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SUBMITTED ELECTRONICALLY VIA <http://www.regulations.gov>

**Re: CMS-1734-P - Medicare Program; CY 2021 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Updates to the Quality Payment Program; Medicare Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or MA-PA plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Proposal to Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy Proposed Rule**

Dear Administrator Verma,

The Society of General Internal Medicine (SGIM), representing about 3000 general internists, appreciates the opportunity to provide comments on the CY2021 Medicare Physician Fee Schedule (MPFS) proposed rule. Our members provide clinical services and conduct research and educational activities to improve the health of adults, often with multiple complex, chronic conditions.

The members of SGIM are deeply appreciative of the flexibilities the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) have implemented to address the COVID-19 public health emergency; these have preserved our patients' access to medically necessary care. As COVID-19 has threatened the financial sustainability of our practices, SGIM remains fully committed to continuing to address the immediate needs of our patients while containing the spread of the SARS-Cov-2 virus.

The Society welcomes the opportunity to continue to work with CMS to address the ongoing needs of Medicare beneficiaries. We are deeply appreciative of the agency's proposals that will continue to reduce burden and expand flexibilities for providers and patients both during the public health emergency and once the public health emergency concludes. As such, in this letter we provide comments on the following sections of the proposed rule:



- Refinements to the Outpatient Evaluation and Management Services Policy
- Telehealth and Other Services Involving Communications Technology
- Modifications related to Medicare Coverage for Opioid Use Disorder
- CY 2021 Updates to the Quality Payment Program, including the MIPS Value Pathways and Qualified Clinical Data Registries

### **Refinements to the Outpatient Evaluation and Management (E/M) Services Policy**

SGIM members primarily bill outpatient E/M services and have advocated for revision to the definitions, valuations, and documentation expectations of the outpatient evaluation and management (E/M) service codes for over a decade. We are deeply appreciative of the agency's actions to implement long overdue changes to this code family and the proposal to extend the outpatient E/M code valuation changes to the ancillary codes, the Welcome to Medicare Code or Initial Preventative Physical Exam (IPPE), the Annual Wellness Visits (AWVs) and the Transitional Care Management Codes (TCMs). **We strongly urge CMS to implement the policy finalized in the CY 2020 MPFS final rule without further modifications on January 1, 2021.**

This policy addresses valuation distortions that were identified at the inception of the resource-based relative value scale (RBRVS) in 1992. The changes being implemented by the agency will have profound benefits for all Medicare beneficiaries and all other patients that SGIM members serve. The improved valuations for the new and established outpatient E/M codes, the IPPE, AWVs, and TCMs are a vital and absolutely essential step to rebuilding the primary care workforce. As a society of clinical educators, SGIM is deeply committed to ensuring access to Medicare beneficiaries as well as all other patients.

As we have previously commented, SGIM believes these changes to outpatient E/M services are an important first step to value the work of general internists and other physicians who deliver appropriate non-procedural care. SGIM has reviewed the service code definitions as they have been presented to CMS by the American Medical Association's (AMA) Current Procedural Terminology (CPT) Editorial Panel, and have ongoing concern about the biases inherent in the service code descriptions. As they stand, the existing new and established outpatient E/M code descriptions do not capture the work "intensity" of the general internist. This is best exemplified by the Level 5 codes. Rather than acknowledge the complex decisions for the multiple chronic conditions (MCCs) that our members find challenging and intellectually rigorous, the descriptions continue to focus on those patients who present with a single, acute, severe condition. Those with MCCs are the very patients that make up the vast bulk of our care for Medicare beneficiaries.

SGIM's teaching physicians are charged with introducing physicians-in-training to the world of general internal medicine, a world defined by the care of patients with MCCs. Medical students on clinical rotations in Internal Medicine (IM) see firsthand how IM physicians manage MCCs, including the extended amount of time it takes to care for these patients. We are fully committed to training the next generation of physicians, yet medical students today are well



aware that IM is not only mentally challenging and complex, but also poorly reimbursed and therefore, do not seek careers in IM. The attraction to higher compensation levels lead to career choices that are understandable, but have left our country's workforce of front-line IM physicians over extended and close to exhaustion. The response of the agency to this crisis comes at the right moment as our country faces serious clinical workforce issues.

To address this and other continuing limitations of the E/M code family, SGIM urges CMS to convene an expert panel as recommended by the Cognitive Care Alliance, Appendix A. **The expert panel should be charged with developing an evidence-based approach to assess how the current E/M service codes are defined and relatively valued within the RBRVS paradigm and address any and all documentation expectations that continue to pose undue burden.**

As a Society with many health service researchers, we have identified that there are critical knowledge gaps that must be addressed. SGIM is deeply committed to the practice of evidence-based medicine. Likewise, the relative valuation of services within the MPFS must be based on the best evidence available and that new evidence should be created with representative and peer reviewed health services research. There are existing databases that can be employed to inform Medicare processes and data collection instruments already in use that can be refined to support accurate payment policies. Currently, there are many economists and clinicians that are systematically excluded from the AMA's processes because they are not members of the AMA's House of Delegates (HOD).

SGIM has spent years discerning the methodologies used by the AMA's Relative Value Scale Update Committee (RUC) and find their data collection to be unrepresentative and their data analysis biased. SGIM is not alone with this concern. There is an entire literature questioning the RUC and its undue influence on Medicare payment policy. MedPAC has reiterated its concern for years. We believe that the RUC's limitations are most pronounced when valuing E/M and other cognitive work. The proposed expert panel would initiate the process of providing Medicare and all other payers with an evidence base to better understand E/M work. Should the expert panel succeed, CMS will be armed with the data and information needed to describe non-procedural work that is part of ongoing evaluation and management.

#### ***Complexity Add-on Code (HCPCS Code GPC1X)***

SGIM supports CMS' implementation of HCPCS code GPC1X as finalized in the CY 2020 rulemaking and agrees that the revised outpatient E/M family does not fully capture the work of our members who deliver primary care to Medicare beneficiaries or that of certain specialists who form longitudinal relationships with beneficiaries. We, however, recognize that stakeholders have requested additional clarity regarding how to bill this add-on properly and wish to provide additional information to help CMS better define this service.

CMS defined this service to describe the "visit complexity inherent to evaluation and management associated with the medical care services that serve as the continuing focal point



for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex condition." SGIM agrees the additional patient-based work "intensity" arising from three input categories not included in the existing outpatient E/M service codes is not captured by the E/M codes themselves, and this add-on code captures the following work components:

1. The clinical complexity of care provided by our members in the context of patient characteristics;
2. The nature of the physician-patient relationship developed and maintained, in many cases indefinitely; and
3. The responsibility assumed by physicians to continually update and maintain the knowledge base required to deliver cognitively intense services.

In a primary care relationship, add-on code GPC1X will capture the work associated with a primary care relationship that is continuous and comprehensive; and in the case of the non-primary care specialties, it captures the work associated with the continuous and comprehensive care of a single condition or a cluster of conditions. SGIM also believes the add-on code captures the work required to maintain cognitive expertise, an input that outpatient E/M codes have never captured. The concept of education and training contributing to service code valuations was part of the original RBRVS model but was later eliminated in the name of simplification. SGIM is not suggesting that CMS change its longstanding definition of work "intensity." Rather, we support the implicit message that there are unique professional obligations among those who are primarily practicing continuous care, both generalists and specialists, which requires continuous knowledge updates. The experience with the COVID-19 pandemic over the last six months demanded that virtually every member of SGIM rapidly master new science and understand the full clinical spectrum of SARS-CoV-2 infection.

Since the add-on code will be applicable to all levels of the new and established patient outpatient E/M code families, we wish to provide the following vignettes to demonstrate the circumstances under which this service would apply for multiple visit levels:

- LEVEL 3: A 68-year old man with hypertension presents to his primary care physician for follow-up. He has not been checking his blood pressure at home, but his blood pressure is high in the office today. His blood pressure medication dose is increased, and the physician asks the patient to start monitoring his blood pressure at home and report these back via phone call at the end of next week.
- LEVEL 4: A 68-year old man with hypertension, diabetes, and congestive heart failure presents to his primary care physician for follow-up. He presents with an extensive rash following yard work. He has widely disseminated poison ivy and will require a short course of prednisone. In the setting of starting steroids, he will need to follow his blood



sugars and blood pressures at home since steroids could elevate both, and report these back via phone call at the end of the week.

- LEVEL 5: A 68-year old man with hypertension, diabetes, and congestive heart failure presents to his primary care physician for follow-up. He complains of shortness of breath and new leg swelling. On exam, his blood pressure is very elevated; he has crackles (extra sounds) in both lung fields consistent with pulmonary edema (fluid in his lungs). The physician considers sending the patient to the ER due to the exacerbation of the patient's congestive heart failure, but given that the patient's respiratory status seems stable and reliable home care is available, the physician counsels the patient about low salt diet, escalates his home diuretic (fluid management) program, and asks the patient to monitor daily blood pressure, heart rate, and weight and report these back via phone call at the end of the week. The patient will also need to get his blood drawn for a lab check and the doctor will review the labs, as diuretics can cause acute kidney injury and low potassium even under the best circumstances.

For purposes of program integrity and audit, there are three elements in each vignette:

1. A statement of the relationship. In each case, this is a primary care encounter.
2. A statement of the conditions addressed and the implied interactions.
  - a. Level 3: One condition
  - b. Level 4: Three chronic condition with an unstable or active condition that affects all the others
  - c. Level 5: Three chronic conditions, one with a higher level of instability and risk. There are many levels of interaction, in this case heart failure management affects blood pressure and vice versa, heart failure affects diabetes management, etc.

SGIM welcomes the opportunity to continue to work with CMS to define the appropriate use of this add-on code more clearly.

***Prolonged Office/Outpatient E/M Visits (CPT code 99XXX)***

SGIM continues to support the implementation of this prolonged service add-on code to be used with 99205 and 99215 when a physician chooses to bill by time as well as the agency's new proposal to allow this code to be billed only once the top time threshold for the level 5 codes has been met. However, the Society urges CMS to reconsider its policy that requires a provider to spend a full 15 minutes beyond the maximum level 5 time before CPT code 99XXX can be billed. This policy, as finalized, contradicts CPT's guidance for time-based codes which considers a unit of time to be attained when the midpoint is passed (e.g., a code requiring 15 minutes can be reported when 8 minutes have passed). To be consistent with existing CPT coding conventions



and reduce confusion, **SGIM recommends that CMS align its reporting rules for 99XXX with CPT's coding conventions for other time-based services and permit this code to be used once the 8-minute mark of the 15-minute interval is reached.**

### ***Revaluing Services Analogous to E/M***

In this proposal, CMS proposes to incorporate the higher outpatient E/M service values into those services whose values are tied directly to the value of outpatient E/M codes, including those that use the E/M values as building blocks. **SGIM supports this proposal to update the value of the IPPE, AWWs, TCMs, and end-stage renal disease services, and urges CMS to finalize it as proposed.**

### ***10- and 90-Day Global Services***

SGIM recognizes that the agency did not propose any changes to the 10- and 90-day globals because the research on these services has not concluded. As noted, SGIM has a large and active contingent of health service researchers and we are professionally committed to evidenced based payment policy. **SGIM urges CMS to develop an evidence-based policy to reform these services to ensure that they accurately reflect the care delivered to patients.** SGIM believes change is long overdue as our members regularly treat post-operative patients with complications whose care should have been included in the global period. In addition, if CMS chooses to eliminate both the 10- and 90-day globals or just one, as noted above, the CPT code descriptors will need to be revised to clearly specify the appropriate code choices for routine care and levels of increasing post-procedure care intensity.

### **Telehealth and Other Services Involving Communications Technology**

SGIM is deeply appreciative of the telehealth policy changes that CMS and HHS implemented to ensure patients have maintained access to medically necessary care during the COVID-19 pandemic. Our members quickly adjusted their practices to primarily deliver care virtually and believe that Medicare should continue to support virtual care post-pandemic. As the administration begins to contemplate post-pandemic telehealth policy, SGIM offers the following recommendations:

- Maintain Coverage and Enhanced Payment for Audio-only Evaluation and Management Services
- Revise Payment for Telehealth Services to Accurately Reflect the Resources Required
- Relax the Telehealth Originating Site and Geographic Eligibility Requirements
- Retain the Flexibilities in Direct Supervision by Physicians
- Retain the Revised Policies for Remote Patient Monitoring

### ***Addition of Services to the Permanent Telehealth List and the Creation of a Temporary List***

CMS is proposing to add eight services to the Medicare telehealth services list permanently as they believe they are similar to those already on the list:



- GPC1X - E/M complexity add-on code
- 99XXX - Prolonged outpatient E/M service
- 99334-5 - Domiciliary or rest home visit for the evaluation and management of an established patient
- 99347-8 - Home visit for the evaluation and management of an established patient

SGIM supports the addition of these services to the permanent telehealth list, particularly GPC1X and 99XXX, which will be billed with the outpatient E/M services already on the permanent telehealth list as we anticipate our members will use these add-on codes regularly when they become effective on January 1.

Besides supporting the additions to the permanent telehealth list, **SGIM supports CMS' proposal to create a temporary Medicare telehealth list, which would allow the delivery of the listed services by telehealth until the end of the year after the public health emergency expires.** This would include services added during the public health emergency for which there is likely to be a clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence available to adding the service permanently under existing criteria.

#### ***Coding and Payment for Virtual Services***

SGIM supports the continued use of communications technology-based services (CTBS), like chronic care management, virtual check-ins, and remote physiologic monitoring, which CMS has added to the MPFS in recent years and fall outside of the restrictions on telehealth services. We urge the agency to continue to work with stakeholders to add additional CTBS services to the fee schedule to compensate providers and recognize care services that have been non-reimbursable.

During the pandemic, our members have encountered the need for Medicare to cover home blood pressure monitoring devices for patients; however, patients will continue to require this resource beyond the COVID-19 public health emergency. Home self-recorded blood pressure readings have been shown to correlate more closely with 24-hour ambulatory blood pressure monitoring (the "gold standard") than office visits<sup>1,1,2</sup>. It is also cheaper and more practical than 24-hour ambulatory blood pressure monitoring already covered by Medicare once a year. SGIM is confident the benefits and flexibility of home blood pressure monitoring will persist long after COVID-19, for those who can access it. Improving disparities in care is one of SGIM's goals and should be paramount for CMS. The cost of a home blood pressure device is prohibitive for some and discouraging to many Medicare beneficiaries on a fixed income. **SGIM strongly recommends that CMS expand Medicare coverage of a validated automated brachial blood pressure monitoring device beyond those receiving hemodialysis, to include all patients with**

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<sup>1</sup> Andersen MJ et al. Home Blood Pressure Monitoring in CKD. *Am J Kidney Dis.* 2005; 45(6):994

<sup>2</sup> Verberk WJ et al. Home Blood Pressure Measurement: A Systematic Review. *J Am Coll Cardiol.* 2005;46(5):743.



**prehypertension, hypertension, diabetes, cardiovascular disease, renal disease, cerebrovascular disease, or at high risk for development of the preceding conditions.**

The Society recognizes the provider burden and practice expense associated with collecting such data points over time, for interpretation and management. To address this, SGIM supports the use and reimbursement of the remote physiologic monitoring services (CPT codes 99453-54) and the remote physiologic monitoring treatment management services (CPT codes 99457-58) to account for the associated staff and physician work.

### ***Audio-only Services***

SGIM members believe that it will take months to years to achieve full control of the COVID-19 pandemic. Our personal experiences since the beginning of the pandemic have been formative, as we were forced to utilize a whole range of communication platforms, forgoing traditions of in-person contact, examinations, and rapid access to laboratory data. Initially, we had to improvise and rapidly found that telephonic care was necessary under the circumstances. For the sicker patients, there is a slow decline that can then be followed by an astoundingly precipitous collapse. We have set up “watch lists” with daily phone calls for these patients. Those that are less sick need to be tracked and the patients who have been exposed to the virus are worried and need advice.

This all came in the context of our normal workload as general internists, namely the care of patients with many chronic conditions. Some patients were able to master audio-visual platforms but many were not 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. In all cases, the work was the same as in person care if not more. The review of all inputs, the assessment, and the medical decision making (MDM) continued to match the levels of care that we have used in the past. Having telehealth options for at least a year beyond the end of the PHE will provide more flexibility and better care for Medicare beneficiaries, especially those who continue to fear coming to an outpatient office.

SGIM appreciates the flexibility CMS has provided during the public health emergency to allow providers to deliver E/M visits to patients by telephone using CPT codes 99441-43. At the start of the pandemic, we advocated for coverage of CPT codes 99441-43 for patients unable to establish a simultaneous audio/visual connection for a number of reasons to continue to access care without unnecessary exposure to COVID-19. We recognize the agency is not proposing for these codes to be billable on a permanent basis since the agency’s telehealth regulations require the delivery of telehealth services using a telecommunications system that includes two-way audio/video communication technology as well as that these services cannot qualify as CTBS because they replace a service that would otherwise be delivered in-person. **SGIM urges CMS to continue payments at the current levels for 99441-3 for at least a year beyond the end of the PHE.** The extension of payment for these services will allow data to be collected. Both the



agency and providers are gaining the experience to determine how to integrate telehealth services into practice on a permanent basis effectively, and SGIM believes that the agency's future decisions regarding telehealth must be based on the data being collected now. **We also respectfully request that CMS to revise its telehealth regulations to allow for telephone-only care, either by using CPT codes 99441-3 or a revised set of telephone E/M codes that are more similar in structure to outpatient E/M codes 99202-5 and 99211-5, in appropriate circumstances once the public health emergency concludes.** Eliminating this flexibility will limit access to some of the most vulnerable Medicare beneficiaries based upon our members' experiences.

When we first advocated for the coverage of these services, SGIM anticipated a number of Medicare beneficiaries would not have access to the technology for a simultaneous audio/visual connection and others would refuse to be on video. Members have encountered these situations, and would support the continuation of coverage for audio-only E/M care in order to reduce health disparities in the Medicare population. Other situations where audio-only care has been critical to preserving access include the following:

- Medicare beneficiaries with multiple chronic conditions often suffer from cognitive impairment (due to stroke, dementia, etc.) or simply lack the technical skills needed to implement video;
- Many beneficiaries have financial constraints and lack broadband or cellular access as well as those who have cellular access but have limited data plans without the means to afford overage charges;
- Patient-facing health apps have poor usability for populations with limited health literacy; additionally, few digital health tools explicitly consider digital literacy, health literacy, age, or English proficiency in their design;
- Due to lack of reimbursement, most health systems do not provide training or teaching to populations on how to use these tools, though studies have shown this to be an effective approach for ensuring adoption of digital health tools.
- Inability to include an interpreter in an audio/visual visit, limiting access to patients who speak languages other than English as their primary language;
- Failing to support technical or logistical challenges when scheduling video visits, mostly because support staff cannot bill for the time it takes to support such issues. Staff time is required to enroll patients in the portal, ensure the patient has the right internet browser to support the visit, and facilitate timely connections for these visits; and
- Visits scheduled with an audio/visual connection, but experience technical issues, must be converted to audio-only, resulting in the staff work required to set up the visit becoming uncovered practice expense.

According to our members, audio/visual visits do not differ significantly from audio-visits, which require far less staff work. Physicians use the same electronic tools to deliver care; have the



same access to history and concurrent condition information; and the same disposition options regardless of the visit's modality. Through audio-only visits, 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. We offer the following examples of how SGIM members have utilized audio-only visits:

- A 69 year-old man with diabetes, hypertension, chronic kidney disease, and depression, lives in a motorhome, which often breaks down, limiting his attendance at in- person clinic visits. He also has no computer service or smartphone. Through frequent audio-only visits, his primary care physician was able to get his diabetic control the best it has ever been, and his depression has improved.
- A 67 year-old man with significant bipolar disorder and multiple medical problems including hypoparathyroidism, hypertension, fluid overload, and impaired gait, is now under the situation where his primary care team--and his psychiatrist--can schedule telephone visits. His issues are all under better control now compared to pre-pandemic when he often canceled visits because he did not have reliable transportation.

In these cases, previous attempts to manage the patients with regular nursing calls failed because the calls were not scheduled and the patients often would not return the phone call. Now that the phone calls are scheduled visits with the physician and/or care team, the providers can regularly reach the patients to deliver the ongoing care management their conditions require. These situations demonstrate why it is so important for CMS to allow audio-only care after the pandemic.

Additionally, SGIM strongly recommends CMS provide support for the community collaborations needed to expand access to video visits in vulnerable Medicare populations. This would include supporting outreach programs to all patients over 65 years old; staff members would walk patients with scheduled visits through the required patient portal enrollment and ensure the required video platform was installed and operational as well as create video tutorials for patients and sample workflows for how to set up and conduct video visit preparation. These examples of technical support should be high-priority for CMS and HHS as patient care will depend on a navigable technological structure. SGIM welcomes the opportunity to work with CMS to identify circumstances for which this flexibility may be appropriate during patient care.

### ***Virtual Check-ins***

CMS currently reimburses for a virtual check-in: G20X2 (Brief communication technology-based service, e.g. virtual check-in, by a qualified health care professional who cannot report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion). **SGIM supports CMS' proposal for the creation of a longer virtual check-in for encounters of 11-20 minutes and recommends it be placed on the MPFS on a permanent basis.**



SGIM recognizes several virtual check-ins may be clustered together for a single patient. COVID-19 management is a good example of this. Providers advise mildly symptomatic patients to quarantine and nursing staff conduct daily check-ins until the patient recovers. Some patients deteriorate quickly after a 3-7-day period of mild symptoms, which would require several days of successive check-ins to monitor the patient. The Society, therefore, recommends the flexibility to bill this code daily, provided that brief documentation as to why the check in was warranted is placed on the chart. In addition, should the brief virtual check-in result in the consultation of a healthcare professional for provision of an E/M service, that E/M services should be provided for and reimbursed, but also should not negate the initial time spent conducting the brief virtual check-in. The Society welcomes the opportunity to work with CMS to ensure this code is implemented and utilized appropriately.

***Direct Supervision by Interactive Telecommunications Technology***

SGIM supports CMS' proposal to allow direct supervision to be provided through audio/video real-time communications technology, subject to the clinical judgement of the supervising physician through the latter of the end of the calendar year in which the public health emergency ends or December 31, 2021. This flexibility has been particularly valuable for members who teach residents and fellows, and we believe that it will continue to have utility post-pandemic. Examples where this flexibility facilitates access to primary care include:

- A resident or teaching physician is quarantining after a potential COVID exposure but fully able to conduct or supervise telemedicine visits from home with appropriate interactive telecommunications technology.
- A resident or teaching physician is assigned to work off site to reduce crowding in the clinic with a plan to conduct/supervise telemedicine visits.
- A resident or teaching physician can only provide clinical care from home given childcare/eldercare/personal constraints.

In cases like these, remote supervision is crucial in enabling the flexibility that will best sustain clinical capacity and helps support equity and guard against burnout in the healthcare workforce.

During the PHE, local COVID incidence or a high prevalence of undifferentiated respiratory symptoms among providers, clinic staff, and patients may dictate shifts toward predominantly telemedicine care and minimal on-site clinical practice. In such cases, the capacity for remote supervision would be especially important. Even after the public health emergency, as telemedicine is likely to remain a significant component of clinical care, greater flexibility for remote supervision will continue to support better access to care. By better enabling providers to provide care from where they are, patients will be better able to receive care where they are. Teaching models are already evolving to incorporate remote supervision into practice, and we anticipate this evolution will continue throughout and beyond the public health emergency.



Patient safety is of course a paramount consideration when it comes to changes in supervision rules. SGIM believes remote supervision supports robust patient care safety and quality standards provided the following: 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.

SGIM would note that the explicit requirement for audio and visual real-time communications technology is not likely to add significant value from a supervision or patient safety standpoint. Audio-only contact would generally suffice for communication between resident and teaching physician, and is well suited to interactions where both physicians can reference the electronic medical record visually while discussing the case.

#### **Modifications related to Medicare Coverage for Opioid Use Disorder (OUD) Services Furnished by Opioid Treatment Programs**

SGIM members have long been committed to combating the opioid epidemic and work with other providers to care for patients with OUDs. **SGIM supports the agency's proposal to expand the bundled service codes beyond OUD treatment also to include substance use disorder treatment.** The Society also supports the agency's continued efforts to integrate prescription drug monitoring programs into electronic health records to the fullest extent possible.

#### **CY 2021 Updates to the Quality Payment Program, including the MIPS Value Pathways and Qualified Clinical Data Registries**

SGIM appreciates CMS' efforts to support providers through these unprecedented times and ensure they are not unduly penalized in the MIPS program because of the COVID-19 pandemic, including the changes the agency has made to the extreme and uncontrollable circumstances in the interim final rules that have been released this year. The Society also thanks the agency for proposing to provide additional relief in this proposed rule, including lowering the performance threshold to 50 points, the cost category weight to 20 percent, and doubling the complex patient bonus to 10 points. Yet, SGIM does not feel these policies go far enough to protect the providers that care for the most vulnerable populations in our country, and to directly create accountability for achieving equity for all Medicare beneficiaries, both within and outside the context of the COVID-19 pandemic.

Numerous research studies and comprehensive reports have demonstrated that practices caring for the most socially at-risk patients fare worse in pay-for-performance programs, like the Quality Payment Program. The Assistant Secretary for Planning and Evaluation's (ASPE) initial 2016 report on social risk has understandably been unable to fully identify the exact reasons, but a combination of more challenging circumstances, like patient factors and under-resourced clinics, and poorer quality of care likely contribute. SGIM acknowledges the ongoing difficulty in identifying specific elements of social risk that affect outcome and performance in value-based programs, and thus how best to incorporate social risk into such programs. CMS states in the



proposed rule that they will continue to review the 2020 ASPE final report and make program changes in the future incorporating ASPE’s findings and recommendations. **SGIM does not believe ASPE’s 2020 final report is the end of the discussion and policy changes, given the explicitly stated need for long-term interventions (e.g. creation of equity focused quality measures) as well as ongoing research and monitoring.**

Both *Health Affairs* and the *Journal of the American Medical Association*<sup>3,4,5</sup> have published additional research on this topic during this rulemaking period. They examined the MIPS program directly, and the complex patient bonus specifically, and have again demonstrated that providers and practices caring for more socially complex patients, as determined by dual eligible status, perform worse in MIPS. SGIM appreciates CMS willingness to continue to evaluate and modify MIPS policy, and welcomes the opportunity to continue to engage in these discussions.

SGIM believes CMS can do more to support practices caring for socially at-risk patients beyond what the 2020 ASPE report recommends, thereby moving to improve the health of all Medicare beneficiaries. Most importantly, SGIM believes that the magnitude of payment adjustments in MIPS and its current scoring structure, exacerbated by COVID-19 related financial challenges, means many practices caring for the most vulnerable Medicare beneficiaries are at risk of financial ruin before meaningful, long-term recommendations from the 2020 ASPE report can be implemented. **SGIM, therefore, strongly urges CMS to take action now to support safety net providers financially, while ongoing research and long-term policy changes are considered.**

Given the ample evidence that safety net providers are at a disadvantage in value-based programs, SGIM strongly recommends that CMS make improvements now rather than waiting for an agreement on best practices. The agency has the opportunity to lead the efforts to promote equity in health care by reversing years of structural disadvantages to caring for socially at-risk patients. Our SGIM primary care providers choose to work in safety net clinics because of their commitment to the mission, despite having less support and resources and earning less money than would be possible in another clinic or health system. While there are undoubtedly quality of care issues that must be improved, only offering technical assistance while continuing to place such clinics at a financial disadvantage will not lead to quality improvement.

SGIM fully agrees with ASPE’s long-term recommendations to develop a standard risk adjustment framework, including functional risk, prior utilization and spending in risk adjustment; adjust resource use measures for social risk; support development of health equity specific measures for use in quality reporting and value based purchasing programs; and set high quality standards for all beneficiaries by not adjusting process and outcome measures for social

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<sup>3</sup> Johnston KJ et al.. Clinicians With High Socially At-Risk Caseloads Received Reduced Merit-Based Incentive Payment System Scores. *Health Aff (Millwood)*. 2020 Sep;39(9):1504-1512.

<sup>4</sup> Khullar D et al.. Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA*. 2020 Sep 8;324(10):975-983.

<sup>5</sup> Johnston KJ et al. Association of Clinician Health System Affiliation With Outpatient Performance Ratings in the Medicare Merit-based Incentive Payment System. *JAMA*. 2020 Sep 8;324(10):984-992.



risk. SGIM recognizes that not adjusting measures for social risk is controversial, but support ASPE’s position since there are other ways to achieve equity by risk adjusting other factors like cost and utilization and implementing bonus points or financial incentives. We also agree that medical providers must work directly with social service providers and community organizations to address social determinants of health, which is the ultimate goal, not simply fair treatment in value-based programs. SGIM also agrees with ASPE’s recommendation that CMS should explore ways to encourage providers to collect additional information on social risk, but believe a stronger approach is required. Dual eligible status remains a crude marker of social risk, for risk adjustment purposes and especially for the purposes of addressing and improving social determinants, where information on specific social needs such as housing instability and food insecurity is critical. Numerous examples of programs collecting more granular social risk information exist, including the CMMI Accountable Health Communities demonstration, MassHealth, and Department of Veterans Affairs (VA). Specific options include incorporating zip-code linked measures of social risk (e.g. area deprivation index, social vulnerability index) and using Z codes. Uptake of Z codes has been slow, with only 1.9% of hospital admissions including Z codes according to recent literature<sup>6</sup>. CMS could create incentives to increase Z code utilization, similar to MassHealth tying quality incentive payments to Z codes, and the VA use of housing related Z codes in its resource allocation model (Veteran’s Equitable Resource Allocation, VERA). CMS has cited prior National Quality Forum reports that incorporating factors besides dual eligible status have not demonstrated meaningful changes in models, but additional research is needed. Such research cannot be conducted without adequate collection of granular social risk factors.

SGIM also agrees with ASPE’s recommendation that “CMS should support providers and plans addressing social risk through models, supplemental benefits, and VBP payment adjustments” and recommends CMS enact specific changes. Within ASPE’s framework of recommendations, SGIM recommends the following:

- 1. Strengthen temporary supports to safety net providers while enacting long-term changes.**

ASPE’s final report recommends ultimately removing peer grouping to move towards the goal of holding all providers to the same high standards, but not removing such protections until more nuanced comprehensive approaches, including enhanced risk adjustment methods accounting for frailty, prior utilization and spending, can be implemented simultaneously. The ASPE report also supports permanent mechanisms such as bonus points for providers caring for more socially at-risk patients. Eliminating peer grouping, which does not exist in MIPS, but does in programs such as the Hospital Readmissions Reduction Program (HRRP), would require establishing the appropriate magnitude and structure of bonus, which presents significant challenges. SGIM agrees

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<sup>6</sup> Truong, HP et al. Utilization of Social Determinants of Health ICD-10 Z-Codes Among Hospitalized Patients in the United States, 2016–2017, *Medical Care*: September 11, 2020 - Volume Publish Ahead of Print



with ASPE that peer grouping and other protections should not be removed from CMS programs until evidence-based long-term changes are implemented. As currently structured the MIPS complex patient bonus provides inadequate support to the safety net providers it was intended to benefit. As such, SGIM recommends stronger short-term protections must be enacted, such as peer grouping or a bonus to safety net providers that addresses the limitations of the current complex patient bonus.

As highlighted by the September 2020 *Health Affairs* study by Johnston et al<sup>3</sup>, the complex patient bonus does not apply to those who do not submit data; safety net and small practices who may lack the resources do represent the bulk of those who do not submit data. The goal of the complex patient bonus, therefore, is not reaching practices who need it the most. Despite COVID- related flexibilities and ongoing CMS-provided technical support, many of these practices may simply shut down or be purchased by health systems, rather than successfully navigating the changes imposed by too blunt a policy rule. Should these practices close, beneficiaries will no longer have access to care or may face higher costs associated with mergers and acquisitions by larger health systems. SGIM recommends ensuring the complex patient bonus to be applicable to all providers

As CMS considers longer-term solutions to social complexity than the complex patient bonus, **SGIM recommends not tying bonuses intended to support safety net practices to requirements and regulations which they may struggle to meet for exactly the reasons the bonus was created.**

The magnitude of the complex patient bonus as it relates to social complexity becomes less and less meaningful protection as the performance threshold increases year by year, and is inadequate to provide meaningful support to many providers. For the 2022 performance year, as CMS currently projects, the composite performance threshold is projected to be above 70 points, thus with a threshold above 17 points to avoid the maximum negative penalty of -9%. The complex patient bonus returns to five total points maximum in 2022. Providers with the highest proportion of socially complex patients will see a very small total point bonus over other providers, resulting in far smaller protections than reported in the literature for peer grouping within HRRP after enactment of changes resulting from the 21<sup>st</sup> Century Cures Act (Public Law No: 114-255). **SGIM urges CMS to increase the complex patient bonus commensurate with the increase in the performance threshold to address this issue, or to create a separate safety net bonus until long-term refinements in measurement of and accounting for social risk are enacted.**

## **2. Create permanent financial incentives and payment adjustments to care for socially complex patients**



CMS has stated its intention for the complex patient bonus to be temporary, while deciding upon permanent ways to incorporate social risk within MIPS. ASPE's 2020 final report includes long-term recommendations to provide support to providers caring for socially complex patients, stating that bonus points in value-based payment programs are appropriate as additional tools and resources.

Current MIPS bonus points do not provide adequate protection or incentive to care for socially at-risk patients. Safety net clinics have long faced inadequate financial support for the care they provide. Furthermore, studies have demonstrated repeatedly that socially at-risk patients cost the health care system more, even after adjusting for medical complexity. While CMS is not responsible for payer mix and the overall financial status of such clinics, Medicare has always served as the policy bellwether, and can move to increase payments to safety net clinics, thereby supporting such clinics and their patients, and incentivizing rather than penalizing providers to care for these vulnerable Medicare beneficiaries. **SGIM requests CMS consider creating a permanent bonus to care for socially at-risk patients, and ensure the magnitude of such a bonus is adequate to provide meaningful support and incentive.**

### **3. Incentivize providers to focus improvement efforts on reducing disparities**

MIPS now includes a list of health equity related improvement activities, which is laudable as CMS can incentivize providers to focus on disparities through this mechanism. SGIM recommends CMS:

- Expand the list of Health Equity Improvement Activities
- Set all Health Equity Improvement Activities to have high weighting.

#### ***MIPS Value Pathways***

**SGIM supports CMS' proposal to delay the transition to MIPS Value Pathways (MVP) in response to the public health emergency as providers work to address COVID-19 in their communities.** In the proposed rule, the agency stated that it will revisit potential MVP implementation through future rulemaking, possibly beginning with the 2022 performance period. We recognize that this would mean that in the CY 2022 rulemaking cycle, the agency will simultaneously propose an initial set of MVPs while also establishing implementation policies. SGIM urges the agency to consider delaying the implementation of MVPs by an additional year to ensure that the final MVPs and the related policies are not burdensome to providers and their practices who we hope will be recovering from the COVID-19 pandemic at that point. SGIM welcomes the opportunity to work with the agency to ensure the MVPs allow for reduced burden and meaningful participation for all physicians.

SGIM appreciates the opportunity to provide comments on this proposed rule. If you have any questions or wish to discuss our comments further, please contact Erika Miller at [emiller@dc-crd.com](mailto:emiller@dc-crd.com).



Sincerely,

A handwritten signature in black ink that reads "Jean S. Kutner". The signature is written in a cursive style with a large, prominent initial "J".

Jean S. Kutner, MD, MSPH



## Appendix A

### Proposal to Form an Expert Panel to Review Evaluation and Management Services

#### **Request:**

The Cognitive Care Alliance (CCA), representing over 60,000 physicians from seven cognitively focused specialty societies, proposes that the Centers for Medicare & Medicaid Services (CMS) convene an expert panel to develop recommendations on how to appropriately define, document, and value evaluation and management (E/M) services.

#### **Background/ Statement of Need:**

The CCA thanks CMS for finalizing significant changes to the outpatient E/M services in the CY 2020 Medicare Physician Fee Schedule (MPFS) that will become effective January 1, 2021. We believe these changes are an important first step to appropriately value cognitive work and should be implemented as finalized. The deficiencies in the E/M coding structure and values have resulted in cognitive workforce shortages and limited Medicare beneficiary access to certain primary care and cognitive services. The principle architect of the Resource-Based Relative Value Scale (RBRVS), Dr. William Hsiao from Harvard University, clearly stated that the development of the E/M portion of the MPFS was not adequately supported and that more refinement was needed.<sup>7</sup>

Changes to the outpatient E/M services are being implemented at a time when the practice of medicine looks significantly different than it did when the RBRVS was established. Now CMS spends approximately \$100 billion on MPFS services. Forty percent of that spending is on E/M services - the outpatient E/M services account for 27 percent of MPFS spending. Since the late 1980s, the methodologies of health services research have evolved, the principles of representative databases have been firmly established, methods of adjustment to reflect the influences of health, social, economic, geographic and other factors are more robust, and the unintended consequences of the existing pricing mechanisms have become more clear.<sup>8</sup> All of these factors provide CMS with new tools to value cognitive work.

CMS' revisions to the outpatient E/M services have been lauded by the member societies of the CCA and by most of the medical community, yet our societies continue to express concern that these changes do not address the legacy mis-valuation of E/M services. Most importantly, the agency must sustain its commitment to fully understand the resources and work required to deliver cognitive E/M services in both outpatient and inpatient settings, including the expertise demanded to manage the "complexity density" of each encounter, and to accurately define and value service codes that capture current medical practice.

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<sup>7</sup> Hsiao, WC, Braun, P, Dunn DL et al. Med Care 1992;30 (11) Supplement: NS1-NS12.

<sup>8</sup> Goodson JD. Unintended consequences of resource-based relative value scale reimbursement. JAMA. 2007; 298(19): 2308-10.



The CCA has called on CMS to conduct research to better understand the components, inputs, interactions, outputs, and implications for all E/M services. We propose that CMS create an expert panel with the express purpose of establishing a permanent mechanism to ensure that the relative valuation of physician services is data driven and reflects the current practices of medicine to achieve the best possible outcomes for all Medicare beneficiaries. Again, this panel would not delay or change the E/M payment reforms finalized in the CY 2020 MPFS. Rather, this panel would assist CMS to ensure that cognitive work is accurately defined and valued under the MPFS.

### **Proposed Panel Charge, Responsibilities and Composition:**

#### **Charge**

Using an evidence-based approach, the panel will assess the current definitions, documentation expectations and valuations of existing E/M services and develop a set of recommended changes to address identified data gaps and/or inadequacies.

#### **Responsibilities**

- **Evaluate and summarize** the current data and research related to E/M services.
- **Review** the current methodologies and procedures used to define and value services under the MPFS.
- **Identify** the specific knowledge gaps including parameters for additional data needs and research required to study key topics and answer key questions, including:
  - Does the existing E/M code set adequately define and describe the full range of E/M services?
  - If adequate, are the current values for E/M services appropriate? Are the gradations of valuation aligned with the gradations of service intensity?
    - Do they appropriately account for all input elements that contribute to the intensity of work valuation, including the development and maintenance of cognitive expertise, the complexity of the clinically relevant interactions among individual patient characteristics, diagnoses and therapeutics, and the risks and implications that arise from different levels of encounter intensity?
    - Are the existing code definitions clear and accurate? If so, then code definitions should be reviewed to ensure linkage to definable auditing metrics.
  - If inadequate, what changes to the E/M service codes or additional codes are needed to address the possible deficiencies noted above?



- Collaborate with the Office of the National Coordinator for Health Information Technology (HIT) to ensure that documentation requirements are easily integrated in the electronic health record (EHR).
- Consider and research the development of guidelines for the future relative valuation of physician services. Propose a process whereby CMS can ensure that the MPFS is based on accurate and updated service code definitions, including service code times, and a reliable process of relative valuation based on data collected from patients, physicians, enterprises, and institutions.
  - Assess the utility of data describing E/M services from current resources, including the National Ambulatory Medical Care Survey (NAMCS), the Medical Expenditure Panel Survey (MEPS), de-identified Medicare payment data, and de-identified electronic health record data sources.
- **Develop** new valuation concepts, if warranted, to capture the breadth and value of E/M services and determine how these can be best integrated in with existing RBRVS.
- **Recommend** changes, if warranted, that should be made to the current E/M code set to ensure the valuations of these codes reflect current medical practice.
- **Oversee the development of and provide input for** any new E/M services including:
  - service descriptions,
  - billing and coding guidelines, and
  - program integrity requirements

#### **Panel Composition**

To ensure diverse perspectives are factored into the development and refinement of E/M services, membership should include:

- Clinicians, such as general practice and specialty medicine physicians, and other qualified health professionals;
- Medicare Beneficiaries;
- Health economists and health services researchers;
- Experts in medical coding and code valuation;
- Health informatics experts;
- Experts in program integrity and compliance; and
- Stakeholders with expertise in Medicare payment policy.



**Cognitive Care Alliance Member Organizations:**

American Association of the Study of Liver Diseases

American Gastroenterological Association

American Society of Hematology

Coalition of State Rheumatology Organizations

Endocrine Society

Infectious Diseases Society of America

Society of General Internal Medicine