and enable timelier reporting of equity results until other ways to improve demographic data accuracy materialize. The agency notes that indirect estimation techniques do not impose additional data collection burden on hospitals, since these are derived using administrative and census-linked data. **We do not support the use of indirect estimation techniques due to data inaccuracy.** Health systems are currently collecting self-reported sociodemographic data from their populations through a variety of methods. Inaccurate measure stratification can disrupt ongoing efforts to improve disparities in care. **Instead, we urge CMS to rapidly and meaningfully pursue efforts to improve access to directly collected race and ethnicity data from self-reported sources.**

Additionally, **we recommend that all efforts to stratify measures by race and ethnicity begin with confidential reporting and appropriate risk adjustment to account for factors associated with outcomes that cannot be addressed by providers**. We must avoid a perverse cycle, wherein we deny resources in the form of both payment penalties and income by discouraging beneficiaries from using providers that care for patients in marginalized communities, subsequently leading to unequal care for those patients due to lack of equal resources to treat them. It is critical that information publicly shared on

disparities in care is accurate and can be understood by consumers. Moreover, while stratification and comparing providers with similar populations helps identify opportunities for improvement, it does not provide hospitals with all the tools necessary to address any underlying factors contributing to health inequities. **These efforts must be combined with a broader set of supports to enable providers to respond to disparities in care**, such as learning networks and data on available community support services.

Finally, we request that CMS also focus on stratifying measures using a broader set of sociodemographic factors, such as income and other social determinants of health.

Improving Demographic Data Collection

CMS seeks input on improving data collection practices to improve capture of demographic elements. We strongly encourage CMS to focus its efforts on driving toward standardization of data capture and measurement, leveraging resources currently available and accessible to providers, and streamlining administrative burden across programs.

Health systems are currently capturing sociodemographic data, but this information is not easily translatable for CMS purposes. For example, despite an available framework for mapping the more than 900 race ethnicity codes provided by the CDC to the OMB, race and ethnicity codes captured in the EHR cannot be consistently mapped. This is a result of lack of use of standard taxonomies—in part by the EHRs and in part by the providers to allow the category selections to align with how their populations would like to report information. Similarly, there are an abundance of tools to screen for social determinants of health with underlying definitions for certain social risk factors (e.g. food insecurity) significantly varying even when the same tool is used by different providers.

Standardization is vital to providers' success in driving towards health equity, as it will foster the development and sharing of best practices within and among clinical settings, health systems, and delivery system designs. The Agency for Healthcare Research and Quality (AHRQ) has found that one of the biggest barriers most health systems face in improving quality and reducing disparities within their own walls is systematically identifying the populations they serve, addressing the needs of these populations, and monitoring improvements over time. AHRQ further found that the principal challenges in obtaining race, ethnicity, and language data for use in quality improvement assessments include a lack of standardization and understanding of why the data are being collected.

We ask that CMS make a concerted effort to advance standards for the collection of socio-demographic information, using existing tools such as the United States Core Data for Interoperability (USCDI), Z-codes, HL7 and Fast Healthcare Interoperability Resources (FHIR) standards.

SPLIT (OR SHARED) E/M VISITS

A split (or shared) visit refers to an E/M visit that is performed by both a physician and a non-physician practitioner (NPP) who are in the same group. Billing for split visits vary based on the setting in which the service is furnished. For visits in the non-facility setting (e.g., office), the physician is permitted to bill for the split visit if the visit meets the conditions for services furnished "incident to" a physician's professional service. For visits furnished in the facility setting (e.g., hospital), CMS' longstanding split billing policy allows a physician to bill for the split E/M visit only if the physician performed the substantive portion of the visit.

CMS is proposing to codify in regulation its split billing policy for facility visits, as well as further define several aspects of the policy. Specifically, the physician or NPP who performs the substantive portion of the E/M visit in the facility setting would be permitted to bill for the visit. CMS proposes to define the "substantive portion" as more than half of total time spent performing the visit.

We are concerned that CMS' proposal to define "substantive portion" based on time will create a significant administrative burden on care teams and may ultimately discourage team-based care. While CMS references recent changes to E/M visit guidelines, which allow level selection based on either time or medical decision making (MDM), these changes are only applicable to office visits. Providers furnishing E/M visits in the inpatient setting still bill under the level selection criteria using elements of history, physical examination, or MDM. Time is only used when counseling or coordination of care dominates the service. As a result, the proposed split billing policy would require physicians and NPPs to track time using two different definitions to determine how to bill for the visit. We are concerned that the burden of complying with these requirements may result in fewer split visits and less coordination between physicians and NPPs.

Additionally, CMS' proposal to define "substantive" as the majority of time spent during the visit assumes that all minutes dedicated to a visit are of equal weight and substance. However, there might be instances where a physician or NPP may have done the bulk of an assessment or exam with the patient, but may have taken less time than the other practitioner. For example, a NPP may need to spend additional time with a patient he or she has not seen before in order to obtain the patient's medical history. Conversely, the physician may already have an established relationship with the patient and is able to furnish the physical exam or counseling in less time.

Premier recommends that CMS provide an alternative method for determining substantive portion of the split visit based on either history of present illness, physical exam, or MDM that is consistent with prior guidance.[4] If a physician furnishes one of these key components of the E/M visit, he or she should be considered to have performed the substantive portion of the visit and chose the appropriate E/M service. At a minimum, CMS should delay implementing this new time-based definition until CMS has revised the E/M coding guidelines for services furnished in the inpatient setting and providers have had sufficient time to adapt to these changes.

MONOCLONAL ANTIBODIES USED TO TREAT COVID-19

We appreciate CMS soliciting feedback regarding patient access and provider payments for monoclonal antibodies used treat COIVD-19 that are infused in the patient's home. Premier believes the current structure that provides a separate payment during the PHE for monoclonal antibodies infused in the home setting to treat COVID-19 is appropriate and necessary for home infusion providers to deliver this service.

As noted in previous comments (CMS-1689-P, RIN 0938-AT29, CMS-1689-FC, RIN 0938-AT29, CMS-1711-P, 0938-AT68, CMS-1730-P, RIN 0938-AT-06), the current home infusion benefit is untenable as is. CMS' interpretation of "infusion drug administration calendar day" severely underpays for Medicare home infusion services. As a result, providers are being forced out of the benefit, reducing access for beneficiaries in need of home infusion therapy. Appropriate reimbursement for home infusion drugs, supplies and equipment, and associated services is necessary for a workable and sustainable benefit, which is also applicable to the reimbursement for monoclonal antibodies delivered in the home.

[4] CSG, "Split/Shared Visits," March 22, 2021, https://www.cgsmedicare.com/partb/pubs/news/2021/03/cope21142.html

The additional payment to deliver monoclonal antibodies in the home is necessary to keep vulnerable or potentially vulnerable beneficiaries out of institutional settings and, rather, in the home where treatment is optimal from a quality and safety perspective. **Premier urges CMS to extend this separate payment beyond the expiration of the PHE, because without the separate payment there is an insufficient Medicare home infusion benefit to support the home administration of monoclonal antibodies.** We encourage CMS to continue evaluating the payment structure and rates to ensure patients maintain access to this service in their home.

ELECTRONIC PRESCRIBING FOR CONTROLLED SUBSTANCES FOR A COVERED PART D DRUG UNDER A PRESCRIPTION DRUG PLAN OR AN MA-PD PLAN

Premier has long been supportive of moving to electronic transmission of prescription information because of the many benefits it offers over written prescriptions. In the proposed rule, CMS amends the timeline for implementing mandated electronic prescribing for Schedule II, III, IV, or V controlled substance under Medicare Part D. The SUPPORT for Patients and Communities Act (P.L. 115-271) required such systems be implemented beginning January 1, 2021. After delaying implementation and requirements until January 1, 2022 through previous rulemaking, CMS is now proposing a delay until January 1, 2023. CMS describes this delay as necessary to recognize the unique challenges that prescribers are facing during the COVID-19 PHE. Additionally, CMS would establish a January 1, 2025 compliance timeline for prescriptions written for beneficiaries in a long-term care facility (LTCF). CMS does not propose a specific LTC waiver or exception and does not anticipate extending the compliance deadline beyond January 1, 2025.

Premier appreciates CMS providing flexibility for providers who are struggling with the challenges of the current PHE and the difficulties they are facing implementing new systems or upgrades when many key personnel may be unavailable or working offsite because of the PHE. We also commend CMS for recognizing that some LTC settings/services in rural communities do not have sufficient capabilities to support the National Council for Prescription Drug Programs (NCPDP) SCRIPT 2017071 standard.

Additionally, the NCPDP Work Group 11 (ePrescribing and Related Transaction) is in the process of developing SCRIPT Standard changes to address the ePrescribing three-way communication needs of the LTC community. In May 2021, NCPDP began balloting a new standard solution that would allow tri-party communication between the provider, long-term care pharmacy (LTCP) and LTCF using a new “copy of a prescription” standard. Comments on these ballots are expected to be adjudicated at the NCPDP Work Group’s November 2021 meeting. If approved, these changes will be included in the forthcoming NCPDP SCRIPT Standard (v2022011) issued in January 2022. However, in consideration of the timing of NCPDP’s process, should CMS finalize the proposal as written, it would require that Part D Plans (PDPs) to implement opioid ePrescribing using the NCPDP guidance that likely will be superseded before the end of this year.

Rather than establishing arbitrary dates as proposed in the rule, Premier recommends CMS adopt the following provisions in the final rule:

- **Implementation of the requirements 12 months after the end of the PHE.**
- **Establishing a compliance timeline for prescriptions written for beneficiaries in an LTC facility that is 24 months following the establishment of sufficient capabilities to support the NCPDP SCRIPT 2017071 standard.**

Further, as we discuss technology improvements for providers, **we urge CMS to enhance its efforts to develop standards and measures for data exchange and sharing across all care settings, including**

post-acute care. Ensuring interoperability across EHR systems and settings of care can unlock barriers to data sharing and care coordination between health systems, physician group practices, independent physicians, and PAC settings. Many PAC providers rely on paper-based transmission of information and are not using EHRs or are using EHRs that are not designed for interoperability. CMS must address this barrier to truly support efforts to standardize patient data, improve care quality, and reduce costs across the continuum.

CONCLUSION

In closing, the Premier healthcare alliance appreciates the opportunity to submit these comments on the CY 2022 PFS Proposed Rule. If you have any questions regarding our comments or need more information, please contact Aisha Pittman, vice president, policy, at aisha_pittman@premierinc.com or 202.879.8013.

Sincerely,

Blair Childs
Senior Vice President, Public Affairs
Premier healthcare alliance