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September 13, 2021

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

SUBMITTED ELECTRONICALLY VIA 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

Dear Administrator Brooks-LaSure:

The Society of General Internal Medicine (SGIM) appreciate the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) proposed rule for calendar year (CY) 2022 Medicare Physician Fee Schedule (MPFS). SGIM is a member-based medical association of more than 3,300 of the world's leading academic general internists, who are dedicated to improving the access to care for all populations, eliminating health care disparities, and enhancing medical education. Our members are committed to ensuring patients have equitable and affordable access to the highest quality of care possible. As such, we look forward to commenting on the following section of the proposed rule:

- Practice Expense Clinical Labor Pricing Update
- Comment Solicitation for Codes involving Innovative Technology
- Telehealth Services
- Principal Care Management and Chronic Care Management
- Split (or Shared) Evaluation and Management Visits
- Payment for the Services of Teaching Physicians
- MIPS Value Pathways
- Health Equity Improvement Activities
- Future Potential Stratification of Quality Measures by Race and Ethnicity
- Improving Demographic Data Collection
- Health Equity Measures in MVPs
- Complex Patient Bonus

Practice Expense Clinical Labor Pricing Update

CMS is proposing to update the clinical labor inputs using the most current Bureau of Labor Statistics data in CY 2022 in conjunction with the final year of the supply and equipment pricing update. SGIM supports this proposal particularly since the current inputs are based on data from

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2002 and believes the agency should always develop reimbursement policies, and specific payment rates, using the best available data. This action is long overdue; however, ***SGIM recommends that CMS phase in this update over a four-year period as was done for the supply and equipment update to minimize the reimbursement reductions to specific services in CY 2022.*** These decreases coupled with the conversion factor cut of 3.75 percent could be detrimental to Medicare beneficiary access to services as providers across the country are still struggling to address the COVID-19 pandemic and related disruptions. SGIM recognizes that CMS cannot prevent or minimize the 3.75 percent conversion factor cut in a budget neutral system, and therefore, urges the agency to act where it does have the authority as it does with this proposed update. ***Additionally, CMS should develop processes to ensure that a more regular review of inputs occurs both to improve the accuracy of Medicare payments, but also to avoid the significant decreases resulting from this proposal.***

Comment Solicitation for Codes involving Innovative Technology

CMS recognizes rapid advances in innovative technology are having a profound effect on health care delivery and is soliciting public comment to better understand the resource costs for services involving the use of innovative technologies, including but not limited to software algorithms and artificial intelligence (AI). The agency is particularly interested in how software can help to address health equities. ***SGIM thanks CMS for looking to use innovative technologies as a tool to address health inequities and agrees these technologies have an important role to play.*** However, software costs and maintenance can burden large and small practices financially and are a roadblock to more widespread adoption. ***We welcome the opportunity to work with CMS to determine how technologies, including software and AI, can be developed to in a cost-efficient manner and be deployed to improve access, patient engagement, patient safety, and self-care.***

Telehealth Services

SGIM commends CMS for implementing telehealth flexibilities within its emergency authority to ensure patients have maintained access to medically necessary care during the COVID-19 pandemic. Our members have adjusted their practices to utilize these flexibilities and believe Medicare should continue to support virtual care post-pandemic as its statutory authority allows. Therefore, we are pleased CMS is proposing to expand access to certain telehealth services based on the authority Congress provided in the Consolidated Appropriations Act, 2021 (P.L. 116-260) and respectfully request the agency consider our additional recommendations.

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

During the COVID-19 pandemic, CMS established Category 3 telehealth services which includes services added on a temporary basis during the public health emergency. CMS is now proposing to revise the timeframe for services added to the telehealth list under Category 3 and allow them to remain until the end of CY 2023***. SGIM strongly supports this extended timeframe.*** We believe the additional time will provide for the collection of additional telehealth utilization data which will allow for stakeholders and the agency to make evidence-based decisions when

recommending and considering these services for permanent addition to the telehealth list. ***SGIM supports all efforts to develop and implement evidence-based policy.***

During the public health emergency, the agency added a number of services to the telehealth list on an interim basis, but not on a Category 3 basis; these services will be removed when the public health emergency expires. These services include hospital inpatient services (CPT codes 99221-3), observation care services (CPT codes 99218-20, 99234-6), and telephone visit services (CPT codes 99441-3). The telephone evaluation and management (E/M) services have been an important tool for our members to deliver needed care to Medicare beneficiaries during the pandemic and we believe they will continue to improve access and adherence for patients with chronic conditions after the public health emergency concludes. SGIM recognizes that Congress must act to provide CMS with the statutory authority to continue to cover audio-only services for care outside of furnishing services for mental health conditions. In the proposed rule, CMS explained that the services most commonly billed with the audio-only modality were mental health services. ***SGIM respectfully requests the agency share with the public the audio-only utilization data that has been collected during the public health emergency to provide stakeholders with a better understanding of how these services have been utilized outside of the treatment of mental health conditions.***

Expanded Access to Mental Health Medicare Telehealth Services

CMS is proposing to eliminate the originating site and geographic restrictions for mental health services based on the authority provided in the Consolidated Appropriations Act of 2021. Given the shortage of mental health professionals and limited broadband access in some areas, the agency will allow mental health services to be delivered to established patients using the audio-only modality when the originating site is their home, despite the agency's program integrity concerns in an instance where the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology. SGIM will continue to advocate that Congress eliminate the originating site and geographic restrictions more broadly and provide the agency with the statutory authority to continue covering audio-only services in appropriate circumstances.

The ability to delivery audio-only services is important for the patients our members treat who lack access to technology required for video visits. During the COVID-19 pandemic, many of our patients were not able to master audio-visual platforms due to a range of factors beyond patient or physician control such as a lack of broadband, a smartphone, or an ability to understand the technology needed for visual connection with a clinician. Audio-only visits protect vulnerable patients with chronic conditions, who may not have access to the internet, or whose internet does not support video.

Through audio-only visits, our physicians have successfully managed various chronic diseases, including diabetes and hypertension, particularly when patients are equipped with the home monitoring tools needed to monitor their numbers. However, SGIM is concerned that CMS' definition of home as it is applied here may be too limited as many patients may not have a

home in the traditional sense and experience housing insecurity which could potentially disqualify them from receiving necessary medical care. ***We respectfully request CMS provide its definition of the home in the final rule and ensure it does not perpetuate existing inequities.*** SGIM is concerned that verifying a patient is in their "home" could pose challenges/additional burden for physicians.

Other Non-Face-to-Face Services Involving Communications Technology under the PFS Expiration of PHE Flexibilities for Direct Supervision Requirements

CMS is soliciting information on whether the public health emergency-related flexibilities related to direct supervision should be made permanent. Specifically, the agency seeks comment on the extent to which the flexibility to meet the immediate availability requirement for direct supervision through the use of real-time, audio/video technology is being used during the public health emergency, and whether physicians and practitioners anticipate relying on this flexibility after the public health emergency concludes. ***SGIM believes these services have been valuable for our members during the pandemic, particularly when physicians were assigned to work off-site to reduce crowding in the clinic, and recommend they continue following the conclusion of the public health emergency.*** As an example, this flexibility helps to facilitate care when a teaching physician can only provide care from home given childcare, eldercare, or other personal constraints. By better enabling providers to provide care from where they are, patients will be better able to receive care where they are. We believe this flexibility is another important tool to expand access to care, particularly in shortage specialties like general internal medicine.

Once the public health emergency concludes, remote supervision will continue to sustain clinical capacity and support equity, as many teaching sites deliver care to vulnerable populations. Our members, many of whom serve as the primary internal medicine faculty of every medical school and major teaching hospital in the United States, have found that teaching models continue to evolve and incorporate remote supervision into practice. We believe the following is absolutely necessary for remote supervision to support robust patient care safety and quality standards: 1) adequate telecommunications technology access, 2) presence at clinic of an on-site teaching physician for in-person supervision as needed for any in-person resident clinic visits, and 3) appropriate training and practice standards for resident and teaching physicians on the scope of telemedicine practice.

Virtual Check-in

In the CY 2021 MPFS final rule, CMS adopted a longer virtual check-in – HCPCS code G2252 – on a temporary basis. In this proposed rule, the agency is proposing to permanently adopt this code and payment, based on the support it has received from stakeholders. ***SGIM supports the agency's proposal to permanently adopt this case, as it recognizes the time spent by providers delivering chronic care management. However, SGIM does not believe these check-ins eliminate the need for continued coverage of audio-only E/M services, and as mentioned, we will continue to advocate for their continued coverage.***

Principal Care Management and Chronic Care Management
The American Medical Association RVS Update Committee (RUC) recently resurveyed the Chronic Care Management (CCM) code family, including Complex Chronic Care Management (CCCM) and Principal Care Management (PCM), and added five new CPT codes 99X21, 99X22, 99X23, 99X24, and 99X25. In this proposed rule, the agency is proposing to adopt the work and PE values as recommended by the RUC. ***SGIM supports CMS' proposal to adopt the RUC recommended values, as these services are commonly billed among our members and allow us to manage the complex care patients require and improve patients' outcomes.***

Split (or Shared) Evaluation and Management Visits
CMS is proposing changes to its split (or shared) E/M visit policy. Specifically, the agency is redefining its rules when these services are delivered in the facility setting where the "incident to" billing rules do not apply, limiting the billing practitioner to either the physician or non-physician provider (NPP) who provides more than half of the patient visit as indicated by time. SGIM would like to commend CMS for supporting and working to promote team-based care. While we understand the agency is attempting to distinguish between split (or shared) visits and services furnished incident to the professional services of a physician, SGIM is concerned that this may become burdensome for physicians and NPPs who will be forced to become clock watchers to determine which practitioner performed the majority of the visit. Under the new E/M documentation guidelines, it is more common to select visit level by medical decision-making (MDM) rather than time, so this proposal represents a significant disruption to usual practice patterns***. We respectfully request CMS reconsider this policy and develop an alternate that does not increase burden on providers and recognizes typical practice patterns in medicine.***

Payment for the Services of Teaching Physicians
SGIM recognizes that CMS is not proposing to make changes to the services residents can deliver under the primary care exception. Outside of the COVID-19 public health emergency, certain lower and mid-level office/outpatient E/M services provided in certain primary care centers are exempt from the physical presence requirement under the primary care exception. However, to address the COVID-19 pandemic, the agency expanded the list of services on a temporary basis. This expansion included all levels of an office/outpatient E/M service (CPT codes 99202-99205 and 99211-99215) provided in primary care centers may be provided under direct supervision of the teaching physician by interactive telecommunications technology. SGIM has found this flexibility important in managing the care of many chronically ill Medicare beneficiaries. ***As such, SGIM requests that the agency permanently expands the services that can be provided under the primary care exception using virtual supervision to CPT codes 99214 and 99215.*** The pandemic has highlighted the need for resident physicians to be available to provide primary care, and due to pandemic-related social distancing restrictions, it is almost impossible to provide direct, in-person supervision for all resident encounters.

MIPS Value Pathways in MVPs
CMS is continuing to move forward with the development of MIPS Value Pathways (MVPs) but is proposing to delay the transition to MVPs to the CY 2023 performance year due to the COVID-19

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pandemic. ***SGIM supports this decision and believes CMS should finalize this proposal.*** Given the challenges continuing to be posed by the COVID-19 pandemic, a January 1, 2022 start date would provide unnecessary burden for providers.

Additionally, SGIM supports CMS' focus on the development and implementation of MVPs, a framework linking measures and activities across the four MIPS performance categories to create a more coherent program. Many SGIM members treat vulnerable patients at safety net institutions, and therefore, we support the steps the agency is taking to do a better job facilitating the collection of more meaningful and comparable performance data using fewer, but more relevant, measures while minimizing measure selection bias. We ultimately believe this will better enable providers and CMS to improve the quality of care delivered to patients. Further, we support the implementation of MVPs that will allow providers to be measured against others delivering similar types of care to similar patient populations.
However, SGIM does have significant concerns about CMS' proposal to sunset traditional MIPS at the end of the CY 2027 performance period and require mandatory MVP reporting in the CY 2028 performance period and subsequent years. ***SGIM urges CMS to delay the phase-out of traditional MIPS or at least not set a date certain for its elimination until more MVPs have been developed and the agency and stakeholders have a better understanding of the timeline for the development and deployment of new MVPs.***

Health Equity Improvement Activities

SGIM appreciates the new and modified MIPS improvement activities under the Achieving Health Equity subcategory. SGIM commends CMS on the Anti-Racism Plan and Food Insecurity Identification and Treatment improvement activities. ***However, SGIM recommends that all health equity subcategory Improvement Activities receive high weighting to emphasize CMS' commitment to achieving health equity and to incentivize behavior change.***

Future Potential Stratification of Quality Measure Results by Race and Ethnicity

SGIM appreciates CMS' desire to identify care gaps in vulnerable populations, such as traditionally marginalized racial and ethnic groups. However, SGIM strongly cautions against focusing on race and ethnicity alone, as race and ethnicity are not the social determinants of health (SDOH) which are the direct primary mediators of inequities and poor health outcomes. As an example, a New England Journal of Medicine article cites a large cohort study in Louisiana, in which *"76.9% of the patients who were hospitalized with Covid-19 and 70.6% of those who died were black, whereas blacks comprise only 31% of the Ochsner Health population. Black race was not associated with higher in-hospital mortality than white race, after adjustment for differences in sociodemographic and clinical characteristics on admission[1]."* The assignment of race is historically based on social constructs, and decades of oppressive policies regarding these social constructs and interpretations of race have dictated the resources allocated to these

[1] Price-Haywood EG, Burton J, Fort D, Seoane L. Hospitalization and Mortality among Black Patients and White Patients with Covid-19. N Engl J Med. 2020 Jun 25;382(26):2534-2543. doi: 10.1056/NEJMsa2011686. Epub 2020 May 27. PMID: 32459916; PMCID: PMC7269015.

groups. For these reasons and others, SGIM believes that census-tract level indices of community social vulnerability are the best way to currently assess social risk.

Furthermore, to truly close the health equity gap, SGIM recommends that CMS not only stratify existing clinical quality measures by social risk but also support the creation of health equity measures that specifically evaluate the care being provided to address SDOH for at-risk populations. Collecting SDOH data should first and foremost be for the purpose of screening the health-related needs of patients (e.g., housing insecurity, food insecurity) so that they can be addressed. Drawing from the Accountable Health Communities Model, SGIM believes that equity measures must be developed to evaluate aspects of health care delivery, such as:

- Demonstration of language-concordant care delivery at levels that match the language proficiency of the communities served;
- Appropriate screening for social needs (e.g., food and housing insecurity), referrals for social services, use of navigators, and the degree to which those referrals are acted upon and completed, with the loop being closed;
- Participation in Community Health Needs Assessments;
- Degree to which needs assessment findings are acted upon;
- Level of investment in social services; and
- Level of community partnerships, including collaboration with county health departments and the state departments of health.

Improving Demographic Data Collection

Building on the Agency for Healthcare Research and Quality's framework for addressing health equity, SGIM supports CMS' efforts to describe disparities in health outcomes using more nuanced social risk data. We support using and developing methodologies that link Medicare administrative data to census-tract data.

We agree with a standard approach to assessing SDOH that is conducted across all health systems that care for Medicare and Medicaid beneficiaries. We also agree that the collection of structured, robust, individual-level SDOH data has the potential to help describe health-related unmet needs in the Medicare population. ***SGIM recommends CMS invest in the development of a nationwide SDOH tool to capture this relevant data on a regular basis, in line with the current standards of determining beneficiary access. However, we also caution that the collection of socioeconomic data at a more individual patient level can be a sensitive topic, open to potential abuse, and may retraumatize patients already affected by bias, barriers and structural racism.*** Furthermore, training of clinic and health system staff to collect this information in a sensitive and robust way is time- and resource-intensive. Mandating practices to collect this data without adequate support and training in well-established frameworks, alongside fully engaged and empowered community partners, can have unintended consequences. Possible unintended consequences include inaccurate data collection (e.g., assigned rather than self-reported race/ethnicity/gender), patient mistrust (particularly among individuals historically traumatized by the healthcare system), psychological harm, and moral injury to providers, who feel they have "nothing to offer" their patients.

Notwithstanding these issues, when social and demographic data are captured for individual care through trusted and trained healthcare teams empowered with community resources and partnerships to address social determinants, this data may serve as a powerful tool to combat existing health inequities at their source. It is our expert opinion that significant resources are required to develop frameworks for structured systems to collect, maintain, and utilize these socioeconomic data in trusted, caring, and sensitive ways. In our experiences, it is likely that the persons tasked with collecting such sensitive information are those who share longitudinal and trusted relationships with patients, perhaps in the form of patient navigators, community health workers, and nurse care coordinators who “follow” patients across the healthcare continuum (e.g., across inpatient and outpatient settings and health systems). ***SGIM believes such frameworks must be created to build health equity-focused value metrics in the inpatient, outpatient and post-acute settings, and across transitions of care.***

Health Equity Measures in MVPs – Request for Information

SGIM commends CMS on their commitment to prioritize the development of health equity measures in future cycles of measure development. SGIM agrees that health equity measures should be included in the foundational layer of all MVPs as a required component. Developing health equity measures will clearly be a multistakeholder collaboration. Many examples do already exist, ranging from state Medicaid programs to the Accountable Health Communities model. ***As stated above in the health equity RFI section, SGIM believes that measures explicitly addressing social determinants of health, such as food and housing insecurity, must be developed, as well as measures evaluating engagement with appropriate community partners.*** SGIM welcomes the opportunity to engage with CMS leadership on this in the future.

Complex Patient Bonus

SGIM appreciates CMS’ incorporation of recent studies[2] into the complex patient bonus calculation and the detailed description of its own evaluation. CMS’ ongoing efforts to improve equity by increasing the support to the providers caring for the most complex patients, specifically those at highest social risk, have proven to be invaluable for our members. In the short term, SGIM agrees with the changes proposed by CMS to continue the increased complex patient bonus with a value up to 10 points, as well as the methodologic changes to apply the bonus only to the providers/practices with social or medical complexity scores above the median. However, we continue to advocate for additional changes in CMS’ approach to account for social risk to achieve CMS’ two stated goals – protecting access to care for socially complex patients and placing providers who care for socially complex patients at a disadvantage. We believe dual eligible status continues to be an incomplete proxy measure for social risk. Using dual eligible status as the only marker for social complexity under-captures social risk for some populations, such as the working poor, and most notably, those in non-Medicaid expansion

[2] Johnston KJ, Hockenberry JM et al (Sept 2020) “Clinicians With High Socially At-Risk Caseloads Received
Reduced Merit-Based Incentive Payment System Scores” HEALTH AFFAIRS 39, NO. 9 (2020): 1504–1512.

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states. Most of these states are in the South, where a higher share of the Black population resides[3], thereby perpetuating structural racism in health care.

Further, neighborhood indices which evaluate the social vulnerability of the communities which providers serve based on census-tract data are widely accepted as better measures of social risk, do not require additional data to be captured by the providers/practice, and have been used in various studies of Medicare payment models.[4][5][6][7] Many such composite measures of social determinants of health exist, including the Social Vulnerability Index, the Area Deprivation Index, the Community Needs Index, and the Distressed Communities Index. ***SGIM recommends that CMS explore the use of such indices as the basis for fairly evaluating social risk and adjusting value-based payments.***

SGIM believes that having a combined complex patient bonus accounting for clinical complexity and social complexity together reduce the emphasis on equity that has become a central focus of the Biden Administration. Social determinants of health are the major driver of health care inequities, and thus ***SGIM recommends that CMS make explicit the importance of accounting for social risk by creating a separate measure, as SGIM has previously suggested.***

While the complex patient bonus offers potential to level the playing field, identifying the appropriate magnitude of bonus remains challenging, as evidenced by the Johnston et al paper, as well as CMS' request for comments on the appropriate multiplier and cap for the complex patient bonus for 2022. Peer grouping practices (as per the Hospital Readmissions Reduction Program) according to social complexity would mitigate this concern until the appropriate magnitude of the complex patient bonus can be identified. ***As such, SGIM recommends peer grouping based on social complexity to ensure providers and practices caring for the most socially vulnerable patients are not unfairly penalized.***

In the long-term SGIM continues to recommend stronger action to support practices caring for the most complex patients, especially socially complex patients. CMS states the intent of this complex patient bonus to be temporary. While clinical risk adjustment methodology continues to be refined at a detailed level, there continues to be no other accounting for social risk within MIPS or MVPs besides this bonus. As addressed in more detail above, heath equity measures

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[3] https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-coverage-by-race-and-ethnicity/

[4] Zhang Y, Li J, Yu J, Braun RT, Casalino LP. Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. JAMA Netw Open. 2021 Jun 1;4(6):e2113212. doi: 10.1001/jamanetworkopen.2021.13212. PMID: 34110394; PMCID: PMC8193453.

[5] Ash, A. S., et al. (2017). "Social Determinants of Health in Managed Care Payment Formulas." JAMA Intern Med 177(10): 1424-1430

[6] Joynt Maddox KE, Reidhead M, Hu J, Kind AJH, Zaslavsky AM, Nagasako EM, Nerenz DR. Adjusting for social risk factors impacts performance and penalties in the hospital readmissions reduction program. Health Serv Res. 2019 Apr;54(2):327-336. doi: 10.1111/1475-6773.13133. PMID: 30848491; PMCID: PMC6407348.

[7] Hu J, Kind AJH, Nerenz D. Area deprivation index predicts re-admission risk at an Urban Teaching Hospital. Am J Med Qual. 2018;33(5):493-501.

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must be developed. In the meantime, a strong complex patient bonus (or peer grouping based on social risk) remains a critical tool to promote equity in MIPS to ensure that safety net providers/practices supporting the most socially complex Medicare beneficiaries are not financially penalized due to inadequate accounting for social determinants of health.

Thank you again for the opportunity to provide comments on the MPFS. We look forward to continuing to work with CMS and welcome the opportunity to discuss these issues with you further. Should you have any questions, please do not hesitate to contact Erika Miller at emiller@dc-crd.com.

Sincerely,

Monica L. Lypson, MD, MHPE
President, Society of General Internal Medicine

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