Edition Base EHR definition'' defined at 45 CFR 170.102, we are proposing to add a reference to the revised name ''Base EHR definition,'' proposed in the ONC HTI–1 proposed rule, to ensure, if finalized, it is applicable for the CEHRT definitions going forward (88 FR 23759). Next, we are proposing to replace our references to ''2015 Edition health IT certification criteria,'' with ''ONC health IT certification criteria'' and to add the regulatory citation for ONC health IT certification criteria in 45 CFR 170.315. By removing the reference to the ''2015 Edition,'' and pointing to the regulations at 45 CFR 170.315, we believe this proposal, if finalized, will ensure the CEHRT definitions do not need to be updated to reflect modified terminology unless ONC changes the location of these certification criteria.

While these proposed revisions would allow us to maintain more permanent cross-references to ONC's regulations and terminology, we recognize that ONC has historically updated, and will likely in the future continue to update over time, the underlying certification criteria contained in 45 CFR 170.315.

Previously under the year-themed ''editions'' construct, we periodically revised the language in our regulatory CEHRT definitions to refer to a new Edition in order to incorporate ONC's updates to health IT certification criteria. Then, in the CY 2021 PFS final rule (85 FR 84818 through 84825), to incorporate ONC's updates to certification criteria in its 2015 Edition Cures Update, which ONC finalized under the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961), we did not revise the language of the CEHRT definitions for the Medicare Promoting Interoperability Program and the Quality Payment Program. Instead, we finalized that technology used to satisfy the CEHRT definitions must be certified under the ONC Health IT Certification Program, in accordance with the 2015 Edition Cures Update certification criteria as finalized in the ONC 21st Century Cures Act final rule.

Consistent with ONC's proposal to move away from year-themed ''editions,'' and in order to further simplify our regulatory approach, we are proposing revisions to our definitions of CEHRT to ensure we would not necessarily be required to update our regulatory text each time ONC proposed or finalized any updates to its definition of Base EHR or certification criteria.

This proposal would establish that any certification criteria adopted or updated in 45 CFR 170.315 would be applicable for the CEHRT definitions in our programs' regulations at 42 CFR 495.4 and 42 CFR 414.1305, if ONC's applicable regulations are referenced directly in our CEHRT definitions. If finalized, this proposal would allow the CEHRT definitions in our regulations to automatically incorporate ONC's updates to relevant certification criteria without pursuing additional rulemaking.

It is important to note that this proposal, if finalized, would not mean that any update to a certification criterion finalized by ONC would necessarily be immediately required for use in CEHRT for our Medicare Promoting Interoperability Program, Quality Payment Program, and Shared Savings Program. We remind readers that ONC sets timelines through their rulemaking for when health IT developers must ensure their health IT products meet ONC's new or updated certification criteria to maintain certification under the ONC Health IT Certification Program, including time for health IT developers to implement these updates for their customers who may participate in programs that require use of CEHRT (88 FR 23761). We also note that CMS will continue to determine when new or revised versions of measures that require the use of certified health IT would be required for participation under the Medicare Promoting Interoperability Program and the Quality Payment Program. In determining requirements for any potential new or revised measures, we will consider factors such as implementation time and provider readiness to determine when we propose requiring participants to complete measures that require the use of certified health IT.

We believe this approach would provide us with more flexibility to finalize updates and is more consistent with the incremental approach to revising measures and technology requirements described above. Moreover, this additional flexibility would allow eligible hospitals, CAHs, and MIPS eligible clinicians to adopt, implement, and use ONC's updated certification criteria for health IT, including EHRs, as it becomes available from their chosen vendor, without the need to wait for us to first amend the regulations at 42 CFR 495.4 and 42 CFR 414.1305 through separate rulemaking.

In summary, we are proposing to revise the definitions of CEHRT for the Medicare Promoting Interoperability Program at 42 CFR 495.4, and for the Quality Payment Program at 42 CFR 414.1305. Specifically, we are proposing to add a reference to the revised name of ''Base EHR definition,'' proposed in the ONC HTI–1 proposed rule, to ensure, if finalized, it is applicable for the CEHRT definitions going forward (88 FR 23759). We are also proposing to replace our references to the ''2015 Edition health IT certification criteria'' with ''ONC health IT certification criteria'' and add the regulatory citation for ONC health IT certification criteria in 45 CFR 170.315. We also propose to specify that technology meeting the CEHRT definitions must meet ONC's certification criteria in 45 CFR 170.315 ''as adopted and updated by ONC.'' We believe that these revisions to the CEHRT definitions, if finalized, would ensure that updates to the definition at 45 CFR 170.102 and updates to applicable health IT certification criteria in 45 CFR 170.315 would be incorporated into the CEHRT definitions, without additional regulatory action by CMS.

Finally, we note that while this proposal is consistent with the approach in ONC's HTI–1 proposed rule (88 FR 23746 through 23917), we do not believe that ONC must finalize its proposed revisions for us to be able to finalize the changes proposed in this section for our regulatory definitions of CEHRT.

We are inviting public comment on these proposals.

S. A Social Determinants of Health Risk Assessment in the Annual Wellness Visit

Medicare coverage for the Annual Wellness Visit (AWV) under Part B is primarily described in statute at section 1861(hhh) of the Act, and in regulation at 42 CFR 410.15. We propose to exercise our authority in section 1861(hhh)(2)(I) of the Act to add other elements to the AWV by adding a new Social Determinants of Health (SDOH) Risk Assessment as an optional, additional element with an additional payment. The proposed new SDOH Risk Assessment would enhance patient-centered care and support effective administration of an AWV. There are no deductible requirements or Part B coinsurance for the AWV. See §§ 410.160(b)(12) and 410.152(l)(13). Our proposal builds upon our separate proposal described earlier to establish a stand-alone G code (GXXX5) for SDOH Risk Assessment furnished in conjunction with an Evaluation and Management (E/M) visit (see section II.E. of this proposed rule).

1. Background

The AWV includes the establishment (or update) of the patient's medical and family history, application of a health risk assessment and the establishment (or update) of a personalized prevention

plan. The AWV also includes an optional Advance Care Planning (ACP) service. The AWV is covered for eligible beneficiaries who are no longer within 12 months of the effective date of their first Medicare Part B coverage period and who have not received either an Initial Preventive Physical Examination (IPPE) or AWV within the past 12 months. The goals of AWV are health promotion, disease prevention and detection and include education, counseling, a health risk assessment, referrals for prevention services, and a review of opioid use. Additional information about the AWV is available on the CMS website at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html.*

It is estimated [282] that around 50 percent of an individual's health is directly related to SDOH, which is defined by Healthy People 2030 [283] as, ''The conditions in the environment where people are born, live, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.'' Healthy People 2030 also defines the broad groups of SDOH as: economic stability, education access and quality, healthcare access and quality, neighborhood and built environment, and social and community context. These parameters include factors like housing, food and nutrition access, and transportation needs. Given the large impact on health these factors have, the health care system broadly has been working to take these factors into account when providing care and rendering services.

Several Federal agencies, including the CDC, AHRQ, ACL, ACF, SAMHSA, HRSA, and ASPE are developing policies and implementation frameworks to better address the impact SDOH has on patients, in support of HHS's Strategic Approach to Addressing Social Determinants of Health to Advance Health Equity.[284] At CMS, addressing SDOH is an essential piece of the CMS Framework for Health Equity,[285] and it is tied in heavily with the CMS Strategic Pillar to advance equity. SDOH was also a foundational concept with the CMS Innovation Center Accountable Health Communities (AHC) Model that ended in 2022. Given the importance of and focus surrounding SDOH and enhancing equity, CMS is exploring ways to recognize and quantify practitioner work currently being done in this area, and to provide support to enable practitioners to assess and intervene when SDOH is relevant to the assessment, prevention and treatment plan of a Medicare patient.

CMS tested the AHC Model between 2017 and 2022. One element of the model test was the development and application of the AHC Health-Related Social Needs (HRSN) Screening Tool, which helps providers to identify patients' SDOH related needs, including housing instability, food insecurity, family and community support and mental health. Additional information on the AHC model is available on the CMS website at *(https://innovation.cms.gov/innovation-models/ahcm).*

We have heard from many health care professionals and beneficiary groups that there are barriers to completing the AWV, including, but not limited to, language and communication, differences in cultural perspectives and expectations regarding engagement with the healthcare system. We increasingly understand the importance that SDOH be considered in an assessment of patient histories, patient risk, and in informing medical decision making, prevention, diagnosis, care and treatment.

In February 2018, Health Affairs published an article titled, ''Practices Caring for the Underserved Are Less Likely to Adopt Medicare's Annual Wellness Visit,'' which described findings from a statistical study of Medicare primary care providers and AWV's from 2011 to 2015. The article points out, ''One of our most striking results was that while underserved patients were less likely to receive an annual wellness visit regardless of where they sought care, practices in rural areas and those caring for underserved and sicker populations were less likely to provide such visits to any of their patients—which suggests these practices may face resource constraints or have priorities that compete with adoption of the visit.'' [286]

In August 2022, the Journal of the American Geriatrics Society published an article titled, ''Medicare's annual wellness visit: 10 years of opportunities gained and lost.'' The article expresses the concern, ''currently AWVs are a 'one size fits all','' approach. This uniform approach does not sufficiently take into consideration the medical, psychological, functional, racial, cultural and socio-economic diversity of older adults. Updated AWVs should be tailored to meet the needs and priorities of older adults receiving them.'' It goes on to recommend, ''Medicare AWVs should include screening and counseling for social determinants of health as a means of mitigating the growing disparities in health and longevity for underserved older adults.'' [287]

2. Statutory and Regulatory Authority

Section 4103 of The Patient Protection and Affordable Care Act (ACA) (Pub. L. 111–148) expanded Medicare coverage by adding the AWV benefit at section 1861(hhh) of the Act, effective for services furnished on or after January 1, 2011. We subsequently implemented the AWV in CMS regulations at § 410.15. The AWV is a wellness visit that focuses on identification of certain risk factors, personalized health advice, and referral for additional preventive services and lifestyle interventions (which may or may not be covered by Medicare). The elements included in the AWV differ from comprehensive physical examination protocols with which some providers may be familiar since it is a visit that is specifically designed to provide personalized prevention plan services as defined in the Act. The AWV includes a health risk assessment (HRA) and the AWV takes into account the results of the HRA. The AWV is covered for eligible beneficiaries who are no longer within 12 months of the effective date of their first Medicare Part B coverage period and who have not received either an IPPE or AWV within the past 12 months. Section 1861(hhh)(2) of the Act describes a number of elements included in the AWV and section 1861(hhh)(2)(I) of the Act authorizes the addition of any other element determined appropriate by the Secretary.

We note that § 410.15(a) requires that the first AWV include the following:

- Review (and administration if needed) of a health risk assessment (as defined in § 410.15).
- Establishment of an individual's medical and family history.

[282] *https://aspe.hhs.gov/sites/default/files/documents/e2b650cd64cf84aae8ff0fae7474af82/SDOH-Evidence-Review.pdf.*

[283] *https://health.gov/healthypeople.*

[284] *https://aspe.hhs.gov/sites/default/files/documents/aabf48cbd391be21e5186eeae728ccd7/SDOH-Action-Plan-At-a-Glance.pdf.*

[285] *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[286] Ganguli I, Souza J, McWilliams JM, Mehrotra A. Practices Caring For The Underserved Are Less Likely To Adopt Medicare's Annual Wellness Visit. Health Aff (Millwood). 2018 Feb;37(2):283–291. doi: 10.1377/hlthaff.2017.1130. PMID: 29401035; PMCID: PMC6080307.

[287] Coll PP, Batsis JA, Friedman SM, Flaherty E. Medicare's annual wellness visit: 10 years of opportunities gained and lost. J Am Geriatr Soc. 2022 Oct;70(10):2786–2792. doi: 10.1111/jgs.18007. Epub 2022 Aug 17. PMID: 35978538.

• Establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the individual.

• Measurement of an individual's height, weight, body-mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements as deemed appropriate, based on the beneficiary's medical and family history.

• Detection of any cognitive impairment that the individual may have, as that term is defined in § 410.15.

• Review of the individual's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the health professional may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations.

• Review of the individual's functional ability and level of safety, based on direct observation or the use of appropriate screening questions or a screening questionnaire, which the health professional as defined in § 410.15 may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.

• Establishment of the following:

++ A written screening schedule for the individual such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices, and the individual's health risk assessment (as that term is defined in § 410.15), health status, screening history, and age-appropriate preventive services covered by Medicare.

++ A list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through an IPPE (as described under § 410.16), and a list of treatment options and their associated risks and benefits.

++ Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.

++ At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

++ Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

++ Screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

++ Any other element determined appropriate through the national coverage determination process.

We note that § 410.15(a) requires that a subsequent AWVs include the following:

• Review (and administration, if needed) of an updated health risk assessment (as defined in § 410.15).

• An update of the individual's medical and family history.

• An update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual as that list was developed for the first AWV providing personalized prevention plan services or the previous subsequent AWV providing personalized prevention plan services.

• Measurement of an individual's weight (or waist circumference), blood pressure and other routine measurements as deemed appropriate, based on the individual's medical and family history.

• Detection of any cognitive impairment that the individual may have, as that term is defined in § 410.15.

• An update to the following:

++ The written screening schedule for the individual as that schedule is defined in paragraph (a) of § 410.15 for the first AWV providing personalized prevention plan services.

++ The list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual as that list was developed at the first AWV providing personalized prevention plan services or the previous subsequent AWV providing personalized prevention plan services.

++ Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs as that advice and related services are defined in paragraph (a) of § 410.15.

++ At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

++ Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

++ Screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

++ Any other element determined appropriate through the national coverage determination process.

In the CY 2016 PFS final rule (80 FR 70885), we finalized a proposal to include ACP as an optional element (at beneficiary discretion) within the AWV. We stated in the final rule 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 (80 FR 70958). We also added this policy to the regulatory text at § 410.15(a).

3. Proposal

We propose to exercise our authority in section 1861(hhh)(2)(I) of the Act to add elements to the AWV by adding a new SDOH Risk Assessment as an optional, additional element of the AWV with an additional payment. We recognize that, for some patients, identification and consideration of SDOH is critical to furnishing a fully informed health assessment and personalized prevention plan in the AWV. We have heard from interested parties that the current elements of the AWV may not directly or adequately identify those SDOH challenges. We propose that the SDOH Risk Assessment be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same

date of service as the AWV. We propose that the SDOH Risk Assessment service include the administration of a standardized, evidence-based SDOH risk assessment tool, furnished in a manner that all communication with the patient be appropriate for the patient's educational, developmental, and health literacy level, and be culturally and linguistically appropriate. We believe that services that are culturally and linguistically appropriate are critical to providing effective, equitable, understandable, and respectful quality care that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs of each patient. We recognize that patients with SDOH risks and challenges may often also experience communication barriers of various kinds when interacting with the health care system. We believe that the SDOH Risk Assessment would only be effective in informing the greater AWV (including the health assessment and personalized prevention plan) when furnished in a manner that is intelligible and appropriate to the individualized characteristics and circumstances of the patient. Additional information on culturally and linguistically appropriate services in healthcare can be found at (*https://thinkculturalhealth.hhs.gov/clas*). We believe the SDOH Risk Assessment Tool would be most effective and actionable when furnished in a setting with staff-assisted supports in place to ensure follow-up for health-related social needs associated to the visit. We also encourage partnerships with community-based organizations such as Area Agencies on Aging to help address identified social needs. We propose that the SDOH Risk Assessment be furnished as part of the same visit and on the same date of service as the AWV, so as to inform the care the patient is receiving during the visit, including taking a medical and social history, applying health assessments and prevention services education and planning. We believe our proposal will directly reduce barriers, expand access, promote health equity and improve care for populations that have historically been underserved by recognizing the importance that SDOH be considered and assessed, where appropriate, in support of the existing AWV. In addition, we hope that our proposal will help spread general awareness among health professionals about the importance of providing cultural and linguistically appropriate services, which in turn will encourage clinicians to adopt language services and technologies to achieve high quality communication between the practitioner and patient. Our goal is the development of a personalized prevention plan that takes SDOH into account and is truly tailored to the individual patient. We invite public comment on our proposal, including whether a SDOH Risk Assessment would ultimately inform and result in the development of steps to address and integrate SDOH in the patient's AWV health assessment and personalized prevention plan.

We recognize that SDOH risk assessments are an emerging and evolving tool in healthcare and so we do not restrict our proposal to a specific list of approved assessments. In selecting an evidence-based tool, we encourage clinicians to explore the many widely adopted and validated tools available, including the CMS Accountable Health Communities [288] tool, the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (PRAPARE) tool,[289] and instruments identified for Medicare Advantage Special Needs Population Health Risk Assessment.[290] We also encourage clinicians, where feasible, to select screening instruments that maximize opportunities to collect and analyze standardized, quantifiable, and actionable data. For instance, clinicians are encouraged to utilize screening instruments where questions and responses are computable and mapped to health IT vocabulary standards (that is, have available LOINC® coding terminology), to ensure that data captured through assessments is interoperable and can be shared, analyzed and evaluated across the care continuum.

Our proposal builds upon our separate proposal described earlier to establish a stand-alone G code (GXXX5) for SDOH Risk Assessment furnished in conjunction with an E/M visit. See section II.E. for additional information on coding, pricing, and additional conditions of payment for the proposed new SDOH Risk Assessment service. Upon finalization of the CY 2024 PFS, CMS will issue public guidance in the Medicare Learning Network, the Medicare & You Handbook, and more formal, in-depth policy and payment instructions in the Medicare Benefit Policy Manual and the Medicare Claims Processing Manual on the CMS website.

Over the past several years, we have worked to develop payment mechanisms under the PFS to improve the accuracy of valuation and payment for the services furnished by physicians and other health care professionals, especially in the context of evolving models of care. Section 1862(a)(1)(A) of the Act generally excludes from coverage services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Practitioners across specialties have opined and recognized the importance of SDOH on the health care provided to their patients by recommending the assessment of SDOH through position or discussion papers,[291] [292] [293] organizational strategic plans,[294] and provider training modules,[295] among others. As described earlier in our proposed rule, we have discussed how the practice of medicine currently includes assessment of health-related social needs or SDOH in taking patient histories, assessing patient risk, and informing medical decision making, diagnosis, care and treatment. The taking of a social history is generally performed by physicians and other health professionals in support of patient-centered care to better understand and help address relevant problems that are impacting medically necessary care. Practitioners are expending resources to obtain information from the patient about health-related social needs, and to formulate diagnosis and treatment plans that take these needs into account as part of a person-centered care plan for the treatment of medical problems. This work currently is reported and paid for, in part, under the PFS under E/M visit codes, and we believe as such, is undervalued and not optimized to allow the health professional and patient to benefit from the full value of a dedicated SDOH assessment and have that assessment immediately inform the health assessment and prevention planning services in the AWV.

We propose that Medicare would pay 100 percent of the fee schedule amount for the SDOH Risk Assessment service (beneficiary cost sharing would not be applicable) when this risk assessment is furnished to a Medicare beneficiary as an optional element within an AWV (as part of the same visit with the same date of service as the AWV). Our proposal is

[288] *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.*

[289] *https://www.nachc.org/research-and-data/prapare/.*

[290] CMS–10825.

[291] *https://www.aafp.org/about/policies/all/social-determinants-health-family-medicine-position-paper.html.*

[292] *https://doi.org/10.7326/M17–2441.*

[293] *https://nam.edu/social-determinants-of-health-201-for-health-care-plan-do-study-act/.*

[294] *https://www.ama-assn.org/system/files/2021–05/ama-equity-strategic-plan.pdf.*

[295] *https://edhub.ama-assn.org/steps-forward/module/2702762.*

analogous to our current approach to the ACP service, which is an optional service for which beneficiary cost sharing is not applicable when furnished as part of the same visit and on the same date of service as the AWV. Beneficiary cost sharing is not applicable to the AWV and, because the SDOH Risk Assessment would be an optional element within the AWV, there would not be any beneficiary cost sharing for the SDOH Risk Assessment either. See §§ 410.160(b)(12) and 410.152(l)(13). We note that beneficiary cost sharing would apply to the SDOH Risk Assessment if furnished in conjunction with another service (outside of the AWV) that is subject to beneficiary cost sharing. We are proposing that the SDOH Risk Assessment would be optional for both the health professional and the beneficiary to empower clinicians and patients to employ this assessment only when appropriate and desired.

We propose to add regulatory text at § 410.15 that will include the new SDOH Risk Assessment service as an optional element within the AWV, at the discretion of the health professional and beneficiary. Furthermore, we propose to add regulatory text that the SDOH Risk Assessment be standardized, evidence-based, and furnished in a manner that all communication with the patient be appropriate for the beneficiary's educational, developmental, and health literacy level, and be culturally and linguistically appropriate. We invite public comment on our proposal.

We have also received feedback from interested parties that the AWV may be more effectively furnished if elements were allowed to be completed over multiple visits and days, or prior to the AWV visit. We invite public comment on this issue for consideration in future rulemaking.

4. Summary

In conclusion, we are proposing to add a new Social Determinants of Health (SDOH) Risk Assessment as an optional element within the AWV. We are also proposing the SDOH Risk Assessment be paid at 100 percent of the fee schedule amount of the risk assessment. We are proposing that the new SDOH Risk Assessment be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV. We believe our proposal will directly reduce barriers, expand access, promote health equity and improve care for populations that have historically been underserved by recognizing the importance that SDOH be considered and assessed, where appropriate, as an additional, optional element in the AWV service.

IV. Updates to the Quality Payment Program

A. CY 2024 Modifications to the Quality Payment Program

1. Executive Summary

a. Overview

This section of the proposed rule sets forth changes to the Quality Payment Program starting January 1, 2024, except as otherwise noted for specific provisions. We continue to move the Quality Payment Program forward, including focusing more on our measurement efforts and refining how clinicians would be able to participate in a more meaningful way, to achieve continuous improvement in the quality of health care services provided to Medicare beneficiaries and other patients through the Quality Payment Program's Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) for the CY 2024 performance period/2026 MIPS payment year.

Authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015), the Quality Payment Program is a payment incentive program, by which the Medicare program rewards clinicians who provide high-value, high-quality services in a cost-efficient manner. The Quality Payment Program includes two participation tracks for clinicians providing services under the Medicare program: MIPS and Advanced APMs. The statutory requirements for the Quality Payment Program are set forth in section 1848(q) and (r) of the Act for MIPS and section 1833(z) of the Act for Advanced APMs.

For the MIPS participation track, MIPS eligible clinicians (defined in 42 CFR at 414.1305) are subject to a MIPS payment adjustment (positive, negative, or neutral) based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. We assess each MIPS eligible clinician's total performance according to our established performance standards with respect to the applicable measures and activities specified in each of these four performance categories during a performance period to compute a final composite performance score (a ''final score'' as defined at § 414.1305). In calculating the final score, we must apply different weights for the four performance categories, subject to certain exceptions, as set forth in section 1848(q)(5) of the Act and at § 414.1380. Unless we assign a different scoring weight pursuant to these exceptions, for CY 2024 performance period/2026 MIPS payment year, the scoring weights are as follows: 30 percent for the quality performance category; 30 percent for the cost performance category; 15 percent for the improvement activities performance category; and 25 percent for the Promoting Interoperability performance category.

Once calculated, each MIPS eligible clinician's final score is compared to the performance threshold we have established in prior rulemaking for that performance period to calculate the MIPS payment adjustment factor as specified in section 1848(q)(6) of the Act, such that the MIPS eligible clinician will receive in the applicable MIPS payment year: (1) a positive adjustment, if their final score exceeds the performance threshold; (2) a neutral adjustment, if their final score meets the performance threshold; or (3) a negative adjustment, if their final score is below the performance threshold. The actual amount paid to the MIPS eligible clinician in MIPS payment year, once the MIPS payment adjustment factor is applied, is subject to further calculations such as application of the scaling factor and budget neutrality requirements, as further specified in section 1848(q)(6) of the Act.

Section 1848(q) of the Act sets forth other requirements applicable to MIPS, including opportunities for feedback and targeted review and public reporting of MIPS eligible clinicians' performance. Section 1848(r) of the Act sets forth more specific requirements for development of measures for the cost performance category under MIPS.

If an eligible clinician participates in an Advanced APM and achieves Qualifying APM Participant (QP) or Partial QP status, they are excluded from the MIPS reporting requirements and payment adjustment (though eligible clinicians who are Partial QPs may elect to be subject to the MIPS reporting requirements and payment adjustment). Eligible clinicians who are QPs for the 2023 performance year receive a 3.5 percent APM Incentive Payment in the 2025 payment year, and, beginning with the 2024 performance year (payment year 2026), a higher PFS payment rate (calculated using the differentially higher ''qualifying APM conversion factor'') than non-QPs. QPs will continue to be excluded from MIPS reporting and payment adjustments for the applicable year.

As we move into the seventh year of the Quality Payment Program, we are