American Hospital Association™
Advancing Health in America

Regulatory Advisory

Aug. 1, 2022

Medicare Physician Fee Schedule Proposed Rule for CY 2023

The Centers for Medicare & Medicaid Services (CMS) July 7 issued its physician fee schedule proposed rule for calendar year (CY) 2023. The rule also includes proposals related to the Medicare Shared Savings Program and the Quality Payment Program (QPP), both of which were created by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. Comments on the proposed rule are due to CMS by Sept. 6. The final rule will be published on or around Nov. 1 and policies generally take effect Jan. 1, 2023.

KEY HIGHLIGHTS

CMS' proposed policies would:

- Reduce the PFS conversion factor to $33.08 in CY 2023, as compared to $34.61 in CY 2022, which reflects: the expiration of the 3% statutory payment increase; a 0.0% conversion factor update; and a budget-neutrality adjustment.
- Delay for one year (until Jan. 1, 2024) CMS' implementation of its policy to define the substantive portion of a split (or shared) visit based on the amount of time spent by the billing practitioner.
- Provide advance shared savings payments to "low-revenue" ACOs that are both new to the MSSP and serve underserved populations, and also provide increased flexibility for these ACOs to share in savings.
- Provide ACOs with a more-gradual glide path to two-sided risk.
- Modify the ACO benchmarking methodology to help ensure that ACOs do not have to compete against their own best performance.
- Modify MSSP quality scoring by adopting a sliding scale for shared-savings eligibility, and adding a new health equity adjustment.
- Create a new bundled payment category for chronic pain management.
- Add five new Merit-Based Incentive Payment System Value Pathways for CY 2023.
- Increase the quality data completeness threshold.
- Revise objectives and measures in the MIPS Promoting Interoperability category.

AHA TAKE

The AHA is concerned with CMS' proposed payment update, which would reduce CY 2023 payments from their CY 2022 levels and, as a result, have a negative impact on patients' access to certain services. Our concern is heightened by the fact that this cut

is coming in the wake of nearly two years of unrelenting financial pressures on the health care system due to the ongoing COVID-19 public health emergency (PHE).

However, we are pleased that CMS is proposing to delay implementation of its split/shared visit policy, which would have resulted in a significant reduction in physician revenue on top of this proposed rule's other cuts. In addition, we are closely evaluating CMS's proposals on the MSSP, which reflect several priorities on which we have worked with the agency. For example, CMS states that its proposals are designed to help encourage providers to take on additional risk without penalizing those who need additional time and experience to do so.

WHAT YOU CAN DO

- Share this advisory with your chief medical officer, chief financial officer and other members of your senior management team, as well as key physician leaders and nurse managers.
- Assess the potential impact of the proposed payment and quality changes on your Medicare revenue and operations.
- **Submit comments to CMS with your specific concerns by Sept. 6 at www.regulations.gov.** The final rule will be published on or around Nov. 1, 2022, with policies contained within generally taking effect Jan. 1, 2023.

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CONVERSION FACTOR UPDATE

The proposed payment update for CY 2023 reflects several different factors, some of which are unique to this year so as to account for policy changes implemented last year. **Specifically, CMS proposes to cut the conversion factor to $33.08 in CY 2023, as compared to $34.61 in CY 2022.** This update includes: the expiration of a 3% increase in the PFS conversion factor for CY 2022 *only,* which was provided by the Protecting Medicare and American Farmers From Sequester Cuts Act; a 0% update factor as required by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015; and a budget-neutrality adjustment.

CHANGES TO PAYMENT FOR MEDICARE TELEHEALTH SERVICES

Category 3 Services. To assess requests for adding or deleting services from the Medicare telehealth list of services under Section 1834(m) of the Social Security Act, CMS historically assigned the requests to one of two categories. Category 1 services are similar to services that are currently on the Medicare telehealth list, whereas Category 2 services are not similar to services on the list, and, as such, CMS requires supporting evidence of its clinical benefit to add said service to the list.

In the CY 2021 PFS final rule, CMS added a *third* category of criteria for adding services to the Medicare telehealth list on a temporary basis. This "Category 3" describes services added during the PHE for which there is clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence to consider the services as permanent additions under Category 1 or Category 2 criteria. Any service added under Category 3 will remain on the Medicare telehealth services list through the calendar year in which the PHE ends; it would then need to meet the Category 1 or 2 criteria to be added on a permanent basis.

CMS previously finalized a policy to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023. However, in this rule, regarding services that are temporarily included on the telehealth list during the PHE, but not on a Category 1, 2, or 3 basis, the agency proposes to maintain these services on the list for 151 days following the end of the PHE, as required by the Consolidated Appropriations Act, 2022 (CAA, 2022).

In addition, CMS received several requests to permanently add services to the Medicare telehealth services list for 2023. Specifically, CMS proposes that certain services (as listed in Table 8 in the rule) be added to the telehealth list on a temporary Category 3 basis, such as psychophysiological therapy and an eye exam for an established patient. CMS believes that including these as Category 3 services will provide additional time for the development of evidence for potential permanent inclusion on to the telehealth list.

Statutory Telehealth Flexibilities. CMS proposes to implement the telehealth provisions in the CAA, 2022 through program instructions or other subregulatory

guidance. These provisions extend the following policies for 151 days after the PHE ends:

- waiving the geographic and originating site rules to allow telehealth services to be furnished in any geographic area and in any originating site setting, including the beneficiary's home;
- allowing certain services to be furnished via audio-only telecommunications systems;
- allowing physical therapists, occupational therapists, speech-language pathologists and audiologists to furnish telehealth services; and
- allowing continued payment for telehealth services furnished by FQHCs and RHCs using the methodology established during the PHE.

The CAA, 2022 also delays the in-person visit requirements for mental health services furnished via telehealth until 152 days after the end of the PHE.

Expiration of PHE Flexibilities for Direct Supervision Requirements. During the PHE, CMS allowed providers to satisfy "direct supervision" requirements for diagnostic tests, physicians' services and some hospital outpatient services through virtual presence, using real-time audio/video technology. In the CY 2021 PFS final rule, CMS finalized the continuation of this policy through the end of the calendar year in which the PHE ends *or* Dec. 31, 2021, whichever is later. In this rule, CMS continues to seek comment on whether it should make this flexibility permanent, including whether this should be allowed only for a subset of services.

PAYMENT FOR EVALUATION AND MANAGEMENT (E/M) VISITS

Split/Shared E/M Visits. A "split" or "shared" E/M visit is one that is performed by both a physician and a non-physician practitioner (NPP) in the same group. Because Medicare provides higher PFS payment for services furnished by physicians than those furnished by NPPs, CMS has addressed when physicians can bill for split visits. Specifically, physicians in a facility setting may bill for an E/M visit when both the billing physician and an NPP in the same group each perform portions of the visit, but only if the physician performs a "substantive" portion of the visit. If the physician does not perform a substantive part of the split visit and the NPP bills for it, Medicare will pay only 85% of the fee schedule rate.

In last year's rulemaking, CMS finalized a policy under which, for 2022, the "substantive portion" of non-critical care split (or shared) visits was defined as the performance of either: one of the three key components of a visit (history, physical exam or medical decision-making), or more than half of the total time performing the visit. For 2023 and beyond, the agency would define the substantive portion of the visit only as more than half of the total time spent. However, CMS now proposes delaying implementation of this policy for one year, until Jan. 1, 2024. Thus, for 2023, the substantive portion would continue to be defined as either: one of the three key components of a visit, or more than half of the total time.

Chronic Pain Management (CPM) Bundles. CMS proposes to create separate coding and payment for CPM services beginning Jan. 1, 2023. There is currently no existing CPT code that specifically describes the work of clinicians who performs comprehensive, holistic CPM; further, CMS believes that existing codes – for E/M, Chronic Care Management (CCM), Complex Chronic Care Management, and Principal Care Management – may not reflect all of the services and resources required to furnish comprehensive, chronic pain management to beneficiaries living with pain. Therefore, the agency proposes to establish a monthly payment bundle for the care of chronic pain, which is defined in the rule as "persistent or recurrent pain lasting longer than three months."

CMS proposes to create two new HCPCS G-codes. GYYY1 would cover services in a monthly bundle, including:

- Diagnosis
- Assessment and monitoring
- Administration of a validated pain rating scale or tool
- The development, implementation, revision and maintenance of a person-centered care plan that includes strengths, goals, clinical needs and desired outcomes
- Overall treatment management
- Facilitation and coordination of any necessary behavioral health treatment
- Medication management
- Pain and health literacy counseling
- Any necessary chronic pain related crisis care
- Ongoing communication and care coordination between relevant practitioners furnishing care

The add-on code, GYYY2, would cover each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional. To bill for this code, a physician or other qualified health professional would have to conduct an initial face-to-face visit of at least 30 minutes. Follow-up or subsequent visits could be non-face-to-face. CMS asks for comments on how best to conduct the initial visit and subsequent visits, e.g. in person or via telehealth; the agency also notes that it will consider whether to add the codes to the Medicare Telehealth Services list.

CMS acknowledges in the rule that patients often receive pain management services from their primary care physician, but treatment involves practitioners across the full spectrum of health providers (including pain management specialists). Thus, CMS proposes to permit one additional billing by another practitioner after HCPCS code GYYY1 has already been billed in the same calendar month by a different practitioner. In addition, CMS would allow CPM codes to be billed in the same month as another care management service, such as CCM or Behavioral Health Integration, as well as other bundled services such as those for opioid use disorders. However, CMS proposes

that these services could not be billed on the same date of service as CPT codes 99202-99215 (office/outpatient visits new). The proposed CPM codes would be limited to beneficiaries in office or other outpatient or domiciliary settings.

CMS also proposes to require that the beneficiary's verbal consent to receive CPM services at the initiating visit be documented in the beneficiary's medical record. CMS proposes to use the work RVU and PE inputs associated with CPT code 99424 (Principal care management services, for a single high-risk disease) to determine the value of GYYY1. CMS would value GYYY2 using a crosswalk to CPT code 99425 (each additional 30 minutes provided personally by a physician or other qualified health care professional), but at half the direct PE inputs associated with that code as GYYY2 covers only an additional 15 minutes.

However, the RHC all-inclusive-rate and the FQHC PPS amounts do not include the non-face-to-face time required to coordinate care in these services. As such, CMS generally proposes to allow for separate payment of these services. However, CMS proposes to pay the initial code (GYYY1), but not the add-on code (GYYY2) because RHCs and FQHCs do not pay their practitioners based on additional minutes spent by practitioners, as is the case for practitioners under the PFS.

New Coding and Payment for General Behavioral Health Integration (BHI) Billed by Clinical Psychologists (CPs) and Clinical Social Workers (CSWs). CMS proposes to create a new G code describing general BHI performed by CPs or CSWs. In previous rulemaking, the agency established codes to describe monthly services that enhance "usual" primary care by adding care management support and regular psychiatric inter-specialty consultation. Certain professionals, including CPs and CSWs, are not eligible to report the initiating visit codes for BHI services; however, these professionals sometimes serve as a primary practitioner that integrates medical care and psychiatric expertise. To improve access to care by removing barriers to treatment, CMS would create HCPCS code GBHI1. This code covers care management services for behavioral health conditions, at least 20 minutes of CP or CSW time, per calendar month, with the following required elements:

- initial assessment or follow-up monitoring, including the use of applicable validated rating scales;
- behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes;
- facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare law to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and
- continuity of care with a designated member of the care team.

As with other care management codes in the PFS, these services would be allowed under general supervision. CMS would value the code based on a crosswalk to CPT

code 99484. CPs are authorized to furnish and bill for services that are provided by clinical staff incident to their professional services, whereas CSWs would only be able to bill for services they furnish directly and personally. GBH1 could be billed during the same month as other care management bundles.

Under current BHI requirements, providers must conduct an initiating visit for new patients or beneficiaries not seen within a year of commencement of BHI services. Existing eligible initiating visit codes are not entirely within the scope of the CP's practice, so CMS proposes to allow a psychiatric diagnostic evaluation (CPT code 90791) to serve as the initiating visit for BHI.

"INCIDENT TO" PHYSICIAN SERVICES REGULATION FOR BEHAVIORAL HEALTH SERVICES

Currently, CMS does not pay separately for professional services of licensed professional counselors (LPCs) and licensed marriage and family therapists (LMFTs). Payment for these services can only be made under the PFS indirectly when an LPC or LMFT performs services under the *direct* supervision of the billing physicians or practitioner. To improve access to behavioral health care by making greater use of the services of LPCs and LMFTs, CMS proposes to allow behavioral health services to be furnished under the *general* supervision of a physician or NPP.

CHANGE IN PROCEDURE STATUS FOR FAMILY PSYCHOTHERAPY

CMS proposes to remove the restricted status indicator from the CPT codes that describe family psychotherapy and instead assign the code the Active indicator. Codes with the "R" restricted coverage indicator carry special coverage instructions; while they are payable under Medicare, the Medicare Administrative Contractor (MAC) may require certain documentation to provide coverage. Changing the status indicator from "R" restricted to "A" active does not mean that the family psychotherapy codes (90846 and 90847) are automatically covered – there are still national coverage determinations carrying documentation requirements and guidelines that the MAC can consider – but it could result in less scrutiny (or the automatic application of *restrictions*) for these services by MACs.

PAYMENT FOR VACCINE ADMINISTRATIVE SERVICES

CMS proposes to annually update the payment amount for the administration of Part B preventive vaccines (HCPCS codes G0008-G0010) based upon the increase in the Medicare Economic Index. CMS also proposes to adjust this payment amount geographically using the geographic adjustment factor (GAF). The agency also would update the $35.30 add-on payment for vaccine administration in the same manner. In addition, CMS proposes to update the $40 payment amount for COVID-19 vaccine administration using the MEI as long as the Emergency Use Authorization (EUA) declaration is still in place.

REVISING THE MEI

CMS is proposing to rebase and revise the MEI based on a methodology that uses publicly available data sources for input costs that represent all types of physician practice ownership. Currently, the MEI is based on data representing only self-employed physicians. The agency would not applying the new weights to its payment methodology, so the payment impact will not occur this year.

Under the agency's methodology, the portion of the MEI accounted for by practice expense would increase, while the portions accounted for by physician work and malpractice would decrease, as per the table below. While the proposed MEI is higher than the current MEI by 0.1 to 0.2 percentage points for any given year, changes in the component weighting could result in significant redistributions in payment. As such, while CMS is soliciting comments on its proposals to and methodology for rebasing and revising the MEI, it is not actually proposing to apply the new weights to its payment methodology in 2023.

Component	Current MEI	Proposed MEI
Physician Work	50.9%	47.3%
Practice Expense	44.8%	51.3%
Malpractice	4.3%	1.4%

RURAL HEALTH CLINICS AND FEDERALLY QUALIFIED HEALTH CENTERS

Provider-Based RHC Payment-Limit Per-Visit. Under the law, beginning April 1, 2021, a provider-based RHC is subject to a limit on its all-inclusive-rate (AIR). If the RHC was already subject to a per-visit limit in 2020, its 2021 AIR limit will be the higher of its base year limit (its 2020 AIR limit) increased by the MEI or the national per-visit limit. If the RHC was not already subject to a per-visit limit in 2020, its 2021 AIR limit will be the higher of its base year (its reasonable costs per visit) or the national limit. Subsequent limits for both categories of provider-based RHCs will equal the greater of the previous year's limit increased by the MEI or the national limit.

In the proposed rule, CMS clarifies how the base year limit will be determined for provider-based RHCs. For provider-based RHCs subject to a per-visit limit in 2020, the agency would use their cost report ending in 2020, as long as it is 12 consecutive months. If the RHC does not have a 12 consecutive month cost report ending in 2020, the agency would use the next most-recent final settled cost report that reports costs for 12 consecutive months.

For provider-based RHCs not already subject to a per-visit limit in 2020, the agency would use their cost report ending in 2021, as long as it is 12 consecutive months. If the RHC does not have a 12-consecutive-month cost report ending in 2020, the agency would use the next most-recent final settled cost report that reports costs for 12 consecutive months.

REQUIRING HOSPITAL OUTPATIENT DEPARTMENTS (HOPD) AND AMBULATORY SURGICAL CENTERS (ASC) TO REPORT DISCARDED AMOUNTS OF CERTAIN SINGLE-DOSE OR SINGLE-USE PACKAGE DRUGS

Currently, when a provider discards an unused portion of a drug from a single-dose container or single-use package, Medicare provides payment for the discarded amount as well as the dose administered, up to the amount of the drug indicated on the vial or package labeling. On a Medicare Part B claim, the JW modifier is a Healthcare Common Procedure Coding System (HCPCS) modifier used to report the amount of a drug that is discarded and eligible for payment. Beginning in 2017, in order to more effectively identify and monitor billing and payment for discarded amounts of drugs, CMS began to require the uniform use of this JW modifier for all claims for separately payable drugs with discarded drug amounts from single use vials or single use packages payable under Part B. The policy does not apply to drugs that are not separately payable, such as drugs packaged under the outpatient prospective payment system (OPPS) or drugs administered in the FQHC or RHC setting.

The Infrastructure Investment and Jobs Act requires drug manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. As such, the CY 2023 PFS proposed rule includes proposals to implement these provisions, including a proposal that HOPDs and ASCs be required to report the JW modifier, or any successor modifier, to identify discarded amounts of refundable single-dose container or single-use package drugs that are separately payable under the OPPS or ASC payment system.

Specifically, CMS proposes that, for the purpose of calculating the refund amount during a relevant quarter, the JW modifier would be used to determine the total number of billing units of the HCPCS code of a refundable single-dose container or single-use package drug; specifically those with HCPCS codes assigned status indicators “K” or “G” under the OPPS, that were discarded for dates of service during such quarter. The agency further proposes that the JW modifier would not be required to identify discarded amounts of drugs that are not separately payable, including OPPS drugs with HCPCS codes assigned a status indicator “N” and ASC drugs with HCPCS codes assigned a payment indicator of “N1”. Also, CMS proposes to exclude from the refund amount those units of drugs for which payment is packaged into a comprehensive ambulatory payment classification service, i.e. those with an OPPS status indicator of “J1” or “J2”. The JW modifier would not apply to drugs administered in the FQHC or RHC setting.

The agency is aware that although use of the JW modifier is currently required, it is often omitted on claims, and it is unclear whether its absence on a claim for a single-dose container drug indicates that there were no discarded amounts or that the modifier was incorrectly omitted from the claim. Therefore, CMS also proposes that HOPDs and ASCs use a separate new modifier, JZ, in cases where no billing units of such drugs

were discarded and for which the JW modifier would be required if there were discarded amounts.

Finally, CMS also proposes:

- For a drug to meet the definition of "refundable single-dose container or single-use package drug," all national drug codes assigned to the drug's billing and payment code must be single-dose containers or single-use packages, as described in each product's labeling.
- To implement other definitions and exclusions contained in the Infrastructure Investment and Jobs Act, specifically that the term "refundable single-dose container or single-use package drug" excludes drugs that are either radiopharmaceuticals or imaging agents, drugs that require filtration during the drug preparation process, and drugs approved on or after the date of enactment of the Infrastructure Act for which payment under Part B has been made for fewer than 18 months.
- That Medicare review contractors would periodically review Part B medication claims to ensure the JW modifier, JZ modifier and discarded drug amounts are billed appropriately consistent with the agency's normal claims audit policies and protocols.

CLINICAL LABORATORY FEE SCHEDULE (CLFS)

CLFS Revised Data Reporting Period and Phase-In of Payment Reductions. In accordance with the Protecting Medicare and American Farmers from Sequester Cuts Act, CMS proposes to make certain conforming changes to the CLFS data reporting and payment requirements, including changes to the definitions of the "data collection period" and "data reporting period" and changes to the agency's phase-in of CLFS payment reductions.

Laboratory Specimen Collection Fee. CMS proposes to codify and clarify various laboratory specimen collection fee policies, which are currently described only in the Medicare Claims Processing Manual. Specifically, CMS proposes:

- To maintain the collection fee of $3 for all specimens collected in a single patient encounter when collected from patients other than a patient in a skilled nursing facility (SNF) or by a laboratory on behalf of a home health agency (HHA).
- To maintain the collection fee of $5 for a specimen collected in a single patient encounter by a laboratory technician from an individual in either a SNF or by a laboratory on behalf of an HHA to a homebound patient.
- That the $5 fee for specimen collection would only be paid for an individual in a SNF or on behalf of an HHA when no qualified personnel are available at the facility to collect a specimen.
- That the specimen collection fee would only be paid for blood collected through venipuncture and urine through catheterization. The specimen collection fee

would not be payable for any other specimen types, for example, a throat culture or a routine capillary puncture for clotting or bleeding time.
- That for the specimen collection fee to be paid, it would be required to be drawn by a "trained technician."

Laboratory Specimen Collection Travel Allowance. CMS proposes to codify in regulations and make modifications and clarifications to the Medicare CLFS specimen collection travel allowance policies in order to improve and simplify the administration of this payment policy. Specifically, it states that laboratories should use HCPCS code P9604 to bill for the flat-rate travel allowance basis for shorter trips to one location, and HCPCS code P9603 to bill for the per-mile travel allowance basis for longer trips to one location and trips to multiple locations. This is intended to ensure payment for specimen collection services are based upon eligible miles required for such travel and address stakeholder concerns about the provision of specimen collection services for individuals residing in remote locations.

PROPOSED UPDATES TO MEDICARE'S OPIOID TREATMENT PROGRAM (OTP) BENEFIT

CMS proposes a few updates to the pricing methodology used for certain aspects of the bundled payment for episodes of care for the treatment of opioid use disorder furnished by OTPs.

Methadone Pricing. First, CMS proposes a revision to the methodology for pricing the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone. In previous rulemaking, the agency finalized a policy under which these payments would be updated annually using the most recent data available for either the average sales price (ASP) or the TRICARE rate. In late 2021, CMS found that available manufacturer-reported ASP data suggested an over 50% drop in ASP for oral methadone; however, CMS does not believe this voluntarily reported data is representative of actual utilization. In response, CMS issued an interim final rule with comment period that established a limited exception to the annual update and instead froze the payment amount for methadone furnished during an episode of care in CY 2022 at the previous (higher) amount. Commenters supported this policy, noting that cutting reimbursement for OTPs would have harmful consequences.

After considering alternative methods for calculating a payment amount for methadone in the OTP setting, CMS is proposing to base the payment amount for the drug component of HCPCS codes G2067 (Medicare assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed) and G2078 (take-home supply of methadone; up to seven additional-day supply; list separately in addition to code for primary procedure) for CY 2023 and subsequent years on the payment amount for methadone in CY 2021, and to update this amount annually to account for inflation using the Producer Price Index for Pharmaceuticals for Human Use (Prescription). CMS

estimates this would result in a payment amount of $39.29, but will update this amount in the CY 2023 PFS Final Rule if more recent data become available.

Rate for Individual Therapy. In previous rulemaking, CMS finalized its policy that would price the rate for individual therapy included in the non-drug component of the bundled payment for an episode of care based on a crosswalk to CPT code 90832, which describes 30 minutes of psychotherapy. Since then, CMS has received feedback indicating that this rate does not accurately reflect the resource costs involved with furnishing this service in the OTP setting, and that patients typically receive weekly 50-minute individual therapy sessions for the first several months of treatment. CMS thus proposes to instead base the rate for individual therapy on a crosswalk to CPT code 90832, which describes 45 minutes of psychotherapy, in order to account for the generally greater severity of needs of the patient population receiving services at OTPs.

Mobile Components Operated by OTPs. CMS proposes to amend regulatory language to clarify that it will apply geographic locality adjustment to payments for services furnished via mobile OTP units as if the service were furnished at the OTP registered with the U.S. Drug Enforcement Agency.

Use of Telecommunications for Initiation of Treatment with Buprenorphine. CMS proposes to allow OTPs to initiate treatment with buprenorphine via two-way audio-video communications, and via audio-only communication technology when audio-video technology is not available to the beneficiary. Currently, SAMHSA regulations require a complete physical evaluation before a patient begins treatment at an OTP; however, OTPs were granted the flexibility to initiate treatment via telehealth without first conducting an in-person evaluation for the duration of the PHE.

Given this and other flexibilities permanently afforded to OTPs to increase access to care, CMS believes it appropriate to permanently allow this mode of service as long as all other applicable requirements are met. In addition to this proposal, CMS seeks comment on whether it should allow period assessments to continue to be furnished using audio-only communication technology following the end of the PHE for patients receiving treatment with buprenorphine, methadone, or naltrexone.

REQUIREMENT FOR ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCE (ECPS) FOR PART D DRUGS UNDER A PRESCRIPTION DRUG PLAN OR MA-PD PLAN

In previous rulemaking, CMS finalized policies to implement section 2003 of the SUPPORT Act, which requires prescribers to use electronic prescribing for controlled substances under Part D. CMS will begin initial EPCS compliance actions on Jan. 1, 2023 by issuing non-compliance letters.

CMS proposes to use Prescription Drug Event (PDE) data from the evaluated year in determining compliance. As such, the agency proposes to determine compliance in CY 2023 based on CY 2023 PDE data, and will thus issue non-compliance letters the

following year. Accordingly, CMS proposes to use data from the evaluated year to determine whether a prescriber qualifies for a "small prescriber" (i.e. fewer than 100 controlled substance prescriptions for Part D drugs per calendar year).

CMS also proposes to use the address listed in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) to determine whether a prescriber qualifies for an exception for a declared emergency rather than the address listed in the National Council for Prescription Drug Programs (NCPDP) Pharmacy Database.

Finally, CMS seeks public comment on additional meaningful penalties to enforce the EPCS requirement. Such penalties would go into effect no sooner than Jan. 1, 2025. Options that CMS is considering include:

- requiring a non-compliant prescriber to enter into a corrective action plan and come into compliance within two years;
- posting a non-compliant prescriber's name on the CMS website;
- public reporting of EPCS compliance status on the Care Compare website;
- referring non-compliant prescribers to the DEA to support potential investigations;
- sharing the list of non-compliant prescribers with state-level entities; and
- referring consistent non-compliant prescribers for review for potential fraud, waste and abuse.

RFI ON INTENSIVE OUTPATIENT MENTAL HEALTH TREATMENT

CMS seeks comment on whether the current coding and payment mechanisms under the PFS adequately account for intensive outpatient services such as partial hospitalization programs and intensive outpatient programs (IOP), with the agency requesting feedback on whether there is a gap in coding that may be limiting access to these programs, and whether these gaps would be addressed by creating new codes, revaluing existing codes or revising particular billing rules. Generally, CMS asks for information about IOP services, including details on the settings for these programs, the range of services offered, types of practitioners that furnish the services, and other relevant information.

RFI ON PAYMENT FOR BEHAVIORAL HEALTH SERVICES UNDER THE PFS

CMS acknowledges that the PFS rate-setting methodology and application of budget neutrality may impact certain services, such as primary therapy and counseling services, more significantly than others; for example, for codes in which direct PE inputs for a service are very low, the valuation methodology may not allow for a site of service differential that accurately reflects the relative indirect costs involved in furnishing services in non-facility settings. Thus, the agency seeks comment on how it can adjust the rate-setting methodology to address the impact on behavioral health services paid under the PFS.

MEDICARE SHARED SAVINGS PROGRAM (MSSP)

CMS proposes numerous policy changes to the Medicare Shared Savings Program, many for which the AHA has advocated.

Advance Investment Payments (AIPs) for Certain ACOs. The agency states that ACOs treating underserved populations have stated that to be successful in the model they need upfront capital in order to make necessary investments. Therefore, the agency is proposing to make advance shared savings payments (referred to as AIPs) to certain ACOs participating in the MSSP. CMS proposes that ACOs meeting all of the following criteria would be eligible:

- not a renewing ACO or re-entering ACO;
- has applied to participate in the MSSP under any level of the BASIC track glide path (because this participation option is indicative of an ACO's inexperience with performance-based risk, in which ACOs are typically less experienced with risk and are more likely to benefit from up-front funding or ongoing financial assistance);
- eligible to participate in the MSSP;
- inexperienced with performance-based risk Medicare ACO initiatives; and
- designated a low-revenue ACO (defined as the ACO's Medicare Parts A and B FFS revenue equaling less than 35% of the Medicare Parts A and B FFS expenditures for its assigned beneficiaries).

Qualifying ACOs may receive a one-time fixed payment of $250,000, as well as quarterly payments for the first two years of the five-year agreement period. CMS also seeks comment on alternatives such as allowing the one-time payment to vary based on the number of assigned beneficiaries, the risk factors of the ACO's assigned beneficiary population, or both. The quarterly AIPs would be based on the number of assigned beneficiaries (capped at 10,000), adjusted by a risk factors-based score for each beneficiary, taking into account dual-eligibility status and the area deprivation index national percentile ranking of the census block group of the beneficiary's primary address.

AIPs would be recouped once the ACO begins to achieve shared savings, under the following terms:

- AIPs would be recouped from any shared savings earned by the ACO in any performance year (PY) until CMS has recouped all AIPs;
- if there are insufficient shared savings to recoup the AIPs in a PY, that remaining balance would be carried over to subsequent PY(s);
- CMS would not recover an amount of AIPs greater than the shared savings earned by an ACO in that PY; and
- if an ACO terminates its participation agreement during the agreement period in which it received an AIP, the ACO must repay all AIPs it received.

ACOs must use these payments to improve health care provider infrastructure, increase staffing, or provide accountable care for underserved beneficiaries, which may include addressing social needs. CMS proposes that the initial application cycle to apply for advance investment payments would occur during CY 2023 for a Jan. 1, 2024, start date.

Transition to Performance-based Risk. In response to feedback from AHA and other stakeholders that the MSSP requires too much risk too soon, CMS is proposing more-gradual transitions for certain ACOs. First, CMS proposes to modify the definition of "experience with performance-based risk Medicare ACO initiatives." Specifically, it would consider only Levels C through E of the BASIC track as "experience," not the one-sided Levels A and B. The agency would consider the five most recent PYs when assessing an ACO's status.

ACOs currently in the BASIC Track Level A or B, and those that begin a Track A or B agreement period on Jan. 1, 2023, would be able to elect to remain there for the remainder of their agreement period. ACOs beginning agreement periods on Jan. 1, 2024, would be able to participate in Level A, for all five years of the agreement period if the following requirements are met:

- The ACO is participating in its first agreement period under the BASIC track
- The ACO is not participating in an agreement period under the BASIC track as a renewing ACO or a re-entering ACO that previously participated in the BASIC track's glide path
- The ACO is inexperienced with performance-based risk Medicare ACO initiatives

These ACOs would generally be eligible for a second agreement period within the BASIC track's glide path, giving two additional years under one-sided models (Levels A and B), for a total of seven years before transitioning on to two-sided risk (Levels C, D and E).

CMS proposes that an ACO determined to be inexperienced with performance-based risk Medicare ACO initiatives, but not otherwise eligible to enter the BASIC track's glide path may enter either the BASIC track Level E for all PYs of the agreement period, or the ENHANCED track. An ACO determined to be experienced with performance-based risk Medicare ACO initiatives, would be permitted to complete the remainder of its current PY in a one-sided model of the BASIC track, but would be ineligible to continue participation in the one-sided model after the end of that PY. Instead, it would be automatically advanced to Level E of the BASIC track at the start of the next PY.

Finally, for agreement periods beginning on Jan. 1, 2024, and after, CMS proposes to allow an ACO to remain in Level E of the BASIC track indefinitely; participation in the ENHANCED track would be optional for all ACOs.

Modifications to ACO Benchmarks. CMS makes numerous proposals designed to improve the calculation of ACO benchmarks. It states that they are designed to help

ensure that high performing ACOs have incentives to remain in the program for the long-term, including by helping to ensure that an ACO does not have to compete against its own best performance.

Specifically, the agency would:

- incorporate a prospective, external trend factor in growth rates used to update the historical benchmark;
- adjust ACO benchmarks to account for prior savings;
- reduce the impact of the negative regional adjustment
- calculate county FFS expenditures to reflect differences in prospective assignment and preliminary prospective assignment with retrospective reconciliation;
- improve the risk adjustment methodology to better account for medically complex, high-cost beneficiaries and guard against coding initiatives; and
- increase opportunities for low-revenue ACOs to share in savings.

Trend Factor. To establish an ACO's historical benchmark for an agreement period, CMS uses historical expenditures for beneficiaries that would have been assigned to that ACO in the three most-recent years prior to the start of the agreement period. The per-capita costs for each benchmark year are then trended forward to current year dollars and a weighted average is used to obtain the ACO's benchmark. The benchmark is then updated each PY by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program.

In this rule, CMS proposes to incorporate a prospectively projected administrative growth factor, a variant of the United States Per Capita Cost (USPCC) referred to in the proposed rule as the Accountable Care Prospective Trend (ACPT), into a three-way blend with national and regional growth rates to update an ACO's historical benchmark for each PY in the ACO's agreement period. The agency believes that doing so would help insulate a portion of the annual update from any savings occurring as a result of the ACO actions and address the impact of increasing market penetration by ACOs in a region.

Adjusting Benchmarks to Account for Prior Savings. CMS proposes to incorporate an adjustment for prior savings that would apply when establishing benchmarks for renewing ACOs and re-entering ACOs that were reconciled for one or more PYs in the three years preceding the start of their agreement period. The agency states that such an adjustment would help to mitigate the benchmark rebasing ratchet effect issue that stakeholders have repeatedly raised concerns about. Furthermore, CMS believes that returning dollar value to benchmarks through a prior savings adjustment could help address an ACO's effects on expenditures in its regional service area.

CMS would adjust an ACO's benchmark based on the higher of either a prior savings adjustment or the ACO's positive regional adjustment; detailed calculations of each are

described in the rule. It would also use a prior savings adjustment to offset negative regional adjustments for ACOs that are higher spending compared to their regional service area.

Tables 55 through 58 in the rule present hypothetical examples of how the adjustment for prior savings would work in practice. In its simulations using 2020 data, CMS states that no ACOs would receive a lower benchmark and about 22% of all ACOs would receive a higher benchmark under this policy.

Negative Regional Adjustment. CMS proposes two policy changes designed to limit the impact of negative regional adjustments on ACO historical benchmarks and further incentivize program participation among ACOs serving high cost beneficiaries. Specifically, it proposes to reduce the cap on negative regional adjustments from negative 5% to negative 1.5% of national per capita expenditures for Parts A and B services under the original Medicare FFS program in the third benchmark year. It also proposes that after the cap is applied to the regional adjustment to gradually decrease the negative regional adjustment amount as an ACO's proportion of dual eligible Medicare and Medicaid beneficiaries increases or its weighted average prospective risk score increases.

The agency also seeks comment on two alternative benchmarking policies. Specifically, it requests feedback on excluding an ACO's own assigned beneficiaries from the population used in regional expenditure calculations, as well as on expanding the definition of the ACO regional service area to use a larger geographic area to determine regional FFS expenditures.

Differences in Assignment. In calculating regional FFS expenditures, CMS currently uses risk adjusted county-level FFS expenditures determined based on expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to the relevant benchmark or performance year. However, the agency believes this approach creates a systematic bias that favors ACOs under prospective assignment. As such, CMS proposes to calculate regional FFS expenditures using county-level values computed from a time-period consistent with an ACO's beneficiary assignment time-period for the performance year. It states that it believes this would remove the bias and bring greater precision to its calculation.

Risk Adjustment. Currently, CMS uses prospective hierarchical condition category (HCC) risk scores to adjust ACOs' benchmarks and account for changes in severity and case mix. However, the adjustment is subject to a cap of positive 3% for the agreement period. Stakeholders have raised concerns that this cap unfairly penalizes certain ACOs that may, for example, see higher volatility due to smaller sample sizes, or serve larger proportions of high-severity beneficiaries. Therefore, CMS is proposing to modify cap, such that an ACO's aggregate prospective HCC risk score would be subject to a cap equal to the ACO's aggregate growth in demographic risk scores between the last benchmark year and the performance year plus three percentage points.

Low-revenue ACOs. CMS proposes to provide more flexibility in how certain ACOs can qualify for shared savings. This change would apply to qualifying ACOs entering an agreement period in the BASIC track beginning on or after Jan. 1, 2024, including new, renewing, and reentering ACOs. Specifically, ACOs in the BASIC track that do not meet the minimum savings rate (MSR) requirement, but that do meet the quality performance standard would qualify for a shared savings payment if:

- The ACO has average per-capita Medicare Parts A and B fee-for-service expenditures below the updated benchmark
- The ACO is a low-revenue ACO at the time of financial reconciliation for the relevant performance year
- The ACO has at least 5,000 assigned beneficiaries at the time of financial reconciliation for the relevant performance year.

Eligible ACOs that meet the quality performance standard to share in savings at the maximum sharing rate, but do not meet the MSR, would instead receive half of the maximum shared rate (20% instead of 40% under Levels A and B, and 25% instead of 50% under Levels C, D, and E). For eligible ACOs that do not meet the quality performance standard required to share in savings at the maximum sharing rate, but meet the proposed alternative quality performance standard, the sharing rate would be further adjusted using a sliding scale approach.

Quality Performance Standard. MSSP policy requires ACOs to meet a minimum "quality performance standard" in order to be eligible for shared savings or avoid owing maximum losses. Currently, that standard is the 30th percentile of MIPS quality scores for CY 2023, and the 40th percentile for CY 2024 and beyond. In the proposed rule, CMS expresses concern that the current policy may lead to a "cliff" in which small differences in quality score – for example, between the 29th and 30th percentiles – could eliminate any possibility of shared savings, or lead to owing large amounts of shared losses.

Therefore, beginning in CY 2023, CMS proposes that ACOs that do not meet the minimum quality performance standard could still be eligible for shared savings (or owe shared losses) at a lower rate if they score at the 10th percentile or above on at least one of the four APM Performance Pathway (APP) outcomes measures used in the MSSP. The lower rates of shared savings/losses would be calculated on a sliding scale tied to the ACO's quality performance score. For ACOs in shared savings tracks, CMS would multiply the maximum sharing rate for the ACO's track by the ACO's quality performance score to determine the reduced rate of shared savings. ACOs in the ENHANCED track meeting the criteria described above would be subject to a shared loss rate of one minus the product of the maximum shared loss rate of the ENHANCED track and the ACO's quality performance score.

Extension of MIPS APP Reporting Incentive to CY 2024. Over the past two PFS final payment rules, CMS has adopted policies to phase out the use of CMS web interface measures in the MSSP after CY 2024, and replace them with the measures CMS

adopted for MIPS APP. To incentivize ACOs to transition to the use of the APP measure set, CMS established a temporary incentive that relaxed the quality performance standards for those ACOs that successfully report the electronic clinical quality measures/ MIPS clinical quality measures (eCQMs/MIPS CQMs) in the APP measure set. CMS previously established that CY 2023 would be the final year that the transitional incentive would be available.

However, in this rule, CMS proposes to extend the incentive to report the APP measure set through the CY 2024 performance period. CMS also solicits feedback on whether it should streamline its APP reporting incentive so that it only requires ACOs to meet the 10th percentile of performance on one of the four outcome measures in the APP to be eligible for maximum shared savings or avoid maximum losses for CYs 2023 and 2024. CMS proposed policies for applying its MSSP quality performance standard are detailed in the table below.

Proposed MSSP Reporting Requirement and Quality Performance Standard Policies – CY 2023 and beyond

Performance Year	Web Interface Option	APP Measure Option
2023	ACO meets all Web Interface data reporting and submission requirements and achieves quality performance score at or above the 30th percentile of all MIPS quality category scores. ACOs scoring below the 30th percentile could share savings/owe losses at reduced percentages (calculated on sliding scale) if they score at least the 10th percentile on one of the four outcome measures in the APP.	To encourage APP measure reporting, if ACO meets reporting requirements for all three MIPS CQM/eCQMs, ACO will meet the quality performance standard if it achieves a quality performance score of: • At least the 10th percentile on at least one of the four outcome measures in the APP measure set; -***and***- • At least the 30th percentile on at least one of the remaining five APP measures. ACOs that do not meet the above standard could share savings/owe losses at reduced percentages (calculated on sliding scale) if they score at least the 10th percentile on one of the four outcome measures in the APP.
2024	ACO meets all data reporting and submission requirements	To encourage APP measure reporting, if ACO reports all three

	and achieves quality performance score at or above the 40th percentile of all MIPS quality category scores. ACOs scoring below the 40th percentile could share savings/owe losses at reduced percentages (calculated on sliding scale) if they score at least the 10th percentile on one of the four outcome measures in the APP.	MIPS CQM/eCQMs, ACO will meet quality performance standard if it achieves a quality performance score of: - At least the 10th percentile on at least one of the four outcome measures in the APP measure set; -***and-*** - At least the 40th percentile on at least one of the remaining five APP measures. ACOs that do not meet the above standard could share savings/owe losses at reduced percentages (calculated on sliding scale) if they score at least the 10th percentile on one of the four outcome measures in the APP.
2025 and beyond	Not available	ACO meets all data reporting and submission requirements and achieves quality performance score at or above the 40th percentile of all MIPS quality category scores. ACOs scoring below the 40th percentile could share savings/owe losses at reduced percentages (calculated on sliding scale) if they score at least the 10th percentile on one of the four outcome measures in the APP.

Health Equity Adjustment. In the proposed rule, CMS expresses concern that the MSSP's quality measures and performance standard do not adequately incentivize ACOs to provide high quality care to "underserved" Medicare beneficiaries, and may not adequately guard against the avoidance of underserved patients in ACOs. The agency also is concerned that the MSSP quality measurement approach does not adequately account for the potential impact to quality scores of ACOs that serve large proportions of underserved patients.

CMS acknowledges the stakeholder feedback it has received suggesting that the agency risk adjust MSSP quality measures for demographic and social risk factors. However, CMS states its belief that directly risk adjusting its quality measures for these

factors could either mask differences in quality by those factors, or unintentionally set a lower standard of quality for underserved populations.

In this context, CMS proposes to adopt a "health equity adjustment" beginning with the CY 2023 performance period that it believes would better support those ACOs caring for large proportions of underserved patients while incentivizing high quality care for all populations that ACOs serve. CMS proposes to add up to 10 bonus points to the quality performance score of each ACO based on a combination of its performance on each MSSP quality measure and the proportion of its underserved beneficiaries.

The resulting health equity-adjusted quality performance score would be used to determine whether ACOs meet the MSSP quality performance standard. Importantly, the bonus points would be available to only those ACOs that report the APP measure set.

The MSSP health equity adjustment would be determined in the following way:

Step 1: Calculate the ACO's measure performance scaler. CMS would determine each ACO's performance on each individual measure in the MSSP. Then, for each measure, ACOs would be placed into one of three "performance groups" representing the top, middle and bottom third of performance on the measure. ACOs would receive a value of four for each measure in the top third of performance, two for each measure in the middle third, and zero for each measure in the bottom third. CMS would sum the value assigned to each measure to determine the measure performance scaler, and the maximum value of the scaler would be 24. The table below drawn from the proposed rule includes an example of how the measure performance scaler calculation would work for six hypothetical ACOs.

Example of Measure Performance Scaler Determination

Measure (MIPS#)	**ACO 1 and 2 – High Measure Performance**		**ACO 3 and 4 – Middle measure performance**		**ACO 5 and 6 – Low Measure Performance**	
	Performance Group	*Value*	*Performance Group*	*Value*	*Performance Group*	*Value*
321	Top Third	4	Top third	4	Middle third	2
479	Top Third	4	Middle third	2	Bottom third	0
484	Top Third	4	Middle third	2	Bottom third	0
001	Top Third	4	Top third	4	Bottom third	0
134	Top Third	4	Top third	4	Middle third	2
236	Top Third	4	Middle third	2	Middle third	2
	Total Value per ACO	24	*Total Value per ACO*	18	*Total Value per ACO*	6

Step 2: Calculate the ACO's underserved multiplier. The underserved multiplier would be a proportion between 0 and 1 that reflects the higher of two calculations:

- The proportion of the ACO's performance year assigned beneficiary population residing in a census block group with an area deprivation index (ADI) percentile rank of at least 85; or
- The proportion of the ACO's performance year assigned beneficiary population that are dually eligible for Medicare and Medicaid.

CMS would require the underserved multiplier to be at least 0.2 (20%) in order to receive health equity adjustment bonus points.

As described in the AIP section of this advisory, the ADI is NIH-developed composite measure of social risk derived from the US Census Bureau's American Community Survey. It includes 17 different input variables (shown in the table below) on education, income/employment, housing and household characteristics that are calculated at the census block level. The ADI is a relative score that is reported by nationwide percentile (1-100) or statewide decile (1-10), with higher scores indicating a greater disadvantage.

CMS proposes to use each assigned beneficiary's most recent mailing address to determine their census block and thereby determine their ADI percentile rank. CMS also proposes to use the most recently available version of the ADI, which is currently from 2019.

Area Deprivation Index Input Variables from Census Data

Domain	Variable
Education	% population aged 25 years and older with less than nine years of education % population aged 25 years and older with at least a high school diploma % employed population aged 16 years or older in white collar occupations
Income/ Employment	Median family income (in US dollars) Income disparity % families below Federal poverty level (FPL) % population below 150% of FPL % Civilian labor force population aged 16 years and older who are unemployed
Housing	Median home value (in US dollars) Median gross rent (in US dollars) Median monthly mortgage (in US dollars) % owner occupied housing units % occupied housing units without complete plumbing
Household Characteristics	% single parent households with children younger than 18 % households without a motor vehicle % households without a telephone

	% households with more than one person per room

Using the same hypothetical example in the table above, the table below provides an example of how the underserved multiplier would be determined for six different ACOs.

Example of Underserved Multiplier Determination

	[A] Proportion of Assigned Beneficiaries with ADI above 85th percentile	[B] Proportion of assigned beneficiaries that are dual eligible	Underserved Multiplier (higher of A or B)
ACO 1	0.4	0.6	0.6
ACO 2	0.1	0.2	0.2
ACO 3	0.3	0.3	0.3
ACO 4	0.1	0.1	N/A (below 0.2)
ACO 5	0.8	0.6	0.8
ACO 6	0.2	0.1	0.2

Step 3: Calculate the ACO's health equity adjustment bonus points. This calculation would be the product of the ACO's measure performance scaler and the equity multiplier. The table below provides an example of this calculation using the same hypothetical ACOs as above.

Example of Health Equity Adjustment Bonus Points Calculation

	[A] Measure Performance Scaler	[B] Underserved Multiplier	Health Equity Adjustment Points (A x B)
ACO 1	24	0.6	10
ACO 2	24	0.2	4.8
ACO 3	18	0.3	5.4
ACO 4	18	N/A	N/A
ACO 5	6	0.8	4.8
ACO 6	6	0.2	1.2

Step 4: Add the health equity adjustment bonus points to the ACO's quality performance score to determine the health equity adjusted quality performance score. The table below provides an example of this calculation using the same hypothetical ACOs as above.

Example of Application of Health Equity Adjustment Bonus Points to Quality Performance Scores

	[A] Quality Performance Score	[B] Health Equity Adjustment Bonus Points	Health Equity-adjusted Performance Score

			(A+B)
ACO 1	90	10	100
ACO 2	90	4.8	94.8
ACO 3	85	5.4	90.4
ACO 4	85	N/A	85
ACO 5	60	4.8	64.8
ACO 6	60	1.2	61.2

Administrative Requirements. CMS sets forth proposals related to ACO marketing materials and beneficiary notification requirements, as well as refinements to the SNF 3-day rule waiver process. Specifically, the agency would eliminate the requirement for an ACO to submit marketing materials to CMS for review and approval prior to their dissemination. In addition, it proposes to reduce the frequency with which beneficiary information notices are provided to beneficiaries from annually to a minimum of once per agreement period. However, at the beneficiary's next primary care service visit or no later than 180 days after the notice has been provided, the beneficiary must be given a meaningful opportunity to engage with an ACO representative and to ask questions. The follow-up communication opportunity may be verbal or written, but must be tracked and documented, and does not create a billable service.

CMS also proposes to streamline the process by which an ACO that bears two-sided risk can request a waiver of the SNF three-day rule. Specifically, it would eliminate the requirement that the ACO submit three narratives with its application: communications plan, care management plan, and beneficiary evaluation and admission plan. The ACO, however, would be required to provide narrative materials about its capacity to manage patients under the waiver upon request.

Requests for Information (RFIs). In the proposed rule, CMS includes RFIs on potential future quality measures for the MSSP program. This includes the potential inclusion of the health-related social needs (HRSN) screening measure that CMS has proposed for the MIPS in this rule, and for hospitals in the fiscal year 2023 inpatient prospective payment system rule. Additional details on this measure are provided in the MIPS section of this advisory.

CMS also solicits comment on adding survey questions to the Consumer Assessment of Healthcare providers and Systems (CAHPS) for MIPS survey related to health disparities and price transparency. The items are as follows:

Health Disparities: In the last six months, did anyone from a clinic, emergency room or doctor's office where you got care treat you in an unfair or insensitive way because of any of the following things about you: health condition, disability, age, culture, sex (including sexual orientation and gender identify) and income?

Price Transparency: In the last six months, did you and anyone on your health care team talk about how much your prescription medicines cost?

CMS believes the disparities-related question would align with the agency's framework for advancing health equity, and potentially identify important patient insights into how they feel they are being treated in health care interactions. CMS also believes that the disparities question, when combined with the request related to transparency, would help support the agency's implementation of the No Surprises Act. CMS indicates that the No Surprises Act requires them to "ensure that all individuals, particularly those from underserved and minority communities, trust and believe the information they receive related to healthcare costs and coverage."

CHANGES TO THE QUALITY PAYMENT PROGRAM

The rule proposes updates to the requirements of the QPP for physicians and other eligible clinicians mandated by the MACRA. The QPP includes two tracks – the default Merit-based Incentive Payment System (MIPS) and advanced alternative payment models (APMs). Most of the rule's proposed policies apply to what eligible clinicians must report for the QPP's 2023 performance period, which affects eligible clinicians' payment under the Medicare PFS in CY 2025.

In this rule, CMS proposes updates to its policies for MIPS Value Pathways (MVPs). CMS also proposes updates to the requirements of each MIPS category, and minor changes to the requirements of the Advanced APM track. To supplement the proposed rule, CMS has provided detailed summaries of the proposed policy changes on its QPP resource website.

Overview of the MIPS. Eligible clinicians participate in the MIPS either as individuals or as groups. Individual eligible clinicians are defined as a single clinician identified by national provider identifier (NPI) tied to single tax identification number (TIN). Groups are defined as two or more clinicians – as identified by NPI – that have reassigned their billing rights to a single TIN.

CMS assesses performance on four categories: quality measures, cost/resource use measures, improvement activities and promoting interoperability. Each MIPS performance category has a weight, as outlined below in Table 1. The Bipartisan Budget Act (BBA) of 2018 permits CMS to adopt a more gradual increase of the weight of the MIPS cost category – with corresponding decreases to the quality category. The BBA requires the equal weighting of cost and quality categories at 30% each starting with the CY 2024 payment year.

Table 1: MIPS Performance Category Weights

MIPS Performance Category	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024 and beyond[s]
Quality	60%	50%	45%	45%	40%	30%

MIPS Performance Category	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024 and beyond[S]
Cost / Resource Use	0%	10%	15%	15%	20%	30%
Improvement Activities	15 %	15%	15%	15%	15%	15%
Promoting Interoperability	25%	25%	25%	25%	25%	25%

S = Statutory requirement

CMS combines the scores across the categories to create a MIPS "final score." Based on their MIPS final score, eligible clinicians and groups will receive positive, neutral or negative payment adjustments under the Medicare PFS of up to 9% in CY 2022 and beyond.

The MIPS has evolved over the past several years beyond what CMS now calls the "Traditional MIPS" program to include multiple pathways for participation. This includes the APM Performance Pathway for clinicians and groups participating in APMs that meet CMS's criteria, and MIPS Value Pathways, which are described in more detail in the next section of this advisory.

MIPS Value Pathways (MVPs). In prior rulemaking, CMS adopted a framework for MVPs that the agency intends as a replacement for the current MIPS. MVPs organize the measure and reporting requirements for each MIPS category around specific medical conditions, clinical specialties or episodes of care. CMS has indicated it belief that MVPs would improve upon the "traditional MIPS" program by providing a "more cohesive participation experience" by aligning MIPS reporting requirements around specific topics.

In this rule, CMS proposes five additional MVPs that would be available beginning with the CY 2023 performance period: cancer care, kidney health, episodic neurological conditions, neurodegenerative conditions and promoting wellness. CMS also proposes updates to the seven MVPs that it adopted in last year's PFS final rule. Appendix 3 of the proposed rule includes the details of the measures included in each previously finalized and proposed MVP. CMS also proposes modifications to its processes for establishing and scoring MVP "subgroups" within larger physician practices.

MVP Development and Maintenance Processes. In prior rulemaking, CMS adopted several criteria to guide its development, implementation and maintenance of MVPs. In this rule, CMS proposes to adopt a process to obtain feedback on candidate MVPs in advance of formal rulemaking. Draft versions of MVP could be posted to the QPP website for 30 days, and CMS would use the feedback to determine whether additional changes to the MVP are need before formally proposing it. In addition, CMS clarifies its MVP development guidance to encourage the development of MVPs that involve multiple clinician types. Lastly, CMS proposes to, when feasible, host an annual public webinar to obtain input on potential revisions to previously established MVPs.

MVP Eligibility. In prior rulemaking, CMS adopted a phased approach by which eligible clinicians and groups could opt into participating in MVPs. For the CY 2023 through CY 2025 performance periods, CMS will allow the following types of MIPS-eligible clinicians to participate:

- Individual clinicians
- Single specialty groups, which CMS proposes to define as a group in which the eligible clinicians have only one specialty type
- Multi-specialty groups, which CMS proposes to define as a group that consists of eligible clinicians from two or more specialty types
- Subgroups of multi-specialty groups
- APM entities that are assessed on an MVP for all MIPS performance categories

The formation of subgroups will be optional for multi-specialty practices for the CY 2023 through CY 2025 performance periods. However, beginning with the CY 2026 performance period, CMS will require that any multi-specialty group practices that wish to participate in MVPs form subgroups.

In this rule, CMS proposes as the data source for specialty determination to use Medicare part B claims, rather than the Medicare Provider Enrollment, Chain and Ownership System (PECOS).

MVP Subgroup Registration. In prior rulemaking, CMS created the processes for establishing and registering subgroups for MVP participation. These processes remain largely unchanged, but with two modifications. First, CMS would require subgroups to provide a description of the composition of the subgroup at the time of registration. CMS would allow registrants to write their own narratives, or select from a list of available descriptions. Second, CMS proposes that clinicians may only register for one subgroup per TIN. CMS notes that it wants to encourage flexibility in how clinicians may form subgroups in order to support team-based care approaches.

MVP Subgroup Scoring. Last year, CMS adopted policies for how each MIPS category would be scored for MVP subgroups. In this rule, CMS proposes changes to how it would calculate performance for subgroups on measures that are calculated using administrative claims. In general, CMS proposes to assign the subgroup its larger affiliate group's scores for measures in the MVP foundational layer, as well as measures in the quality and cost categories.

MIPS Quality Category. For CY 2023 quality reporting, CMS is carrying over most previously adopted requirements and scoring approaches. However, in addition to updating the inventory of available quality measures, CMS adopts several notable changes to reporting requirements and category scoring.

Definition of High Priority Measure. CMS proposes to expand its definition of high priority measures to include health equity-related measures. Consistent with change, CMS also has proposed a new health-related social needs screening measure that

would be available beginning with the CY 2023 reporting period. Under the traditional MIPS program, clinicians and groups are required to report a total of six quality measures, of which at least one must be an outcome or other high priority measure.

Measure Benchmarks. Under current MIPS policy, quality measure benchmarks are based on data from two years prior to the performance period, unless those data are unavailable. In those cases, CMS would use data from the performance period itself to establish quality measure benchmark scores.

In this rule, CMS that performance period benchmarks for administrative claims-based measures would be based on the performance period itself. CMS believes this approach would allow it to use more current data to calculate measure performance without additional burden to providers since the measures are calculated by CMS.

Data Completeness. Current MIPS policy requires MIPS participants to report performance data on at least 70% of denominator-eligible encounters for each quality measure. For the CY 2024 and 2025 performance periods, CMS proposes to raise the data completeness threshold to 75%. CMS believes this approach would ensure the MIPS program uses complete, accurate data.

CAHPS for MIPS Case Mix Adjustment. The CAHPS for MIPS measure includes adjustment for patient characteristics that could affect how patients respond to surveys. Under current MIPS policy, the case mix adjustment for the measure includes the following variables: age; education; self-reported health status; self-reported mental status; Medicaid dual-eligibility; proxy response; eligibility for Medicare's low-income subsidy; and Asian language survey completion.

However, CMS proposes to broaden the language adjustor to include any language other than English spoken at home. CMS believes this approach will more broadly capture the experiences and response patterns of patients that may have similar experiences interacting with the health care system (i.e., not speaking English as their primary language at home).

MIPS Cost Category. CMS proposes no new measures for the MIPS cost category, and minimal changes to the category's requirements. However, to conform to statutory requirements, CMS proposes to establish a cost improvement score of up to 1 percentage point starting with the CY 2022 performance period. CMS previously established an improvement score methodology for the cost category, but had not tied any improvement points to it because of the requirements of the Bipartisan Budget Act of 2018 that did not allow CMS to reward providers for improved performance using data from years two through five of the MIPS program.

MIPS Improvement Activity Category. The MACRA requires that CMS establish a MIPS performance category that rewards participation in activities that improve clinical practice, such as care coordination, beneficiary engagement and patient safety. Most of the requirements for the improvement activity category finalized in prior rulemaking

would carry over for CY 2022 and beyond. As it does each year, CMS proposes updates to the improvement activity inventory by adding four new improvement activities, modifying five activities, and removing six activities.

MIPS – Promoting Interoperability Category. For CY 2023, CMS is proposing several changes to the Promoting Interoperability performance category. These changes mirror many of the same changes that CMS proposed for the hospital Promoting Interoperability program in the FY 2023 Inpatient PPS proposed rule.

Query of Prescription Drug Monitoring Program Measure. CMS proposes to require the reporting of the Electronic Prescribing objective's Prescription Drug Monitoring Program (PDMP) measure. The measure would continue to have 10 points associated with its reporting, but would no longer be considered bonus points. The proposal would require a "yes/no" response. In addition, CMS proposes to expand the measure to include Schedule II, III and IV drugs, instead of just Schedule II drugs. CMS believes this expansion would facilitate more informed prescribing practices and improve patient outcomes. CMS also believes it support HHS initiatives related to the treatment of opioid and substance use disorders by expanding the types of drugs included in the Query of PDMP measure while aligning with the PDMP requirements in a majority of states.

Of note, CMS would exclude any clinician that is unable to electronically prescribe Schedules II opioids, and Schedule III and IV drugs in accordance with applicable law. In addition, CMS would exclude any MIPS eligible clinician that writes fewer than 100 permissible prescriptions during the performance period.

New Trusted Exchange Framework and Common Agreement (TEFCA) Measure in the Health information Exchange (HIE) Objective. CMS proposes to add a new Enabling Exchange under the TEFCA measure as an optional alternative to fulfill the objective, beginning with the CY 2023 EHR reporting period. With this proposed change, MIPS eligible clinicians would have three reporting options for the Health Information Exchange Objective:

a) report on both the Support Electronic Referral Loops by Sending Health Information measure (or the exclusion, if applicable) and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure (or the exclusion, if applicable);
b) report on the HIE Bi-Directional Exchange measure; or
c) report on the proposed Enabling Exchange Under TEFCA measure. We propose the Enabling Exchange Under TEFCA measure would be worth the total amount of points available for the Health Information Exchange Objective.

Levels of Active Engagement for Measures in Public Health and Clinical Data Exchange Objective. CMS proposes to consolidate the current options for "active engagement" from three to two levels:

- Option 1: Pre-production and validation (which combines current “Option 1” that reflects completed registration to submit data, and current option 2, which reflects testing and validation of data);
- Option 2: Validated data production (current option 3: production).

CMS does not make substantive changes to the individual options or requirements for selecting the individual options. CMS would also require the reporting of the level of active engagement for the measures under the objective beginning with the CY 2023 EHR reporting period.

CMS also proposes that MIPS eligible clinicians may spend only one performance period at the Pre-production and Validation level of active engagement per measure, and that they must progress to the Validated Data Production level in the next performance period for which they report a particular measure.

Scoring Methodology. CMS proposes several changes to points for each meaningful use objective. CMS would increase the points associated with the Electronic Prescribing objective from 10 to 20 points given that the Query of PDMP measure is being converted into a required measure. CMS also proposes to increase the number of points associated with the Public Health and Clinical Data Exchange objective from 10 to 25 points. CMS would reduce the points associated with the Health Information Exchange objective from 40 to 30 points, and the Provider to Patient Exchange objective from 40 to 25 points. These changes are summarized in the table below.

Proposed MIPS Promoting Interoperability Category Scoring Methodology for the CY 2023 EHR Reporting Period

Objective	**Measures (Reflects CY 2023 Proposals)**	**Current Maximum Points**	**Proposed Maximum Points**
Electronic Prescribing	e-Prescribing	10 points	10 points
	Query of PDMP	10 points (bonus)	10 points (required)
Health Information Exchange (HIE)	Support Electronic Referral Loops by Sending Health Information	20 points	15 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	20 points	15 points
	-OR-		
	HIE Bi-Directional Exchange	40 points	30 points
	-OR-		

	Enabling Exchange under TEFCA	N/A	30 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points	25 points
Public Health and Clinical Data Exchange	Report the following two measures: • Immunization Registry Reporting • Electronic Case Reporting	10 points	25 points
	Report one of the following 2 measures: • Syndromic Surveillance Reporting • Public Health Registry Reporting • Clinical Data Registry Reporting	5 points (bonus)	5 points (bonus)

CMS also proposes to continue to reweight the Promoting Interoperability performance category for certain types of non-physician practitioner MIPS eligible clinicians. This includes physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians, clinical social workers or nutrition professionals. However, CMS would not continue the reweighting policy for nurse practitioners, physician assistants, clinical nurse specialists and certified registered nurse anesthetists.

Request for Information on Patient Access to Health Information Measure. CMS is requesting public input on how to further promote equitable patient access and use of their health information without adding unnecessary burden on the MIPS eligible clinician or group. Specifically, CMS seeks information on tools found to be useful in promoting patient access and use of their health information, strategies to address existing bias in EHRs, common barriers to patient access and use of their health information, solutions for the disparate patient portal landscape, and the status of the API and app ecosystem.

Request for Information- Advancing the Trusted Exchange Framework and Common Agreement. CMS believes that health information exchange enabled by the Trusted Exchange Framework and Common Agreement (TEFCA) can advance CMS policy and program objectives related to care coordination, cost efficiency, and patient-centered care. Notably, the Common Agreement includes an expanded set of Exchange Purposes than are supported by most nationwide exchange today. These include

Treatment, Individual Access Services, Payment, Health Care Operations, Public Health, and Government Benefits Determination.

As noted above, CMS proposes to add a new measure to the Promoting Interoperability performance category called "Enabling Exchange Under TEFCA". Through this new measure, MIPS eligible clinicians can earn credit for the Promoting Interoperability performance category's Health Information Exchange objective if they participate in secure, bi-directional exchange, governed by the Common Agreement, for all unique patients of eligible clinicians, and all unique patient records stored or maintained in the EHR and use the functions of Certified Electronic Health Record Technology (CEHRT) to support bi-directional exchange. However, CMS is exploring additional levers to incentivize exchange under TEFCA through other programs which incentivize high quality care. CMS seeks public input on what use cases can be enabled through TEFCA, how CMS should approach incentivizing information exchange under TEFCA, and any barriers to or concerns about enabling exchange under TEFCA.

Request for Information - Continuing to Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs. In the CY 2022 PFS final rule, CMS stated their aim to move completely toward digital quality measurement in CMS quality reporting and value-based purchasing programs via an incremental approach. CMS seeks public input on the transition to digital quality measurement including: a definition of a digital quality measure (dQM) and feedback on potential considerations for harvesting data from non-EHR data sources; specific FHIR implementation guides under consideration; and transitioning to FHIR-based eCQM reporting. Future notice-and-comment rulemaking must take place to change specific program requirements related to how MIPS eligible clinicians provide data for quality measurement and reporting.

MIPS Final Performance and Payment Adjustment Approach. As required by the MACRA, CMS calculates a final composite score of zero to 100 points for each eligible clinician and group in the MIPS. The MIPS final score is used to determine whether the clinician or group receives positive, neutral or negative payment adjustments under the MIPS. CMS carries over most aspects of the scoring approach finalized in the CY 2018 QPP final rule. The AHA's 2018 QPP Final Rule Regulatory Advisory includes more details on the approach. In this rule, CMS proposes mostly minor methodology changes.

Complex Patient Bonus. Since the CY 2018 performance period, CMS has calculated a "complex patient bonus" to better account for the clinical and sociodemographic differences across patient populations. CMS updated the methodology of the complex patient bonus in the CY 2022 PFS final rule to award up to 10 points to the MIPS final scores of clinicians and groups based on their standardized hierarchical condition category (HCC) scores and their ratio of patients dually eligible for Medicare and Medicaid.

Starting with the CY 2023 MIPS performance year, CMS proposes to allow facility-based MIPS eligible clinicians to receive the complex patient bonus even if they do not submit data on at least one MIPS performance category. This approach would align with the policy used for groups and APM entities.

The proposed rule also includes a request for comment on whether CMS should include additional or different indicators of medical and social risk in calculating the complex patient bonus. For example, CMS asks whether the ADI it is using to calculate the MSSP's health equity adjustment should be used in the MIPS complex patient bonus.

Facility-based Measurement. Beginning with the CY 2019 QPP, facility-based clinicians have the option of having their MIPS quality and cost scores tied to their hospital's CMS value-based purchasing (VBP) program total performance score (TPS). For the most part, CMS's approach to facility-based measurement is unchanged from prior rulemaking with one change. CMS previously finalized that clinicians and groups meeting the eligibility criteria for facility-based measurement would be scored using the facility-based measurement methodology unless they received a higher combined MIPS cost and quality category score using another MIPS data submission.

This approach basic approach remains unchanged. However, starting with the CY 2023 performance period, CMS proposes to permit facility-based measurement for virtual groups as long as 75% or more of its clinicians meet the definition of a facility-based MIPS eligible clinician.

MIPS Final Score Thresholds. MACRA requires CMS to implement MIPS payment adjustments in a budget-neutral manner. That is, the agency may not pay out more in incentive payments than it recoups in penalties. For payment years 2019 through 2024, CMS is required to pay out $500 million each year in "exceptional performance bonuses" to groups that perform exceptionally well on the MIPS. This exceptional performance bonus is above and beyond the budget-neutral MIPS payment adjustment.

As outlined in Figure 1, CMS is required by law to identify two final score thresholds to translate MIPS final scores into a payment adjustment:

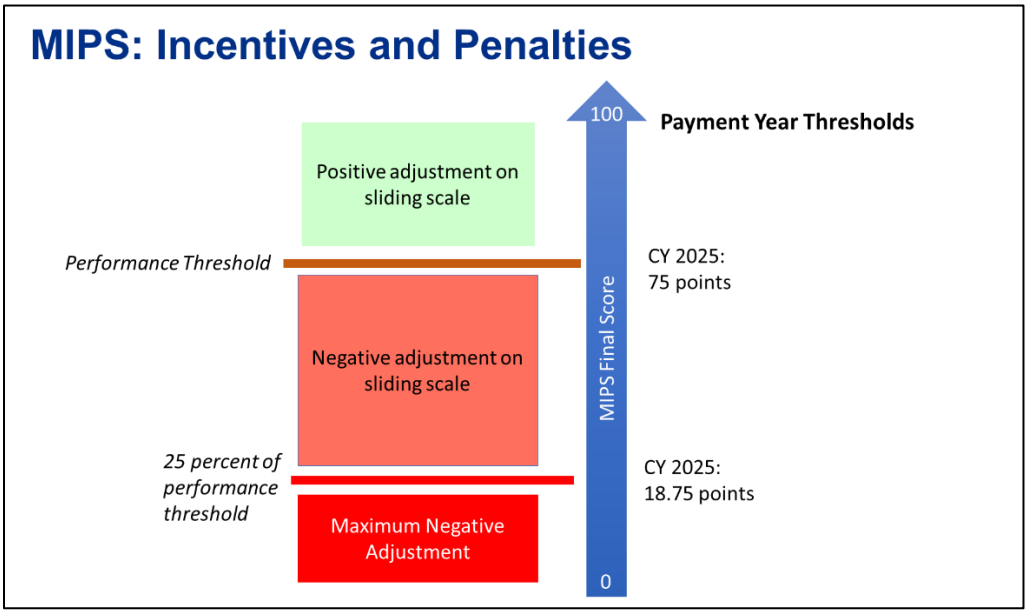
- **A performance threshold** *above which* there are positive payment adjustments on a sliding scale, and *below which* there are negative payment adjustments on a sliding scale. The MACRA requires that CMS publish this number prior to the start of the performance period so that MIPS participants know what level of performance is expected in order to receive positive or negative adjustments. For the CY 2024 MIPS payment adjustments, the performance period is CY 2022.

- For the CY 2023 performance/CY 2025 payment years, CMS proposes to retain the 75-point performance threshold it set for CY 2022 performance/CY 2024 payment year. As required by law, beginning with the CY 2022 performance period, CMS must set the performance threshold at the either the mean or median MIPS performance score from a prior payment adjustment year. In this

case, CMS chose the CY 2019 payment year because it results in a more gradual increase than the alternatives.

- **25% of the performance threshold final score,** *at or below which* MIPS-eligible clinicians and groups receive the maximum negative payment adjustment (-9% in CY 2025). As a result, this score would be 18.75 points beginning for the CY 2023 performance/CY 2025 payment years.

Figure 1: Translating MIPS Final Score into Payment Adjustments
CY 2025 Payment Year



Advanced APMs. The MACRA provides incentives for physicians who participate in advanced APMs. These include a lump-sum bonus payment of 5% of payments for professional services in 2019 through 2024; exemption from MIPS reporting requirements and payment adjustments; and higher base payment updates beginning in 2026. In 2016, CMS finalized the criteria by which clinicians will be determined to be qualified APM participants to receive these incentives.

Advanced APM criteria and processes largely carry over from prior rulemaking with two key updates starting with the CY 2023 performance year:

- *Generally Applicable Nominal Risk Standard.* CMS proposes to make permanent its 8% generally applicable nominal financial risk standard for Advanced APMs. The standard had been set to expire after CY 2024, but in prior rulemaking, CMS indicated it would reevaluate the standard to ensure the amount of financial risk remained sufficiently high. CMS believes the standard remains appropriate for advanced APM participants.

- *Medical Home Clinician Limit.* Per the MACRA statute, participants can qualify as advanced APMs if they participate in certain qualifying medical homes. CMS adopted a relaxed nominal financial risk standard for medical homes in prior rulemaking, but limited its availability to APM entities owned and operated by organizations with 50 or fewer clinicians. In response to stakeholder concern that applying the clinician limit to the "parent organization" was arbitrary, CMS proposes to instead apply the 50 clinician limit at the APM entity level. CMS would identify clinicians by using the TIN/NPIs on the APM Entity's participation list.

FURTHER QUESTIONS

Please contact Joanna Hiatt Kim, AHA's vice president of payment policy, at jkim@aha.org if you have further questions.