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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 425, and 495

[CMS-1631-FC]

RIN 0938-AS40

Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This major final rule with comment period addresses changes to the physician fee schedule, and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute.

DATES: Effective date: The provisions of this final rule with comment period are effective on January 1, 2016, except the definition of “ownership or investment interest” in §411.362(a), which has an effective date of January 1, 2017.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 29, 2015. (See the **SUPPLEMENTARY INFORMATION** section of this final rule with comment period for a list of provisions open for comment.)

ADDRESSES: In commenting, please refer to file code CMS-1631-FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to www.regulations.gov. Follow the instructions for “submitting a comment.”
2. By regular mail. You may mail written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1631-FC,
P.O. Box 8013,
Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1631-FC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:
 - a. For delivery in Washington, DC--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT:

Donta Henson, (410) 786-1947 for issues related to pathology and ophthalmology services or any physician payment issues not identified below.

Abdihakim Abdi, (410) 786-4735, for issues related to portable X-ray transportation fees.

Gail Addis, (410) 786-4522, for issues related to the refinement panel.

Lindsey Baldwin, (410) 786-1694, for issues related to valuation of moderate sedation and colonoscopy services.

Jessica Bruton, (410) 786-5991, for issues related to potentially misvalued code lists.

Roberta Epps, (410) 786-4503, for issues related to PAMA section 218(a) policy.

Ken Marsalek, (410) 786-4502, for issues related to telehealth services.

Ann Marshall, (410) 786-3059, for issues related to advance care planning, and for primary care and care management services.

Geri Mondowney, (410) 786-4584, for issues related to geographic practice cost indices, malpractice RVUs, target, and phase-in provisions.

Chava Sheffield, (410) 786-2298, for issues related to the practice expense methodology, impacts, and conversion factor.

Michael Soracoe, (410) 786-6312, for issues related to the practice expense methodology and the valuation and coding of the global surgical packages.

Regina Walker-Wren, (410) 786-9160, for issues related to the “incident to” proposals.

Pamela West, (410) 786-2302, for issues related to therapy caps.

Emily Yoder, (410) 786-1804, for issues related to valuation of radiation treatment services.

Amy Gruber, (410) 786-1542, for issues related to ambulance payment policy.

Corinne Axelrod, (410) 786-5620, for issues related to rural health clinics or federally qualified health centers and payment to grandfathered tribal FQHCs.

Simone Dennis, (410) 786-8409, for issues related to rural health clinics HCPCS reporting.

Edmund Kasaitis (410) 786-0477, for issues related to Part B drugs, biologicals, and biosimilars.

Alesia Hovatter, (410) 786-6861, for issues related to Physician Compare.

Deborah Krauss, (410) 786-5264 and Alexandra Mugge, (410) 786-4457, for issues related to the physician quality reporting system and the merit-based incentive payment system.

Alexandra Mugge, (410) 786-4457, for issues related to EHR Incentive Program.

Sarah Arceo, (410) 786-2356 or Patrice Holtz, (410) 786-5663 for issues related to EHR Incentive Program-Comprehensive Primary Care (CPC) initiative and Medicare EHR Incentive Program aligned reporting.

Rabia Khan or Terri Postma, (410) 786-8084 or ACO@cms.hhs.gov, for issues related to Medicare Shared Savings Program.

Kimberly Spalding Bush, (410) 786-3232, or Sabrina Ahmed (410) 786-7499, for issues related to value-based Payment Modifier and Physician Feedback Program.

Frederick Grabau, (410) 786-0206, for issues related to changes to opt-out regulations.

Lisa Ohrin Wilson (410) 786-8852, or Matthew Edgar (410) 786-0698, for issues related to physician self-referral updates.

Christiane LaBonte, (410) 786-7234, for issues related to Comprehensive Primary Care (CPC) initiative.

JoAnna Baldwin (410) 786-7205, or Sarah Fulton (410) 786-2749, for issues related to appropriate use criteria for advanced diagnostic imaging services.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard,

Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

Provisions open for comment: We will consider comments that are submitted as indicated above in the “Dates” and “Addresses” sections on the following subject areas discussed in this final rule with comment period: interim final work, practice expense (PE), and malpractice (MP) RVUs (including applicable work time, direct PE inputs, and MP crosswalks) for CY 2016; interim final new, revised, potentially misvalued HCPCS codes as indicated in the Preamble text and listed in Addendum C to this final rule with comment period; and the additions and deletions to the physician self-referral list of HCPCS/CPT codes found on tables 50 and 51.

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In addition, because of the many organizations and terms to which we refer by acronym in this final rule with comment period, we are listing these acronyms and their corresponding terms in alphabetical order below:

AAA	Abdominal aortic aneurysms
ACO	Accountable care organization
AMA	American Medical Association
ASC	Ambulatory surgical center
ATA	American Telehealth Association
ATRA	American Taxpayer Relief Act (Pub. L. 112-240)
AWV	Annual wellness visit
BBA	Balanced Budget Act of 1997 (Pub. L. 105-33)
BBRA	[Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106-113)
CAD	Coronary artery disease
CAH	Critical access hospital
CBSA	Core-Based Statistical Area

c. Advance Care Planning Services

For CY 2015, the CPT Editorial Panel created two new codes describing advance care planning (ACP) services: CPT code 99497 (Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health professional; first 30 minutes, face-to-face with the patient, family member(s) and/or surrogate); and an add-on CPT code 99498 (Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health professional; each additional 30 minutes (List separately in addition to code for primary procedure)). In the CY 2015 PFS final rule with comment period (79 FR 67670-71), we assigned a PFS interim final status indicator of “I” (Not valid for Medicare purposes. Medicare uses another code for the reporting and payment of these services) to CPT codes 99497 and 99498 for CY 2015. We said that we would consider whether to pay for CPT codes 99497 and 99498 after we had the opportunity to go through notice and comment rulemaking.

In the CY 2016 PFS proposed rule, for CY 2016 we proposed to assign CPT codes 99497 and 99498 PFS status indicator “A,” which is defined as: “Active code. These codes are separately payable under the PFS. There will be RVUs for codes with this status. The presence of an “A” indicator does not mean that Medicare has made a national coverage determination regarding the service. Contractors remain responsible for local coverage decisions in the absence of a national Medicare policy.” We proposed to adopt the RUC-recommended values (work RVUs, time, and direct PE inputs) for CPT codes 99497 and 99498 beginning in CY 2016. The services could be paid on the same day or a different day as other E/M services. Physicians’ services are covered and paid by Medicare in accordance with section 1862(a)(1)(A) of the Act. Therefore, under our proposal CPT code 99497 (and CPT code 99498 when applicable) would be reported when the described service is reasonable and necessary for the diagnosis or treatment

of illness or injury. For example, this could occur in conjunction with the management or treatment of a patient's current condition, such as a 68 year old male with heart failure and diabetes on multiple medications seen by his physician for the E/M of these two diseases, including adjusting medications as appropriate. In addition to discussing the patient's short-term treatment options, the patient may express interest in discussing long-term treatment options and planning, such as the possibility of a heart transplant if his congestive heart failure worsens and advance care planning including the patient's desire for care and treatment if he suffers a health event that adversely affects his decision-making capacity. In this case the physician would report a standard E/M code for the E/M service and one or both of the ACP codes depending upon the duration of the ACP service. However the ACP service as described in this example would not necessarily have to occur on the same day as the E/M service.

We solicited comment on this proposal, including whether payment is needed and what type of incentives the proposal might create. In addition, we solicited comment on whether payment for advance care planning is appropriate in other circumstances such as an optional element, at the beneficiary's discretion, of the annual wellness visit (AWV) under section 1861(hhh)(2)(G) of the Act.

We received approximately 725 public comments to the proposed rule regarding payment for ACP services. We received comments from individual citizens; several coalitions; professional associations; professional and community-based organizations focusing on end-of-life health care; healthcare systems; major employers; and many individual healthcare professionals working in primary care, geriatrics, hospice/palliative medicine, critical care, emergency medicine and other settings. We also received comments from chaplains, ethicists, advanced illness counseling companies and other interested parties. The majority of commenters expressed support for the proposal, providing recommendations on valuation, the types of professionals who should be able to furnish or bill for the services and the appropriate setting of

care, intersection with existing codes, the establishment of standards or specialized training, and beneficiary cost sharing and education. Some commenters opposed or expressed provisional support for the proposal because they believed it might create perverse financial incentives relating to termination of patient care. We summarize all of the comments below.

Valuation

Comment: Many commenters supported the separate identification and payment for ACP, either by adopting CPT codes 99497 and 99498 or other unique code(s). Many commenters supported the proposal broadly, advocating for improved Medicare coverage and payment of ACP. Several commenters supported our proposal to adopt the RUC-recommended payment inputs. Several other commenters stated the proposed payment amount was insufficient, and one of these commenters recommended a payment rate equal to the payment for CPT code 99215 (Office or other outpatient visit for the E/M of an established patient) in order to appropriately account for the physician's time.

Response: We appreciate the commenters' support for separate identification and payment for voluntary ACP services. We believe the RUC-recommended inputs accurately reflect the resource costs involved in furnishing the services described by CPT codes 99497 and 99498, and therefore, are finalizing our proposal to adopt the RUC-recommended values for both codes.

Comment: Regarding the time required to furnish ACP services, the commenters cited times ranging from 10 minutes to several hours over multiple encounters, depending on the setting and the patient's condition. Several commenters requested payment for increments of

time of less than 30 minutes (for example, 10-15 minutes). One said the services typically require 30-45 minutes of face-to-face time with the patient and family. Several commenters recommended payment for services lasting less than 30 minutes, for example, by pro-rating the add-on code.

Response: We believe the CPT codes describe time increments that are appropriate for furnishing ACP services in various settings. Therefore we are finalizing our proposal to adopt the CPT codes and CPT provisions regarding the reporting of timed services.

Comment: Many commenters recommended that CMS issue a national coverage decision to avoid any local variation in coverage.

Response: We believe it may be advantageous to allow time for implementation and experience with ACP services, including identification of any variation in utilization, prior to considering a controlling national coverage policy through the National Coverage Determination process (see 78 FR 48164, August 7, 2013). By including ACP services as an optional element of the AWW (for both the first visit and subsequent visits), as discussed below, this rule creates an annual opportunity for beneficiaries to access ACP services should they elect to do so.

Comment: Many commenters recommended limits on utilization to prevent abuse, while others recommended no utilization limits in order to increase access and ensure periodic updates to advance care plans. Several commenters were concerned that the lack of utilization limits would lead to practitioners harassing patients.

Response: In general, we do not agree with the commenters who suggested that this service is more likely to be subject to overutilization or abuse than other PFS services without our adoption of explicit frequency limitations. We believe the CPT codes describe time increments that are appropriate for furnishing ACP services in various settings. Therefore, we are finalizing our proposal to adopt the CPT codes and CPT provisions regarding the reporting of timed services. Since the services are by definition voluntary, Medicare beneficiaries may

decline to receive them. When a beneficiary elects to receive ACP services, we encourage practitioners to notify the beneficiary that Part B cost sharing will apply as it does for other physicians' services (except when ACP is furnished as part of the AWV, see the discussion below). We plan to monitor utilization of the new CPT codes over time to ensure that they are used appropriately.

Intersection with Other Services

Comment: Many commenters supported our proposal to pay for ACP services when furnished either on the same day or a different day than other E/ M services. Several commenters asked CMS to specify whether and how the ACP codes could be billed in conjunction with E/M visits or services that span a given time period, such as 10- or 90-day global codes or Transitional Care Management (TCM) and Chronic Care Management (CCM) services. One commenter recommended that CMS unbundle ACP services from critical care services and pay at a higher rate, but did not suggest an alternative payment amount.

Response: We believe that CPT guidance for these codes is consistent with the description and recommended valuation of the described services. When adopting CPT codes for payment, we generally also adopt CPT coding guidance. In this case, CPT instructs that CPT codes 99497 and 99498 may be billed on the same day or a different day as other E/M services, and during the same service period as TCM or CCM services and within global surgical periods. We are also adopting the CPT guidance prohibiting the reporting of CPT codes 99497 and 99498 on the same date of service as certain critical care services including neonatal and pediatric critical care.

Who Can Furnish/Setting of Care

Comment: Many commenters who supported the proposal provided recommendations regarding which practitioners and support staff should be able to provide or be paid for ACP services. Many commenters sought clarification regarding who would qualify as the "other

health care professionals” described by or able to bill the CPT codes. Many commenters described ACP services as being routinely provided by a multidisciplinary team under physician supervision. For example, they stated that ACP is routinely provided by physicians, non-physician practitioners and other staff under the order and medical management of the beneficiary’s treating provider. They stated that often a team approach is used, involving coordination between the beneficiary’s physicians, non-physician practitioners (such as licensed clinical social workers or clinical nurse specialists) and other licensed and credentialed hospital staff such as registered nurses.

Similarly, other commenters described social workers, clinical psychologists, registered nurses, chaplains and other individuals as appropriate providers of ACP services, either alone or together with a physician, and recommended payment for the services of these individuals. For example, one commenter stated that a significant portion of ACP discussions occur between patients and registered nurses or allied health professionals functioning as care coordinators, care navigators or similar roles; that a growing proportion are performed at home; and that CMS should enable care coordinators and navigators to bill the ACP codes either by defining them as “other qualified health professionals” or under “incident to” provisions.

Some commenters specifically recommended allowing social workers and chaplains qualified under the hospice benefit to bill the ACP codes. One community oncologist association stated that best practices have evolved to include a multi-disciplinary approach utilizing trained physician, advanced practice provider and social worker skill sets, and that nearly half of their oncology network’s ACP is performed by licensed clinical social workers. This commenter stated that while it is typical for a physician to initiate the ACP discussion with patients, ACP usually occurs with a mid-level provider or social worker and therefore the association requested that CMS allow clinical social workers to bill for these services. Another national association stated that it was working towards the development of new CPT codes for

practitioners such as social workers who the commenter believed would not be able to directly bill the proposed codes.

Some commenters argued that such non-medically trained individuals are qualified and have special training and expertise (whether psychosocial, spiritual or legal) that are needed on ACP care teams. Some believed that ACP is sometimes appropriate for physicians to perform, but that physicians do not have enough time to supply all of the demand for ACP services. Some commenters similarly argued that inclusion of social workers and other non-medically trained individuals including Spiritual Directors, Chaplains, Clinical Pastoral Counselors and others would alleviate concerns about undue influence over patient decisions. These commenters stated that part of the ACP conversation is emotional and spiritual and not merely clinical, so it is important to include individuals who can address the non-clinical aspect of ACP. Some commenters argued that widening the field of professionals who can initiate these conversations within their scope of practice will further encourage appropriate and frequent ACP. Several commenters stated that physicians should not be paid for ACP services due to an ethical or financial conflict of interest, and that communities should take more responsibility for these services.

In contrast, several commenters were concerned that allowing ACP to be paid to certain trained facilitators would undermine physician authority in treating patients. These commenters described the use of trained facilitators in certain community models that offer group discussions by trained lay and health professionals. These commenters were concerned that such facilitators would qualify as “other qualified professionals” under the CPT code descriptor and be given control over ACP, shaping physician behavior. One commenter stated that to prevent coercion of patients, it would be better if payment was limited to non-employees of hospitals.

Response: We appreciate the many comments we received on existing or recommended practice patterns for the provision of ACP services. We acknowledge the broad range of

commenters that stated that the services described by CPT codes 99497 and 99498 are appropriately provided by physicians or using a team-based approach provided by physicians, non-physician practitioners and other staff under the order and medical management of the beneficiary's treating physician. We note that the CPT code descriptors describe the services as furnished by physicians or other qualified health professionals, which for Medicare purposes is consistent with allowing these codes to be billed by the physicians and NPPs whose scope of practice and Medicare benefit category include the services described by the CPT codes and who are authorized to independently bill Medicare for those services. Therefore only these practitioners may report CPT codes 99497 or 99498. We note that as a physicians' service, "incident to" rules apply when these services are furnished incident to the services of the billing practitioner, including a minimum of direct supervision. We agree with commenters that advance care planning as described by the proposed CPT codes is primarily the provenance of patients and physicians. Accordingly we expect the billing physician or NPP to manage, participate and meaningfully contribute to the provision of the services, in addition to providing a minimum of direct supervision. We also note that the usual PFS payment rules regarding "incident to" services apply, so that all applicable state law and scope of practice requirements must be met in order to bill ACP services.

Comment: Several commenters recommended that CMS not require direct supervision for ACP services or allow it to be furnished "incident to" under general supervision.

Response: As discussed above, we understand that the services described by CPT codes 99497 and 99498 can be provided by physicians or using a team-based approach where, in addition to providing a minimum of direct supervision, the billing physician or NPP manages, participates and meaningfully contributes to the provision of the services. We note that the "incident to" rules apply when these services are provided incident to the billing practitioner, including direct supervision. We do not believe it would be appropriate to create an exception

to allow these services to be furnished incident to a physician or NPP's professional services under less than direct supervision because the billing practitioner must participate and meaningfully contribute to the provision of these face-to-face services.

Comment: Many commenters made recommendations regarding the settings of care that would be appropriate for payment of ACP services. Some of these commenters specified that payment should be made in both ambulatory and inpatient settings. Many commenters stated that ACP is ideally performed in a primary care setting, where the patient has a longstanding relationship with a physician and can engage in planning prior to illness, at which time they may be most receptive and most likely to have full decision making capacity. However many commenters believed payment was also appropriate in inpatient and other acute care settings. A few commenters recommended payment for an outpatient code or a code that would not be payable in the intensive care setting. Some commenters recommended that ACP should only be payable in clinical settings and that CMS should explicitly exclude group information sessions and similar offerings. Commenters stated that patients should be able to choose any location for ACP services including at home; in community-based settings; or via telehealth, telephone or other remote technologies. A few commenters were concerned that CMS might limit payment to certain specialists and recommended against such a policy.

Response: We agree with commenters that ACP services are appropriately furnished in a variety of settings, depending on the condition of the patient. These codes will be separately payable to the billing physician or practitioner in both facility and non-facility settings and are not limited to particular physician specialties. We refer commenters to the CY 2016 hospital outpatient prospective payment system final rule with comment period for a discussion of how payment will be made to hospitals for ACP services furnished in hospital outpatient departments.

Comment: Many commenters supported payment for ACP along the entire health continuum, in advance of acute illness, and revisiting the advance care plan with changes in the

patient's condition. These commenters stated ACP is a routine service that should be regularly performed like preventive services. These commenters responded affirmatively to our solicitation as to whether or not ACP services should be included as an optional element, at the beneficiary's discretion, of the annual wellness visit (AWV) under section 1861(hhh)(2)(G) of the Act. Several of these commenters specified that ACP should remain separately paid even if included as an optional element of the AWV.

Response: We appreciate the response of commenters regarding our request for comment on whether or not we should include ACP as an optional element, at the beneficiary's discretion, of the annual wellness visit (AWV) under section 1861(hhh)(2)(G) of the Act. Based on the commenters' positive response to this solicitation, we are adding ACP as a voluntary, separately payable element of the AWV. We are instructing that when ACP is furnished as an optional element of AWV as part of the same visit with the same date of service, CPT codes 99497 and 99498 should be reported and will be payable in full in addition to payment that is made for the AWV under HCPCS code G0438 or G0439, when the parameters for billing those CPT codes are separately met, including requirements for the duration of the ACP services. Under these circumstances, ACP should be reported with modifier -33 and there will be no Part B coinsurance or deductible, consistent with the AWV.

Regarding who can furnish ACP when it is furnished as an optional element of the AWV, we note that AWV cannot be furnished as an "incident to" service since the AWV has a separate, distinct benefit category from "incident to" services. However, the current regulations for the AWV allow the AWV to be furnished under a team approach by physicians or other health professionals under direct supervision. Therefore, the rules that apply to the AWV will also apply to ACP services when furnished as an optional element of the AWV, including the requirement for direct supervision.

Comment: We received several comments requesting that ACP be added as a billable visit for FQHCs, and several comments requesting that we ensure that Medicare Administrative Contractors (MACs) are aware that a standalone ACP counseling session with an FQHC billable provider qualifies as a “billable visit” under Medicare’s Prospective Payment System (PPS) for FQHCs.

Response: RHCs and FQHCs furnish Medicare Part B services and are paid in accordance with the RHC all-inclusive rate system or the FQHC PPS. Beginning on January 1, 2016, ACP will be a stand-alone billable visit in a RHC or FQHC, when furnished by a RHC or FQHC practitioner and all other program requirements are met. If furnished on the same day as another billable visit, only one visit will be paid. Coinsurance will be applied for ACP when furnished in an FQHC, and coinsurance and deductibles will be applied for ACP when furnished in an RHC. Coinsurance and deductibles will be waived when ACP is furnished as part of an AWW. Additional information on RHC and FQHC billing of ACP will be available in sub-regulatory guidance.

Standards/Training

Comment: Many commenters recommended that CMS establish standards or require specialized training as a condition of payment for ACP services. Many commenters recommended standards or special training in relevant state law and advance planning documents; content and time; communication, representation, counseling, shared decision making and skills outside the scope of physician training. Several commenters recommended standards regarding the use of certified electronic health record technology; contractual or employment relationships with nurses, social workers and other clinical staff working as part of an ACP team; use of written protocols and workflows to make ACP part of routine care; and working with professional societies and other organizations including the National Quality Forum and the Agency for Healthcare Research & Quality to establish quality standards for

clinician-patient communication and ACP that would be tied to payment. Many commenters recommended policies to ensure documentation and transmission of the results of ACP among health care providers. Some of these commenters encouraged CMS to use technology to enhance the use and portability of advance directives across care settings and state lines, or recommended a universal registry.

Several commenters were concerned about the nature of the services that would be payable under the proposed codes, noting that ACP should extend beyond education about advance directives and completing forms. Several recommended the development of content criteria or quality measures to ensure that ACP services are meaningful and of value to patients. Some commenters expressed concern about ensuring appropriate services were furnished as part of ACP. For example, they expressed concern that payable services would include mere group information sessions, filling out forms or similar offerings. One commenter recommended that CMS require some minimal element like one personal real-time encounter, whether face-to-face or by phone or telemedicine.

Response: Since CPT codes 99497 and 99498 describe face-to-face services, we do not believe it would be appropriate at this time to apply additional payment standards as we have for certain non-face-to-face services such as CCM services. We will continue to consider whether additional standards, special training or quality measures may be appropriate in the future as a condition of Medicare payment for ACP services. We note that we did not propose to add ACP services to the list of Medicare telehealth services, so the face-to-face services described by the codes need to be furnished in-person in order to be reported to Medicare.

Comment: Several commenters supported advance care planning between patients and clinicians, but expressed concern about the potential for bias against choosing treatment options involving living with disability, requiring physicians to discuss questionable treatment options (such as physician assisted suicide or other patient choices that might violate individual

physician ethics) and similar issues. Some commenters were concerned that patients might change their decisions once care was actually needed and be unable to override previous advance directives; or that the government would be making healthcare decisions instead of patients, physicians, and families.

Response: As discussed above, based on public comments we received, we believe the services described by CPT codes 99497 and 99498 are appropriately provided by physicians or using a team-based approach where ACP is provided by physicians, non-physician practitioners and other staff under the order and medical management of the beneficiary's treating physician. We also note that the CPT code descriptors describe the services as furnished by physicians or other qualified health professionals, which for Medicare purposes, is consistent with allowing these codes to be billed by the physicians and NPPs whose scope of practice and Medicare benefit category include the services described by the CPT codes and who are authorized to independently bill Medicare for those services. Therefore only these practitioners may report CPT codes 99497 or 99498, and "incident to" rules apply when these services are provided incident to the services of the billing practitioner under a minimum of direct supervision. We agree with commenters that advance care planning as described by the new CPT codes is primarily the provenance of patients and physicians. Accordingly we expect the billing physician or NPP, in addition to providing a minimum of direct supervision, to manage, participate and meaningfully contribute to the provision of the services. Also, we note that PFS payment rules apply when ACP is furnished incident to other physicians' services, including where applicable, that state law and scope of practice must be met. Since the ACP services are by definition voluntary, we believe Medicare beneficiaries should be given a clear opportunity to decline to receive them. We note that beneficiaries may receive assistance for completing legal documents from other non-clinical assisters outside the scope of the Medicare program. Nothing in this final rule with comment period prohibits beneficiaries from seeking independent

counseling from other individuals outside the Medicare program – either in addition to, or separately from, their physician or NPP.

Beneficiary Considerations

Comment: Several commenters suggested that CMS pursue waivers of cost sharing for ACP services or that cost sharing should vary by the condition of the patient.

Response: We lack statutory authority to waive beneficiary cost sharing for ACP services generally because they are not preventive services assigned a grade of A or B by the United States Preventive Services Task Force (USPSTF); nor may CMS vary cost sharing according to the patient’s diagnosis. Under current law, the Part B cost sharing (deductible and coinsurance) will be waived when ACP is provided as part of the AWW, but we lack authority to waive cost sharing in other circumstances. We would recommend that practitioners inform beneficiaries that the ACP service will be subject to separate cost sharing.

Comment: One commenter recommended beneficiary education through Medicare & You, partnerships with senior advocacy groups and other means.

Response: We agree that beneficiary education about ACP services, especially the voluntary nature of the services, is important. We welcome such efforts by beneficiary advocacy and community-based organizations and will consider whether additional material should be added to the Medicare & You handbook to highlight new payment provisions for these voluntary services.

In summary, we are finalizing our proposal to assign CPT codes 99497 and 99498 PFS status indicator “A” with RVUs developed based on the RUC-recommended values. We are also adding ACP as an optional element, at the beneficiary’s discretion, of the AWW. We are also making the conforming changes to our regulations at §410.15 that describe the conditions for and limitations on coverage for the AWW.

We note that while some public commenters were opposed to Medicare paying for ACP services, the vast majority of comments indicate that most patients desire access to ACP services as they prepare for important medical decisions.