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Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1654-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 (CMS–1654–P)

Dear Mr. Slavitt:

The American Geriatrics Society (“AGS”) greatly appreciates the opportunity to comment on the Physician Fee Schedule (“PFS”) Proposed Rule for Calendar Year (“CY”) 2017 (CMS–1654-P) [hereinafter, “Proposed Rule”]. 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.

Below we discuss our comments on a number of proposals regarding payment for behavioral health, cognitive impairment, chronic care management, mobility disorders, and telehealth services made in the above-captioned proposed rule. We commend CMS for its focus on payment for codes that provide additional value and improve quality of care. The members of the AGS provide all of the services discussed in this comment letter and we urge CMS to adopt the following recommendations:

I. RECOMMENDATIONS

- **AGS applauds CMS’ proposal to add Advance Care Planning (ACP) services to the telehealth list, and strongly recommends that CMS finalize this proposal without modification.**
- **We recommend that the 000 day global services reported more than 50 percent with an Evaluation and Management (E/M) as listed in Table 7 be reviewed by the RUC for potential misevaluation.**
- **AGS recommends that if CMS, in the future, decides to make any adjustments to the relative values of pre-operative and post-operative care, the agency should consider carefully any**

changes to E/M codes to ensure that providers of primary care services and beneficiaries who pay Part B's 20 percent coinsurance are not harmed financially as a result of those changes.

- AGS commends CMS for creating G-codes that parallel the recently approved CPT codes that describe services consistent with the psychiatric Collaborative Care Model (CoCM), which aims to improve the integration of physical and mental health care.
- We recommend that CMS consider that the work of the psychiatric consultant is more similar to E/M than psychotherapy and is of significantly greater intensity due to the patient complexity and condensed presentation provided by the Behavioral Health Care Manager (BHCM).
- We concur with the creation of GPPPX, care management services for behavioral health conditions. CMS should align this code with that of 99490, Chronic Care Management (CCM) services, at least 20 minutes of clinical staff time per calendar month, and should not create an add-on code for additional time increments. We recommend that CMS adopt appropriate but not unduly restrictive billing requirements to delineate practitioner eligibility, supervision requirements, patient eligibility, patient agreement requirements, and the scope or required elements of the service. These should align with the changes CMS proposes to the scope of service elements and billing requirements for CCM, as described in Table 11 of the proposed rule. CMS should consider the parity of requirements for 99490 and general behavioral health care management services, other than patient condition.
- We recommend that CMS modify the proposed requirements to allow the BHCM to work off-site, under the general supervision of the treating physician or other Qualified Health Care Professional (QHP) when reporting GPPP1-3 and also allow this when reporting GPPPX consistent with requirements of 99490.
- We recommend that CMS finalize its proposal with respect to the initiating visit. Specifically, we support CMS' proposal to allow the same types of services to serve as the initiating visit for CCM services and the Behavioral Health Integration (BHI) codes (GPPP1-GPPP3, GPPPX). Additionally, CMS should finalize its proposal to adopt a beneficiary general consent standard for the general and BHI CoCM services. CMS should allow reporting GPPP7 with the initiating visit for these four codes.
- AGS commends CMS for proposing to create a G-code for assessment and care planning for patients with cognitive impairment in CY 2017 and for accepting the CPT language with revisions to allow Transitional Care Management (TCM) reporting and with additional guidance on G codes that CPT does not list. We believe Care Plan Oversight (CPO) services are distinct and should be allowed. A typical time should be published to allow proper reporting of prolonged services codes, which should be allowed. GPPP6 and GPPP7 should not be reported together. We believe the CMS proposals for physician work and clinical staff time should be finalized after consideration of the RUC recommended values and inputs.
- CMS should implement the assessment and care planning add-on code GPPP7, for CY 2017, and should clarify in the final rule the number of minutes of services that are included in the code descriptor in this and other codes that may be eligible for face-to-face or non-face-to-

face prolonged services codes. CMS should also indicate the base codes that allow reporting of this service. This service should also be allowed when assessments and plans are directed to future use of GPPP1-3 and GPPPX, but not be required to be reported in advance of reporting any care management or complex care management services.

- CMS should finalize the proposed work RVUs but should solicit comment on revisions to the work RVUs two years after implementation so that appropriate changes can be made once physicians have gained experience using the code.
- CMS should allow 99358 and 99359 to be reported with GPPP7.
- CMS should not require an additional initiating visit for CCM, Complex CCM (CCCM), BHI CoCM or BHI CCM in patients who have received any E/M service from the practice in the previous year.
- If CMS finalizes GDDD1 it should clarify the use of the assistive devices discussed in the proposed rule and it should allow the code to be billed with any face-to-face E/M service provided in the physician office setting.
- CMS should closely monitor the use of the GDDD1 code to make sure it is being used appropriately in accordance with the policies articulated in the final rule.
- If CMS finalizes the GDDDD1 code, it should finalize a crosswalk to 99212 and solicit comment in two years as to whether that crosswalk is appropriate. This will allow physicians to gain experience using the code before reevaluation occurs.
- CMS should not use high volume use estimates if applying budget neutrality with respect to GDDD1.
- CMS should finalize its proposal to make separate payment for 99358 and 99359.
- CMS should finalize its proposal to make payment for 99354, 99358, and 99359 based on the RUC recommendations for physician work.
- CMS should strongly consider use of 99358 and 99359 as defined in CPT, but if not acceptable, should finalize its proposal to require 99358 and 99359 be performed on the same date as the underlying E/M or E/M like services. CMS should clarify which services allow reporting of 99358-99359.
- We strongly recommend that CMS finalize its proposals to make separate payment for CPT codes 99487 and 99489 and to base payment on the RUC recommendations for physician work and practice expense inputs.
- We strongly recommend that CMS finalize all its proposals with respect to initiating visits, electronic records, access and continuity and consent to facilitate access to CCM, CCCM, BHI CoCM and BHI CCM services.

- **AGS recommends that, if CMS proposes changes to the payment for Diabetes Self-Management Training (DSMT), that the agency work with the RUC and diabetes educators to collect data and inform such decisions.**
- **CMS should finalize its proposal to permit the provision of services incident to TCM and CCM services under general physician supervision of auxiliary staff, rather than under direct supervision, in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).**
- **With respect to Appropriate Use Criteria (AUC), AGS recommends that CMS refine the proposed clinical area of “low back pain” and “headache” to reflect differences between the elderly and non-elderly populations. The AGS recommends that CMS work with specialty societies to identify AUC that are based on guidelines that are specific to the elderly population and, when guidelines suggest that the AUC are different for elderly patients, CMS should require that Clinical Decision Support Mechanisms (CDSMs) include those elderly-specific AUC.**
- **CMS should carefully assess the feasibility of implementing AUC processes in the proposed timeframes.**
- **AGS recommends that CMS finalize its proposal to create exceptions from use of a CDSM in emergency situations, inpatients, and individuals who have been granted a significant hardship exception.**
- **CMS should not finalize its proposal to eliminate notice to the applicable provider and the obligated provider in the event of a recoupment of an overpayment.**
- **CMS should finalize its proposal to permit individuals to report Physician Quality Reporting System (PQRS) measures if their Accountable Care Organization (ACO) failed to do so on their behalf.**
- **CMS should clarify in the final rule how to implement provider enrollment rules in MA in a way that does not inadvertently exclude long-term services and supports (LTSS) caregivers who cannot presently bill Medicare directly.**
- **CMS should adopt the recommendations of the National PACE Association to ensure access to PACE services is uninterrupted.**
- **CMS should finalize its proposal to expand the Diabetes Prevention Program (DPP) on a nationwide basis. CMS should require DPP coaches to obtain a National Provider Identifier (NPI) and require that they enroll in Medicare. CMS should create an application form that providers can use to document that the criteria for patient entry in DPP have been met. CMS should create a process to check that DPP suppliers who are granted Medicare billing rights, prior to being fully recognized by the CDC, actually receive the CDC approval within a specified time period, and that DPP suppliers that do not get recognized are dis-enrolled.**

- **CMS should exclude projected additional PFS spending on DPP from the budget neutrality adjuster to the PFS as this is a benefit change.**
- **CMS should finalize its proposals to align the Shared Savings Program and the Quality Payment Program (QPP), which will ensure that clinicians who participate in both MIPS and APMs can move seamlessly between the two programs.**
- **In calculating accurate reporting any thresholds and re-calculations should be based upon sound methods and a general threshold should not be applied if a targeted audit is performed.**

More detailed comments on specific proposals from the CY 2017 PFS proposed rule are set forth below.

II. PROVISIONS OF THE PROPOSED RULE

C. Medicare Telehealth Services

AGS supports CMS' proposal to add two Advance Care Planning (ACP) services (99497 and 99498) to the list of services that may be provided via telehealth. We agree that ACP services are similar to the annual wellness visits (HCPCS codes G0438 and G0439), which are currently on the telehealth list, and believe that through this policy CMS will support the adoption of ACP in everyday medical practice. Like annual wellness visits, ACP services are underutilized by the population of Medicare beneficiaries who might benefit from having an ACP in place. CMS recently published data showing that only one in six seniors are taking advantage of preventive services that are available to them, despite those services being free to beneficiaries.¹ AGS appreciates CMS' publishing a clarifying FAQ on the use of the ACP codes in July 2016 and hopes that it will help increase use of the services for patients and their families.²

AGS enthusiastically supports CMS' proposal to add the codes describing ACP to the list of services that may be provided via telehealth.

Recommendation II-C

- **AGS applauds CMS' proposal to add ACP services to the telehealth list, and strongly recommends that CMS finalize this proposal without modification.**

¹ E. Mullin, "Preventive Services for Seniors Available, but Underutilized." Dorland Health, accessed August 10, 2016, at <http://www.dorlandhealth.com/dorland-health-articles/preventive-services-for-seniors-available-but-underutilized>.

² CMS, "Frequently Asked Questions about Billing the Physician Fee Schedule for Advance Care Planning Services." Accessed August 10, 2016, at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/FAQ-Advance-Care-Planning.pdf>.

D. Potentially Misvalued Services Under the Physician Fee Schedule (PFS)

CMS proposes a list of 000 day global services that are potentially mis-valued as they are typically performed with an Evaluation and Management (E/M) service (Table 7). These include some services that are commonly performed by primary care clinicians when treating multiple problems at the same encounter (e.g., an arthrocentesis when a patient is being seen for hypertension follow-up and osteoarthritis). We recommend that these services be reviewed through the AMA/Specialty RBRVS (RUC) processes.

Recommendation II-D-i

- **We recommend that the 000 day global services reported more than 50 percent with an E/M as listed in Table 7 be reviewed by the RUC for potential misevaluation.**

Section 523 of the Medicare Access and CHIP Reauthorization Act (MACRA) prohibits the Secretary from implementing a policy to transition all 10-day and 90-day global codes to 0-day global codes and requires CMS to develop a process to gather information needed to value surgical services from a representative sample of physicians. Rather than using a sampling methodology, CMS has proposed comprehensive claims-based reporting of G codes for pre- and post-surgical visits and documentation of the services provided for all physicians/NPPs nationwide. AGS understands that CMS is relying on its authority under the Protecting Access to Medicare Act of 2014 (PAMA), which permits the Secretary to collect data on direct and indirect resources “collected or obtained from any eligible professional or any other source.” AGS appreciates CMS’ concerns with voluntary reporting and sampling methodologies, and generally supports CMS’ commitment to collecting auditable, objective data to increase the accuracy of the values for surgical services. AGS notes that revaluing surgical codes paid on the MPFS affects the relative values of other non-surgical codes because of the budget neutrality adjustment. Separate reporting of E/M potentially affects beneficiary cost sharing. Additionally, any restructuring of E/M related to surgical global period reporting has the potential for very significant implications with respect to E/M use by other specialties.

Recommendation II-D-ii

- **AGS recommends that if CMS, in the future, decides to make any adjustments to the relative values of pre-operative and post-operative care, the agency should consider carefully any changes to E/M codes to ensure that providers of primary care services and beneficiaries who pay Part B’s 20 percent coinsurance are not harmed financially as a result of those changes.**

E. Improving Payment Accuracy for Primary Care, Care Management Services, and Patient-Centered Services

a. Behavioral Health Services (GPPP1, GPPP2, GPPP3 and GPPPX)

CMS is proposing a family of four G-codes to facilitate separate payment for services covering Behavioral Health Integration (BHI) in the primary care setting. Three of the codes (GPPP1, GPPP2, and GPPP3) parallel recently approved CPT codes. GPPPX describes services furnished using a different application of BHI in the primary care setting.

Recommendation II-E-i

- **The AGS commends CMS for creating G-codes that parallel the recently approved CPT codes that describe services consistent with the psychiatric Collaborative Care Model (CoCM), which aims to improve the integration of physical and mental health care.**

We commend CMS' decision to propose coverage for the CoCM starting in January 2017. As noted in the American Psychiatric Association's September 8, 2015 letter to CMS "the lack of reimbursement for key components of this model has been the principal barrier to its widespread implementation. Although there may be other treatment models that engage primary care clinicians and behavioral health specialists, the specific Collaborative Care Model [CoCM] that CMS refers to in the July 15 [2015] Federal Register is the only model that has compelling scientific data supporting its effectiveness."

We appreciate CMS' proposal to adopt the recently approved CPT descriptors for these codes; language which has been vetted through the CPT Editorial Panel process. Further, we support the decision not to restrict eligible diagnoses to a subset of behavioral health conditions. There is sufficient experience to demonstrate that a wide range of mental health and substance use disorders can be effectively treated in a primary care setting that has appropriate psychiatric support and care coordination described by this model.

While we appreciate CMS' proposal to provide coverage for these services and generally support the proposed values as they relate to the primary care physician and behavioral health care manager (BHCM), we have concluded that the proposed values assigned to the GPPP1, GPPP2, and GPPP3 codes do not adequately reflect the work of the psychiatric consultant and as a result may not be sufficient to sustain the model. We think that the CMS proposal to crosswalk the work of the psychiatric consultant in codes GPPP1, GPPP2, and GPPP3 to CPT code 90836, *Psychotherapy, 45 minutes with patient and/or family member when performed with an evaluation and management service*, for a work RVU of 0.42, does not reflect the medical work involved.

As we stated above however, we think the proposed work RVU for the psychiatric consultant, which has been cross-walked to a psychotherapy service, is not representative of the actual work being performed, and consequently is low. The focus of the psychiatrist's work in these services is not psychotherapy as described by the CPT code. Instead, it is inherently medical in nature and equivalent to the medical decision making of an E/M service. The consultant must have prescription authority and medication management is E/M. The task is medical decision making, again E/M. Because the history and psychiatric exam are performed by the BHCM/primary care physician team, the consultant psychiatrist is presented with a distilled encounter preserving the most intense portion of the E/M encounter, decision-making. Patients enrolled in the collaborative care program are typically those who have not responded to standard care and need additional psychiatric evaluation and involvement to enable the development of an appropriate and effective treatment plan and are therefore more complex than the typical E/M of a brief encounter.

Recommendation II-E-ii

- **We recommend that CMS consider that the work of the psychiatric consultant is more similar to E/M than psychotherapy and is of significantly greater intensity due to the patient complexity and condensed presentation provided by the BHCM.**

We concur with the proposed creation of GPPPX, care management services for behavioral health conditions. CMS should align the unit of service definition of this code with that of 99490, CCM services, at least 20 minutes of clinical staff time per calendar month, and should not create an add-on code for additional time. Lacking time-specific data from practitioners themselves (which should be supplied in a future RUC survey), we believe the initial proposal for a BHI code with a time interval of 20 minutes appears to be appropriate and creates consistency with 99490.

Further clarification is useful regarding the proposed code for “care management services for behavioral health conditions” (GPPPX). We commend CMS’ effort to expand Medicare coverage and payment to additional services involving care for patients with behavioral health conditions based on the recognition that significant time and resources are expended on patients with behavioral health conditions that are not currently compensated. However, it is not clear from the proposed rule precisely which services, practitioners, patients, and circumstances would qualify for the billing of the GPPPX code. We generally recommend that CMS adopt appropriate but not unduly restrictive billing requirements which delineate practitioner eligibility, supervision requirements, patient eligibility, patient agreement requirements, and scope of service elements. These should align with the changes CMS proposes to the scope of service elements and billing requirements for CCM, as described in Table 11 of the proposed rule. Patients eligible for these services would have a psychiatric and/or substance use disorder that requires care management services. Similar to CCM and CoCM services, we would recommend new patients and patients not seen within one year be seen for an initiating visit for the development of the care plan and that general beneficiary consent should be sufficient prior to being enrolled in the program. The proposed broader definition of an initiating visit should be adopted for general BHI CM.

There should be continuity of care with a designated member of the care team. A written plan of care should be developed and shared with the patient, and a comprehensive assessment of the patient’s psychiatric condition as well as any medical, functional, and psychosocial needs should be performed and updated as necessary. At a minimum patient progress should be routinely evaluated using validated rating scales, with progress tracked using a patient registry. All services should be documented in the patient’s medical record and available to other treating professionals.

As with the CoCM codes, we would recommend that if eligible to individually furnish and report services, the care manager may report separate services in the same calendar month. These could include: psychiatric evaluation (90791, 90792), psychotherapy (90832, 90833, 90834, 90836, 90837, 90838), psychotherapy for crisis (90839, 90840), family psychotherapy (90846, 90847), multiple family group psychotherapy (90849), group psychotherapy (90853), smoking and tobacco use cessation counseling (99406, 99407), and alcohol or substance abuse structured screening and brief intervention services (99408, 99409). Time spent by the BHCM on activities for services reported separately may not be included in the services reported using time applied to the GPPPX code. CMS states that E/M does not recognize BHI Care Management (CM) services and we concur, therefore, the time of a BHCM should be allowed, even when the service is performed on the same date as an E/M, unlike the current rules for Complex CCM (CCCM) and CCM. We do note that while this prohibition in CCCM and CCM was written

to avoid potential overlap counting of clinical staff, that medical care managers are not usually the same clinical staff supporting the E/M service, but have a higher level of training and experience. The most appropriate time to provide CCCM and CCM includes services on the date of a face-to-face visit with the primary continuity clinician. Yet these services are not recognized.

We believe that because different staff may be used in providing CCCM and CCM (99487, 99489, 99490) and BHI CoCM and CM (GPPP1-3, GPPPX), that these services be allowed to be reported in the same time period, so long as no time is counted twice. While the minimal requirements for the proposed GPPPX may not require a comprehensive assessment in all cases, in most cases competent BHI care planning and delivery will require the consideration/assessment of medical conditions, social supports, community services (used and/or available), financial barriers, IADL and family/social dynamics and require a care plan. Accordingly, we recommend that CMS clarify that the proposed add-on code GPPP7 be allowed when the care planning relates to BHI.

Finally, CMS proposes payment of general BHI CM using a staff category that is a higher cost resource than for CCM. We agree with this. We do note however, that CMS should avoid making the requirements for 99490 to be more burdensome than those for GPPPX. We are not proposing the patient condition requirements be the same, just the procedural and infra-structure requirements. Because BHI is very challenging, as is CCM, we support minimization of barriers.

Recommendation II-E-iii

- **We concur with the creation of GPPPX, care management services for behavioral health conditions. CMS should align this code with that of 99490, CCM services, at least 20 minutes of clinical staff time per calendar month, and should not create an add-on code for additional time increments. We recommend that CMS adopt appropriate but not unduly restrictive billing requirements to delineate practitioner eligibility, supervision requirements, patient eligibility, patient agreement requirements, and the scope or required elements of the service. These should align with the changes CMS proposes to the scope of service elements and billing requirements for CCM, as described in Table 11 of the proposed rule. CMS should consider the parity of requirements for 99490 and general BHI CM, other than patient condition.**

We urge CMS to allow the BHCM to work off-site, under the general supervision of the treating physician or other Qualified Health Care Professional (QHP), similar to the current requirements for care managers for CCM services when performing general or CoCM BHI CM. CMS has indicated in the proposed rule that it expects that the BHCM would furnish CoCM services incident to services of the treating physician/QHP; be a member of the clinical staff of the treating physician/QHP; and work on-site at the location where the treating physician/QHP furnishes services to the beneficiary. CMS suggests that the patient, not the model should determine general BHI CM and appears to be silent on the location of the BHCM.

For CCM services, CMS originally proposed requiring that care managers be part of the clinical staff of the treating physician/QHP, and that they also be physically on-site with that physician/QHP. But CMS subsequently decided to allow the care managers to work under general supervision. CMS also specifically allowed the billing physicians/QHPs to arrange to have CCM services provided by clinical staff “external to the practice,” including under arrangements with case management companies, so long as

all “incident to” and other rules for billing CCM are met and the individuals providing the services are located in the United States. In the interest of learning from past experience, CMS should start with requirements that are similar to those for CCM (including the changes proposed in this rule, as described in Table 11) and consider future changes to this policy as experience with these new codes accumulates.

The AIMS Center at the University of Washington has trained practices of all sizes, including solo practices and small rural clinics, in the CoCM. In small to medium sized practices, a single BHCM may work for two or more clinics or practices. Additionally, practices in rural and some urban/suburban areas may be unable to find a qualified person in their region to fill the position. A number of sites that have successfully adopted the model and demonstrated its effectiveness in improving care have shared a BHCM who functions out of one office and visits the other sites on an as needed basis and/or who works remotely using the telephone and telemedicine/video technology to accomplish the work of this model. For psychiatric CoCM services, the BHCM must be available at all times to serve their entire patient population, even when they are physically working at another practice or clinic. Thus, it is crucial that the BHCM be allowed to work under general supervision and off-site. Off-site BHCM is consistent with an evidence based model of care, GPXX1-3. We believe these considerations should also apply to the care manager for the GPPPX code.

Recommendation II-E-iv

- **We recommend that CMS modify the proposed requirements to allow the BHCM to work off-site, under the general supervision of the treating physician or other QHP when reporting GPPP1-3 and also allow this when reporting GPPPX consistent with requirements of 99490.**

Recommendation II-E-v

- **We recommend that CMS finalize its proposal to require the initial visit. Specifically, we support CMS’ proposal to allow the same types of services to serve as the initiating visit for CCM services and the BHI codes (GPPP1-GPPP3, GPPPX). Additionally, CMS should finalize its proposal to adopt a beneficiary general consent standard for BHI services.**

We agree there should be an initiating visit with the beneficiary before the BHI codes (GPPP1, GPPP2, GPPP3 and GPPPX) can be billed. We also support allowing the same types of services to serve as the initiating visit for CCM services and the BHI codes. Likewise, beneficiary consent should be consistent for all the BHI and CCM codes. We support CMS’ proposal to adopt a general consent standard for the BHI codes. Prior to initiating these services, the primary care physician or QHP would be required to obtain and document that the beneficiary has consented to consultation with relevant specialists, which would include conferring with a psychiatric consultant, and was informed of the beneficiary cost-sharing (deductibles and coinsurance). While we acknowledge the statutory restrictions regarding coinsurance, we think that coinsurance is counterproductive and is an impediment to patient engagement in collaborative care. We recommend moving ahead with coverage while also simultaneously establishing a CMMI demonstration project to assess the impact of coinsurance on beneficiary participation. As stated we believe a care planning visit add-on service (proposed GPPP7) should be allowed, when performed, with initiating visit services.

- **We recommend that CMS finalize its proposal with respect to the initiating visit. Specifically, we support CMS’ proposal to allow the same types of services to serve as the initiating visit**

for CCM services and the BHI codes (GPPP1-GPPP3, GPPPX). Additionally, CMS should finalize its proposal to adopt a beneficiary general consent standard for the general and CoCM BHI services. CMS should allow reporting GPPP7 with the initiating visit for these four codes.

b. Assessment and Care Planning for Cognitive Impairment (GPPP6)

CMS proposes to establish a G-code (GPPP6) for CY 2017 that parallels a new CPT code for CY 2018 that describes assessment and care planning for Medicare beneficiaries with cognitive impairment. CMS is proposing a physician work value of 3.3 based on the sum of the work for 99204 and half the work RVU from G0181. CMS is also proposing 70 minutes of clinical staff time for this code.

In order to be reported, the service requires a number of required elements including the presence of a caregiver, a cognition focused history and physical examination, functional assessment, safety assessment, medication reconciliation, neuropsychiatric evaluation, advanced care planning, development of a care plan, medical decision making of moderate or high complexity, and assessment of the caregiver's knowledge, needs and abilities, by a physician or other QHP in office or other outpatient setting or home or domiciliary or rest home.

CMS also proposed that GPPP6 cannot be billed with 90785 (Psytx complex interactive), 90791 (Psych diagnostic evaluation), 90792 (Psych diag eval w/med srvc), 96103 (Psycho testing admin by comp), 96120 (Neuropsych tst admin w/comp), 96127 (Brief emotional/behav assmt), 99201-99215 (Office/outpatient visits new), 99324-99337 (Domicil/r-home visits new pat), 99341-99350 (Home visits new patient), 99366-99368 (Team conf w/pat by hc prof), 99497 (Advncd care plan 30 min), 99498 (Advncd care plan addl 30 min), planning services, such as care plan oversight services (99374), home health care and hospice supervision (G0181, G0182), or GPPP7 but that it can be billed on the same date-of-service or within the same service period as 99487, 99489, 99490 (CCM services), 99495, 99496 (TCM services), and the psychiatric care collaboration codes (GPPP1, GPPP2, GPPP3, GPPPX).

As CMS notes, a CPT code with the identical descriptor will be included in CPT for CY 2018. As part of the CPT/RUC evaluation process, work and practice expense input recommendations were made by multiple medical specialty societies (including the AGS) after a work survey and an expert panel process. These recommendations were presented to the RUC where they underwent extensive review and close scrutiny. We believe the RUC recommendations should be considered by CMS. CPT and/or CMS should formalize the typical time so that, as appropriate, prolonged services codes may be reported.

CMS also seeks comment on the following issues:

- *Are there circumstances where multiple care planning codes could be furnished without significant overlap?*

Response

The required components of GPPP6 (and the parallel CPT code) are face-to-face services and do not overlap with the physician work or clinical staff time spent on CCM, BHI CoCM/CM or Care Plan Oversight (CPO) services because CCM, BHI CoCM/CM and CPO services are all non-face-to-face services that occur over a calendar month and not a single encounter. Time spent during the E/M or similar cognitive assessment and care planning services may not count towards the CCM or CPO services. The

post-service physician work of GPPP6 is largely related to the immediate documentation review of the care plan and not a minimum 30 minutes of time over the month. CPO also does not presently include time spent with family and caregivers, though we believe it appropriate for CMS to accept CPT descriptors for CPO, which do include patient/caregiver interactions. Although CCM does involve developing, revising and/or maintaining a care plan, we believe that the overlap with GPPP6 is minimal and that if GPPP6 and CCM are billed in the same month that the medical record should support that any work on the care plan performed as part of the CCM service is distinct from the care planning work reported under GPPP6, even if time rules are deemed insufficient to distinguish the services.

Similarly, GPPP6 does not overlap with TCM services. We believe it would be extremely unusual for the required face-to-face TCM service to be GPPP6. Face-to-face TCM services are complex, focused and timely. The cognitive assessment would require a separate encounter, even if performed in some 30 days and would be similar to a separately allowed E/M. GPPP6 does not include care management for a 30-day period. It is an assessment and plan creation service, not an episode of management. Further, TCM does not involve developing a care plan.

We note that CMS is proposing to establish an add-on code (GPPP7, see discussion below) to provide additional payment for developing a care plan at the time of the visit that initiates CCM services. We agree that GPPP6 and GPPP7 should not be billed on the same date of service for the same patient as there is substantial overlap in those codes, both are assessment and care plan creation services.

- *Even though CMS proposes that GPPP6 may serve as a companion or primary E/M code to the prolonged service codes (those that are currently separately paid, and those proposed for separate payment beginning in 2017), it is interested in public input on whether there is any overlap between GPPP6 and these other E/M services.*

Response

Face-to-face prolonged-services codes can only be reported after GPPP6 (or another E/M) is performed and at least 30 minutes of additional face-to-face physician time has been spent on patient care. Therefore, we do not believe there is any overlap between GPPP6 and the face-to-face prolonged services codes. A typical time should be published for GPPP6 (or the CPT version) and that service should be added to the base code list for the face-to-face prolonged services codes. We later recommend that CMS accept the CPT reporting rules for non-face to face prolonged services. If CMS elects not to do so and requires that the services be the same day as the face-to-face encounter GPPP6, we do note that there will limited potential overlap, not dissimilar from other similar E/M services such as 99215. This is minimized when the typical face-to-face time is the time elapsed from the initiation to the close of the face-to-face interaction with any member of the practice as this service is a team service. Same day prolonged services would count when the patient is not in the office suite. If the time is predominantly post-service on another day, the 30 minutes threshold sufficiently eliminates overlap. We believe that CMS should allow billing of non-face-to-face prolonged services with GPPP6.

With respect to other E/M codes, we agree with the CMS proposal to not allow GPPP6 to be reported on the same date as the other E/M codes it lists (see above) in the proposed rule and to be reported with the E/M section services it proposes to allow.

- *CMS seeks comment on how to best delineate the post-service work for GPPP6 from the work necessary to provide the prolonged services code.*

Response

See above regarding face-to-face and non-face-to-face prolonged services.

- *CMS seeks comment on potential overlap between GPPP6 and existing PFS billing codes, as well as the other primary care/cognitive services addressed in this section of the proposed rule.*

Response

We believe the proposed payment policies for GPPP6 address the potential overlap with other proposals in this section of the proposed rule and are more precise than the CPT exclusionary list. We do note our disagreement with respect to the preclusion of CPO services.

Recommendation II-E-vi

- **AGS commends CMS for proposing to create a G-code for assessment and care planning for patients with cognitive impairment in CY 2017 and for accepting the CPT language with revisions to allow TCM reporting and with additional guidance on G codes that CPT does not list. We believe CPO services are distinct and should be allowed. A typical time should be published to allow proper reporting of prolonged services codes, which should be allowed. GPPP6 and GPPP7 should not be reported together.**
- **We believe the CMS proposals for physician work and clinical staff time should be finalized after consideration of the RUC recommended values and inputs.**

c. Assessment for Chronic Care Management (CCM) Care Plan (GPPP7)

CMS is proposing an add-on payment for the visit during which CCM services are initiated to reflect the time and resources associated with the assessment for, and development of, a new care plan. The proposed code descriptor is: “Comprehensive assessment of and care planning by the physician or other qualified health care professional for patients requiring chronic care management services (billed separately from monthly care management services). (Add-on code, list separately in addition to primary service).”

The code would be billable for beneficiaries who require extensive face-to-face assessment and care planning by the billing practitioner (as opposed to clinical staff), through an add-on code to the initiating visit. CMS proposes that the billing practitioner initiating CCM must personally perform extensive assessment and care planning beyond the usual effort described by the billed E/M code (or AWV or IPPE code), in order to bill GPPP7 in addition to the E/M code for the initiating visit (including if the initiating visit is the AWV or IPPE). The practitioner could bill GPPP7 in addition to the E/M code for the initiating visit (or in addition to the AWV or IPPE), and in addition to the CCM CPT code 99490 (or proposed 99487 and 99489) if all requirements to bill for CCM services are also met. CMS is proposing to require an initiating visit only for new patients or patients not seen within one year instead of for all beneficiaries receiving CCM services. There is no recommendation to require reporting of GPPP7 to define an

initiating visit. The proposed code is specifically designed to capture the additional physician work not captured in the initiating visit code that is required to do care planning. CMS proposes a physician work value of 0.86 (half the work of G0181) for this code. The care plan that the practitioner must create in order to bill GPPP7 would be subject to the same requirements as the care plan included in the monthly CCM services.

Per CMS, this code may be appropriate to bill when the initiating visit is a less complex visit (level 2 or 3 E/M visit), although could be billed along with higher level visits if the billing practitioner's effort and time exceeded the usual effort described by the initiating visit code. It could also be appropriate to bill GPPP7 when the initiating visit addresses problems unrelated to CCM, and the billing practitioner does not consider the CCM related work he or she performs in determining what level of initiating visit to bill.

Consistent with general coding guidance, the work that is reported under GPPP7 (including time) could not also be reported under or counted towards the reporting of any other billed code, including any of the monthly CCM services codes. The care plan that the practitioner must create in order to bill GPPP7 would be subject to the same proposed revised requirements as the care plan included in the monthly CCM services, namely it must be an electronic patient-centered care plan based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports; a comprehensive care plan for all health issues. This would distinguish it from the more limited care plan included in the BHI codes GPPP1, GPPP2, GPPP3, or GPPPX which focus on behavioral health issues, or the care plan included in GPPP6 which focuses on cognitive status. CMS does not seem to articulate a position as to whether GPPP7 would be allowed for GPPP1-3 or GPPPX, even while noting the difference between these services and 99487, 99489 and 99490 and solicits comments.

Discussion

We appreciate CMS recognition of the time and work it takes to develop and implement a care plan for patients with two or more chronic conditions and we agree with this proposal.

CMS specifically solicits comments on the following:

- *Potential overlap between GPPP7 and GPPP1, 2, 3, and X.*

Response

We believe GPPP7 should be billable in the same month as GPPP1, 2, 3, and X as developing and implementing a care plan is typically necessary and outside of the usual work of the initiating visit. It is also not part of the monthly service, just as it is not part of the monthly CCCM or CM services. See also above comments and recommendations on GPPP1-3 and GPPPX.

- *The potential intersection of the prolonged service CPT codes 99358 and 99359 with proposed code GPPP7. Specifically, regarding how distinctions among these services can be clearly delineated, including how the prolonged time can be clearly distinguished from typical pre- and post-service time, which is continued to be bundled with other codes.*

Response

As an initial matter we note that GPPP7 as an add-on code should not have significant pre- or post-service time. We believe it would be very unusual for GPPP7 to be billed with 99358 and 99359 because of the time requirements that must be met to bill for prolonged services. However, if those time requirements are met (e.g., for patients where extensive medical record review and communication with multiple health care professionals or caregivers is required in order to develop the care plan) then we believe that 99358 and 99359 should be billable if the time requirements are met. In other words, if the sum of the time of the underlying E/M, GPPP7, and the additional 30 minutes beyond the time of the underlying E/M are met, then 99358 and 99359 should be billable. Of course the time and work for all services must be documented in the medical record. CMS would need to specify the typical time of GPPP7 to clarify when the time has been exceeded for the reporting of face-to-face prolonged services. For non-face-to-face prolonged services this would also be useful or simply state that GPPP7 is face-to-face only and because there is no significant post-service time in valuation, that all non-face-to-face time rules applicable to the base E/M (or G code) are carried forward regardless of reporting GPPP7.

- *Requiring the initiating visit only for new patients or patients not seen within one year instead of for all beneficiaries receiving CCM services; especially whether a period of time shorter than one year would be more appropriate.*

Response

We distinguish between GPPP7 and the concept of an initiating visit and agree with requiring an initiating visit for new patients (i.e., patients who have not been seen by the practice for any services for three years). We do not believe that GPPP7 should be required as a definition of an initiating visit (or be required to be reported for CCCM/CCM to be reported). We also believe there are circumstances when home services are limited and CM services rely upon use of visits by professionals who may not report directly to Medicare (e.g. RNs), therefore, we believe that requiring a face-to-face encounter for established patients every year may be onerous, especially if that patient has had CCM services provided during the previous year. Specifically, if a patient has been seen face-to-face or has received CCM in the previous year, an initiating visit should not be required. However, if a patient has not received any E/M services (including CCM services) in over a year, then an initiating visit to “re-establish” the care plan and assure that CCM is necessary and provided appropriately, should be required. Additionally, the same principles would apply to BHI CoCM and CM whether or not GPPP7 is reportable with these services.

Recommendation II-E-vii

- **CMS should implement the assessment and care planning add-on code GPPP7, for CY 2017, and should clarify in the final rule the number of minutes of services that are included in the code descriptor in this and other codes that may be eligible for face-to-face or non-face-to-face prolonged services codes. CMS should also indicate the base codes that allow reporting of this service. This service should also be allowed when assessments and plans are directed to future use of GPPP1-3 and GPPPX, but not be required to be reported in advance of reporting any care management or complex care management services.**

- **CMS should finalize the proposed work RVUs but should solicit comment on revisions to the work RVUs two years after implementation so that appropriate changes can be made once physicians have gained experience using the code.**
- **CMS should allow 99358 and 99359 to be reported with GPPP7.**
- **CMS should not require an additional initiating visit for CCM, CCCM, BHI CoCM or BHI CCM in patients who have received any E/M service from the practice in the previous year.**

d. Improving Care for Patients with Mobility Disorders (GDDD1)

CMS is proposing payment adjustments for routine visits furnished to beneficiaries whose care requires additional resources due to their mobility-related disabilities. CMS proposes the following code descriptor: “Resource-intensive services for patients for whom the use of specialized mobility-assistive technology (such as adjustable height chairs or tables, patient lifts, and adjustable padded leg supports) is medically necessary and used during the provision of an office/outpatient evaluation and management visit (Add-on code, list separately in addition to primary procedure).”

CMS proposes that the value of the code be based on a crosswalk to 99212 and that the practice expense inputs include the following items: a stretcher, a high/low table, a patient lift system, a wheelchair accessible scale, and a padded leg support positioning system.

CMS proposes that GDDD1 can be billed with new and established patient office/outpatient E/M codes (99201-99205, and 99212-99215), as well as TCM (99495, 99496), when the additional resources described by the code are medically necessary and used in the provision of care.

AGS appreciates CMS’ concern about providing appropriate care to patients with disabilities and agrees with the intent of the code. That said, we have some concerns with the proposal as written.

First, as this is a new category of service that Medicare has never recognized for separate payment, budget neutrality adjustment should not apply to it, at least initially.

Second, we believe that CMS needs to clarify whether it intends for this code to be reported for patients with a temporary mobility disorder due to fracture or other temporary condition. The utilization of this code could vary dramatically depending on its intended use.

Third, CMS needs to clarify what assistive equipment it discusses in the proposal (see above) is required to be used in order to report the service. It appears it is any assistive technology.

Many physicians do not presently have specialized technology and there is always slow uptake of new services. Due to the above considerations, we believe that CMS has drastically overestimated the utilization of this proposed code and that \$700 million in expenditures is at least a 10-fold overestimate of utilization. We note that in the very recent past CMS has dramatically overestimated the utilization for TCM and CCM and we believe this is a similar overestimate. If CMS finalizes this code and applies budget neutrality, we ask that CMS assume utilization of no more than 200,000 services to reflect use of between 50 and 100 times a year for 1,000-2,000 physician practices who own the equipment required

for this service. CMS should trim its cost estimate accordingly and exclude this new utilization from budget neutrality adjustments.

If CMS finalizes the code, we agree that the code should be reportable with any covered face-to-face E/M service in the physician office. The 99212 cross walk appears reasonable until data and experience become available.

Recommendation II-E-vii

- **If CMS finalizes GDDD1 it should clarify the use of the assistive devices discussed in the proposed rule and it should allow the code to be billed with any face-to-face E/M service provided in the physician office setting.**
- **CMS should closely monitor the use of the GDDD1 code to make sure it is being used appropriately in accordance with the policies articulated in the final rule.**
- **If CMS finalizes the GDDDD1 code, it should finalize a crosswalk to 99212 and solicit comment in two years as to whether that crosswalk is appropriate. This will allow physicians to gain experience using the code before reevaluation occurs.**
- **CMS should not use high volume use estimates if applying budget neutrality with respect to GDDD1.**

e. Prolonged Service Without Direct Patient Contact (CPT codes 99358 and 99359)

CMS is proposing to pay for two existing CPT codes (99358 and 99359) that describe prolonged E/M services before and/or after direct patient care. These codes describe significant additional non-face-to-face work performed by the physician in the review of medical records and other clinical information or other care coordination services not otherwise addressed in the PFS and are needed to care for patients with chronic illnesses that are complex and/or patients who are severely ill and have multiple comorbid conditions. Currently, these codes are considered bundled into the base E/M service being reported and no separate payment is being made. These codes have the following descriptors:

99358 – Prolonged evaluation and management service before and/or after direct patient care; first hour

99359 – Prolonged evaluation and management service before and/ or after direct patient care; each additional 30 minutes

CMS proposes that time counted toward the provision of 99358 or 99359 and for the provision of these services cannot be counted toward the provision of any other PFS service. CMS also proposes to accept the RUC recommendations for physician work for these codes; specifically: 99358 – 3.17; 99359 – 1.52.

Importantly, CMS also proposes to require these prolonged services be furnished on the same day by the same physician or other billing practitioner as the companion E/M code. Further, CMS proposes that these codes should not be reported during the same service period as CCCM (99487, 99489) or TCM (99495, 99496) but that they can be reported during the service period of 99490.

AGS strongly supports the CMS proposal to make separate payment for 99358 and 99359 and we also strongly support the proposal to value these services using the RUC recommended physician work RVUs. CMS should finalize this proposal.

We note that the CMS proposal to require that 99358 and 99359 be performed on the same date as the underlying face-to-face E/M is contrary to CPT instructions and could be confusing. It returns this service to being an add-on code and should have a base code list. We believe that the requirement that the service be same day, same provider is limiting, but is a positive step. While we believe there is sufficient rationale to allow reporting consistent with CPT, the important point is that it be allowed. As noted above in other comments about this service and CM services, the potential for overlap does relate nominally to this issue of same day. CPT is not an episode, but also a single day. Under this proposal, the typical scenario may not be data review, but care coordination with other professionals and facilities.

However, if CMS finalizes its proposal to require that 99358 and 99359 be performed on the same date as the underlying E/M then we strongly disagree with the proposals to not allow these codes to be reported during the service period of CCCM or TCM. This is because, under current policy physicians are not allowed to count any physician or clinical staff toward CCM or TCM on the date of a face-to-face E/M service and under the CMS proposal, 99358 and 99359 would have to be performed on the same date as a face-to-face E/M service and therefore, time and work for those services cannot be counted toward any other service. The episode related work is not on the day of the E/M (in CCCM there may be no E/M in the service period) and while TCM requires a face-to-face service, this is the equivalent of an E/M service. The E/M services will allow use of 99358/99359. In valuing 99490 CMS used a rationale that took the TCM value and carved out the E/M service. Consistency of logic and reporting rules suggest that there is no meaningful overlap.

We also support acceptance of the RUC recommended values for prolonged service code 99354.

Finally, as we have stated publishing typical times and base code lists will facilitate correct coding or code edits.

Recommendation II-E-viii

- **CMS should finalize its proposal to make separate payment for 99358 and 99359.**
- **CMS should finalize its proposal to make payment for 99354, 99358, and 99359 based on the RUC recommendations for physician work.**
- **CMS should strongly consider use of 99358 and 99359 as defined in CPT, but if not acceptable, should finalize its proposal to require 99358 and 99359 be performed on the same date as the underlying E/M or E/M like services. CMS should clarify which services allow reporting of 99358-99359.**

f. Expanded Payment and Improved Access for Chronic Care Management (CCM) (CPT codes 99487, 99489, and 99490)

CMS proposes to make separate payment on the Medicare Physician Fee Schedule for CCCM services described by 99487 and 99489 at the RUC-recommended values for direct PE inputs and work, 1.00

work RVUs for CPT code 99487 (Complex CCM, 60 minutes of clinical staff time per month) and 0.50 work RVUs for CPT code 99489 (Complex CCM, 30 minutes of clinical staff time per month).

CMS also proposes, consistent with CPT guidelines, to require 60 minutes of services for reporting CPT code 99487 and 30 additional minutes for each unit of CPT code 99489, and may only be reported once per service period (calendar month) and only by a single practitioner for the service period.

CMS proposes to require the same CCM practice requirement elements, described in Table 11 in the proposed rule, for CPT codes 99487, 99489 and 99490. In comparison to 2016, where Medicare pays for 99487 but not for the other two codes, CMS proposes changes in the requirements for the initiating visit, 24/7 access to care and continuity of care, format and sharing of the care plan and clinical summaries, beneficiary receipt of the care plan, beneficiary consent, and documentation.

We appreciate that the CMS proposed changes are intended to make CMS policy much more consistent with CPT guidelines and instructions on reporting the CCM codes.

We appreciate and agree with all the CMS proposals except those described above related to reporting other services. We appreciate that CMS acknowledges that the utilization of 99490 is low and recognizes the need to make separate payment for 99487 and 99489. We believe that the availability of all these services will significantly improve access to CCM services and will allow the sickest, most frail beneficiaries to the complex CCM services they need. We also appreciate that CMS is proposing to revise its policies on CCM to make them more consistent with CPT guidelines and instructions.

That said, as we have previously commented to CMS, we continue to be concerned that the requirements for reporting 99490 are excessive and burdensome, and would remain so even with the proposed changes to the scope of service elements. We believe that these requirements are, in part, responsible for the low utilization of this service.

With respect to the scope of services elements for CCCM and CCM, AGS enthusiastically supports CMS' proposals to remove or modify the following requirements: 1) to create a structured clinical summary record using certified EHR technology (CEHRT), 2) to maintain 24/7 access to the electronic care plan, 3) to share care plans electronically 24/7, 4) to give beneficiaries an electronic copy of the care plan, and 5) to document both beneficiary consents and the coordination of physician services with home- and community-based providers using CEHRT.

Recommendation II-E-ix

- **We strongly recommend that CMS finalize its proposals to make separate payment for CPT codes 99487 and 99489 and to base payment on the RUC recommendations for physician work and practice expense inputs.**
- **We strongly recommend that CMS finalize all its proposals with respect to initiating visits, electronic records, access and continuity and consent to facilitate access to CCM, CCCM, BHI CoCM and BHI CCM services.**

F. Improving Payment Accuracy for Preventive Services: Diabetes Self-Management Training (DSMT)

AGS supports CMS' plan to issue program instructions that will clarify the rules for who may furnish Diabetes Self-Management Training (DSMT) services, and the settings and locations in which individual and group DSMT may occur. A meta-analysis review of 21 studies of diabetes self-management education programs showed improvement in HbA1c, fasting blood glucose, knowledge about diabetes, and self-management skills, and showed significant improvement in patient empowerment and self-efficacy.³ Yet CMS' analysis, cited in the proposed rule, shows that only 5 percent of Medicare beneficiaries with newly diagnosed diabetes are using DSMT. CMS asks whether the resource inputs and valuation of DSMT is appropriate. While comments may have been solicited, the RUC HCPAC could review these services.

Recommendation II-F

- **AGS recommends that, if CMS proposes changes to the payment for DSMT, that the agency work with the RUC and diabetes educators to collect data and inform such decisions.**

III. OTHER PROVISIONS OF THE PROPOSED RULE

A. Chronic Care Management (CCM) and Transitional Care Management (TCM) Supervision Requirements in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

AGS supports CMS' proposal to permit the provision of services incident to TCM and CCM services under general physician supervision of auxiliary staff, rather than under direct supervision, when those services are provided in the RHC and FQHC settings. The change will permit RHCs and FQHCs to contract with third parties to provide some CCM components such as 24/7 access. As AGS has noted in prior years, consistent application of the rules for beneficiary eligibility, provider eligibility, billing, and scope of service requirements for these settings of care and the Medicare PFS will reduce administrative burden for physicians and NPPs who bill for CCM services under the PFS.

Recommendation III-A

- **CMS should finalize its proposal to permit the provision of services incident to TCM and CCM services under general physician supervision of auxiliary staff, rather than under direct supervision, in RHCs and FQHCs.**

C. Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services

The 2017 Proposed Rule includes requirements and processes for specification of qualified Clinical Decision Support Mechanisms (CDSMs) under the Medicare Appropriate Use Criteria (AUC) program; the initial list of priority clinical areas; and exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services. AGS has the following comments:

³ Steinsbekk et al., "Group-based Diabetes Self-Management Education Compared to Routine Treatment for People with Type 2 Diabetes Mellitus: A Systematic Review with Meta-Analysis." *BMC Health Services Research*, 2012.

AGS supports CMS' proposal to define an "applicable payment system" for the purpose of AUC as the PFS, HOPPS, or ASC PPS. In 2008, the Government Accountability Office analyzed Medicare Part B claims data and reported spending on office-based imaging services per beneficiary ranged from \$62 in Vermont to \$472 in Florida.⁴ Implementing AUC should reduce variation in practice patterns and improve adherence to evidence-based guidelines.

AGS likewise supports the proposed definition of a qualified CDSM, particularly the emphasis on developing AUC by performing a systematic review of the medical literature and relying on published consensus statements by medical specialty societies. AGS notes that there are several different sets of recommendations for AUC in any given clinical area, and urges CMS to examine a broad range of them to understand the differences between them. Further, CMS should use its ability to approve qualified CDSMs as an opportunity to ensure the AUC are specific to the needs of an elderly population, given the patient demographics of the Medicare program.

One example of AUC is the American Board of Internal Medicine's Choosing Wisely campaign. It has an online database with imaging guidelines for all of the priority clinical areas proposed by CMS except abdominal pain and altered mental status.⁵

Another example is the American College of Radiology's (ACR) Appropriateness Criteria® (AC) which have been developed to assist physicians in making imaging decisions for the majority of priority clinical areas proposed by CMS, not including altered mental status. These guidelines are searchable in an online database by clinical condition, and include numerical appropriateness rankings of the radiologic procedures that should be used per condition. Importantly, there are different decision rules for elderly than non-elderly patients. ACR periodically revises its guidelines, with most recent updates to the appropriate use of diagnostic imaging for patients with chest pain, one of the priority clinical areas specified by CMS.

As a cautionary note, AGS urges CMS to consider whether specialty societies' guidelines (including those in Choosing Wisely) differentiate between elderly and non-elderly populations. This distinction is critical, as described further below.

With respect to the proposed priority clinical areas, AGS has the following comments:

- *CMS asks whether pulmonary embolism should be a stand-alone priority clinical area.*

Response

AGS recommends removing pulmonary embolism from the list of priority clinical areas, as the vast majority of cases are emergent and therefore do not meet the criteria for CMS to require AUC. Further, a recent systematic review of the clinical literature concluded that the current clinical

⁴ Government Accountability Office, "Report to Congressional requesters: Medicare Part B imaging services: rapid spending growth and shift to physician offices indicate need for CMS to consider additional management practices," 2008.

⁵ <http://www.choosingwisely.org/clinician-lists/>

decision rules for assessing risk of pulmonary embolism (Wells criteria) have not been shown to improve appropriate use of diagnostic imaging when compared to clinical judgment alone.⁶

- *CMS proposes a priority clinical area for “low back pain.”*

Response

This is a controversial area where there are many different guidelines that have been developed by various groups. AGS believes it is critically important that CMS takes into account differences in the clinical presentation of low back pain in the elderly versus non-elderly populations. Based on our review of the medical literature, additional criteria may be needed to limit the application of AUC so as not to unduly burden the provision of appropriate care to elderly patients with many chronic conditions. A 2014 *JAMA* study showed a significant tradeoff between more sensitive and more specific measures for several conditions, including low back pain and headache, when claims data were used to measure “low value” care in Medicare retrospectively. The study authors concluded that appropriateness measures that are not sufficiently specific would be difficult to apply prospectively, prior to the care being provided.⁷

A similar analysis by MedPAC found that for imaging for nonspecific low back pain, there was a three-fold difference in the proportion of cases classified as “low value” when a broad definition of appropriateness was used, when compared to a more narrow definition. MedPAC notes that increasing a measure’s specificity leads to less misclassification of appropriate use as inappropriate.⁸

A review of clinical guidelines by the Institute for Clinical and Economic Review (ICER) identified five specialty societies’ guidelines that discussed nonspecific low back pain (American Academy of Family Physicians, American Association of Neurological Surgeons and Congress of Neurological Surgeons, American College of Occupational and Environmental Medicine, American College of Physicians, and North American Spine Society.) Some recommend performing no imaging, others recommend waiting six weeks to perform any imaging (including X-rays), and others recommend waiting six weeks to perform advanced imaging. *None of these recommendations differentiate between elderly- and non-elderly patients.*⁹

ACR’s AC for low back pain state that while advanced imaging is rarely appropriate (rating of 3 or less) for acute, subacute or chronic uncomplicated low back pain or radiculopathy in the general population, most frequently it is appropriate (rating of 7 or more) for patients who have one or more of the following: low velocity trauma (e.g. falling), osteoporosis, elderly individual, or chronic steroid use.¹⁰ Thus, in the elderly Medicare patient population, advanced imaging may be appropriate in many cases where it would not be appropriate in the general population. Clinical decision support

⁶ Clinical Decision Rules for Diagnostic Imaging in the Emergency Department: A Research Agenda. *Academic Emergency Medicine* 22:12, 1406-1416, 2015. Accessed August 17, 2016 at:

<http://onlinelibrary.wiley.com/doi/10.1111/acem.12828/full>

⁷ Schwartz AL, Landon BE, Elshaug AG, et al., “Measuring Low-Value Care in Medicare.” *JAMA Intern Med*, 2014.

⁸ Medicare Payment Advisory Commission, “Data Book: Health Care Spending and the Medicare Program,” 2016.

⁹ Reed, Sarah, et al., “Choosing Wisely Recommendation Analysis: Prioritizing Opportunities for Reducing Inappropriate Care.” Institute for Clinical and Economic Review, 2015.

¹⁰ Davis, Patricia C., et al, “ACR Appropriateness Criteria® on low back pain.” *Journal of the American College of Radiology*, 2009.

tools that fail to account for such differences in their design will burden providers. The ACR appropriateness criteria suggest that in the elderly population, x-ray of the lumbar spine is recommended as the initial imaging study.

- *CMS proposes a priority clinical area for headache.*

Response

CMS should consider whether a more specific definition for headache would be more appropriate for an elderly patient population. According to a 2014 report published in *JAMA Internal Medicine*, neuroimaging was ordered in nearly 12 percent of general headache visits between 2007 and 2010, with most scans finding nothing wrong.¹¹ An analysis of 2008 and 2009 Medicare claims data estimated the excess cost for imaging for uncomplicated headaches ranged from \$146 to \$211 million for the Medicare population.¹²

AGS notes that the Choosing Wisely recommendations by several specialty societies discuss the use of advanced imaging for headache but do not differentiate between elderly and non-elderly patients.¹³

The ACR AC, in contrast, include a variant specific to “new headache in elderly patients” with sedimentation rate higher than 55, temporal tenderness, and suspected temporal arteritis, and suggests that advanced imaging may be appropriate (AC rating of 7, 8 or 9) for certain patients.¹⁴

CMS proposes that a qualified CDSM must make available specified applicable AUC and the related documentation supporting the appropriateness of the imaging service ordered, identify the AUC consulted if the CDSM makes available more than one criterion relevant to a consultation for a patient’s specific clinical scenario, and make available, at a minimum, specified applicable AUC that reasonably encompass the entire clinical scope of all priority clinical areas.

AGS agrees that the process for developing AUC should be transparent and that decision-makers should not have conflicts of interest. However, AGS notes that CMS proposes to have significant discretion in the qualification process, and encourages CMS to work closely with specialty societies to ensure that the qualified CDSMs will contain AUC that are appropriate to the Medicare population and user-friendly for physicians and NPPs who order diagnostic tests. A suite of tools that is developed by information technology vendors and payers without sufficient provider input has the potential to create access barriers for Medicare beneficiaries and administrative burden for providers. CMS should consider the availability of AUC specific to elderly patients; AGS is concerned that inappropriate appropriateness criteria will limit beneficiary access to medically necessary services much more frequently than they will eliminate unnecessary spending.

¹¹ Callaghan, Brian C., et al., "Headaches and neuroimaging: high utilization and costs despite guidelines." *JAMA Internal Medicine*, 2014.

¹² Schwartz AL, Landon BE, Elshaug AG, et al., "Measuring Low-Value Care in Medicare." *JAMA Intern Med*, 2014.

¹³ <http://www.choosingwisely.org/clinician-lists/#keyword=headache>

¹⁴ <https://www.guideline.gov/summaries/summary/47673/acr-appropriateness-criteria--headache>

Recommendation III-C-i

- **With respect to AUC, AGS recommends that CMS refine the proposed clinical area of “low back pain” and “headache” to reflect differences between the elderly and non-elderly populations. AGS recommends that CMS work with specialty societies to identify AUC that are based on guidelines that are specific to the elderly population and, when guidelines suggest that the AUC are different for elderly patients, CMS should require that CDSMs include those elderly-specific AUC.**

CMS proposes that the CDSM must be able to incorporate specified applicable AUC from more than one qualified Provider Led Entity (PLE), determine, for each consultation, the extent to which the applicable imaging service is consistent with AUC or “not applicable,” and produce documentation to the ordering professional.

AGS supports the proposal that “not applicable” should always be an option, as there will be countless clinical scenarios in which the AUC that reside within a CDSM are confounded by the multiple chronic conditions typically seen in an elderly patient. Further, providers confronted with multiple AUC options in a particular CDSM (or in multiple CDSMs within a clinical area) should not be penalized for choosing one over another.

AGS believes that the proposed timeline of nominating and selecting qualified CDSMs by June 30, 2017, for implementation on January 1, 2018, does not give sufficient time for provider-led entities to develop their AUC using a transparent and evidence-based process, and could encourage the rollout of qualified CDSMs that have not been field tested sufficiently to ensure that they can be used in a broad variety of clinical situations, in the Medicare population specifically, and provide AUC information that is significantly better than clinical judgment alone.

Further, given that CMS will be implementing the Merit-Based Incentive Payment System (MIPS) at the same time that AUC are coming online, AGS is concerned about the requirements for interoperability across providers’ electronic health records. We are concerned that providers will likely need to obtain several qualified CDSM systems to cover the range of services they provide where AUC might be required, and that the cost of implementing and integrating such systems into clinical workflow will be significant.

For these reasons, AGS recommends that CMS take the necessary steps to ensure that the implementation of AUC for Medicare is thoughtful, transparent, and engages stakeholders with expertise in geriatrics in the selection of AUC and CDSMs. Once qualified CDSMs have been identified, CMS should ensure that there is adequate time for physicians to adopt and implement the new CDSM tools and modify their clinical workflows and billing systems to collect the required authorizations, documentation, and claims information.

Recommendation III-C-ii

- **CMS should carefully assess the feasibility of implementing AUC processes in the proposed timeframes.**

CMS proposes that consulting and reporting requirements would not apply to orders for applicable imaging services made by ordering professionals under the following circumstances: (1) emergency services when provided to individuals with emergency medical conditions, (2) inpatients and for which payment is made under Medicare Part A, and (3) ordering professionals who are granted a significant hardship exception to the Medicare EHR Incentive Program payment adjustment. AGS agrees that providers will need flexibility and commends CMS for recognizing this at the outset.

Recommendation III-C-iii

- **AGS recommends that CMS finalize its proposal to create exceptions from use of a CDSM in emergency situations, inpatients, and individuals who have been granted a significant hardship exception.**

G. Recoupment or Offset of Payments to Providers Sharing the Same Taxpayer Identification Number (TIN)

CMS proposes to implement an Affordable Care Act provision to recoup overpayments from “applicable providers” for amounts due to Medicare by “obligated providers.” An applicable provider and the obligated provider must have the same Taxpayer Identification Number (TIN) but may have different National Provider Identifiers (NPIs).

AGS disagrees with CMS’ assertion that there is no need for their contractors to notify either party when such a recoupment will be made. CMS’ proposed exception to its notice requirement for instances where the applicable and obligated providers share a TIN will, if finalized, create unnecessary confusion and promote inefficiency across the healthcare system.

While the government has the right to withhold the payments, failing to notify both NPI-level entities of the amount of the recoupment, date(s) of service, and other identifying information about each case will create havoc for providers, their office staff, and their external auditors, particularly in large systems such as academic medical centers. In the absence of such notice, “applicable providers” will receive a shortfall payment against their receivables, not know why the shortfall exists, and spend valuable time and effort trying to determine the reason, appeal the reduced payment, and so on, when a negotiation between the applicable provider and the obligated provider within the TIN would have been more appropriate and more efficient for everyone involved, including the government. Furthermore, this problem will be accentuated over time as more providers consolidate into a single multispecialty TIN to optimize their performance in Advanced Payment Models (APMs) and MIPS.

Recommendation II-G

- **CMS should not finalize its proposal to eliminate notice to the applicable provider and the obligated provider in the event of a recoupment of an overpayment.**

H. Accountable Care Organization (ACO) Participants Who Report Physician Quality Reporting System (PQRS) Quality Measures Separately

CMS’ rules prevent individuals who bill under the TIN of a Shared Savings Program Accountable Care Organization (ACO) from reporting Physician Quality Reporting System (PQRS) measures, even when the

ACO fails to successfully report quality data to CMS. AGS supports CMS' proposal to create a process for individuals and group practices in this situation to report PQRS measures for 2015 and 2016 during the reporting period for 2016.

Recommendation II-H

- **CMS should finalize its proposal to permit individuals to report PQRS measures if their ACO failed to do so on their behalf.**

I. Medicare Advantage (MA) Provider Enrollment

AGS agrees with CMS that, as a general rule, prohibiting Medicare Advantage (MA) plans from paying providers or suppliers that are not enrolled in Medicare, or are excluded by the OIG or have had their approval to bill Medicare revoked, is a sensible policy that would lessen the potential for fraud and abuse. However, AGS notes that many of the providers of long-term services and supports (LTSS) in communities are not eligible to bill Medicare directly. For example, MA plans are increasingly recognizing the value of partnering with community-based organizations toward improving transitional care and better integrating medical care and social services to optimize patient outcomes and avoid hospital readmissions.

AGS also supports the comments of the National PACE Association (NPA). The NPA asks that CMS make technical changes to the regulatory language and establish an alternative way to report information to CMS. The current proposal is that PACE organizations do so through their program agreements. NPA believes that this would be a complicated process since PACE agreements are a three-way agreement signed by CMS, the State and the PACE organization. NPA requests that CMS establish an alternative means of providing the information on providers and suppliers.

Recommendation III-I

- **CMS should clarify in the final rule how to implement provider enrollment rules in MA in a way that does not inadvertently exclude home and community-based LTSS caregivers who cannot bill Medicare directly.**
- **CMS should adopt the recommendations of the National PACE Association to ensure access to PACE services is uninterrupted.**

J. Proposed Expansion of the Diabetes Prevention Program (DPP) Model

AGS supports CMS' proposal to expand the DPP on a nationwide basis, as the program provides common-sense prevention tools to a population of high-risk patients and will likely reduce Medicare's costs over the long run. The American Diabetes Association estimated in 2012 that the total economic cost of diagnosed diabetes in 2012 is \$245 billion, a 41 percent increase from its 2007 estimate of \$174 billion (in 2007 dollars).¹⁵

¹⁵ American Diabetes Association, "Economic costs of diabetes in the US in 2012." *Diabetes Care*, 2013.

AGS notes that CMS' proposed criteria for beneficiaries to receive the DPP benefit are very broad, and suggests that an application form might be helpful to ensure that the criteria are documented in patients' medical records. AGS supports CMS' proposal to require DPP coaches to obtain an NPI and recommends that CMS also require that coaches enroll in the Medicare program.

Finally, AGS believes that the additional PFS spending that is expected to occur as a result of the expansion of the DPP should not be included in the budget neutrality adjustment. Providers who bill the PFS should not be penalized across-the-board as a result of this benefit expansion.

Recommendation III-J

- **CMS should finalize its proposal to expand the DPP on a nationwide basis. CMS should require DPP coaches to obtain an NPI and require that they enroll in Medicare. CMS should create an application form that providers can use to document that the criteria for patient entry in DPP have been met. CMS should create a process to check that DPP suppliers who are granted Medicare billing rights, prior to being fully recognized by the CDC, actually receive the CDC approval within a specified time period, and that DPP suppliers that do not get recognized are dis-enrolled.**
- **CMS should exclude projected additional PFS spending on DPP from the budget neutrality adjuster to the PFS as this is a benefit change.**

K. Medicare Shared Savings Program

The Medicare Shared Savings Program and other ACO/alternative payment systems are very important to AGS. We greatly appreciate the advances that this proposed rule makes in the PFS with regard to recognizing the services provided by geriatrics professionals. However, we feel that ultimately, it is the team based and systems approach of our discipline in managing populations that creates great value. For these reasons, we have commented elsewhere that all organizations should be required to have leadership with geriatric competency. In these transitions from FFS to VBP we seek to facilitate geriatric care providers moving to new payment systems and therefore seek to reduce barriers and create fair systems. CMS proposes several changes to the Medicare Shared Savings Program to align the program with CMS' proposed regulations implementing the Quality Payment Program (QPP) requirements. AGS supports CMS' proposals to amend the Shared Savings Program regulations to indicate that reporting requirements for PQRS, the EHR Incentive program, and Value-based Payment Modifier apply only through the 2016 performance year. AGS supports CMS' proposal to require ACOs to report quality measures through the CMS web interface on behalf of the eligible clinicians who bill under the TIN of an ACO participant in order to satisfy the QPP quality performance category. Like the proposed change to the PQRS program enabling EPs to separately report if the ACO fails to, CMS also proposes to maintain flexibility for EPs to report quality performance category data separately from the ACO. Measure alignment and further reduction in reporting that has marginal transformative or quality measurement potential should continue.

AGS also generally supports CMS' proposed changes to the Quality Measures Validation audits, but we believe that CMS should apply the 90 percent threshold only to random audits, and not to targeted audits. The failure to do so would mean that an MSSP ACO could accurately report and do very well on all but a small subset. Yet that subset could be the target of a review and determine an overall

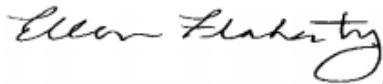
adjustment. Targeted auditing is more efficient and thus may be adopted, but, if so, may not be used for generalized extrapolations.

Recommendation III-K

- **CMS should finalize its proposals to align the Shared Savings Program and the QPP, which will ensure that clinicians who participate in both MIPS and APMs can move seamlessly between the two programs.**
- **In calculating accurate reporting any thresholds and re-calculations should be based upon sound methods and a general threshold should not be applied if a targeted audit is performed.**

We thank CMS for the opportunity to comment on this proposed rule. Please call Alanna Goldstein at the American Geriatrics Society at 212-308-1414 or Paul Rudolf at Arnold & Porter at 202-942-6426 if you have any questions about these comments.

Signed:



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