



October 1, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1734-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244–1850

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

Re: CMS–1734-P: Medicare Program; CY 2021 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; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

Dear Administrator Verma:

The Cognitive Care Alliance (CCA) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Calendar Year (CY) 2021 Medicare Physician Fee Schedule proposed rule. Our membership, representing over 60,000 physicians from seven cognitive specialty societies, including general internal medicine, endocrinology, infectious disease, gastroenterology, hematology, hepatology, and rheumatology, primarily provide evaluation and management (E/M) services to their patients. We continue to advocate for the need for an evidence-based approach to improve the definitions and valuations of E/M services, the shared goal of CCA members.

Outpatient Evaluation and Management Services

The CCA continues to be grateful for the agency's efforts to relax documentation requirements and improve the values of outpatient E/M services as finalized in the CY 2020 MPFS final rule, the first substantive changes to valuation of these services since the implementation of the Resource-based Relative Value Scale (RBRVS). These revisions are an important first step towards appropriately valuing non-procedural E/M care. The concurrent simplification of the documentation expectations will reduce the administrative burden on our members. **The CCA strongly urges the agency to finalize and implement the E/M policy without change on January 1, 2021.**

Despite these changes, the professional societies represented by the CCA continue to be concerned about the undervaluation of non-procedural E/M work elsewhere within the Physician Fee Schedule (PFS). We respectfully request that CMS address the other E/M families, most notably the inpatient E/M family, and standardize the documentation required across these code families. **To address the**

processes by which the entire set of E/M codes are defined, documented, and valued, the CCA urges CMS to establish an expert panel. As the CCA has previously shared with the agency, we envision the panel will be charged with developing an evidence-based approach to assess how the current E/M service codes are defined and valued within the RBRVS paradigm and whether documentation expectations continue to pose undue burden.

Moreover, the expert panel would help to address identified gaps in data and inadequacies in the processes CMS currently employs. If warranted, the expert panel may propose solutions as needed and recommend changes that may be made to the E/M code set to ensure the valuations of these codes reflect current medical practice. Should the expert panel be successful, we believe CMS will be armed with the necessary data and information to describe non-procedural work that is part of ongoing evaluation and management. We have included the expert panel proposal in Appendix A for your convenience.

Complexity Add-on Code: GPC1X

In the CY 2020 PFS final rule, CMS finalized HCPCS add-on code GPC1X to describe the “visit complexity inherent to evaluation and management associated with the medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient’s single, serious, or complex condition.” **The CCA continues to support the implementation of this code as finalized in last year’s rulemaking and we wish to provide additional information to help CMS better define this service.**

The CCA agrees that the revised outpatient E/M family does not fully capture the work of our members who deliver primary care to Medicare beneficiaries or that of certain specialists who form longitudinal relationships with beneficiaries. GPC1X captures the work associated with a primary care relationship that is continuous and comprehensive. In the case of the non-primary care specialties, it captures the work associated with the continuous and comprehensive care of a single condition or a cluster of conditions. In addition, the add-on code captures the work required to maintain cognitive expertise, an input that neither the outpatient E/M codes nor other fee schedule services sufficiently recognize, but is critical to treat Medicare beneficiaries effectively.

GPC1X captures the additional patient-based work “intensity” arising from three input categories not included in the existing outpatient E/M service codes: (1) the clinical complexity of the care provided by our members in the context of patient characteristics; (2) the nature of the physician-patient relationship developed and maintained, in many cases indefinitely; and (3) the responsibility assumed by physicians to continually update and maintain the knowledge-base required to deliver cognitively intense services. In the same manner, GPC1X address the issues of cognitive expertise that the member societies of the CCA share. The need to constantly update and revise the clinical knowledge-base within each of the specialties represented is a defining characteristic of the clinical competencies required for the outpatient E/M provided by the members of the societies represented by the CCA.

The CCA recognizes that CMS has requested for stakeholders to provide examples of utilization and define how this add-on code may be used. As such, our members have developed a series of vignettes describing the clinical scenarios in which this add-on code will be billed:

- General Internal Medicine: A 68-year-old man with hypertension, diabetes, and congestive heart failure presents to his primary care physician for follow-up. He presents with an extensive rash following yard work. He has widely disseminated poison ivy and will require a short course

of prednisone. In the setting of starting steroids, he will need to closely follow his blood sugars and blood pressures and report these back via phone call at the end of the week.

- **Gastroenterology:** A 65-year-old female with ileocolonic Crohn's disease who was recently initiated on immunosuppressants and immunomodulators. The patient was educated on adverse effects related to immunosuppression and need for therapeutic drug monitoring. She also presents with elevated blood sugar due to steroids that were given to help control initial disease. The patient was educated on alternative therapies including potential surgery and discussed health maintenance recommendations including but not limited to vaccinations and cancer screenings.
- **Infectious Disease:** A 67-year-old man with history of diabetes, atrial fibrillation and hypertension develops a foot ulcer- and is eventually diagnosed with osteomyelitis with MRSA and a multi drug resistant proteus. Patient is treated with a six-week course of intravenous antibiotics of vancomycin and ertapenem. The patient requires wound care and a wound vacuum is placed. The patient during the six-week antibiotic treatment requires close monitoring of his creatinine, vancomycin levels and INR as the antibiotics cause a change in the steady dose of Coumadin he has been taking for his atrial fibrillation. The patient requires weekly wound vac changes and while on the antibiotics subsequently develops Clostridium difficile infection.
- **Endocrinology:** A 70-year-old man with complicated obesity and non-alcoholic fatty liver disease who recently underwent pituitary surgery presents to his endocrinologist for follow-up. The patient is educated on the medication regimen and potential adverse effects. Discussed health maintenance recommendations, and medication monitoring plan. The patient will need to closely monitor any adverse events and report back to the endocrinologist on a regular basis via phone call to ensure that the proper medication regimen is being followed.

Prolonged Service Add-on Code: 99XXX

The CCA also continues to support CMS' proposal for CPT add-on code 99XXX (Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each additional 15 minutes) to capture additional time spent on the date of service above that for a level 5 visit. Additionally, we support CMS' proposal to allow for this code to be billed only once the top time threshold for the level 5 codes has been met. At the same time, **the CCA recommends that the agency revise the time-based billing requirements for this add-on to be consistent with the CPT billing guidance for other time-based codes which considers a unit of time to be attained when the midpoint is passed (e.g., a code requiring 15 minutes can be reported when 8 minutes have passed).**

Revaluing Services Analogous to Outpatient E/M

In this proposed rule, CMS identified services with values closely tied to the outpatient E/M codes, including transitional care management (TCM) services (CPT codes 99495, 99496); cognitive impairment assessment and care planning (CPT code 99483); certain end-stage renal disease (ESRD) services (CPT codes 90951 through 90970); and the annual wellness visit (AWV) and initial preventive physical exam (IPPE) (HCPCS codes G0402, G0438, G0439). **The CCA supports CMS' proposal to include the E/M increases in these services that use outpatient E/M as building blocks in their valuation.**

Telehealth Services

The CCA is deeply appreciative of the flexibilities and expansion of telehealth policy that have been implemented by the agency to address the ongoing public health emergency. The swift actions taken by CMS have secured access to care, while preventing unnecessary exposure to COVID-19. The ability to provide services to patients using audio and video communications technology has been essential in our practice and has transformed patient care. **We urge CMS to closely review the data collected on the expanded use of telehealth and audio-only services during the pandemic to inform a future evidence-based telehealth policy.**

Audio-Only Services

The CCA thanks the agency for expanding the use of telehealth through both audio/video and audio-only visits during the public health emergency. We recognize that under normal circumstances, CMS' regulations prohibit the agency from covering audio-only E/M visits since telehealth requires both audio and visual connections and communications technology-based services (CTBS) are not meant to replace face-to-face visits. In this proposed rule, the agency is not proposing to continue to allow audio-only services to be billed post-pandemic; **the CCA acknowledges this and still respectfully requests that the agency revise its telehealth regulations to allow for telephone-only care in appropriate circumstances.** Our members have encountered many circumstances in which patients are unable to establish a simultaneous audio/visual connection during the public health emergency and to eliminate this flexibility once the public health emergency concludes would limit access to care for some of the most vulnerable Medicare beneficiaries.

The pandemic brought to light certain impediments created by adding innovative visual technologies to audio-only telephonic care. CCA members have experienced significant barriers to delivering care with a simultaneous audio/visual connection. For example, Medicare beneficiaries may lack access to broadband connection or appropriate communications devices capable of establishing a simultaneous audio/visual connection. Often, those who have the technology required for the visit are unable to appropriately navigate it. Additionally, telehealth services delivered with a simultaneous audio/visual connection do not allow for necessary translation services for patients or for a patient's caregiver to participate in the visit. Disruption in the audio/visual connection impedes patient care and may pose serious health complications or lead to worsened health conditions.

From the provider perspective, the delivery of care with a simultaneous audio/visual connection or audio-only does not differ significantly. Physicians use the same electronic tools, including their electronic medical records, to deliver care; have the same access to history and concurrent condition information; and the same disposition options.

Should CMS revise its regulations to continue audio-only care post-public health emergency, the telephone E/M code set must be revisited to accurately capture how E/M care is delivered. The CCA is aware that the CPT Editorial Panel will be considering a code change application to revise this family at its October meeting. **Should CMS not revise its telehealth regulations, the CCA recommends that the entire outpatient E/M code families for new and established patients be allowed with audio-only technology for at least one year after the conclusion of the public health emergency.** Recovery from the effects of the COVID-19 pandemic will take multiple years and providers will require all the options available to them to both deal with SARS-CoV-2 infections along with other chronic conditions.

Audio-only services are a principal area in which CMS should carefully review the data on the use of these services during the pandemic to establish future policy. The CCA would welcome the opportunity to work with the agency to establish such policy.

Thank you for the opportunity to provide these comments. If you have any questions or require additional information on any of our comments, please contact Erika Miller, Executive Director of the Cognitive Care Alliance, at emiller@dc-crd.com.

Sincerely,

A handwritten signature in black ink, appearing to read "John Goodson MD". The signature is fluid and cursive, with a long horizontal stroke at the end.

John Goodson, MD
Chair

Cognitive Care Alliance Member Organizations:

American Association of the Study of Liver Diseases
American Gastroenterological Association
American Society of Hematology
Coalition of State Rheumatology Organizations
Endocrine Society
Infectious Diseases Society of America
Society of General Internal Medicine

Appendix A

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

Request:

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

Background/ Statement of Need:

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

Changes to the outpatient E/M services are being implemented at a time when the practice of medicine looks significantly different than it did when the RBRVS was established. Now CMS spends approximately \$100 billion on MPFS services. Forty percent of that spending is on E/M services - the outpatient E/M services account for 27 percent of MPFS spending. Since the late 1980s, the methodologies of health services research have evolved, the principles of representative databases have been firmly established, methods of adjustment to reflect the influences of health, social, economic, geographic and other factors are more robust, and the unintended consequences of the existing pricing mechanisms have become more clear.² All of these factors provide CMS with new tools to value cognitive work.

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

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

¹ Hsiao, WC, Braun, P, Dunn DL et al. Med Care 1992;30 (11) Supplement: NS1-NS12.

² Goodson JD. Unintended consequences of resource-based relative value scale reimbursement. JAMA. 2007; 298(19): 2308-10.

the E/M payment reforms finalized in the CY 2020 MPFS. Rather, this panel would assist CMS to ensure that cognitive work is accurately defined and valued under the MPFS.

Proposed Panel Charge, Responsibilities and Composition:

Charge

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

Responsibilities

- **Evaluate and summarize** the current data and research related to E/M services.
- **Review** the current methodologies and procedures used to define and value services under the MPFS.
- **Identify** the specific knowledge gaps including parameters for additional data needs and research required to study key topics and answer key questions, including:
 - Does the existing E/M code set adequately define and describe the full range of E/M services?
 - If adequate, are the current values for E/M services appropriate? Are the gradations of valuation aligned with the gradations of service intensity?
 - Do they appropriately account for all input elements that contribute to the intensity of work valuation, including the development and maintenance of cognitive expertise, the complexity of the clinically relevant interactions among individual patient characteristics, diagnoses and therapeutics, and the risks and implications that arise from different levels of encounter intensity?
 - Are the existing code definitions clear and accurate? If so, then code definitions should be reviewed to ensure linkage to definable auditing metrics.
 - If inadequate, what changes to the E/M service codes or additional codes are needed to address the possible deficiencies noted above?
 - Collaborate with the Office of the National Coordinator for Health Information Technology (HIT) to ensure that documentation requirements are easily integrated in the electronic health record (EHR).
 - Consider and research the development of guidelines for the future relative valuation of physician services. Propose a process whereby CMS can ensure that the MPFS is based on accurate and updated service code definitions, including service code times, and a reliable process of relative valuation based on data collected from patients, physicians, enterprises, and institutions.
 - Assess the utility of data describing E/M services from current resources, including the National Ambulatory Medical Care Survey (NAMCS), the Medical

Expenditure Panel Survey (MEPS), de-identified Medicare payment data, and de-identified electronic health record data sources.

- **Develop** new valuation concepts, if warranted, to capture the breadth and value of E/M services and determine how these can be best integrated in with existing RBRVS.
- **Recommend** changes, if warranted, that should be made to the current E/M code set to ensure the valuations of these codes reflect current medical practice.
- **Oversee the development of and provide input for** any new E/M services including:
 - service descriptions,
 - billing and coding guidelines, and
 - program integrity requirements

Panel Composition

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

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

Cognitive Care Alliance Member Organizations:

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Coalition of State Rheumatology Organizations
Endocrine Society
Infectious Diseases Society of America
Society of General Internal Medicine