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Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
ATTN: CMS-1715-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: [CMS-1715-P] Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Polices; et al.

Dear Administrator Verma:

The American Geriatrics Society ("AGS") greatly appreciates the opportunity to comment on the Physician Fee Schedule ("PFS") Proposed Rule for Calendar Year ("CY") 2020 (CMS-1715-P).[1] The AGS is a not-for-profit organization comprised of nearly 6,000 physician and non-physician practitioners (NPPs) who are devoted to improving the health, independence and quality of life of all older adults. The AGS provides leadership to healthcare professionals, policy makers, and the public by implementing and advocating for programs in patient care, research, professional and public education, and public policy. Our mission is to advance efforts that promote high quality of care, quality improvement, and increased payment accuracy for physicians and other professionals paid under the PFS and through the Quality Payment Program (QPP).

The AGS appreciates continued efforts by the Centers for Medicare & Medicaid Services (CMS) to identify and address instances in which CMS' policies or requirements may create an undue administrative burden. We also appreciate CMS' engagement with a wide range of stakeholders about refinements to Medicare payment policies under the PFS and the agency's responsiveness to concerns from the provider community who treat Medicare beneficiaries.

CMS proposes significant changes to the payment policy for outpatient Evaluation and Management (E/M) visit codes that was finalized last year and to a range of care management codes. The

[1] CMS. *Medicare Program: CY 2020 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; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancement to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations* (84 Fed. Reg. 40598), August 14, 2019.

AGS believes that these codes describe the services at the core of high quality, patient-centered care and, as described in greater detail below, we recommend that CMS finalize the proposed changes. We also comment on consent for communication technology-based services; physician supervision of NPP services; specific measures and measure sets under the Merit-based Incentive Payment System (MIPS); and concerns about revocation of participation status.

I. Recommendations

AGS recommends that CMS:

- **Finalize the E/M coding and payment changes as proposed to take effect January 1, 2021 (Section II.P).**
- **Finalize changes to the payment policy for care management services, including: revaluing transitional care management codes, creating a new G code to describe extended chronic care management, simplifying complex chronic care management, and creating two principal care management codes (Section II.K).**
- **Allow for a single consent for all communication technology-based codes provided within a one year period (Section II.K.6).**
- **Align the standards related to Physicians' Assistants with those of Nurse Practitioners (Section II.I) and create specialty class designation for all NPPs.**
- **Make changes to the Geriatrics Measure Set and consider alternatives for attributing patients under the Total Per Capita Cost Measure (Section III.K).**
- **Not finalize the proposed expansion of CMS' authority to revoke Medicare enrollment and billing privileges (Section III.H.2).**

II. Payment for Evaluation and Management Visits (Section II.P)

In the final rule updating PFS rates and policies for 2019, CMS finalized the numerous changes to take effect January 1, 2021, including creating a single payment rate for code ranges. AGS raised significant concerns with those changes and urged CMS to work with AGS and other specialty societies to create a coding structure that better meets the agency's goals of improving patient care and reducing burden.

We applaud CMS for listening to provider feedback and concerns. In response to the changes that CMS finalized last year, the Current Procedural Terminology (CPT) Editorial Panel adopted revisions to the office and other outpatient E/M code descriptors, and substantially revised both the CPT prefatory language and the CPT interpretive guidelines that instruct practitioners on how to bill these codes. The CPT changes take effect January 1, 2021 and address issues that CMS had identified as burdensome, including no longer selecting the level of E/M visits based on the type of history and exam.

A. **AGS Supports CMS' E/M Proposals.**

CMS proposes to adopt the CPT coding changes, accept RUC recommended values and to revise CMS' payment policies for 2021 to reflect those changes, including no longer paying a blended rate for Level 2,3, and 4 E/M services. Effective January 1, 2021, CMS proposes to:

- Assign separate payment to each of the office and other outpatient E/M visit codes and the new prolonged visit add-on CPT code (CPT code 99XXX).
- Delete the HCPCS add-on code for extended visits (GPRO1) and allow a new prolonged E/M visit code (99XXX) to only be reported when time is used for code level selection and the time for a level 5 visit is exceeded by 15 minutes or more. Existing codes for prolonged E/M visit without direct patient contact (99358-9) would no longer be reportable for prolonged services on the same date of office or other outpatient E/M visits.
- No longer require the minimum supporting documentation associated with level 2 office or other outpatient E/M visit.
- Simplify, consolidate and revalue the HCPCS add-on codes for primary care (GPC1X) and non-procedural specialized medical care (GCG0X), and allow the new code to be reported with all office or other outpatient E/M visit levels that meet the criteria of the service.

AGS greatly appreciates CMS' willingness to continue to refine and improve payment policy for E/M services and strongly recommends that CMS finalize the proposed changes to the E/M visit codes and payment policies including the proposed work relative value units (RVUs) as proposed. We recommend that CMS implement those changes in 2021. Finalizing the changes in the 2020 final rule to take effect January 1, 2021 will allow 14 months for CMS and providers to prepare for the changes. We believe that this is sufficient time, especially given the broad participation and knowledge of the processes that have led us to the current status.

It appears that CMS is proposing to prohibit the prolonged services codes (99358 and 99359) from being reported on dates other than the date of the face-to-face office or other outpatient E/M. If this is the case, we disagree and recommend that CMS not finalize its proposal. These codes are intended to be reported on dates other than the date of the face-to-face in order to report extensive work performed on a date before or after the visit (e.g., extensive review of medical records) if the time criteria are met. These services are not part of the work of a face-to-face E/M and should be reported and paid separately.

B. **AGS Urges CMS to Continue to Work with Specialty Societies on Additional Adjustments Necessitated by Revised E/M Coding and Payment.**

CMS also asked for comment as to whether the changes in the E/M outpatient office visit codes should be reflected in the RVUs for other codes. Specifically, CMS asks whether the RVUs for services that require an E/M visit as part of the services, such as transitional care management (TCM) (99495, 99496), cognitive impairment assessment and care planning (99483), certain ESRD monthly services (90951 - 90961), the Initial Preventive Physical Exam (G0438) and the Annual Wellness Visit (G0439) should be revised to reflect the RVUs for the revised E/M codes. CMS also asks for comment on whether it would be necessary or beneficial to make systematic adjustment to other services to maintain relativity between

those services and the office or other E/M visits. In particular CMS is interested in whether adjustments are necessary for E/M codes describing visits in other settings, such as home visits, or to codes describing more specific kinds of visits, like counseling visits.

We share CMS' concern that the changes in coding and payment for E/M services in the outpatient office setting may suggest the need for evaluation of refinements in other codes. We particularly urge CMS to consider the impact on other outpatient E/M services, especially services provided to beneficiaries at home or in residential settings such as assisted living and other domiciliary settings, where the new add-on code for a continuous relationship (GPC1X) may be particularly relevant. AGS agrees that other codes may need to be revised to retain relativity to the updated E/M codes and use of those codes may also be improved by adoption of simplified documentation standards. We do not believe that there is a single, one-size-fits-all approach that could be used to appropriately revalue all of the potentially affected codes. Instead, we believe that any adjustments should be made in conjunction with the relevant specialty societies. Some of the administrative simplifications of the new office visit guidelines and descriptors may also be appropriate for other E/M services once CMS has determined it will finalize its current proposal. We urge CMS to continue working with the specialty societies, CPT and the RUC to ensure that all E/M services are appropriately described and valued.

III. **Care Management Services (Section II.K)**

AGS has been a long-time and vocal advocate for expanded access to and payment of care management services. We strongly believe that increased care coordination will improve the quality of care provided, increase beneficiary satisfaction with their care, and reduce the growth in Medicare spending. In this rule, CMS proposes several changes intended to address gaps in coding and payment for care management services and we strongly support those efforts, as described below.

A. **AGS supports proposed Transitional Care Management (TCM) revisions (subsection 2).**

CMS proposes to allow separate payment for 14 of the 57 codes previously identified as overlapping or duplicating TCM services and which cannot be billed with the TCM codes (99495, 99496). The codes proposed for separate payment describe prolonged services without direct patient contact (99358, 99359); INR monitoring services (93792, 93793); end-stage renal disease (ESRD) related services (90960, 90961, 90962, 90966, 90970); interpretation of physiological data (99091); complex chronic care management services (99487, 99489), and care plan oversight services (G0181, G0182). CMS asked for comment on whether any overlap with these services and TCM exists and whether the presence or degree of overlap would depend on whether the same or a different practitioner reports the service.

AGS agrees that the services described by the 14 codes proposed for separate payment do not overlap or duplicate TCM services. Those codes describe services that may support the TCM service but are separate and distinct from TCM and should be paid separately.

CMS also proposes to adopt the RUC recommended work RVUs for the TCM codes of 2.36 for 99495 and 3.10 for 99496. AGS believes that the proposed work RVUs, which represent an increase over the 2019 work RVUs of 12 percent and 2 percent respectively, will pay more appropriately for TCM services. We recommend that CMS finalize the proposed work values.

B. **AGS supports Chronic Care Management (CCM) and Complex CCM revisions (subsection 3).**

CMS is proposing new G codes for CCM (99490 and an add-on time unit) and complex CCM (99487 and 99489). The G codes are intended to improve the payment accuracy for CCM and to remove the explicit requirement for substantial care plan revision from the complex CCM codes. CMS also proposes to change the description of the typical care plan elements commonly provided as part of CCM services by deleting the phrase "community/social services ordered, how the services of agencies and specialists unconnected to the practice will be directed/coordinated, identify the individuals responsible for each intervention" and inserting the phrase "interaction and coordination with outside resources and practitioners and providers."

The four proposed new G codes are:

- GCCC1 Chronic care management services, initial 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; and comprehensive care plan established, implemented, revised, or monitored. (Chronic care management services of less than 20 minutes duration, in a calendar month, are not reported separately)

- GCCC2 Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Use GCCC2 in conjunction with GCCC1). (Do not report GCCC1, GCCC2 in the same calendar month as GCCC3, GCCC4, 99491)

- GCCC3 Complex chronic care management services, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored; moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month. (Complex chronic care management services of less than 60 minutes duration, in a calendar month, are not reported separately)

- GCCC4 Each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Report GCCC4 in conjunction with GCCC3). (Do not report GCCC4 for care management services of less than 30 minutes additional to the first 60 minutes of complex chronic care management services during a calendar month)

AGS strongly supports improving the payment accuracy for CCM, removing the explicit requirement for substantial care plan revision from the complex CCM codes, and changing the description of the typical care plan elements. We recommend that CMS finalize all its CCM payment

policy proposals for CY 2020. However, we note that CMS is not required to create four new G codes in order to finalize the proposed policies. We agree that CMS needs to finalize GCCC2 to finalize its proposals because that code does not currently exist in CPT. However, CMS does not need to create GCCC1, GCCC3, and GCCC4 because the descriptors for those codes already exist in CPT under the numbers 94990, 94987, and 99489, respectively. We are concerned that the creation of three G codes that will be in effect for only one year could be very confusing and is not necessary for CMS to achieve its policy goals. We believe that CMS could continue to recognize 99490, 99487, and 99489 instead of creating the G codes, make it clear that the CMS payment policies for those codes are not identical to those in CPT, and remind stakeholders to review the CMS requirements. Further, we believe it is very likely that CPT will revise the CPT codes and guidelines as soon as practical after CMS finalizes these proposals.

C. **AGS supports the creation of Principal Care Management (PCM) Services (subsection 4)**

CMS identifies as a gap in coding and payment for care management services the fact that the current CCM codes require patients to have two or more chronic conditions and the patient is addressed in a comprehensive manner. CMS proposes to establish separate coding and payment for Principal Care Management (PCM) services which describe care management services for one serious chronic condition.

- GPPP1 Comprehensive care management services for a single high-risk disease, e.g., Principal Care Management, at least 30 minutes of physician or other qualified health care professional time per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities

- GPPP2 Comprehensive care management for a single high-risk disease services, e.g. Principal Care Management, at least 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month with the following elements: one complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities

A patient could receive PCM services from more than one clinician if the patient experiences an exacerbation of more than one complex chronic condition simultaneously but CMS proposes that the same practitioner could not bill for PCM with certain other care management services (CCM, behavioral health integration services, and monthly capitated ESRD payments) for the same patient or during the global period for a surgical service furnished to the same patient. CMS acknowledges that allowing more than one clinician to bill for PCM could result in fragmented care and asks for comment on whether additional requirements such as that the PCM practitioner must document ongoing communication with

the patient's primary care practitioner, that the patient must have had a face-to-face visit with the PCM practitioner within the prior 30 days, or other elements are necessary to prevent potential care fragmentation or service duplication.

AGS supports the establishment of the PCM codes. Better care may require special expertise with scrupulous care coordination. While the patients typically seen by our members are among the most vulnerable and likely to have more than one chronic disease, we believe that many seriously ill patients, including those with a single chronic condition, can benefit from care management. Those with multiple conditions may benefit from care management from a specialist, e.g. in a heart failure program. If the professional reporting PCM is not the primary care clinician, we do believe there should be an expectation of communication to the primary care practice. We also believe that the primary care practice should not be precluded from reporting 99490 or other care management services. Clarifying these expectations would reduce any concerns regarding fragmentation. We believe the requirements for reporting CCM/CCCM and PCM should generally align, including requirements for an assessment visit and practice attributes that promote access and coordination, such as a clear relationship with the care managers and the capacity for in-person care management.

D. AGS supports simplified consent for Communication Technology-Based Services (subsection 6).

Currently, CMS requires clinicians to obtain advance beneficiary consent individually for communication technology-based services (i.e., remote evaluation of patient-submitted video or image (G2010), virtual check-in (G2012), and interprofessional consultations (99446-99449, 99451, and 99452)). In response to ongoing stakeholder concerns that it is burdensome to obtain consent individually for these services, CMS is seeking comment as to whether a single advance beneficiary consent could be obtained and the appropriate interval of time or number of services for which consent could be obtained (i.e., for all those services furnished with a 6 month period) or for a set number of services. CMS also asked for comment on how to minimize any program integrity concerns with allowing a single advance consent.

AGS supports obtaining a single beneficiary consent for the communication technology-based services. While we agree that it is important that beneficiaries are aware that they are responsible for cost sharing on those services, the notification and consent requirements should not be so extensive that they ultimately preclude beneficiaries from having access to the service. We recommend a single consent annually as this will align with new coding and other actions that are finalized and may thus warrant a new notice. An annual notice is sufficient to balance access issues with concerns about program integrity.

IV. Non-Physician Practitioner Services

A. AGS Supports aligning NPP supervision requirements consistent with state licensure law (Section II.I).

Currently, CMS regulations interpret the statutory benefit for services furnished by a PA under the supervision of a physician to require "general" supervision, in which PA services are furnished under a physician's overall direction and control, but without requiring the physician's presence during the

performance of those PA services. In the Proposed Rule, CMS proposes to modify the physician supervision requirement for physician assistants to more closely align with evolving scope of practice laws among the states. CMS proposes that the supervision requirement would be met when a PA furnishes services in accordance with state law and state scope of practice rules for PAs, with medical direction and appropriate supervision as provided by the state law in which the services are performed.

AGS strongly supports the proposed change and agrees with CMS that the proposal will better align the supervision requirement for PAs more closely with the requirement of physician "collaboration" for Nurse Practitioner and Certified Nurse Specialist services. We urge CMS to finalize the change as proposed.

B. AGS recommends capturing the specialty designation for NPPs.

We also urge CMS to refine the specialty designation for NPPs such as PAs and advanced practice nurses to better capture the practitioner's specialty field. Currently, NPPs are assumed to be primary care providers but the Medicare Payment Advisory Commission (MedPAC) recently found that only half of nurse practitioners and 27 percent of PAs practice in primary care.[2] MedPAC recommends that CMS use the Medicare enrollment process to capture and update the specialty designation of NPPs. AGS agrees and urges CMS to require that NPPs identify a specialty designation at the time of enrollment and when enrollment information is revalidated every five years.

V. MIPS Measures (Section III.K)

A. AGS appreciates CMS' support of the geriatrics specialty measure set and further urges CMS to prioritize measures that address the needs of the geriatric population (Table B.34).

The AGS greatly appreciates CMS' support of measure development and promoting ways to provide new, more applicable measures, such as by finalizing the Geriatrics specialty set for use in the Quality performance category last year. We encourage CMS to continue to facilitate and sponsor measure development for the very population CMS expends the most resources upon—that is, the multi-morbid patient with functional impairment who is not institutionalized. We recommend that CMS prioritize measures that specifically address care of the geriatric population and the AGS looks forward to working with CMS on the development of future metrics based on the care episode groups, patient condition groups, and physician-patient relationship categories.

B. AGS supports the following changes to the Geriatrics specialty measure set (Table B.34).

The AGS supports the measures that CMS is proposing to keep in the Geriatrics specialty set and also supports the inclusion of the following 4 measures CMS proposes to add to the set:

[2] MedPAC. Report to Congress: June 2019. p. 162.

- Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older (Measure # 48)
- Falls: Risk Assessment (Measure # 154)
- Falls: Plan of Care (Measure # 155), and
- International Prostate Symptom Score (IPPS) or American Urological Association Symptom Index (AUA-SI) change 6 – 12 months after diagnosis of Benign Prostatic Hyperplasia.

The AGS earlier this year recommended that CMS add these measures to the Geriatrics specialty set and we would like to reemphasize our support for the inclusion of these measures in the final rule. We also support the addition of the measure for a global Adult Immunization Status measure and dropping the individual influenza, pneumococcal and zoster vaccination measures. The new measure is simpler and includes the vaccines that are relevant to older adults.

We also agree with the proposal to remove Measure #46 Medication Reconciliation Post-Discharge from the Geriatrics specialty measure set and MIPS altogether. In a February 2019 letter[3], AGS expressed concern regarding this measure. We noted that (1) the large caregiver burden associated with this measure may lead to slow or little adoption and (2) the cumbersome specifications will lead to inaccurate data.

C. AGS does not support CMS' decision to remove the Dementia: Functional Status Assessment measure from the Geriatrics specialty measure set (Table C).

AGS is concerned with the proposal to remove the Dementia Functional Status Assessment measure (Measure #282) and replace it with the Functional Outcome Assessment measure (Measure # 182). Measure #282 is specific to patients with dementia and captures the percentage of patients for whom an assessment of functional status was performed at least once in the last 12 months. The proposed new measure #182 includes patients aged 18 years and older and requires more frequent assessment and a plan of care. AGS is concerned that by focusing on such a wide age range, we are losing some geriatric specificity. We agree that measuring function for many younger adults may be worthwhile, but that such measurement should be tailored to specific situations (e.g. validated rheumatoid arthritis scales for patients with rheumatoid arthritis or functional measures for low back pain, etc.). Including a blanket metric of functional assessment for all adults over age 18 may lead to a lot of "box-checking" work with limited benefit to patients. We are also concerned that the measure suggests that functional status be assessed using a standardized tool at each visit, rather than during a defined time period (i.e. 12 months). Use of this measure may result in repeated questionnaires for patients who require frequent visits (i.e. screened on a primary visit, but seen the next week for an urgent question). Does the provider need to fill out a questionnaire and make a plan on each day? Because of these concerns about measure #182, we believe that measure #282 should not be considered duplicative and should be retained in the measure set.

D. AGS urges CMS to consider further refinements to the Geriatrics specialty measure set including simplifying the Use of High-Risk Medications in the Elderly measure.

[3] American Geriatrics Society. *Letter to CMS on Revisions to MIPS Geriatrics Specialty Measure Set.* February 2019. https://bit.ly/2IKZQl6

As noted above, in general, AGS supports the measures included in the Geriatrics measure set but we have one recommendation for an improvement. CMS may wish to consider simplifying the Use of High-Risk Medications in the Elderly measure to be a single rate of the percentage of patients ordered at least two of the same high-risk medication. This change would better align with the Pharmacy Quality Alliance, Part C/D 5 Star program and HEDIS 2020.

E. AGS urges CMS to consider alternatives for attributing patients under the Total Per Capita Cost Measure (subsection (2)(b)(ii)).

The Total per Capita Cost (TPCC) measure is intended for use in comparing cost performance among those who can reasonably be expected to take accountability for the totality of a patient's health care costs, which is explicitly understood to mean primary care. Measuring primary care practitioner performance by risk-adjusted total cost of care is a time-tested approach that has been widely accepted by other payers, including by Medicare Advantage plans.

CMS intends to use claims data to identify those who are providing primary care. However, there are no "primary care CPT codes". Primary care providers use the same evaluation and management codes used by all clinicians. Thus, accurate attribution for this primary-care focused measure based on claims has been challenging. In its latest refinement of TPCC, CMS proposes to use a pattern of at least 2 claims (a triggering E/M, and a second E/ M or "other primary care service") to initiate an episode and attribute that episode to the clinician. Clinicians in specialties that are unlikely to provide primary care are excluded from attribution.

We believe these changes are improvements but problems remain. Specialists who are providing longitudinal and continuous care to a patient with a single condition may be (erroneously we think) attributed for TPCC and inappropriately given accountability for the total cost of care. Actual primary care clinicians may find that many of their patients are not attributed for TPCC because the requisite intensity of contact is not met for a given time frame even though an established primary care relationship persists. We think it will be difficult or impossible to link quality performance with cost performance in a meaningful way with this method of attribution. Thus, CMS should seek further refinement of TPCC beyond what is proposed.

A potential future direction is suggested by CMS' proposal to create a new add-on code GPC1X for reporting with E/M services provided by primary care and certain specialties. The proposed descriptor for GPC1X is conceptually similar to the "patient relationship categories" previously adopted by CMS (the broad/continuous and the focused/continuous categories). The clinician who submits GPC1X asserts that the visit being reported occurred in the context as specified in the code descriptor of "*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 chronic condition*."

We believe that the appearance of GPC1X on a claim could trigger attribution for TPCC. To be used for this purpose, the proposed code GPC1X would need to be divided into two codes, one for the first criterion (primary care) and one for the second criterion (continuous focused care) and only the first

criterion should be attributed for TPCC. Of course, an appropriate cost measure could be designed for those who report the specialist code.

Using this approach will allow clinicians to reliably predict which patients will be attributed to them for purposes of determining performance on the TPCC measure. The clinician will know that the patient will be attributed in real time. The decision to submit GPC1X produces a financial benefit, and thus is unlikely to draw criticism for the minimal administrative burden submitting it will impose. In addition, we believe that performance on quality measures should take into consideration all those in a clinician's practice, not just those seen frequently. Under this alternative approach, the population for whom there is attribution for TPCC would form the population for quality measurement and better integrate the cost and quality measurement efforts.

VI. Proposal to Revoke Medicare Enrollment (Section III.H.2)

AGS urges CMS to not finalize the proposed expansion of CMS' authority to revoke Medicare enrollment and billing privileges.

CMS proposes to add a new subsection to 42 C.F.R. § 424.535(a) and to 42 C.F.R. § 424..530(a), which lists the reasons that CMS may revoke a currently enrolled provider or supplier's Medicare billing privileges or deny a provider or supplier' enrollment in Medicare.[4] CMS proposes that a provider or supplier may be denied enrollment or have enrollment revoked if

> "he or she has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm."[5]

AGS strongly disagrees with this proposal for six primary reasons. First, CMS does not have the statutory authority to finalize the proposal. Second, the proposal is vague and unenforceable. Third, this proposal imposes harsh sanctions on providers for potentially minor violations. Fourth, the proposal would negatively affect Medicare beneficiaries' access to care. Fifth, the proposal would have a chilling effect on clinician self-reporting to medical boards and on medical boards' willingness to discipline clinicians. Six, this proposal does not adequately codify in regulations the proposed leniency toward minor violations.

The statutory authority that CMS relies on to support its proposal are the provisions at SSA §§ 1102, 1871, and 1866(j)(1)(A). SSA §§ 1102 and 1871 are general rule-making provisions in the Social Security Act. Specifically, Section 1102(a) authorizes the HHS Secretary to issue regulations that are "not inconsistent with [the SSA]" and that are "necessary to the efficient administration of [the Secretary's] functions" [under the SSA]."[6] SSA § 1871(a) authorizes the Secretary to prescribe regulations "necessary

[4] 84 Fed. Reg. at 40723.

[5] *Id*.

[6] SSA § 1102(a).

to carry out the administration of [the Medicare program]."[7] Neither of these general rulemaking authorities can be construed to provide the authority to CMS to revoke a currently enrolled provider or supplier's Medicare billing privileges or deny a provider or supplier' enrollment in Medicare if the provider has been subject to an IRO determination or administrative action taken by a state oversight board, a federal or state health care program, or other healthcare-related governmental program. CMS' proposal is not "necessary" to run the Medicare program at all, let alone efficiently. In fact, as described in more detail below, the proposal could interrupt the provision of care to Medicare beneficiaries and lead to a more inefficient Medicare program. Therefore, CMS is not authorized to finalize its proposal under the authority granted by either SSA § 1102 or SSA § 1871.

Section SSA § 1866(j)(1)(A) permits CMS to implement enrollment processes - not revocation processes:

> The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under [Title 18 of the SSA]. Such process shall include screening of providers and suppliers in accordance with [the paragraph on provider screening], a provisional period of enhanced oversight in accordance with [the paragraph on provider screening], disclosure requirements in accordance with [the paragraph on increased disclosure requirements], the imposition of temporary enrollment moratoria in accordance with [the paragraph on a temporary moratorium on enrollment of new providers], and the establishment of compliance programs in accordance with [the paragraph on compliance programs].[8]

This section does not include any language related to revoking enrollment or denying enrollment, and speaks solely to regulating the process of enrollment that includes screening and a period of enhanced oversight. It contains no authority allowing CMS to deny enrollment at all, let alone based on an IRO determination or administrative action taken by a state oversight board, a federal or state health care program, or other healthcare-related governmental program.

Therefore, all of the statutory authorities that CMS cites for its proposal do not relate in any way to its authority to deny or revoke a provider's Medicare enrollment after the provider has already been enrolled in the Program. The statue does not provide CMS with the authority to implement its proposal to deny or revoke a provider's Medicare enrollment based on an IRO determination or administrative action taken by a state oversight board, a federal or state health care program, or other healthcare-related governmental program.

In addition to believing that CMS does not have the statutory authority to implement its proposal, AGS strongly believes that an administrative action against a provider for minor violations does not warrant the disproportional punishment of denying or revoking Medicare enrollment. CMS proposes to codify the authority to take administrative action against a physician or other eligible professional based *solely* on an IRO determination or administrative action taken by a state oversight board, a federal or state health care program, or other healthcare-related governmental program and provides no guidance about when it would choose to exercise that authority. IRO determinations or administrative actions may be minor and not relevant to a provider's participation in Medicare. In cases of minor violations, the

[7] SSA § 1871.

[8] SSA § 1866(j)(1)(A).

punishment CMS would impose could far outweigh the scope and gravity of the alleged violation. Furthermore, since the proposal does not include any criteria or process by which CMS would determine when it would deny or revoke enrollment, there is the potential for arbitrary decisions. For example, clinicians with similar actions taken against them could be treated differently - one could continue to be enrolled and the other could have his or her enrollment revoked. In addition, state practice of medicine statutes vary considerably as do the standards by which Boards of Medicine review clinician behavior. Treating all "offenses" as being the same is completely inappropriate and could put clinicians in some states at far greater risk of losing their Medicare billing privileges than clinicians in states with less detailed or strict standards.

CMS states in its proposal that it should not be "assumed" that "a very modest sanction would automatically result in revocation or denial action."[9] However, the text of the proposed regulation does not codify this statement, but instead only lists the factors CMS proposes to consider when making a revocation or denial decision. AGS strongly believes that clinicians should not be required to rely only on an informal statement that a modest sanction would not automatically result in a revocation or denial action. A preamble statement does not provide sufficient certainty or comfort to a provider when the potential consequence of a minor violation is revocation of Medicare enrollment. It also creates the potential for arbitrary decisions to be made. Lastly, we note that the proposal does not describe who will make these decisions. Will it be a CMS contractor or CMS itself? Will clinician review of the case be included? As written, the proposal provides no safeguards against arbitrary decisions made on the basis of an insufficient record.

The proposal could also impede access of beneficiaries to healthcare. In 2017 alone, the Federation of State Medical Boards reports that over four thousand physicians were subject to state medical board actions[10] and that 989 physicians were disciplined by a "reprimand," defined as a "warning or letter of concern."[11] These statistics demonstrate that CMS' proposal has the potential to affect the Medicare enrollment of thousands of clinicians across the U.S., which in turn could affect beneficiary access to medical care. Each time CMS revokes a provider's Medicare enrollment, that provider's patients will be forced to find alternative care.

The proposal could have a chilling effect on clinician self-reporting behavior such as drug abuse or alcoholism to medical boards and create a disincentive for medical boards to discipline clinicians for violations of State medical practice acts because of the potential effect on Medicare enrollment. As described by the AMA Journal of Ethics, "state medical boards are the agencies that license medical doctors, investigate complaints, discipline physicians who violate the medical practice act, and refer physicians for evaluation and rehabilitation when appropriate."[12] The proper venue for taking disciplinary action against clinicians are the state boards of medicine because the proper punishment for clinicians who are found to have violated the law is to take action against the provider's license. AGS is concerned that State medical boards will refrain from disciplining clinicians for minor violations if the medical boards

[9] 84 Fed. Reg. at 40723.

[10] Federation of State Medical Boards, U.S. Medical Regulatory Trends and Actions 2018 19 (2018), https://www.fsmb.org/siteassets/advocacy/publications/us-medical-regulatory-trends-actions.pdf.

[11] *Id*. at 21.

[12] Carlson, Drew and Thompson, James N., The Role of State Medical Boards, 7 AMA J. of Ethics 311-314, 311 (2005).

know that the consequence of a minor violation could be revocation of the provider's Medicare enrollment. Many State medical boards require clinician self-reporting of certain specific occurrences,[13] and an OIG white paper noted that even in the late 1980s, there was "increased use of self-reporting requirements on license renewal forms" which "provides boards with increased opportunities to initiate cases."[14] AGS cautions CMS that clinicians may self-report with less frequency if a consequence of such self-reporting could be revocation of the provider's Medicare enrollment.

Therefore, AGS recommends that CMS withdraw its proposal and rely on the current Medicare enrollment revocation authority. If the agency continues to believe that it needs additional authority to revoke Medicare enrollment in order to address specific behaviors, then CMS should identify those behaviors and propose revocation authority that is appropriately defined and intended to remedy those particular concerns. CMS should avoid establishing an overly broad revocation process which could undermine the state and local agencies which are already engaged in oversight of clinician practices.

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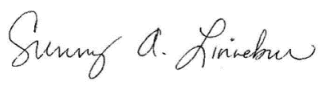
Thank you for the opportunity to submit these comments. We would be pleased to answer any questions you may have. Please contact Alanna Goldstein, agoldstein@americangeriatrics.org.

Sincerely,



Sunny Linnebur, PharmD, BCGP, BCPS, FCCP, FASC
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Nancy E. Lundebjerg, MPA
Chief Executive Officer

[13] *See e.g.,* Cal. Bus. & Prof. Code §§ 801.01(b)(2), 802.1, 2240, and 2021; D.C. Code §§ 3-1205.13a, 7-161; and 22 Tex. Admin. Code § 180.7(f). Many other states have self-reporting requirements in place.

[14] OIG, State Medical Boards and Medical Discipline OEI-01-89-00560, at 98 (August 1990).